

CASE STUDY

Mosaic[®]
Cervical Implant
System

Novel Treatment of Neck
and Arm Pain

Presented by Dr. Choll Kim



NOVEL TREATMENT OF NECK AND ARM PAIN

Can be viewed at: www.spineuniverse.com/mosaic

The case features the Mosaic® Cervical Implant System in a patient presenting with herniation, spondylosis and associated neck and arm pain.

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HISTORY

The patient is a 59-year-old female who presents with neck and arm pain.

EXAMINATION

The patient is pleasant and appropriate to situation, articulate, and a good historian. Gait is brisk with good coordination. She has hyperesthesia of the bilateral arms; left greater than right, maximally at the index and middle fingers. Motor strength testing shows mild weakness of the left deltoid, biceps and triceps. Reflexes are 1+ at the triceps, biceps and brachioradialis bilaterally and symmetrically. Spurling's test is positive with reproduction of pain over the left shoulder and radial side of the arm. Hoffman's test is negative bilaterally and there is no clonus. Visual Analog Scale (VAS) is 8.

PRIOR TREATMENT

Arm pain was relieved for 4 weeks with interlaminar epidural steroid injections. Physical therapy and activity modification produced minimal improvement.



Figure 1. Upright lateral x-ray shows a loss of cervical lordosis and multilevel spondylosis.



Figure 2. A T2-weighted sagittal MRI shows multilevel disc herniation and spondylosis causing bilateral neuroforaminal stenosis and moderate central canal stenosis. There is no myelomalacia.

DIAGNOSIS

Three-level herniated nucleus pulposus, C4-5, C5-6 and C6-7.

TREATMENT



Figure 3

Lateral intraoperative image (**Figure 3**) showing tubular retractor deployed over the C5-C6 disc space. The retractor is held in place with a table-mounted fixation arm. It does not require elevation of the longus colli to secure the retractor. Caspar distraction pins can be used within the retractor to open the disc space as needed during discectomy (not shown).

The longus colli was swept off of the disc spaces laterally, but was not elevated from the vertebral body between the disc spaces, where they are tightly adherent via tendinous attachments. This avoids undue injury to the longus colli muscles, which are typically used to hold self-retaining retractors.

A subtotal discectomy was performed with a combination of curettes and the matchstick burr. The posterior longitudinal ligament was resected and all disc and osteophytes

A left-sided transverse incision was used to expose the C4-C5, C5-C6, and C6-C7 disc spaces. Each disc space was exposed individually. Expandable tubular retractors were inserted and held in place with an attachment to the table, together with Caspar pins.

removed with Kerrison rongeurs and micro-curettes. The endplate cartilage was removed down to punctuate bleeding bone, but care was taken to preserve the endplate bony integrity. The interbody space was sized with the smooth trials. The Mosaic[®] Cervical Implant was inserted, screws fixed into bone and locking mechanism deployed to lock the screws to the plate. Mosaic is an all-in-one device that combines interbody support with a tension band and can be secured with as few as 2 screws.



Figure 4. Mosaic[®] Cervical Implant System. The Mosaic cervical implants' radiolucent material design improves radiographic visualization of the fusion mass.

Each level was treated one-at-a-time with completion of fixation using the Mosaic device. At no time was the entire surgical target site (C4-C7) exposed.

The Mosaic device was chosen to facilitate a minimally invasive strategy. Although it is FDA-cleared specifically for single-level anterior interbody fusions, its stackable design allows for multilevel fusion through a small transverse incision and limited exposure, one-level at a time. This avoids the need to open the entire surgical site from C4-C7 at any one time. A table mounted retractor was used to avoid excessive longus colli dissection and retraction.

Postoperative images (Figs. 5, 6) show the 3-hole device at C4-C5 and C6-C7 and the 2-hole device at C5-C6. The off-set flanges for the bone screws allow the devices to be placed at adjacent levels.



