Mosaic® Cervical Implant System

A Retrospective Review of the Mosaic Spinal Implant System as an Alternative to Traditional ACDF Instrumentation

SPINAL ELEMENTS®

A RETROSPECTIVE REVIEW OF THE MOSAIC® SPINAL IMPLANT SYSTEM AS AN ALTERNATIVE TO TRADITIONAL ACDF INSTRUMENTATION

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INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) is one of the most common treatments performed for degenerative disc disease of the cervical spine.[1] Intervertebral body fusion (IVBF) devices, or cages, and separate anterior cervical plates (ACP) secured by multiple screws have largely replaced anterior grafting without instrumentation, which was used for more than 40 years.[2] Versatile ventral cervical plate systems provide immediate postoperative stability, may enhance fusion, and permit early patient mobilization.[2] The fusion rates for noninstrumented ACDF reportedly range from 80% to 92%.[3] Plating has improved on these fusion rates, as reported in a clinical study that compared outcomes of plated vs. non-plated ACDF in 242 cases.[4] The fusion rate with plating (98%) was significantly higher than without plating (93.5%, *P*=0.029).

We have been using the stand-alone, low-profile Mosaic Cervical Implant System, which combines a plate and cage in one polyetheretherketone (PEEK) device, in our practices for 3 years. The Mosaic system offers distinct advantages over traditional plate-and-cage systems based on its unique all-in-one design, which combines the plate and PEEK interbody into a single implant. Inserting the device is simple and reliable due to a detachable insertion handle, which includes a drill-tap-screw guide for accurate and reproducible placement of the screws. As few as two and up to four screws can be inserted and locked directly into the plate.

PEEK instrumentation has proven effective with a fusion rate ranging from 94.5% (18.9 months postoperatively)[5] to 100% (31 months and 1 year postoperatively).[6,7] The Mosaic device has been used with high success in our practices for both single-level and multi-level ACDF surgeries.

Mosaic's radiolucency allows fusion status to be accurately and dependably assessed. The purpose of this study was to evaluate Mosaic's ability to achieve a solid fusion.

Mosaic inserter with drill-tap-screw guide

MATERIALS AND METHODS

This retrospective review included consecutive patients at three sites who had ACDF using Mosaic instrumentation between May 2007 and February 2009.

Patients were excluded if they had insufficient postoperative follow-up or if their pre- and postoperative radiographs were not available for evaluation. Patient and procedure data were collected from patient records on file with the authors. Patient demographics included birth date, gender, weight, current smoking status, date of surgery, spinal levels treated, and date of last follow-up appointment. Fusion was the primary outcome of interest. The type of bone graft or biologic material used, intraoperative complications, hospital length of stay, and postoperative management were included in the review database if available.

A third-party radiologist (Medical Metrics, Houston, TX) examined 12-month postoperative lateral (required) and AP (optional) radiographs for the presence of bridging bone, radiolucencies, device condition, and fusion status (Table 1). The fusion status was derived by determining the absence or presence of bridging bone and the extent of radiolucencies at the superior endplate (not fused if >50% radiolucent).

Table 1. Radiographic Assessment Criteria

FUSION STATUS (DERIVED)	BRIDGING BONE	RADIOLUCENCIES	DEVICE CONDITION
0 - Not fused	0 - Absent	0 - None	0 - Intact
1 - Fused	1 - Present	1 - Mild	1 - Graft failure
2 - Indeterminate*	2 - Indeterminate*	2 - Moderate	2 - Screw failure
3 - Unable to assess**	3 - Unable to assess**	3 - Severe	3 - Plate failure
		4 - Indeterminate*	4 - Indeterminate*
		5 - Unable to assess**	5 - Unable to assess**

* A reliable determination could not be made from the available imaging due to suboptimal image quality, obscured fusion mass, obstructed view due to parallax effects or other imaging artifacts.

** The relevant images were missing or unavailable for review, or the relevant anatomy was not visible in the field of view.

RESULTS

Table 2 presents the patient demographics. Twenty-five patients had mean follow-up of 12.5 months (10-14 months) and the necessary radiographs to be included in the review. The group included 12 men and 13 women, with an average age of 52.8 years. Smoking status was reported for 24 patients, 10 of whom were smoking at the time of surgery, and 14 of whom were not. Four of the current non-smokers had quit smoking from 2 to 19 years before their surgery. Records for 15 of the 25 patients indicated whether they had undergone previous spinal procedures—seven had, eight had not.

Twenty-five patients had surgery on 39 spinal levels. Grafting material consisted of autograft with demineralized bone matrix (DBM) in 13 cases and bone graft substitute with bone marrow aspirate in 12 cases. The average length of hospital stay, reported for 23 patients, was 1.86 days. There were no intraoperative complications for any of the 25 patients. All patients wore braces postoperatively, either for 2 to 6 weeks with a soft collar or 2 to 4 weeks with a hard collar.

Table 2. Patient Demographics

Average age (n=25)	52.8 years (32 - 78 years)	Current smoking status (n=24)	10 yes 14 no
Gender (n=25)	12 male 13 female	Previous spinal surgery (n=15)	7 yes 8 no
No. of patients undergoing 1-, 2-, or 3-level surgery (n=25)	1 Level - 15 2 Level - 6 3 Level - 4	Average length of hospital stay (n=23)	1.86 days
No. of procedures by spinal level (25 patients, 39 levels)	C3 - C4: 1 C4 - C5: 12 C5 - C6: 14 C6 - C7: 12	Average weight (n=19)	187.9 lbs
Intraoperative complications (n=25)	none		
Average follow-up time (n=25)	12.5 months		

Table 3. Radiographic Results

FUSION STATUS (DERIVED)	BRIDGING BONE	RADIOLUCENCIES	DEVICE CONDITION
100% fused	100% present	none	100% intact

Independent review by a radiologist demonstrated bridging bone and fusion in 100% of the patients (Table 3).

