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CASE REPORT

Core herniation after implantation of a cervical artificial disc: case report

Christopher Brenke · Kirsten Schmieder · Martin Barth

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Abstract
Introduction Cervical artificial discs (CADs) represent an established surgical option in selected patients with cervical spinal disc degeneration. Though CADs have been available for many years, there is a lack of information concerning long-term safety, durability and implant-related failure rates.
Materials and methods The authors describe the failure of a M6-C CAD (Spinal Kinetics, Sunnyvale, CA, USA).
Results Eight years after implantation of a CAD of the M6 type, a 39-year-old female presented with new clinical signs of cervical myelopathy. Radiologically, medullar compression due to posterior core herniation was the suspected cause. The damaged CAD was removed and the segment fused. During revision surgery, rupture of the posterior structures could be detected. Possible mechanisms leading to implant failure are discussed.
Conclusion As there is no standard regarding clinical and radiological follow-up for patients with CADs, radiological long-term follow-up investigations seem to be justified for exclusion of implant failure.

Keywords Core herniation · Cervical artificial disc

Introduction

Implantation of a cervical artificial disc (CAD) represents an accepted treatment option for symptomatic cervical radiculopathy. The most common indication for CAD implantation seems to be soft disc herniation, which is performed predominantly in younger patients with the aim of restoring segmental motion thereby preventing adjacent level degeneration. For that purpose, a multitude of different CAD types is commercially available. However, long-term follow-ups exceeding 2 years are scarce and few long-term reports of CADs exist. Considering the high frequency of CAD implantation, there is a lack of scientific evidence with respect to long-term safety, durability and implant-related complications [1]. In the present report, a case of posterior core herniation of a M6-CAD (M6-C, Spinal Kinetics, Sunnyvale, CA, USA) 8 years after implantation is presented which has led to spinal ataxia.

Case report

In 2007, a 39-year-old female received a CAD (M6-C, Spinal Kinetics, Sunnyvale, CA, USA) due to degenerative, symptomatic cervical disc herniation at level C5/6. After implantation of the device, C6 radiculopathy was resolved. Radiographic control imaging after the operation showed an accurate placement of the CAD (Fig. 1). As the patient was free of symptoms, no clinical or radiographic controls were performed. In 2012, the patient complained of new neck pain, nausea and vomiting in cervical flection. There was no history of spinal trauma, tumor or infection preceding clinical deterioration. Cervical control radiography revealed a posteriorly displaced lower titanium plate, compared to the previous image (Fig. 2). Cervical magnetic resonance imaging (MRI) conducted at the same time showed a narrowed spinal canal with potential cervical medullar compression. As this finding was misleadingly interpreted to be based on metal artifacts caused by the CAD, no action was taken from this finding.

C. Brenke (✉) · K. Schmieder · M. Barth
Department of Neurosurgery, Knappschaftskrankenhaus Bochum, Ruhr-University of Bochum, In der Schornau 23-25, 44892 Bochum, Germany
e-mail: christopher.brenke@kk-bochum.de

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The first presentation to our department occurred in 2013, when the patient experienced more neck pain and signs of spinal ataxia. Cervical radiography showed that the position of the lower titanium plate remained unchanged. To definitively rule out imaging artifacts caused by the CAD endplates, a cervical myelography and contrast-enhanced computed tomography (CT) was performed. As expected, CT showed indirect signs of ventral medullar compression; cerebrospinal fluid constriction was visible above and below the dislocated spinal implant, further a posteriorly dislocated core from the damaged CAD was seen (Fig. 3).

