Granulomatous Reaction on a Double-Level Cervical Total Disc Arthroplasty

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Key words
- Breakdown
- Cervical artificial disc replacement
- Cervicalgias
- Granuloma
- Nylon
- Prosthesis
- Total disc arthroplasty

Abbreviations and Acronyms
ACDF: Anterior cervical discectomy and fusion
TDA: Total disc arthroplasty

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Citation: World Neurosurg. (2019) 122:360-363. https://doi.org/10.1016/j.wneu.2018.11.070

Journal homepage: www.journals.elsevier.com/world-neurosurgery

Available online: www.sciencedirect.com

BACKGROUND: **Cervical total disc arthroplasty (TDA), or cervical artificial disc replacement, is an alternative technique to anterior cervical discectomy and fusion for treatment of symptomatic degenerative cervical spine disease. The main goal of TDA is to maintain cervical motion and lower the risk of deterioration of adjacent levels. Granuloma formation on a cervical TDA is exceptional.**

CASE DESCRIPTION: **A 48-year-old woman with left cervicobrachialgia underwent a double-level TDA (M6-C Artificial Cervical Disc) on C5-C6 and C6-C7 at another hospital in 2010. Two years later, she reported a recurrence of cervicalgia, which was refractory to conservative treatment by rigid collar and analgesics. Cervical magnetic resonance imaging suggested a granulomatous formation on the C6-C7 prosthesis. She underwent removal of the C6-C7 prosthesis, which showed a rupture with nylon thread extrusion. An arthrodesis with plate was subsequently performed. Follow-up showed improvement of her clinical status. Histopathologic studies showed a giant cell granulomatous formation in contact with nylon threads described in hip, shoulder, and ankle arthroplasty. It has been described in 6 cases following lumbar TDA and 2 cases following cervical TDA.**

CONCLUSIONS: **We report a third case of granulomatous reaction on nylon thread extrusion after partial breakdown of a prosthesis for cervical TDA.**

INTRODUCTION

Total disc arthroplasty (TDA) was developed in the early 2000s as an alternative technique to anterior cervical discectomy and fusion (ACDF) in a series of degenerative spine diseases to maintain physiologic spinal mobility and overcome degeneration of adjacent levels observed after arthrodesis. Granuloma is a rare complication described in hip, shoulder, and ankle arthroplasty.[1-3] This complication for TDA has been described in 6 cases following lumbar surgery and 2 cases following cervical spinal surgery.[4-6]

CASE DESCRIPTION

A 48-year-old woman with left cervicobrachialgia underwent a double-level TDA (M6-C Artificial Cervical Disc; Spinal Kinetics, Sunnyvale, California, USA) on C5-C6 and C6-C7 at another hospital in 2010. She reported decreased pain levels during the following 2 years. She then presented to our department with recurrence of cervicalgias without sensorimotor deficit. Conservative treatment including analgesics, rigid collar, rest, and gentle physiotherapy did not produce any improvement. A cervical computed tomography scan showed a large bone defect inside the C6 vertebral body in contact with the C6-C7 prosthesis and smaller bone defects in C5 and C7 vertebral bodies (Figure 1). As we suspected an osteolytic reaction, we performed bone scintigraphy, which showed hyperfixation in the left part of the C6 vertebral body and in the right part of C4 and C5 vertebral bodies but no hyperfixation in the bone defect itself of the C6 vertebral body. A tumoral process seemed an unlikely cause of the osteolysis (Figure 2). Formation of granulomatous process was our first hypothesis, which was confirmed by cervical magnetic resonance imaging (Figure 3).