CASE STUDIES

Several cases illustrate the fusion results attainable with the Mosaic system.

1 Year Postoperative
Lateral View

1 Year Postoperative
AP View

CASE 1 A 58-year-old female with cervical spondylosis, associated disc herniation, and retrolisthesis at C4-C5 and C5-C6 underwent ACDF using the Mosaic implant and locally harvested autologous bone graft and demineralized bone matrix. She was the first patient to undergo Mosaic surgery in our clinic. One year after surgery, radiographs demonstrate successful fusion and the patient reported marked improvement in her symptoms. (Courtesy of Dan Eidman, MD)

1 Year Postoperative
Lateral View

1 Year Postoperative
AP View

CASE 2 A 47-year-old female with cervical spondylosis, central disc herniation, associated radiculopathy and foraminal stenosis at C4-C5, C5-C6 and C6-C7, and retrolisthesis at C5-C6 and C6-C7, underwent ACDF using the Mosaic implant and locally harvested autologous bone graft and demineralized bone matrix. One year after surgery, radiographs demonstrate successful fusion at all levels, and the patient reported overall significant improvement in her symptoms. (Courtesy of Dan Eidman, MD)

Preoperative
Lateral View

1 Year Postoperative
Lateral View

1 Year Postoperative
AP View

CASE 3 This 48-year-old male presented with a herniated nucleus pulposus at C5-C6. ACDF was performed at C5-C6 with the Mosaic implant, locally harvested autologous bone graft and demineralized bone matrix allograft. The postoperative image demonstrates a complete bone bridge from C5 to C6, indicating successful fusion. (Courtesy of Steven DeLuca, DO)

1 Year Postoperative
Lateral View

1 Year Postoperative
AP View

CASE 4 A 59-year-old male with a herniated nucleus pulposus at C4-C5 and C5-C6, which caused severe spinal stenosis and myelopathy, underwent ACDF using the Mosaic implant and locally harvested autologous bone graft and demineralized bone matrix. One year after surgery, radiographs demonstrate successful fusion. Note the excellent visibility of the fusion mass on the AP radiograph due to the translucent design of the Mosaic device. (Courtesy of Steven DeLuca, DO)

14 Months Postoperative
Lateral View

14 Months Postoperative
AP View

CASE 5 Fourteen months before these AP and lateral radiographs were taken this 72-year-old woman underwent ACDF using Mosaic and bone graft substitute combined with marrow aspirate at C5-C6. The vertebrae have solidly fused and her preoperative pain has been alleviated. (Courtesy of Christo Koulisis, MD)

1 Week
Postoperative

8 Months
Postoperative

1 Year
Postoperative

CASE 6 A 42-year-old woman underwent ACDF at C4-C5. Eight months later, the stackable design of Mosaic implants facilitated adjacent-level surgery at C5-C6 without disturbing the first implant. One year after the original surgery, the woman demonstrates solid fusion at C4-C5 and progressing fusion at C5-C6. (Courtesy of Christo Koulisis, MD)

DISCUSSION

In this series the Mosaic system demonstrated its ability to achieve solid fusion at one, two or three cervical levels 1 year postoperatively. This result is similar to that reported for a prospective study of 53 patients implanted with another PEEK device and followed for a mean time of 31 months postoperatively.[6] In that study, the fusion rate for the PEEK group was significantly higher than for a comparative group implanted with titanium cages (100% vs. 86.5%, respectively; *P*=0.0335). Mastronardi et al. also reported a 100% fusion rate 1 year postoperatively for 36 patients who received PEEK implants.[7] Ha et al. reported a slightly lower fusion rate of 94.5% for a PEEK device implanted at 37 levels in 32 patients who had been followed for 18.9 months.[5]

Our results reflect experience with a relatively small patient population. However, fusion was evaluated objectively by an independent radiologist. Longer term follow-up will be necessary to determine the durability of Mosaic implants over time.

We found that the all-in-one Mosaic device, combined with efficient instrumentation and the need for as little as two screws, has greatly streamlined implantation. On insertion, the implant is self-distracting across the disc space and self-centering medial to lateral as it positions itself between the uncovertebral processes, which may eliminate the need for an intraoperative AP X-ray. In our experience, implantation time can be cut, and shorter operating time has been associated with less blood loss.[8]

A small incision,[9] one-level surgery,[10] and shorter retraction times[1] may help protect tissues and reduce the incidence of dysphagia. In addition, Mosaic's stackable design allows existing instrumentation to remain undisturbed when treating adjacent-level disease, which also significantly reduces operative time. The segmental nature of the Mosaic design may potentially reduce stress shielding, especially over long constructs, compared with a rigid plate. Minimizing stress shielding may, in turn, decrease the incidence of pseudoarthrosis. The radiolucent design is optimal for postoperative radiographic analysis of fusion, as there is no plate to obscure the bone graft.

CONCLUSION

The Mosaic system achieved 100% fusion at single and multiple levels in 25 patients from three sites who had mean 1-year follow-up. No evidence of radiolucencies was found at the graft/endplate interfaces.

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INDICATIONS FOR USE

The Mosaic device is intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone.

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