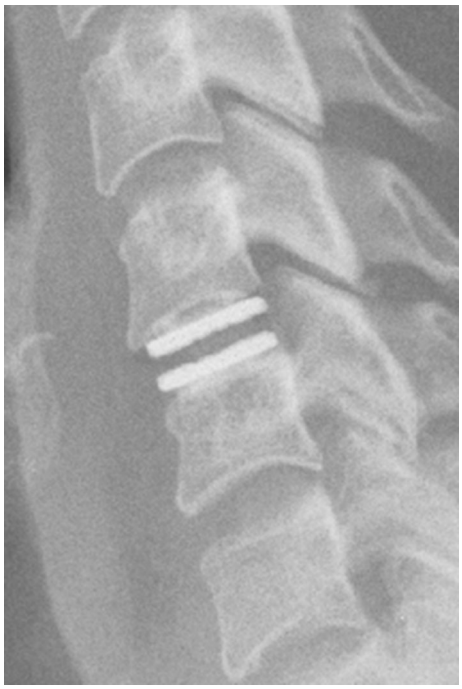

Fig. 1 Lateral cervical X-ray after first surgery

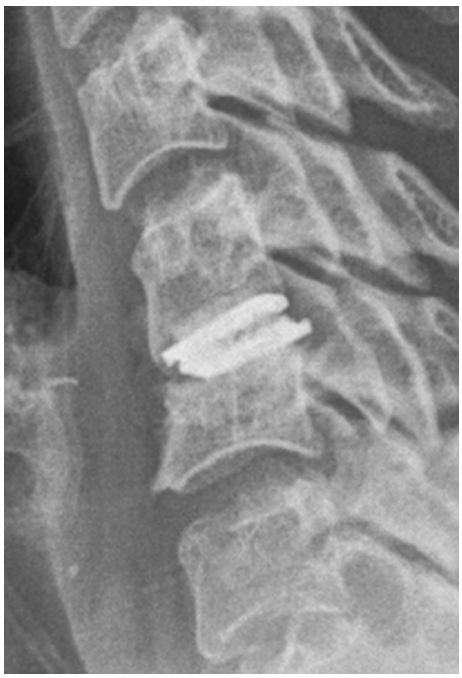

Fig. 2 Lateral cervical X-ray 5 years after surgery

Revision surgery was performed using the original right-sided ventral approach. Distraction retractor screws were placed in the adjacent vertebrae under fluoroscopic control. The segment was distracted to facilitate CAD removal. As the keels of the prosthesis were completely subsided into the upper and lower vertebra, removal of the CAD in one piece was not possible. Therefore, the ventral outer sheath of the CAD was incised (Fig. 4) and the fibers within the CAD removed (Fig. 5). At the dorsal end of the CAD, the posterior defect of the fibers and the displaced core of the CAD could be detected (Fig. 6). After removal of the core with a small nerve hook, the titanium endplates of the CAD could be easily detached with a dissector. Titanium endplates were subsided but not fused with the adjacent vertebra. Finally, a titanium cervical cage was implanted and additionally fixed using a ventral plate (Fig. 7). After revision surgery, clinical symptoms gradually resolved.

Discussion

According to the manufacturer, the design of the M6-C prosthesis belongs to a so-called 'next-generation' design, intended to succeed the ball-socket-designed CADs. By the use of a compressible core, similar to an intact cervical disc, this type of CAD is intended to restore physiologic segmental biomechanics. The parts of the M6-C prosthesis

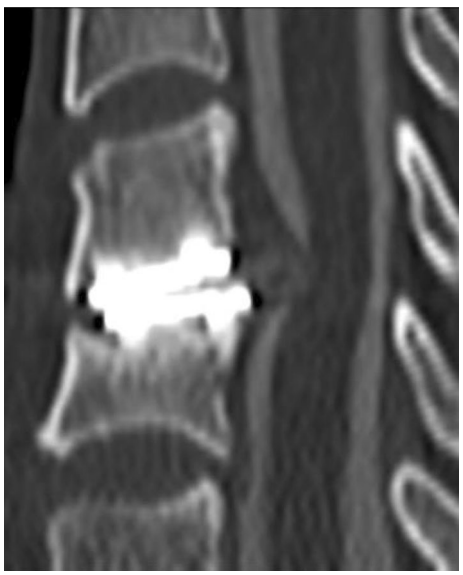

Fig. 3 Sagittal reconstructed CT-myelography

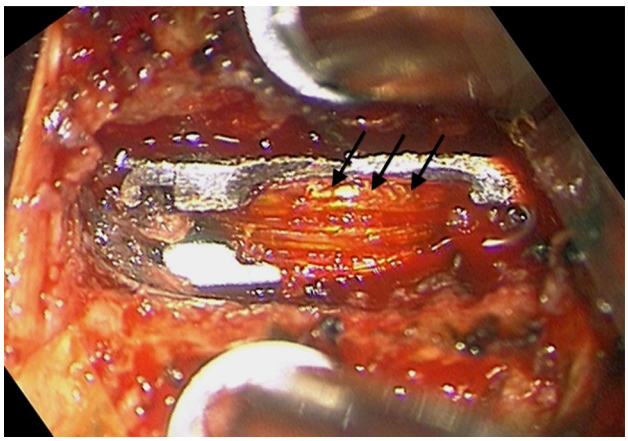

Fig. 4 Intraoperative view of the ventral sheath of the CAD

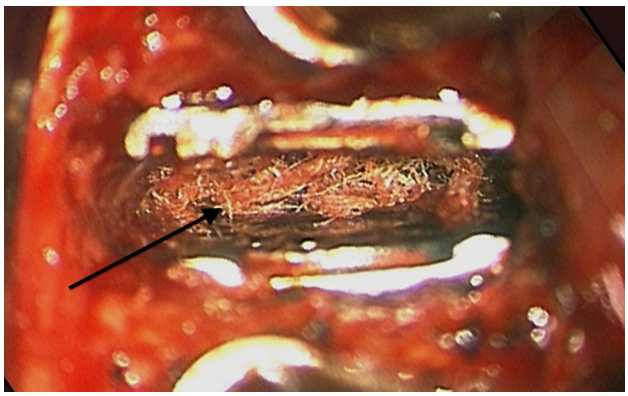

Fig. 5 Intraoperative view of the ventral fibers after removal of the outer sheath

