Chapter

The Aspen MIS Spinous Process Fusion System

Tejas Karnati, Edwin Kulubya, Amir Goodarzi and Kee Kim

Abstract

The primary aim of this chapter will be to present an overview of the functionality and efficacy of the Aspen MIS spinous process fusion system, including a review of recent multicenter randomized data.

Keywords: Aspen, spinous process, posterior, lumbar, thoracic, spinal fusion, minimally invasive

1. Introduction

Over the last couple of decades, there has been a growing trend in the use of minimally invasive techniques in spine surgery because of low rates of complications, reduced hospital length of stay, lower estimated blood loss, and minimal soft tissue trauma [1]. With the growing prevalence of low back pain and lumbar degenerative spine disease, spine surgeons have found the need to expand their surgical armamentarium in treating degenerative spondylosis and spondylolisthesis [2]. Current surgical techniques to fuse two vertebral levels include posterolateral fusion, posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), and extreme lateral interbody fusion associated with pedicle-screw fixation/instrumentation [3–7]; however, all these methods have drawbacks, such as increased operative time, risk of serious complications, and increased stiffness of the fused motion segment which may cause pathologic stresses at the adjacent levels [7]. These drawbacks of pedicle screw fixation (PSF) techniques have necessitated surgeons to explore novel and even more minimally invasive methods to achieve comparable levels of stability and fusion rates. Spinous process fixation (SPF)/interspinous process fixation (ISPF) achieved through the use of interspinous fusion devices (IFD) is not as widely used or known in the spine surgical community as PSF. Such devices aim to secure plates to the lateral aspects of two adjacent spinous processes thereby preventing motion at that segment. It is imperative that IFDs are not mistaken for similar other interspinous devices that offer "dynamic stabilization" such as X-STOP or DIAM etc. IFD placement has been successfully applied as an adjunct to posterolateral fusion and anterior fusion techniques and has shown similar rates of stability and fusion rates as PSF and has also been associated with improved or comparable patient-outcome scores [8].

In this chapter, we present the current evidence behind interspinous process fixation/fusion devices. We describe the primary biomechanical evidence and then present a discussion on clinical evidence of some case–control, case-series, and outcome studies. We then discuss the results of a recently completed randomized control trial of the Aspen® MIS Spinous Process Fusion System (Zimmer

Biomet Spine, Westminster, Colorado) and their implications in the use of IFDs in the future. At the end of the chapter, we describe in detail the components of the Aspen® MIS Spinous Process Fusion System and outline the basic surgical technique of placing this IFD successfully.

2. Evidence behind interspinous fusion/fixation devices

Ex-vivo biomechanical studies have demonstrated that IFDs provide comparable rigidity to PSF in flexion-extension [9]. The data are less clear in lateral bending and axial rotation. Techy et al. in 2013 specifically studied the Aspen interspinous device in comparison to pedicle screw fixation and found that the stability provided by the device was statistically equivalent to both bilateral or unilateral pedicle screw/rod construct in flexion-extension; however, lateral bending and axial rotation tests showed pedicle screw fixation to have significantly greater stability [9]. In contrast, an earlier biomechanical study by Karahalios et al. in 2010 showed no difference in stability provided by IFDs compared to PSF in flexion-extension, lateral bending or axial rotation [10]. Papp et al. showed IFDs preserve adjacent facet joint anatomy [11]; other studies have even suggested IFDs may reduce load on intervertebral discs and potentially reduce the risk of adjacent segment disease [12, 13]. Yu et al. in 2014 studied their own novel IFD and found that interspinous process fixation combined with posterior lumbar interbody fusion (PLIF) was equivalent in biomechanical stability to bilateral pedicle screw/rod fixation with PLIF [14]. In short, it seems that cadaveric studies have shown IFDs to fare pretty well in restricting motion through flexion-extension comparable to the current gold-standard pedicle screw fixation but are likely unable to stabilize a motion segment against shearing forces.

