



Clinical Study

Tantalum trabecular metal implants in anterior cervical corpectomy and fusion: 2-year prospective analysis



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ABSTRACT

Anterior cervical decompression for two or more cervical spondylotic levels can be performed using either multiple anterior cervical discectomies and fusion or anterior cervical corpectomy and fusion (ACCF). A variety of options for ACCF implants exist but to our knowledge, there is no clinical data for the use of tantalum trabecular metal implants (TTMI) for ACCF. A retrospective review was performed of prospectively collected data for ten patients undergoing ACCF with TTMI between 2011 and 2012. Radiological outcome was assessed by measuring the change in cervical (C) lordosis (fusion Cobb and C2–C7 Cobb), graft subsidence (anterior/posterior, determined by the subsidence of anterior/posterior body height of fused segments; cranial/caudal, determined by the cranial/caudal plate-to-disc distances) and rate of fusion using lateral cervical X-rays of patients at 0, 6, 12 and 24 months post-operatively. The Neck Disability Index (NDI) assessed clinical outcome pre-operatively and at 6, 12 and 24 months post-operatively. Cervical lordosis (Cobb angle of fused segment) was $5.2^\circ (\pm 4.2^\circ)$ at 0 months and $6.0^\circ (\pm 5.7^\circ)$ at 24 months post-operatively. Graft subsidence was observed to occur at 6 months post-operatively and continued throughout follow-up. Anterior, posterior and caudal subsidence occurred more in the first 12 months post-operatively than in the following 12 months ($p < 0.05$). Average pre-operative NDI was 45%. Average NDIs were 18%, 13% and 10% at 6, 12 and 24 months post-operatively, respectively. ACCF patients treated with TTMI demonstrated stable cervical lordosis over 2 years of follow-up and 100% fusion rates after 2 years. Measures of subsidence appeared to decrease with time. Patients experienced improved clinical outcomes over the 2-year period.

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1. Introduction

Anterior cervical decompression for two or more cervical spondylotic levels can be performed either using multiple anterior cervical discectomies and fusion (ACDF) or anterior cervical corpectomy and fusion (ACCF). Little data exists in determining the most appropriate choice of intervention, with results suggesting comparable fusion, subsidence and kyphotic angulation rates [1,2]. Variable options for ACCF implants exist, but to our knowledge there is no clinical data for the use of tantalum trabecular metal implants (TTMI) for ACCF. The purpose of this study was to clinically and radiologically evaluate the use of the TTMI for ACCFs.

2. Methods

2.1. Patient population

Between 2011 and 2013, ten patients in our institution underwent an ACCF using TTMI (Zimmer, Minneapolis, MN, USA) and were included in the review. These were patients with spondylotic pathology producing myelopathy or radiculomyelopathy and were refractory to conservative treatment. A total of twelve patients underwent a TTMI ACCF. Of these patients two were lost to follow-up and were excluded from the series. A total of nine patients had a single-level fusion and one patient had a multi-level fusion. One had both ACCF and a posterior lateral mass fusion. Patient demographic data is described in Table 1.

2.2. Surgical technique

All patients were placed supine with a gel liner transversely positioned underneath the shoulder blades. The head was

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Table 1

Demographic data of patients undergoing anterior cervical corpectomy and fusion with tantalum trabecular metal implants

Number of patients	10
Age (years \pm SD)	57.4 \pm 13.1
Number female	4
<i>Level of surgery</i>	
C4	2
C5	4
C6	2
C4–6	1
C5 + C4–C6 lateral mass screws	1

SD = standard deviation.

supported in a gel ring and a posterior cervical support placed *in situ*. Following a lateral X-ray to confirm positioning, a standard right-sided ventral access approach was performed exposing the anterior prevertebral space. Intra-operative level checks were performed followed by a formal exposure and dissection of the longus colli bilaterally. Cervical Koros retractors were placed underneath the longus colli. Distraction pins were placed at the adjacent vertebral bodies and the distractors placed *in situ*. Discectomies were then performed, followed by formal corpectomies exposing the posterior longitudinal ligament. In all cases this was resected to expose the dura. The corpectomy lateral margins were deemed adequate when the pedicles could be palpated with a blunt hook. The endplates were cleaned and the appropriate sized TTMI chosen. Once implanted, anterior plates (Zimmer) were secured with two variable-angle 15 mm screws in the cranial vertebra and two fixed-angle 15 mm screws in the caudal vertebra. Two variable-angle screws were used for the middle vertebra in the multi-level ACCF. A drain was used on one case only. No post-operative orthosis was used.

