

## 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).<sup>1</sup> Studies have since documented long-term maintenance of motion<sup>2</sup> and cost-effectiveness of cervical disc replacement (CDR).<sup>3,4</sup> 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<sup>5–12</sup> and two-level replacements.<sup>13–15</sup>

Complications are low, with 0.8% vascular events and 4.7% short-term dysphagia.<sup>16</sup> 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.<sup>17</sup> Currently 15 different artificial discs are used worldwide,<sup>18</sup> with 7 having received Food and Drug Administration (FDA) approval.<sup>19</sup>

Meta-analysis suggests implant type affects rates of heterotopic ossification and ASD,<sup>20</sup> 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.<sup>21</sup>

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

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

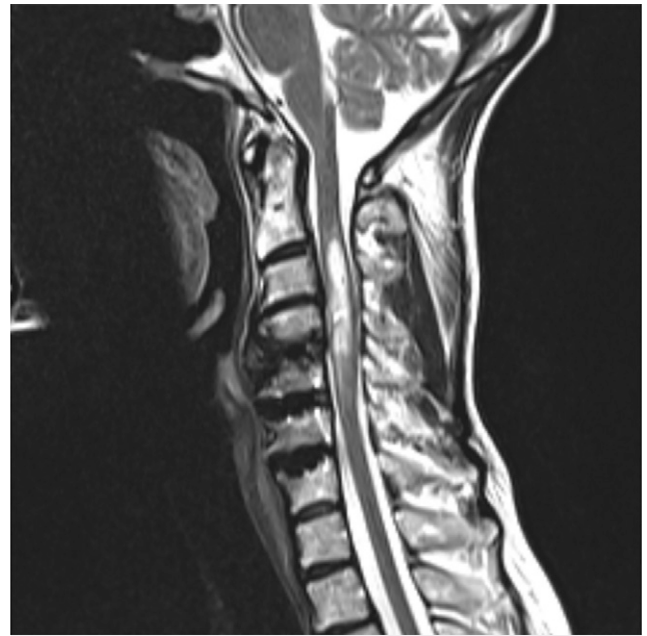
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**FIG. 1.** Cervical spondylosis prior to C4–7 M6-C arthroplasty.

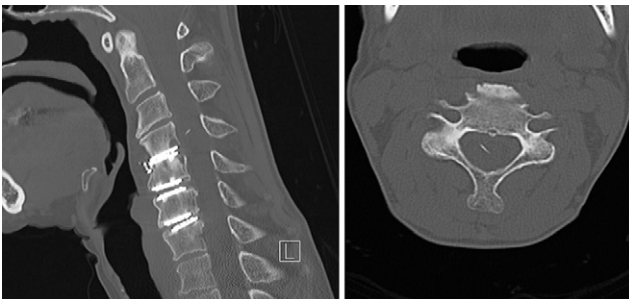


**FIG. 3.** T2 sagittal MRI demonstrating significant cord edema and contusion at level of injury.

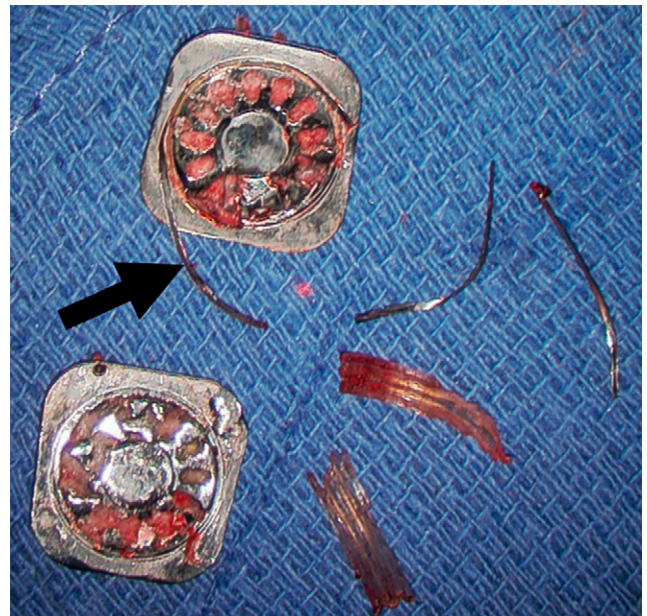
forearms and shoulders, with dysesthesias. Examination was notable for mild weakness of her left deltoid and biceps (4+/5) and loss of sensation over bilateral hands and forearms without myelopathy.