Figure 5



Figure 6

OUTCOME

The patient was discharged home the same day after surgery without dysphagia. Postoperative VAS was 2.

At her 12-month postoperative follow up, VAS was 0-1 with good resolution of arm pain (Figs. 7-10 include flexion-extension views). There is restoration of cervical lordosis. There is no motion at fusion levels.



Figure 7



Figure 8



Figure 9
Flexion



Figure 10
Extension

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.

FINANCIAL DISCLOSURE

Choll Kim, MD serves as a consultant to Spinal Elements[®], Inc.



DISCUSSION

Jason M. Highsmith, MD
Neurosurgeon
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The three-level Anterior Cervical Discectomy and Fusion (ACDF), as Dr. Kim chose, represents the most common treatment modality for multilevel cervical disc disease. Polyetheretherketone (PEEK) interbody devices, with incorporate fixation, shorten operative time, simplify construct implantation, and facilitate better follow-up MR imaging. The single-level fixation of the Mosaic device lends itself nicely to a tubular retractor system. The stackable aspect of this system in particular overcomes many of the limitations of traditional cervical fixation.

My only concern with the off-label use in this case is the lack of

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rigid fixation afforded by the PEEK "plate". This is confounded when multiple PEEK plates are stacked into a single construct, especially when the point of fixation is only half as wide at each transition. While PEEK is an ideal interbody graft, it has limited torsional strength. PEEK rods in vertebrectomy constructs¹ are effective in limiting flexion and extension, but not rotation. A tension band alone may not suffice in a multilevel construct.

On the other hand, bio-absorbable plates have been shown² to be as efficacious as titanium plates in fusing single-level ACDFs. In one study³, PEEK cages without any anterior instrumentation yielded fusion rates of 90.5% in multilevel ACDFs. Likewise, the use of osteoinductive biomaterials may lessen the need for rigid fixation in the traditional sense. In fact, PEEK plates may tolerate subsidence better, especially in multilevel constructs. Clearly the clinical applications of PEEK should be well vetted before drawing conclusions regarding its efficacy.

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AUTHOR'S RESPONSE

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The author appreciates the thoughtful discussion by Dr. Highsmith. It is important to point out that the use of the Mosaic device is FDA-cleared only for single-level anterior interbody fusion. Its use in multilevel interbody fusion is considered off-label. However, the decision to use this device for a multilevel construct is based on the unique ability of the Mosaic device to be placed at adjacent levels without interference between the anterior plates. This facilitates completion of the interbody fusion construct one-level at a time. When using a separate anterior plate, completion of the construct requires the entire surgical target site to be exposed at once.

It is well known that a key risk factor for dysphagia is multilevel surgery.¹ In a prospective study of 310 patients, Lee et al showed that patients undergoing surgery of three or more levels had a 19.3% risk of dysphagia compared to a 9.7% risk in patients undergoing one- or two-level surgery.² Initial results of a pilot study reveal that dysphagia is decreased using minimally

invasive strategies described above. Further studies are planned to test the hypothesis that preservation of the longus colli and use of limited exposure techniques will decrease the incidence of dysphagia in multilevel anterior cervical discectomy and fusion.

The issue of torsional stability is addressed with the biomechanical testing results of the Mosaic device. Comparison of biomechanical test results of one-level constructs show that torsional stiffness between the 2-hole and 3-hole Mosaic device is comparable to a standard plate and interbody (device)*. Recently, a stand-alone interbody device with integrated screws, which is similar in design concept to the Mosaic device, has been shown in cadaveric studies to be biomechanically equivalent to a traditional interbody device with plate fixation³.

The biomechanical characteristics of multilevel constructs have yet to be determined. However, it is clear that stable internal fixation is a requisite for successful arthrodesis in patients undergoing multilevel anterior cervical discectomy and fusion.^{4,5} I agree with Dr. Highsmith that meaningful clinical studies are necessary to confirm the efficacy of the Mosaic device in multilevel anterior cervical interbody fusions.

*Data on file at Spinal Elements

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