Tomii et al. studied the S-plate (Kisco DIR, Osaka, Japan) in a series of 15 patients who underwent PLIF and subsequent IFD placement and found no complications and increase in mean JOA scores from 12.1 to 21.9 with a study follow-up period of 1.5–4 years [15]. Kim et al. showed decreased operative time for IFD placement and PLIF versus PS fixation and PLIF (135.8 minutes versus 170.8 minutes) and lower blood loss. The same study also showed decreased visual analog scale (VAS) scores in the immediate post-operative period of IFD and PLIF compared with PS and PLIF (4.6 vs. 7.0) [13]. However, VAS scores at 1 year follow-up showed no significant differences between the two groups. The Korean Oswestry Disability Index (ODI) scores also showed no significant differences between the two techniques [13].

To assess the value of IFDs in fusion rates, Vokshoor et al. [16] analyzed a sub-cohort of 50 patients who underwent IFD with PLIF or TLIF and showed 94% of them showed interspinous process fusion and 86% of those levels showed solid interbody fusion based on Burkus criteria [17]. Kim et al. [13] also studied fusion rates in their paper by either looking at 6-month post-operative flexion-extension films and/or assessing for trabecular bone on the 6 month post-operative CT scan; they found that IFD with PLIF showed a 92.5% fusion rate, which was similar to 91.6% fusion rates for PLIF with PS fixation. The same paper also reported adjacent segment disease in 12.5% of patients who underwent PLIF with IFD versus 36% in PLIF with PS fixation.

Lastly, Panchal et al. [8] in 2016 reported results from the first randomized, prospective, controlled, multi-center trial comparing outcomes from patients receiving anterior (ALIF) or lateral (LLIF) interbody fusion with adjunctive interspinous fusion with the Aspen® MIS device or pedicle screw fixation. Patients were followed pre-operatively and post-operatively at 6 weeks, 3 months, 6 months, 12 months, and even 24 months. The primary study endpoint was the comparison

of the Oswestry Disability Index (ODI) score from the pre-operative time period to that of the 12-month post-operative time period. The primary hypothesis of the trial was noninferiority of the ODI score change by the Aspen® MIS IFD group (investigation) compared to the pedicle screw fixation group (control).

103 subjects underwent single-level interbody fusion via ALIF or LLIF approach. Sixty-six of them underwent adjunctive interspinous fusion with Aspen MIS spinous process fixation device. Thirty-seven of them were supplemented with pedicle screw fixation. All patients had degenerative disc disease and/or Grade 1 or 2 spondylolisthesis. The trial demonstrated no significant differences between the two groups with respect to patient-reported outcome scores (ODI, SF-36, or VAS) at 1.5, 3, 6, or 12-month time points. Interbody fusion was assessed at 12 months by evaluating computed tomography (CT) scans and scoring them according to the Brantigan, Stelfee, Fraser (BSF) criteria [18]; the authors found no significant difference in the BSF scores, even after adjusting for potential confounders such as anterolateral plating and/or interbody technique. Furthermore, 92% of the patients who had the Aspen® MIS device placed showed bone formation between the device plates bridging the spinous processes [8]. Operative times (47.6 minutes vs. 70.2 minutes), fluoroscopy times (12.2 seconds vs. 58.4 seconds), and blood loss (57.5 cc versus 103.7 cc) were also significantly less between the groups. Notably, no device breakage or dislodgement occurred in the study; however, 6 patients (3.1%) did have spinous process fractures and 3 patients (1.5%) needed to be reoperated due to new or worsening postoperative back and/or leg pain that may have been related to IFD placement.

In short, Panchal et al. was the first randomized multi-center trial to report that interspinous rigid fixation used as a supplement to anterior or lateral interbody fusion techniques is comparable to adjunctive pedicle screw fixation in terms of fusion rates and patient-reported outcomes and has a better intra-operative risk profile.