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 annulus 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.



**FIG. 2.** Sagittal reconstructed and axial computed tomography showing C4–5 failed arthroplasty with metallic fragment extending into cord parenchyma.



**FIG. 4.** M6-C arthroplasty fragments removed. Arrow shows intradural portion.

## 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.<sup>22</sup> 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.<sup>23</sup> Another patient reported an



**FIG. 5.** Sagittal reconstructed computed tomography after revision surgery.

infection 3 years after implantation resulting in sheath disintegration.<sup>24</sup> One report described the herniation of the M6-C core 8 years after implantation causing myelopathy without obvious preceding events.<sup>25</sup>

### 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.<sup>26</sup> Although according to the manufacturer the prosthesis is tested to simulate a lifetime loading, no literature exists regarding fatigability.

### Lessons

As more data suggest patient outcomes are linked to type of prosthesis implanted,<sup>20</sup> 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.

### References

- Anderson PA, Rouleau JP, Bryan VE, Carlson CS. Wear analysis of the Bryan Cervical Disc prosthesis. *Spine (Phila Pa 1976)*. 2003;28(20):S186–S194.
- Walraevens J, Demaerel P, Suetens P, et al. Longitudinal prospective long-term radiographic follow-up after treatment of single-level cervical disk disease with the Bryan Cervical Disc. *Neurosurgery*. 2010;67(3):679–687.
- Kim JS, Dowdell J, Cheung ZB, et al. The seven-year cost-effectiveness of anterior cervical discectomy and fusion versus cervical disc arthroplasty: a Markov analysis. *Spine (Phila Pa 1976)*. 2018; 43(22):1543–1551.
- Overley SC, McAnany SJ, Brochin RL, Kim JS, Merrill RK, Qureshi SA. The 5-year cost-effectiveness of two-level anterior cervical

