Catastrophic delayed cervical arthroplasty failure: illustrative case

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BACKGROUND Cervical disc replacement (CDR) is an increasingly used alternative to fusion for symptomatic cervical disc disease. While more studies have suggested favorability of CDR over fusion procedures, limited data exist regarding implant fatigability. Here, the authors present a unique and previously unreported failure of the M6-C prosthesis causing spinal cord injury.

OBSERVATIONS A 49-year-old female with history of cervical degenerative disease and prior C4–7 M6-C arthroplasty presented 9 years later after a minor fall from standing. She endorsed bilateral hand numbness ascending to forearms and shoulders, with dysesthesias and weakness. Imaging showed fractured arthroplasty penetrating the spinal cord. Revision surgery found a ruptured arthroplasty annulus with metal piece piercing the spinal cord. Partial C4 and C5 corpectomy was performed to remove the integrated fins of the arthroplasty and inspect the cord and dura. This was reconstructed with a corpectomy cage and plate. The patient made an excellent recovery, with improvement in her weakness and resolution of her sensory symptoms.

LESSONS Possibility of fatigue-related failures presenting years after implantation have only been infrequently reported but can be catastrophic for patients. The authors encourage further discussions in this area, increased counseling with patients, and recommend a patient registry to better document adverse events.

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KEYWORDS cervical degenerative disc disease; cervical disc arthroplasty; M6-C prosthesis; case report

Anterior cervical discectomy and fusion (ACDF) has for many years been the primary treatment for symptomatic cervical disc herniations. Starting in the 1990s artificial discs emerged as an alternative to fusion, attempting to preserve segmental motion and prevent adjacent segment disease (ASD). Studies have since documented long-term maintenance of motion and cost-effectiveness of cervical disc replacement (CDR). Many comparisons between ACDF and CDR have shown superiority of arthroplasty in long-term functional outcomes, rates of ASD, and frequency of additional surgeries for single-level and two-level replacements.

Complications are low, with 0.8% vascular events and 4.7% short-term dysphagia. Failures of CDR have mainly focused on the 32.5% incidence of heterotopic ossification that can limit the range of motion of the spinal segment and contribute to ASD. Currently 15 different artificial discs are used worldwide, with 7 having received Food and Drug Administration (FDA) approval. Meta-analysis suggests implant type affects rates of heterotopic ossification and ASD, thus impacting clinical outcomes. However, few studies have investigated long-term safety, durability, and implant-related failure rates.

One of the devices approved by the FDA is the M6-C Artificial Cervical Disc (Orthofix), which is an intervertebral disc prosthesis comprising a polyethylene fiber artificial annulus wound around a polymer core that simulates an artificial nucleus between two titanium-finned endplates. Here, we present a unique and previously unreported catastrophic complication from this device.

Illustrative Case A 49-year-old White female presented after a minor fall at home onto an outstretched arm. The next day she noted numbness in her left hand, progressing to her right hand, and ascending to her shoulder.

ABBREVIATIONS ACDF = anterior cervical discectomy and fusion; ASD = adjacent segment disease; CDR = cervical disc replacement; FDA = Food and Drug Administration.

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forearms and shoulders, with dysesthesias. Examination was notable for mild weakness of her left deltid and biceps (4+ /5) and loss of sensation over bilateral hands and forearms without myelopathy.

The patient had a history of cervical degenerative disc disease (Fig. 1) and had traveled to Germany 9 years prior to have a 3-level arthroplasty from C4–7 using the M6-C. Imaging showed a thin metallic foreign body originating from the C4–5 arthroplasty penetrating the spinal cord causing significant cord edema (Figs. 2 and 3). Given her persistent neurological symptoms and concern for further spinal cord injury, surgery was recommended. Revision surgery using the original left-sided approach was performed. The anulus of the arthroplasty had ruptured, and multiple fragmented pieces were removed, including one which had penetrated the dura and the spinal cord (Fig. 4).

A partial C4 and C5 corpectomy was performed to remove the integrated keels of the arthroplasty and inspect the cord and dura. This was reconstructed with a corpectomy cage and plate (Fig. 5). The patient made an excellent recovery, with improvement in her mild weakness, and slow resolution of her sensory symptoms.

Discussion

The M6-C is a nonarticulating disc with a polycarbonate-polyurethane core surrounded by an artificial annulus of polyethylene fibers designed to replicate the biomechanical characteristics of native disc. Implant failure after M6-C arthroplasty has been described infrequently. One patient experienced loosening of the implant 4 months after implantation following a motor vehicle accident, while two others demonstrated gradual graft subsidence. Another patient reported an
infection 3 years after implantation resulting in sheath disintegration.\textsuperscript{24} One report described the herniation of the M6-C core 8 years after implantation causing myelopathy without obvious preceding events.\textsuperscript{25}

**Observations**

This is the first documented case in which routine use caused catastrophic failure with cord violation. These so-called next-generation arthroplasty devices replace the ball-socket designs and add additional degrees of motion to better resemble physiological biomechanics.\textsuperscript{26} Although according to the manufacturer the prosthesis is tested to simulate a lifetime loading, no literature exists regarding fatigueability.

**Lessons**

As more data suggest patient outcomes are linked to type of prosthesis implanted,\textsuperscript{25} more rigorous long-term safety profiles and failures must be documented. One solution would be the creation of an international patient registry where product failure could be recorded.

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**Disclosures**

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

**Author Contributions**

Conception and design: Ricks. Acquisition of data: both authors. Analysis and interpretation of data: both authors. Drafting the article: both authors. Critically revising the article: both authors. Reviewed submitted version of manuscript: both authors. Approved the final version of the manuscript on behalf of both authors: Ricks. Administrative/technical/material support: Carrera.

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