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Case Report

Stem fracture after total facet replacement in the lumbar spine: a report of two cases and review of the literature

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Abstract

BACKGROUND CONTEXT: A randomized controlled multicenter investigational device exemption clinical trial comparing the total facet arthroplasty system (TFAS) (Archus Orthopedics, Redmond, WA, USA) with posterior fusion was discontinued because of financial reasons. To our knowledge, no clinical outcomes or complications have yet been presented for the TFAS, and no device-related complications have been reported for any other lumbar facet replacement system.

PURPOSE: To report and discuss two cases of stem fracture after total facet replacement in the lumbar spine.

STUDY DESIGN: Case report and literature review.

PATIENT SAMPLE: A 55-year-old man with a body mass index (BMI) of 40 underwent total facet replacement at L4–L5 for Grade 1 spondylolisthesis with stenosis. After 9 months of pain relief, he experienced gradually increasing pain and radiographs showed a broken stem. A 60-year-old woman with a BMI of 31 underwent total facet replacement at L4–L5 for Grade 1 spondylolisthesis with stenosis. She experienced stem fracture 27 months postoperatively.

OUTCOME MEASURES: Visual analog scale for pain, Oswestry Disability Index for function, and computed tomography and X-ray for imaging.

RESULTS: After TFAS stem breakage, both patients underwent interbody fusion through a transpsoas approach and have done well over 24- and 12-month follow-up periods, respectively.

CONCLUSIONS: These are the first cases of stem fracture reported after total facet replacement in the lumbar spine. Biomechanics of TFAS stem breakage may be similar to those of pedicle screw breakage, including fatigue and three-point bending stress. Further biomechanical studies and failure analyses however are needed for adequate understanding to improve the biomechanics of dynamic pedicle–based devices.

Keywords: Archus TFAS; Total facet arthroplasty system; Lumbar facet replacement; Fatigue; Three-point bending

Introduction

A Food and Drug Administration regulated multicenter, prospective, randomized, controlled investigational device exemption (IDE) clinical trial was recently pursued on the total facet arthroplasty system (TFAS) (Archus Orthopedics, Redmond, WA, USA). The TFAS (Figs. 1 and 2) is a new posterior dynamic stabilization device intended to provide spinal stability after neural decompression and facetectomy in the treatment of degenerative facet disease, Grade 1 spondylolisthesis with neurological impairment, or central or lateral stenosis [1–3]. The TFAS is manufactured from implantable grade titanium alloy and consists of multiple components available in a range of sizes and angulations. Two straight stems are inserted with polymethylmethacrylate cement into the pedicles of the inferior vertebra. Bearings made of highly polished, implantable-grade, high carbon content cobalt chromium sit atop these stems and articulate with cobalt chromium spheres located on both ends of a fitted

FDA device/drug status: Investigational (Total Facet Arthroplasty System).

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Fig. 1. Total facet arthroplasty system on a foam spine model.

crossarm. "L"-shaped cephalad stems are then fitted and locked to the crossarm and cemented into the superior vertebra [1,2]. Theoretically, movement is preserved via the crossarm moving superiorly during patient flexion and inferiorly during patient extension.

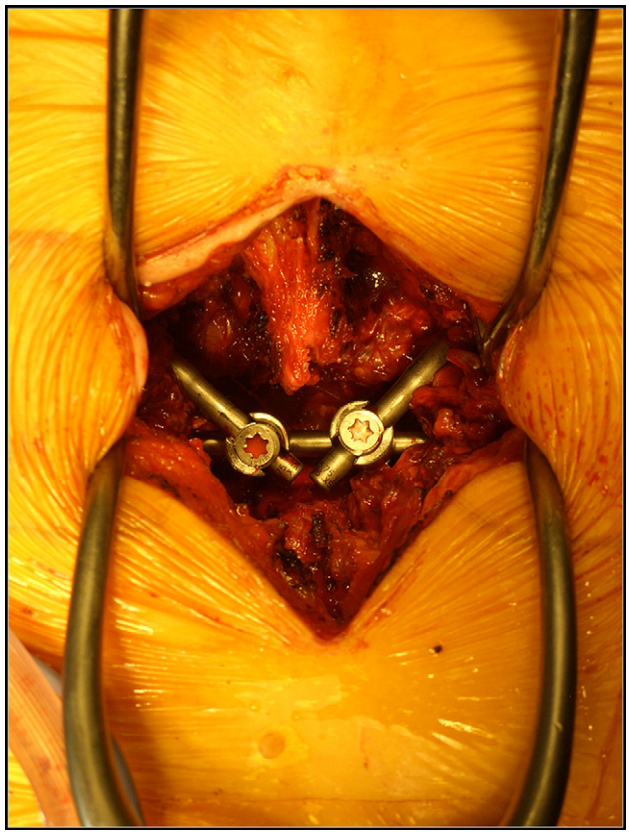

Fig. 2. Intraoperative view of the total facet arthroplasty system.