The senior surgeon (C.R.) removed the C6-C7 prosthesis and debulked the C6 vertebral body. During surgery, we observed the posterior breakdown of the prosthesis with extrusion of nylon threads inside the granulomatous intracorporeal reaction (Figure 4). ACDF was then performed on C6-C7 using the Cloward

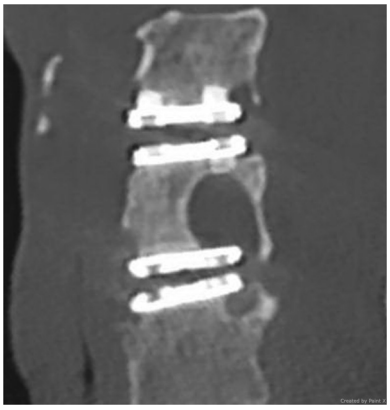

Figure 1. Cervical computed tomography sagittal view after double-level total disc arthroplasty showing large bone defect inside the vertebral body of C6 in contact with the C5-C6 prosthesis and smaller bone defects in the vertebral bodies of C5 and C7.

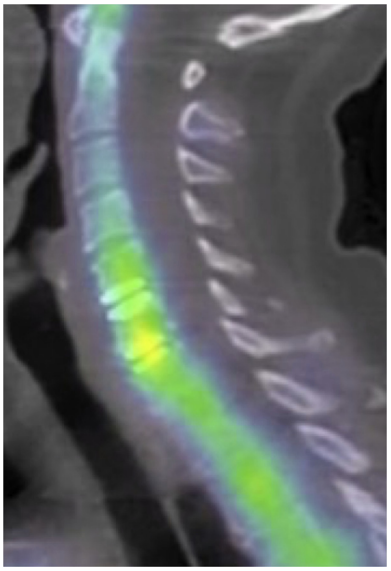

Figure 2. Combined single-photon emission computed tomography/computed tomography showing no hyperfixation in C6 vertebral body gap.

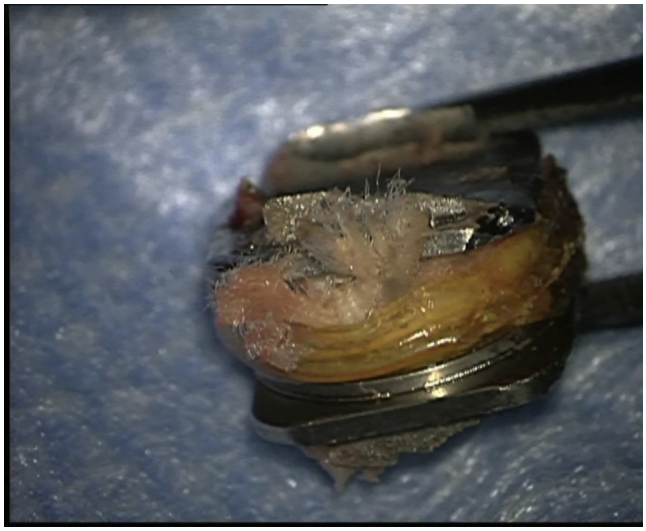

Figure 4. Intraoperative view of the extruded nylon threads (posterior border) on the removed C6-C7 prosthesis.

technique with a bone graft prepared from the tissue bank in the intersomatic space and an anterior plate (Figure 5). Despite the presence of small bone defects in C_5 and C_7 vertebral bodies, supposedly in continuity with the large bone defect in the C6 vertebral body, no further exploration was made on the adjacent vertebral bodies. The nylon thread extrusion was most likely the cause of the osteolytic reaction. Therefore, the probability of recurrence or progression in the future is low, as the foreign body has been explanted. Histopathologic studies confirmed the diagnosis of giant cell granulomatous formation in contact with a foreign body—a nylon thread (Figure 6). Necrotized bone fragments and a small polymorphonuclear neutrophil inflammatory focus were also identified on the specimen. No sign of malignancy was found.

During follow-up, standard spinal radiographs, cervical computed tomography scans, and clinical evaluation showed no signs of complications. The bone defects in C_5, C6, and C_7 did not show signs of progression. The patient was treated conservatively for minor cervicalgias, which remained stable.

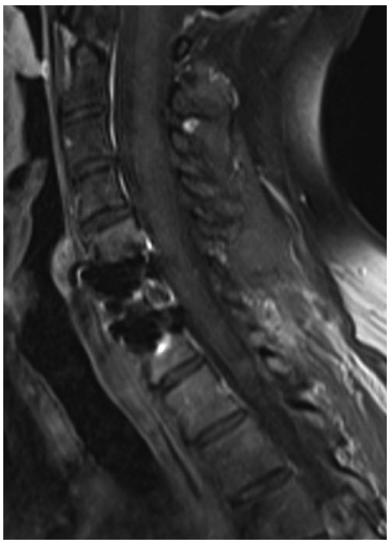

Figure 3. T1 magnetic resonance imaging after gadolinium administration showing no enhancement in C6 vertebral body.