3. Aspen® MIS spinous process fusion system

The Aspen® Minimally Invasive Fusion System is a collection of spinous process fixation devices that are designed for rigid posterior fixation from T1 to S1 levels (see **Figure 1**). Each device consists of spinous process plates that come in three configurations (standard, medium, "Flared 5-1"), a "post plate" (a cylindrical device that is threaded in between the interspinous ligament and eventually joins

Figure 1.
Aspen® MIS fusion system standard size spinous process plate [19].

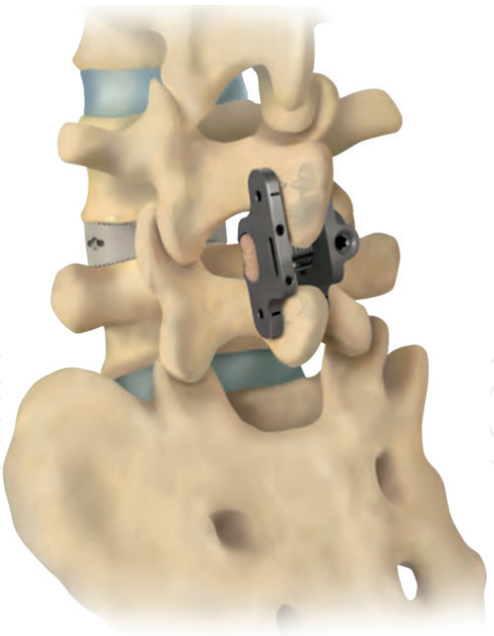

Figure 2.
Aspen® minimally invasive fusion system fully assembled [19].

the two spinous process plates) and a set screw that locks the system together. The cylindrical barrel in between the two plates can also hold approximately 0.5 cc to 3 cc of bone graft material. The system also has its own set of surgical tools to facilitate the insertion.

The final assembled Aspen® Minimally Invasive Fusion System interspinous fixation device is shown in **Figure 2**. The system is FDA approved and indicated for use in the United States as an adjunct to interbody and/or posterior fusion or as a standalone fixation device from T1 – S1 levels [8] in degenerative, traumatic, and deformity pathologies.

4. Surgical technique

The Aspen MIS system is placed with a patient in prone position through a 3–5 cm incision, enough to expose the length of the spinous process. Subperiosteal dissection is used to elevate the paraspinal muscles of the spinous process and lamina. The fusion site should be clear of connective and soft tissue then decorticated. The supraspinous ligament (SSL) can be removed or kept intact. Keeping the SSL intact helps preserves the natural anatomy and can prevent over distraction. The interspinous ligament is pierced as anterior as possible with a dilator (**Figure 3**).

A fluoroscopy image can be taken at this point to confirm anterior placement and appropriate level of dilator. The interspinous space is opened with a lamina spreader and measured to determine implant size. The interspinous space is decorticated with a rasp (**Figure 4**).

The barrel diameter is selected based on the fit of the rasp or spreader. The barrel length comes in a standard 21 mm size, appropriate for thick spinous processes or medium 18 mm when there are hypertrophied facets. The post plate implant is attached first to the left of the spinous process, then the barrel which is packed with graft material through the interspinous space, and finally the locking plate to the right of the spinous process (**Figure 5**).

Autograft and/or allograft can be placed posterior to the graft between the spinous process and across the lamina. The device should sit in the proper anterior