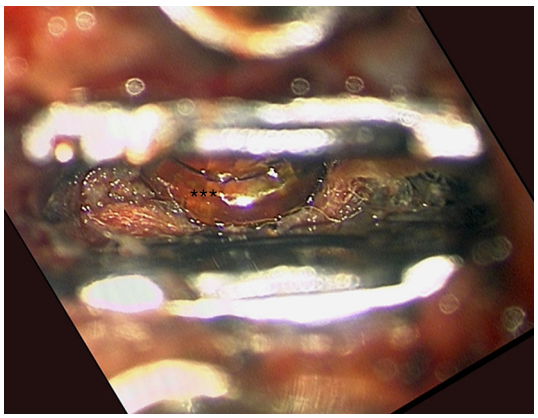

Fig. 6 Intraoperative view of the dorsal hole with the extruded core

consist of a core (polymeric polycarbonate urethane), surrounded by a high-tensile strength, ultrahigh-molecular weight polyethylene woven-fiber construct. A polymer sheath encases the core and fibers to prevent both tissue ingrowth and extrusion of any material from inside the device such as wear debris [2]. The M6-C prosthesis has

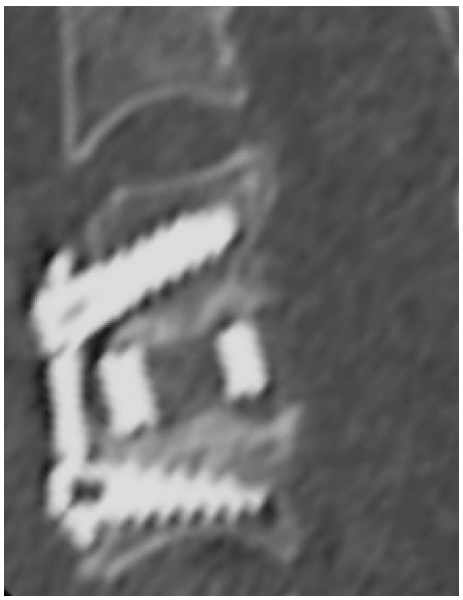

Fig. 7 Sagittal reconstructed CT after revision surgery

been characterized biomechanically and shows higher stiffness compared to intact segments in lateral bending and axial rotation and similar stiffness in flexion–extension [3]. However, no information exists in the literature with regard to fatigue testing. According to the manufacturer, the prosthesis has extensively been tested to simulate a lifetime loading. Results thereof would be particularly interesting, since the design of the M6-C has changed after its introduction in 2007 (L.Beeman, personal communication, 2013) with this explanted M6-C being the first version. Possibly, fatigue testing showed failure of the device under unfavorable experimental conditions. This could be an explanation for the modified design of the M6-C, which has been equipped with stronger fibers and modified endplate anchoring of the fibers.

Three clinical studies have been published with a total of 99 patients receiving a M6-C [2, 4, 5]. The follow-up period was up to 24 months, and no serious adverse events related to the device were reported. The present case is, therefore, the first report on a failure of M6-C CAD.

Possible reasons for device failure of the M6-C remain speculative. As the patient́s history is uneventful with regard to mechanical stress, the following explanations remain conceivable.

The first explanation focuses on fatigue failure primarily of the surrounding sheath which could have occurred over time. This would have allowed for the local enzymatic microenvironment to access the inside of the CAD and to affect the core stabilizing fibers. Finally, the fibers ruptured and allowed herniation of the CAD core.

There is one report in the literature of an implant failure concerning a Bryan disc (Medtronic Sofamor Danek,

Memphis, TN). This failure occurred 8 years after implantation with the formation of a ventral cervical cyst caused by ventral rupture of the CAD sheath [6]. For this CAD model, fatigue testing has been published with device failure occurring after application of 40 million motion cycles, corresponding to 295 years in vivo use [7]. However, rupture of the ventral sheath was observed only 8 years after implantation. Possibly, the local microenvironment in vivo should also be taken into consideration when in vitro test is performed.

The second attempt to explain the M6-C implant failure assumes that the process was initiated by posterior displacement of the lower titanium endplate. During the implantation process, grooves are chiseled into the adjacent vertebral endplates that engage the lower and upper titanium keels of the prosthesis. Pathological sliding could have been provoked by chiseling these grooves too far dorsally into the vertebral endplates. As a result of the prosthesis endplate sliding, abnormal loading may have resulted on the fibers surrounding the core and caused excessive stress over time. When the fibers ruptured, a core herniation resulted.

Both explanations remain hypothetical, as immediate post-operative imaging showed good positioning of the prosthesis.

Unfortunately, there is no information available on the effective number of M6-C implant failures. According to the manufacturer, there is an estimated overall failure rate far below 1 %. However, this number refers only to device failures that have been reported to the manufacturer in relation to the number of globally sold implants. Thus, the true failure rate, particularly of the first version implants of the M6-C device, cannot be determined with sufficient reliability. In our opinion, there is an urgent demand for an independent patient registry that includes cases of definitive implant failures, which certainly should not be restricted to a specific implant.

In conclusion, recurrent symptoms, in particular, after implantation of the first version of the M6-C prosthesis, may be associated with device failure. Diagnostic imaging may be hampered by metallic artifacts. As implants are distributed worldwide, an international patient registry should be established where health professionals have the possibility to report definitive product failures.

Conflict of interest The authors have no disclosures to make.

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