The TFAS investigational device exemption clinical trial was discontinued because of financial reasons. To our knowledge, no clinical outcomes or complications have yet been presented for the TFAS, and no device-related complications have been reported for any other lumbar facet replacement system [4]. Here, we present the two cases of stem fracture from our series of 10 TFAS recipients and a brief literature review on breakage in similar devices.

Case reports

Case 1

A 55-year-old male with a height of 193 cm (6 feet 4 inches) and body mass index (BMI) of 40 kg/m^2 was indicated for surgery by symptomatic L4–L5 Grade 1 spondylolisthesis with stenosis that did not resolve with conservative treatment. Preoperatively, the patient's visual analog scale (VAS) for pain and Oswestry Disability Index (ODI) scores were 30% and 41, respectively. The patient underwent L4–L5 decompression and TFAS instrumentation (Fig. 3, Left) subsequent to the surgeon's four TFAS index cases. The surgery was uneventful. Pain and function improved, depicted by consecutive 3- and 6-month VAS scores of 0% and ODI scores of 10. The patient was pleased with his outcome and returned to work as a respiratory therapy professor. Nine months postoperatively, the patient experienced gradual onset back and buttock pain, reflected by a VAS score of 30% and ODI score of 28. Radiographs confirmed a broken right cephalad stem (Fig. 3, Right, and Fig. 4, Left). A posterior revision would have been complicated by the polymethylmethacrylate, and an anterior approach would have been difficult considering the patient's

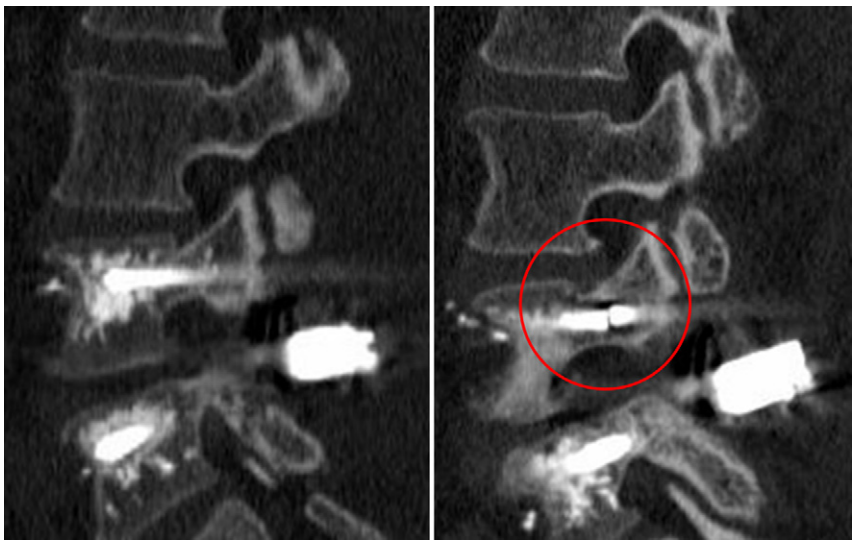

Fig. 3. Case 1 computed tomography images showing total facet arthroplasty system (Left) before stem fracture and (Right) after stem fracture (circled).

large body habitus. Therefore, lumbar interbody fusion was performed through a transpsoas approach, which provided subsequent pain relief [5]. Three months postoperatively, the patient's VAS score was restored to 0%, and his ODI score was reduced to 18. He returned to work and has continued to do well. At 24 months, bony fusion could be observed radiographically (Fig. 4, Right), and the patient stated that, unlike with the TFAS, with the fusion, he noticed slightly restricted motion.

Case 2

A 60-year-old female with a height of 160 cm (5 feet 3 inches) and BMI of 31 kg/m^2 was indicated for surgery by symptomatic L4–L5 Grade 1 spondylolisthesis with stenosis that did not resolve with conservative treatment. Her preoperative VAS score was 80%, and ODI score was 69. The patient underwent L4–L5 decompression and TFAS instrumentation as the third of four TFAS index cases. The surgery was uneventful. Six months postoperatively, physical examination revealed a likely meralgia paresthetica of the L2–L3 distribution on the left side. At 3, 6, 12, 24, and 27 months postoperatively, VAS scores were 20%, 45%, 30%, 50%, and 60%, respectively, and ODI scores were 60, 48, 62, 66, and 66, respectively. At 27 months, the left sided caudal stem was found to be broken on radiographic investigation (Fig. 5, Left, and Fig. 6) and the patient underwent transpsoas lumbar interbody fusion. Within 3 months, the patient's VAS and ODI scores dropped to 40% and 56, respectively. Bony fusion was observed on a postoperative CT scan (Fig. 5, Right), and the patient has continued to do well over 12 months of follow-up besides experiencing some right thigh numbness.