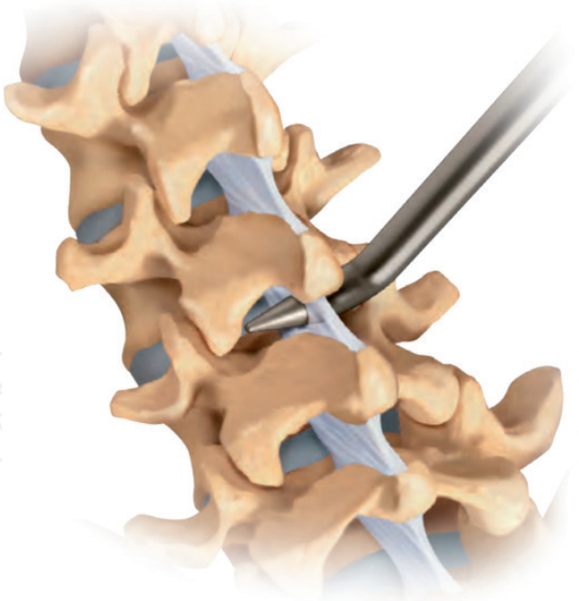

Figure 3.
Dilator is used to create space between the interspinous ligament [19].

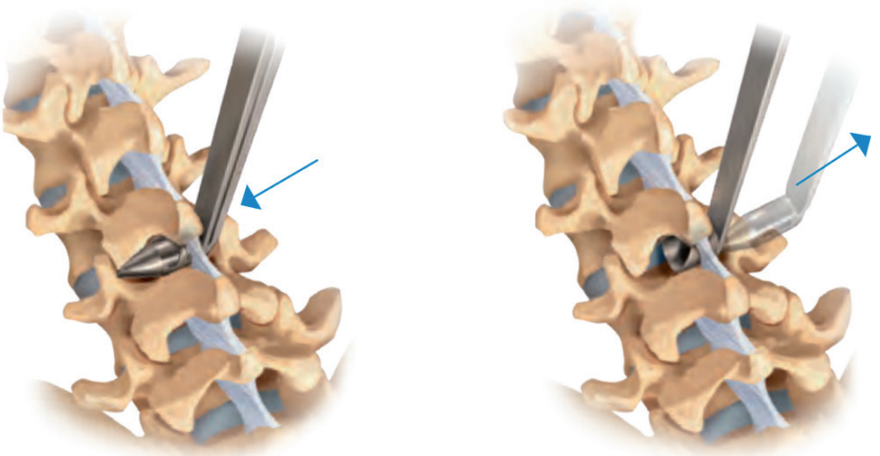

Figure 4.
Rasp for decortication [19].

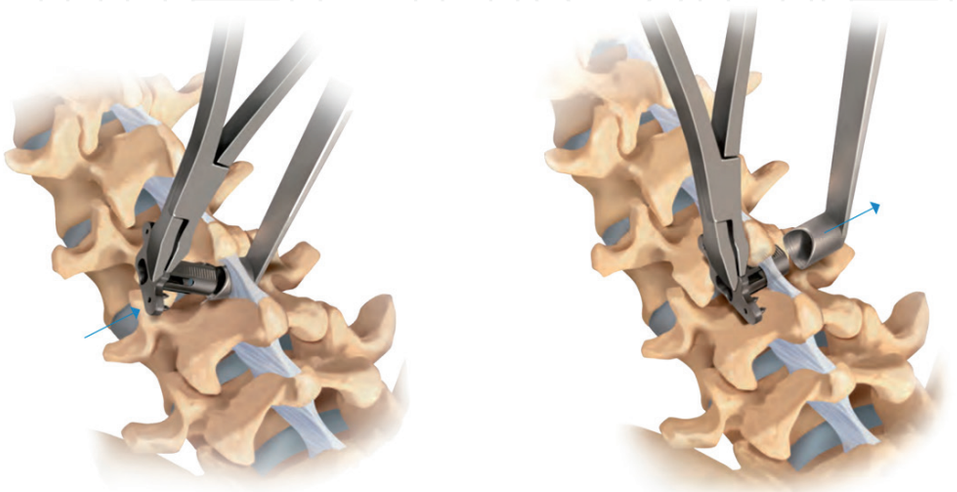

Figure 5.
Attachment of the post plate [18].

