

INTERSPINOUS PROCESS FIXATION: *Safe and Effective Fusion Alternative*

Literature Review

ISP fixation has been shown to be a safe and efficacious alternative to traditional methods of posterior spinal fixation. A high degree of biomechanical stability and reliable fusion rates are achieved with preservation of adjacent level structures when using new iterations of rigid interspinous fixation. Since ISP devices do not violate adjacent facet joints, they potentially can decrease the incidence of adjacent segmental degeneration. ISP devices such as the ZIP™ from Aurora Spine Inc. (Carlsbad, CA) are increasingly gaining acceptance among treating physicians due to **decreased surgical and hospitalization time, reduced complication rates and estimated blood loss, as well as the complimentary effect of decreased overall costs for the procedure.**

Clinical success has been shown in patients with mild to moderate stenosis with or without a stable low grade spondylolisthesis. When used as adjunctive fixation to lumbar interbody fusion, including anterior (ALIF), lateral (DLIF, LLIF, XLIF) and posterior approaches (PLIF, TLIF), ISP devices offer an effective minimally invasive option to traditional pedicle screw fixation.

This manuscript is intended to inform clinicians, insurance company representatives, guideline development company staff, technology evaluators and other stakeholders of Aurora's ZIP™ technology as to its intended benefit over available methods of pedicle screw fixation used in spinal fusion surgeries.

Biomechanical Stability and Clinical Outcome after Interspinous Process Fixation

A Systematic Literature Review

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Study Design. A quantitative meta-analysis was conducted on published studies reporting biomechanical and clinical data on interspinous process fixation procedures for conditions such as stenosis with stable low grade spondylolisthesis and degenerative disc disease.

Objectives. The primary aim of this study was to summarize the literature published on interspinous process (ISP) fixation devices adjunctive to interbody lumbar fusion compared to pedicle screw fixation. As part of this analysis, clinical and mechanical parameters were investigated.

Summary of Background Data. ISP fixation constructs are a minimally invasive alternative for posterior spinal stabilization that have recently gained increased acceptance by treating physicians. ISP devices have become of particular interest due to the reduced surgical time, hospitalization time and post-operative complication rates while demonstrating reliable fusion rates.

Methods. A literature review in the PubMed database was conducted on 'interspinous process fixation' together with 'biomechanics' and 'clinical outcome'. Primary single level rigid ISP devices adjunct to interbody fusion have been evaluated.

Results. Fusion complemented with an ISP device result in less operative blood loss, a shorter procedure time, and reduced hospital length of stay compared to pedicle screw fixation. New iterations of rigid interspinous fixation provide excellent motion restriction in flexion-extension, and comparable results to bilateral pedicle screws in axial rotation. This high degree of stability in multiple planes has resulted in a high rate of arthrodesis when rigid interspinous fixation constructs have been used as an adjunct to interbody fusion. Clinical outcome has been favorable after interspinous process fixation, likely as a result of a low rate of adjacent segment degeneration.

Conclusion. ISP fixation has been shown to be a safe and efficacious alternative to traditional methods of posterior spinal fixation. A high degree of biomechanical stability and reliable fusion rates are achieved with preservation of adjacent level structures when using rigid interspinous fixation. Clinical success can be achieved in patients with mild to moderate stenosis with or without a stable low grade spondylolisthesis. When used as

adjunctive fixation to an interbody fusion construct, ISP devices offer an effective and less invasive option to traditional pedicle screw fixation.

Key Words. Interspinous process fusion, degenerative, fusion device, posterior, lumbar disease, clinical outcome

INTRODUCTION

Spinal decompression and fusion techniques have been the standard of care for conditions of instability and deformity of the lumbar spine for the past 50 years.¹⁻⁴ Several methods and techniques have been developed to accomplish suitable stabilization after segmental decompression. Pedicle screw (PS) fixation constructs are currently the most widely used method of stabilization; however, wide muscle dissection and long operative times can result in postoperative back pain. Other complications associated with the use of PS fixation include increased rates of cerebrospinal fluid leakage, nerve injury, deep wound infection and hardware failure.^{5,6} Posterior fusion with PS fixation has also been linked to adjacent segmental degeneration (ASD) because of the additional forces on the facet joints at adjacent levels⁷⁻⁹.

To reduce the risks associated with pedicle screw fixation, viable alternatives have been developed and are gaining acceptance among treating physicians due to decreased surgical and hospitalization time, reduced complication rates and estimated blood loss as well as the complimentary effect of decreased overall costs.

Initial interest in ISP devices was as minimally invasive, non-fusion spacers to create a localized lumbar kyphosis which indirectly decompressed a stenotic segment while increasing the structural diameter of the neural foramina. They were originally designed to function as standalone, non-fusion devices; however, newer designs have been used in conjunction with anterior column reconstruction procedures as an alternate method of posterior spinal fixation for patients requiring decompression and fusion.⁹⁻¹¹

Recently, there has been an increased use of static ISP devices as a less invasive alternative to pedicle screw fixation for lumbar interbody fusion by providing boney fixation to adjacent spinous processes. A number of ISP fixation devices have been approved for adjunctive fixation in interbody lumbar fusion procedures such as: X/

DLIF, ALIF, PLIF and/or TLIF.