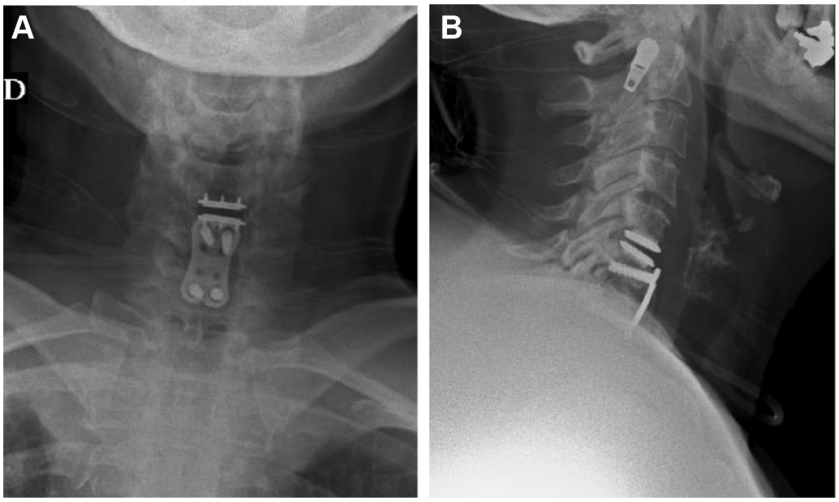

Figure 5. (**A**) Front and (**B**) lateral standard cervical radiographs showing remaining C5-C6 prosthesis and correct position of C6-C7 arthrodesis after removal of C6-C7 prosthesis.

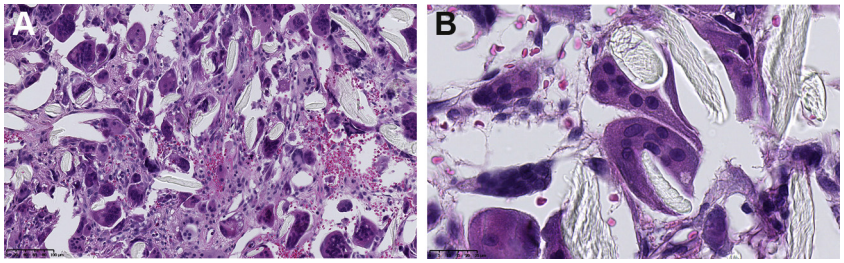

Figure 6. (**A**) Low (×200) and (**B**) high (×800) magnification of specimen showing a giant cell granulomatous formation with phagocytosis of a foreign body (nylon thread).

DISCUSSION

Both ACDF and TDA have shown favorable clinical outcomes. These techniques have been compared in recent literature to determine the best indications for TDA as an alternative to ACDF, which has been considered the gold standard for treatment of cervical degenerative disc disease for decades. Although ACDF is very safe and effective in terms of resolving symptoms, maintaining cervical stability and restoring cervical lordosis are challenging.[7] Multiple high-quality studies have shown that single-level cervical TDA can offer equivalent clinical outcomes with a reduction in secondary procedures and total cost compared with ACDF.[8] Future long-term, multicenter, randomized, controlled studies are needed to validate the safety and efficacy of multilevel cervical disc replacement compared with multilevel ACDF.[7]