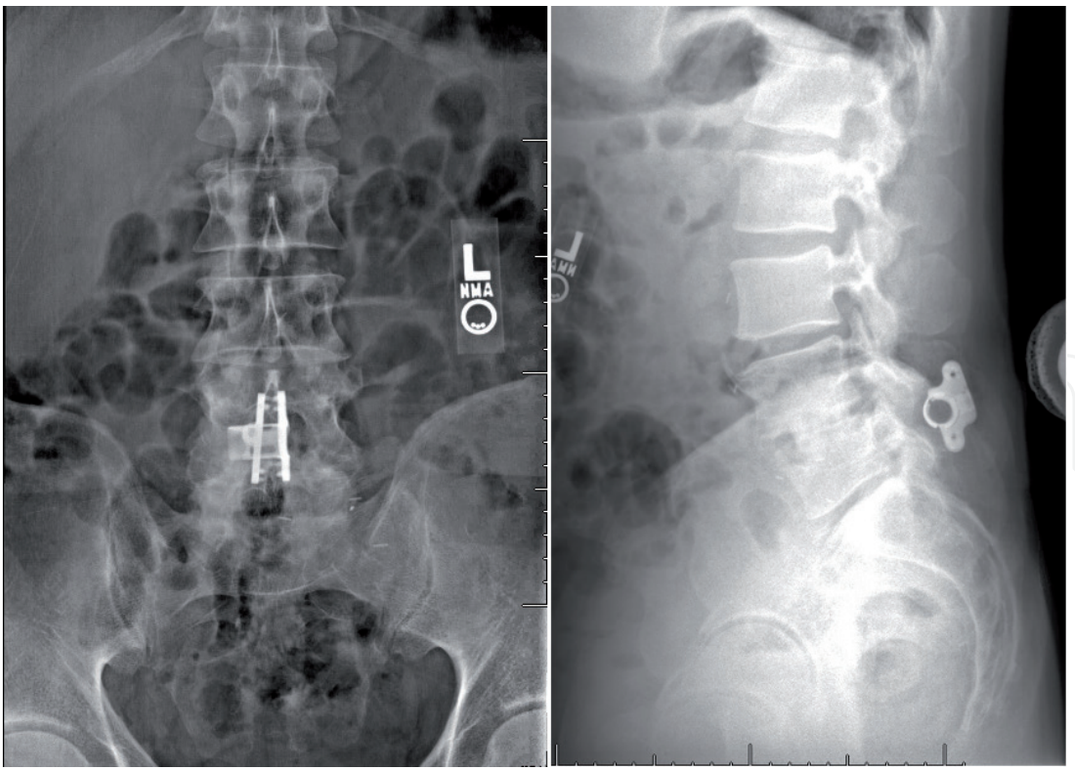

Figure 6.
A/P and lateral images of Aspen MIS fusion system at L4-L5.

placement and not protrude above the lumbodorsal fascia before compressing the plates and tightening the set screw. If the implant is placed too far posterior there is an increased risk of spinous process fracture. The spikes should be fully seated into the bone, but care should be taken to not over-compress and weaken the cortex.

The Aspen® MIS Fusion System should be removed in the case of nonunion or if any components loosen or break. The provided set-screwdriver or a T10 Torque driver can be used to loosen the locking set screw. The plates can then be lifted with a Cobb elevator and removed from the spinous process. **Figure 6** shows lateral and antero-posterior radiographs of a full assembled Aspen® MIS Fusion System.

5. Conclusion

Until recently, IFDs have had only biomechanical and some prospective clinic studies in evaluating their role as an adjunct to thoracolumbar fusion. However, the randomized control trial by Panchal et al. [8] showed outcomes of interspinous process fixation to be comparable and even, in some cases, more favorable to those of pedicle screw fixation. The relative ease with which a surgeon can minimally invasively implant this device combined with a relatively short operative times, low blood loss, and reduce hospital length of stay provides an attractive alternative to pedicle screw fixation.

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