Discussion

Facet replacement devices for the lumbar spine have been recently developed in attempt to provide a motion-preserving fusion alternative. Ideally, such devices would provide adequate stability while preserving some motion to yield benefits observed in both fusion and total disc replacement techniques [6]. Investigational device exemption trials have been undertaken to determine the clinical performance of lumbar facet replacement devices; however,

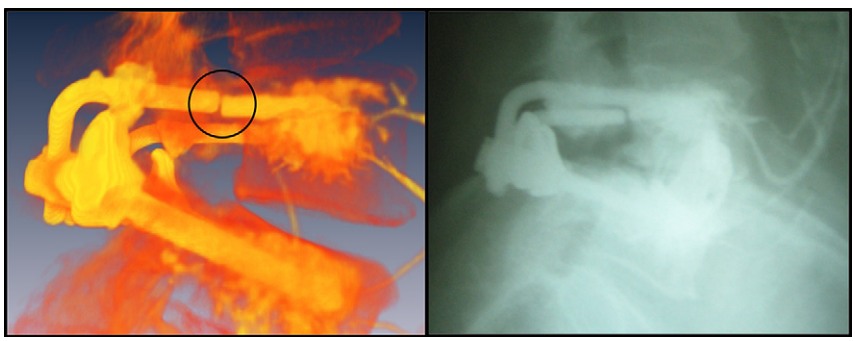

Fig. 4. (Left) Three-dimensional image reconstructed from a computed tomography scan showing the total facet arthroplasty system stem fracture (circled) in Case 1, and (Right) a lateral radiograph showing the presence of bony fusion 24 months after the fusion procedure.

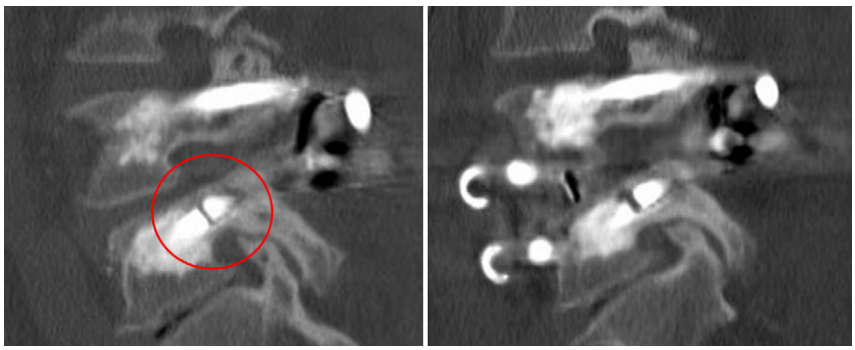

Fig. 5. (Left) Case 2 computed tomography images showing total facet arthroplasty system stem fracture (circled) before and (Right) after fusion procedure. (Right) Note the presence of bony fusion.

until now there have been no reports of associated clinical complications. Here, we describe two cases of stem fracture observed after total facet replacement at L4–L5. The first fracture occurred 9 months postoperatively in an obese 55-year-old male. The second occurred 27 months postoperatively in an obese 60-year-old female.

Stem breakage after TFAS implantation is a clinical dilemma. On the one hand, attempting a salvage fusion procedure posteriorly would be challenging because of the presence of cement in the vertebral body, potentially yielding an increased risk of pseudarthrosis. On the other hand, an anterior approach for anterior lumbar interbody fusion may be difficult for patients with high BMIs from an access point of view. A transpsoas interbody fusion with instrumentation, however, can be achieved minimally invasively with a reasonable outcome.

Therefore, the transpsoas approach was selected for the salvage fusion procedures in the present two cases, and both patients were able to achieve radiographic fusion (Fig. 4, Right and Fig. 5, Right). In Case 1, VAS and ODI scores were decreased from 30% to 0% and from 28 to 18, respectively, and in Case 2, scores were decreased from 60% to 40% and from 66 to 56, respectively.