- discectomy and fusion or cervical disc replacement: a Markov analysis. *Spine J*. 2018;18(1):63–71.
- Burkus JK, Traynelis VC, Haid RW Jr, Mummaneni PV. Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the Prestige prospective randomized controlled clinical trial: clinical article. *J Neurosurg Spine*. 2014;21(4):516–528.
- Coric D, Guyer RD, Nunley PD, et al. Prospective, randomized multicenter study of cervical arthroplasty versus anterior cervical discectomy and fusion: 5-year results with a metal-on-metal artificial disc. *J Neurosurg Spine*. 2018;28(3):252–261.
- Donk RD, Verbeek ALM, Verhagen WIM, Groenewoud H, Hosman AJF, Bartels RHMA. What's the best surgical treatment for patients with cervical radiculopathy due to single-level degenerative disease? A randomized controlled trial. *PLoS One*. 2017;12(8):e0183603.
- Hou Y, Nie L, Pan X, et al. Effectiveness and safety of Mobi-C for treatment of single-level cervical disc spondylosis: a randomised control trial with a minimum of five years of follow-up. *Bone Joint J*. 2016;98-B(6):829–833.
- Janssen ME, Zigler JE, Spivak JM, Delamarter RB, Darden BV 2nd, Kopjar B. ProDisc-C total disc replacement versus anterior cervical discectomy and fusion for single-level symptomatic cervical disc disease: seven-year follow-up of the prospective randomized U.S. Food and Drug Administration Investigational Device Exemption Study. *J Bone Joint Surg Am*. 2015;97(21):1738–1747.
- Lavelle WF, Riew KD, Levi AD, Florman JE. Ten-year outcomes of cervical disc replacement with the BRYAN Cervical Disc: results from a prospective, randomized, controlled clinical trial. *Spine (Phila Pa 1976)*. 2019;44(9):601–608.
- Phillips FM, Geisler FH, Gilder KM, Reah C, Howell KM, McAfee PC. Long-term Outcomes of the US FDA IDE prospective, randomized controlled clinical trial Comparing PCM Cervical Disc arthroplasty with anterior cervical discectomy and fusion. *Spine (Phila Pa 1976)*. 2015;40(10):674–683.
- Vaccaro A, Beutler W, Peppelman W, et al. Long-term clinical experience with selectively constrained SECURE-C Cervical Artificial Disc for 1-level cervical disc disease: results from seven-year follow-up of a prospective, randomized, controlled investigational device exemption clinical trial. *Int J Spine Surg*. 2018;12(3): 377–387.
- Gornet MF, Lanman TH, Burkus JK, et al. Two-level cervical disc arthroplasty versus anterior cervical discectomy and fusion: 10-year outcomes of a prospective, randomized investigational device exemption clinical trial. *J Neurosurg Spine*. 2019;31(4):508–518.
- MacDowall A, Canto Moreira N, Marques C, et al. Artificial disc replacement versus fusion in patients with cervical degenerative disc disease and radiculopathy: a randomized controlled trial with 5-year outcomes. *J Neurosurg Spine*. 2019;30(3):323–331.
- Radcliff K, Davis RJ, Hisey MS, et al. Long-term evaluation of cervical disc arthroplasty with the Mobi-C® Cervical Disc: a randomized, prospective, multicenter clinical trial with seven-year follow-up. *Int J Spine Surg*. 2017;11(4):31.
- Hui N, Phan K, Cheng HMK, Lin YH, Mobbs RJ. Complications of cervical total disc replacement and their associations with heterotopic ossification: a systematic review and meta-analysis. *Eur Spine J*. 2020;29(11):2688–2700.
- Hui N, Phan K, Kerferd J, Lee M, Mobbs RJ. Prevalence of and risk factors for heterotopic ossification after cervical total disc replacement: a systematic review and meta-analysis. *Global Spine J*. 2020;10(6):790–804.
- Nunley PD, Coric D, Frank KA, Stone MB. Cervical disc arthroplasty: current evidence and real-world application. *Neurosurgery*. 2018;83(6):1087–1106.
- Turel MK, Kerolus MG, Adogwa O, Traynelis VC. Cervical arthroplasty: what does the labeling say? *Neurosurg Focus*. 2017; 42(2):E2.

20. Wahood W, Yolcu YU, Kerezoudis P, et al. Artificial discs in cervical disc replacement: a meta-analysis for comparison of long-term outcomes. *World Neurosurg.* 2020;134:598–613.e5.
21. Food and Drug Administration. M6-C Artificial Cervical Disc. Instructions for Use. Important Medical Information. Accessed December 7, 2021. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf17/P170036D.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170036D.pdf).
22. Laurysen C, Coric D, Dimmig T, Musante D, Ohnmeiss DD, Stubbs HA. Cervical total disc replacement using a novel compressible prosthesis: Results from a prospective Food and Drug Administration-regulated feasibility study with 24-month follow-up. *Int J Spine Surg.* 2012;6:71–77.
23. Thomas S, Willems K, Van den Daelen L, Linden P, Ciocci MC, Bocher P. The M6-C Cervical Disk prosthesis: first clinical experience in 33 patients. *Clin Spine Surg.* 2016;29(4):E182–E187.
24. Xia MM, Winder MJ. M6-C cervical disc replacement failure associated with late onset infection. *J Spine Surg.* 2019;5(4):584–588.
25. Brenke C, Schmieder K, Barth M. Core herniation after implantation of a cervical artificial disc: case report. *Eur Spine J.* 2015; 24(suppl 4):S536–S539.
26. Patwardhan AG, Havey RM. Prosthesis design influences segmental contribution to total cervical motion after cervical disc arthroplasty. *Eur Spine J.* 2020;29(11):2713–2721.

### 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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