2.3. Data collection

Lateral cervical radiographs were taken at four time points: immediately post-operatively, and 3, 6 and 12 months post-operatively. Three major characteristics were determined from these films: cervical lordosis, measured with the Cobb angle of fused segment and the C2–C7 Cobb angle, graft subsidence by measuring the anterior/posterior heights of fused segment and the cranial/caudal disc-to-plate distances and assessment of fusion. Figure 1 and 2 define these measurements.

Graft subsidence was determined by four kinds of subsidence (anterior, posterior, cranial and caudal) and the difference between anterior and posterior body height of the fused segment, modelling the method used by Park [1]. Subsidence was measured at four time points—post-operative, 6 months, 12 months and 24 months, using lateral cervical X-rays. All X-rays were calibrated to the known height of the TTMI used in each patient. Surgimap Spine (Nemaris, NY, USA) was used for all measurements.

Fusion was assessed after 12 months and osteointegration was inferred if there was no evidence of motion defined by $\leq 3^\circ$ translation on lateral flexion/extension radiographs and $\leq 5^\circ$ angular motion on lateral flexion and extension radiographs and no evidence of radiolucency greater than 50% around the bone-TM device interface (U.S. Food and Drug Administration [FDA] criteria/guidance).

Pre-operative, 6-, 12- and 24-month Neck Disability Index (NDI) scores were determined.

2.4. Statistical analyses

The amount of subsidence that occurred between time points was compared using paired t-tests. Significance was set at

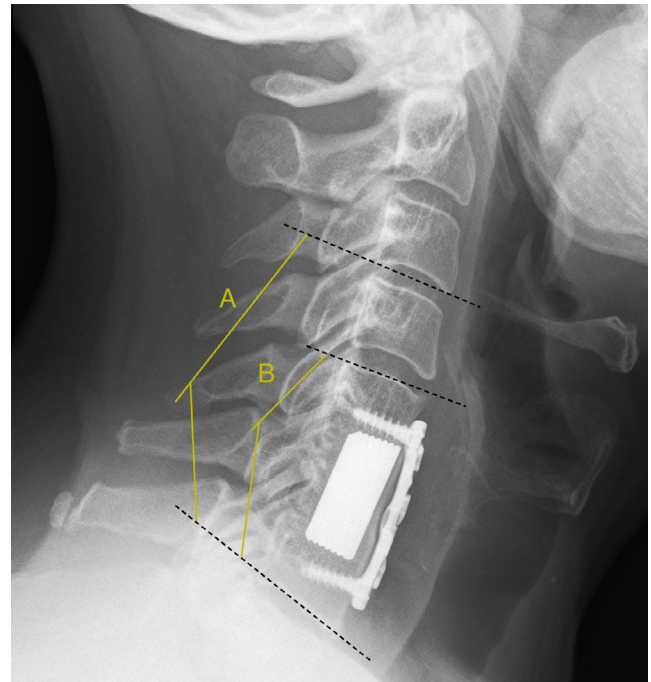


Fig. 1. (A) Cobb angle of cervical 2 to cervical 7 (C2–C7), (B) Cobb angle of fused segment.

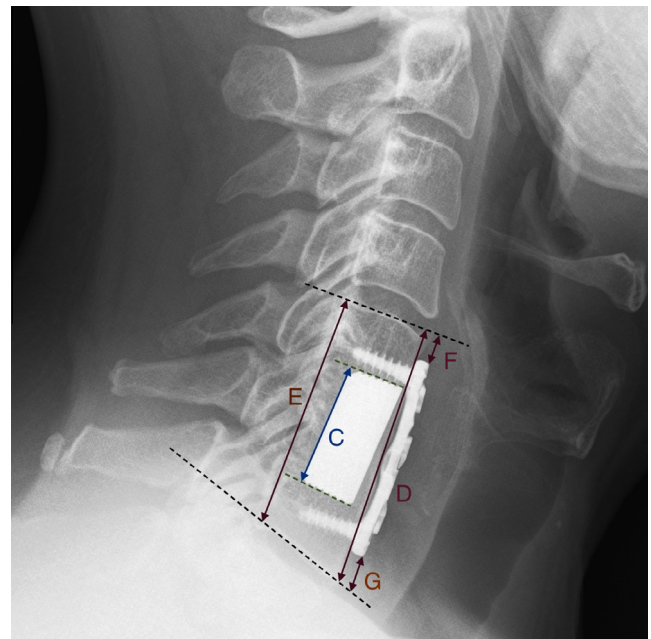


Fig. 2. Lateral X-ray showing fused segment. (C) Known height of implant used as calibration, (D) anterior height of fused segment, (E) posterior height of fused segment, (F) cranial disc-plate height, (G) caudal disc-plate height.

$p < 0.05$ and all analyses were conducted with SAS v9.3 (SAS Institute, Cary, NC, USA).

2.5. Ethical approval

The institutional Committee for Medical Ethics approved the design of the study.

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