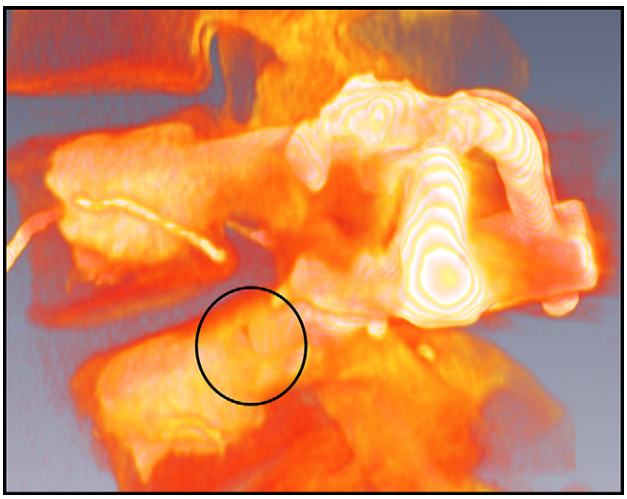

Fig. 6. Three-dimensional image reconstructed from a computed tomography scan showing the total facet arthroplasty system stem fracture (circled) in Case 2.

As can be expected for a new implant, TFAS studies remain relatively scarce in the literature. The only biomechanical data on the TFAS consists of two laboratory investigations regarding range of motion [1,2]. These studies showed the TFAS to restore native motion of cadaveric lumbar spines after an injury model. In addition, Zhu et al. [2] showed that the quality of the motion was also similar to that of the intact spine. Although these studies have shown that TFAS may be a promising alternative to fusion, there are no data on this system regarding its failure modes. The TFAS, however, possesses similarity to pedicle screw fixation systems as it uses the same surgical trajectory and experiences similar loading patterns. Many publications exist in the literature pertaining to pedicle screw fixation system complications and the biomechanics of screw failure. The true mechanism of TFAS stem failure is unknown; however, knowledge gained from pedicle screw systems may be helpful in understanding the fractures in our cases.

Clinical reports have shown that hardware-related pedicle screw fixation failure generally involves screw loosening or breakage [7–12]. In pedicle screw-rod systems where the screw does not pierce the anterior cortex of the vertebral body, caudocephalad loading has been shown to cause screw loosening by way of a ‘‘teeter-totter’’ effect [8,9,13]. The base of the pedicle, that is, the pedicle isthmus, which has the narrowest dimensions between cortices, possesses strong trabecular bone surrounded by a thick cortical rim [14,15]. When the pedicle screw is loaded at the screw head, the pedicle isthmus acts as a fulcrum around which the screw rotates. During this motion, the screw compresses surrounding cancellous bone along the shaft resulting in a ‘‘butterfly-shaped’’ void [8,16,17]. Pedicle screws that pierce the anterior cortex of the vertebral body possess more resistance to loosening [13]. Such bicortical screws also shift the fulcrum to the anterior end of the screw, thereby producing a ‘‘windshield wiper’’ effect rather than a ‘‘teeter-totter’’ effect [13].

Pedicle screw breakage rates of less than 10% are common in the literature [7,11,18]. It is believed that fatigue is

the mechanism by which pedicle screws are broken in vivo [7]. As explained above, repetitive caudocephalad loading of pedicle screws causes rotation of the screw around the fulcrum at the pedicle isthmus. Continued compression of the trabecular bone at the tip of the pedicle screw compacts the bone against the end plate. When the progression of the bone compaction is inhibited by the end plate, the screw experiences bending moments produced by three-point contact, including the fulcrum at the pedicle isthmus and external loading at the screw head. Fatigue of the pedicle screw yields eventual fracture through this mechanism, which is commonly referred to as ''three-point bending.'' It might be possible that three-point bending is a mechanism that contributed to TFAS stem fracture in our cases. It is possible that the fractured stems, loaded posteriorly and fixed at the tip with cement, were stressed at the pedicle isthmus. Because the TFAS is a nonfusion device, this repetitive loading may have caused fatigue fracture (Figs. 3 and 5).

Without any biomechanical data related to the TFAS failure modes to support our conclusions, we can only speculate that the two failed TFAS cases presented here followed the same pattern of pedicle screw fixation failure as reported in earlier clinical investigations. To improve the design and better understand the biomechanics of facet replacement, more laboratory investigations are necessary. From this review, it appears that consideration of BMI, stem strength, and overall construct vulnerability to fatigue and bending stress may provide a good starting point for researchers seeking to improve the biomechanics of dynamic pedicle–based fixation devices. For surgeons faced with salvage quandaries similar to those encountered, here we suggest consideration of the transpsoas approach.

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