The treatment strategy in most reported cases of granulomatous reaction in the literature consisted of removal of the prosthesis to stop mass growth and to reveal symptoms. Berry et al.[9] described 1 case of soft tissue surrounding the lumbar TDA device causing iliac vein occlusion and spinal stenosis, which stopped growing after posterior fixation without extraction of the implant. Device fixation alone during first revision surgery was attempted in an another case of a granulomatous process after metal-on-metal lumbar disc arthroplasty,[4] which led to a high-grade paraparesis and occlusion of the left ureter and both common iliac veins and the infrarenal part of the inferior vena cava. In that particular case, the paraplegic patient had to undergo further revision surgeries and removal of the TDA device. She had residual back pain afterward and was dependent on a wheelchair. Elimination of device motion is not sufficient: the device has to be removed.[4] Reported cases described onset of symptoms owing to granuloma formation and expansion between 6 months and 2 years following TDA.[4-6,9,10] The slow onset of symptoms and the potential devastating consequences of this complication are arguments in favor of a longer follow-up and an increased awareness. Our case was different from the previous ones owing to the osteolysis in the C6 vertebral body and the fact that the patient underwent double-level cervical TDA.

With similarities to pseudotumor tissue found in metal-on-metal hip arthroplasty, histological findings in this field bring to light 2 main causes of granulomatous formation: reactions to high wear and metal hypersensitivity.[11] Particulate debris generated by wear, fretting, or fragmentation induces the formation of an inflammatory reaction, which at a certain point promotes a foreign-body granulation tissue response that has the ability to invade the bone-implant interface.[12] Biomaterials studies led authors to list independent risk factors for inflammatory pseudotumor formation following hip resurfacing, including female sex, age <40 years, and, possibly, smaller component size.[13] In the first 2 cases of delayed hyperreactivity after cervical TDA,[5,6] reaction to the implant metal was the most plausible etiology. The same hypothesis was put forward for all the cases of hyperreactivity after lumbar TDA.[4,5,9,12] In our case, we did not find metal debris in the specimen, and the physiopathology of this inflammatory response leading to osteolysis is most likely hypersensitivity to the nylon thread from the artificial annulus, described as ultra-high-molecular-weight polyethylene fiber material, made by some medical device companies (**Figure 7**).[14] To our knowledge, this is the first reported case of hyperreactivity to the internal material of a prosthesis after TDA.

We know of no described cases of granulomatous reaction following ACDF. The immobilization of the Smith and Robinson technique and the Cloward technique may lower the risk of wear. As ACDF devices contain fewer materials than TDA devices, they are less likely to provoke foreign-body hypersensitivity. As TDA receives increasing attention by the neurosurgical community, it is important to report cases of complications to fully understand the pros and cons of its use.

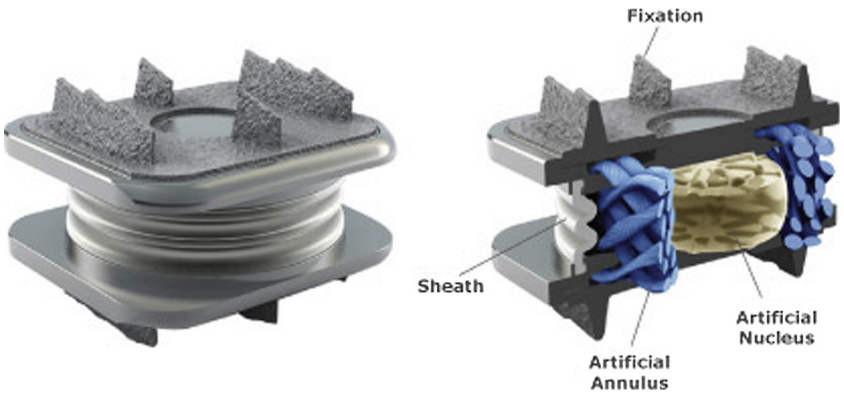

Figure 7. Schematic of the M6-C Artificial Cervical Disc (Spinal Kinetics) showing artificial annulus as potential origin of nylon threads breaking through the sheath and the metallic plate. (Image provided courtesy of Spinal Kinetics.)

CONCLUSIONS

We report a third case of painful granulomatous reaction on nylon thread extrusion after partial breakdown of a prosthesis for TDA. Surgeons must keep in mind this late complication after TDA, especially when a gradual onset of symptoms owing to mass effect is observed during follow-up.

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Received 7 July 2018; accepted 8 November 2018

Citation: World Neurosurg. (2019) 122:360-363.
https://doi.org/10.1016/j.wneu.2018.11.070

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