Aurora Spine, Inc. (Carlsbad, CA) recently received 510k clearance for its ZIP Ultra™ MIS Interspinous as a supplemental single level fusion device for the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. In general, the ZIP™ implants along with other similar ISP devices (Figure 1) are implanted as a less invasive option to traditional pedicle screw devices. These devices have been shown to have shorter operating and quicker recovery times in addition to multiple supplementary benefits. This meta-analysis reviews the pertinent preclinical biomechanical literature and clinical data related to the use of these devices as adjunctive fixation for lumbar interbody fusion (Figure 2).



Figure 1: An example of the rigid ISP fusion device, ZIP™ from Aurora Spine Inc. (Carlsbad, CA).

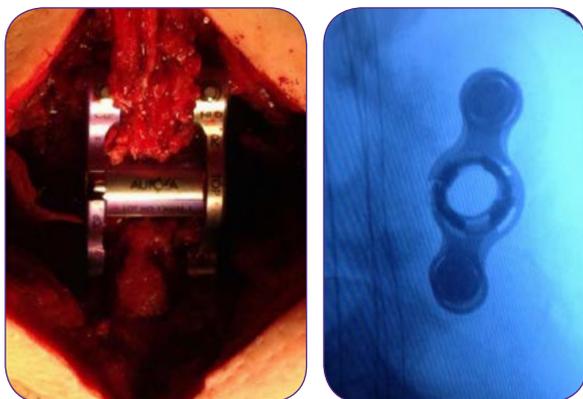


Figure 2: An example of implanted rigid ISP fusion device. Intraoperative antero-posterior (left) and radiographic lateral view (right) of implanted MIS ZIP™ from Aurora Spine, Inc. (Carlsbad, CA)

MATERIALS AND METHODS

We searched PubMed (February 2014) for English publications related to one level interspinous process fixation. Literature related to interspinous spacers and posterior dynamic stabilizers as well as those used without interbody fusion, was mostly eliminated. All interbody

fusions such as PLIF, XLIF, TLIF, and ALIF were included in the review resulting in a total of 20 articles. All findings were summarized qualitatively without statistical pooling or performing meta-analysis.

FUSION RATES

Vokshoor et al. observed that 91% (41 of 45) of levels treated with lumbar interbody fusion supplemented by an interspinous fixation device demonstrated solid bridging bone on 2 year post-operative CT imaging (Figure 3).¹² Similarly, Kim et al. showed comparable fusion rates between the patient in the ISP (92.5%) and PS group (91.6%).¹³

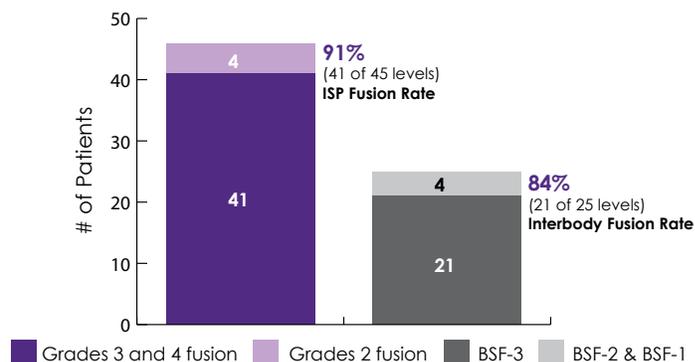


Figure 3: Fusion success outcome: ISP-Grade 1 indicates small islands of bone; Grade 2 shows larger islands of coalescence with bridging to the surrounding anatomy; Grade 3 indicates some solid incorporation and bridging bone, Grade 4 shows solid fusion, with incorporation and obvious stability and maturity; Classification of interbody fusion success was based on the BSF scale by Brantigan, Steffee, and Fraser (SPINE 1993;18:2106-7).¹²

BIOMECHANICAL EVALUATION FOR RANGE OF MOTION

Clinical instability of the lumbar spine can be characterized by excessive sagittal plane translation. Reducing intersegmental range of motion is paramount in treating instability, and ultimately the goal of spinal fixation strategies is to achieve rigid stabilization and promote fusion.^{4,9,10} Wang et al. studied the biomechanical characteristics of an ISP device on 109 cadaveric specimens in an in vitro test and determined that the ISP device achieved excellent mean restriction of range of motion (ROM).⁹ Flexion-extension ROM decreased significantly to 4.14° for ISP with lumbar interbody fusion when compared to the intact spine (10.1°) whereas ROM for pedicle screw fixation with lumbar interbody fusion 5.03°. With this, the ISP fixation has proven to provide enough segmental rigidity to make it a viable alternative to pedicle screw fixation.

These new iterations of rigid ISP fixation offer excellent stability in flexion-extension equivalent to bilateral pedicle screw fixation, and motion restriction in axial rotation and lateral bending equivalent to unilateral pedicle screw systems.^{9,14,15} Previous studies demonstrating multi-plane

biomechanical stability and a high rate of arthrodesis indicate that rigid ISP fixation is a safe and effective minimally invasive technique in lumbar fusion surgery with consistently reliable fusion rates and may be a viable alternative to PS fixation as an adjunct to interbody fusion including anterior (ALIF), lateral (DLIF, LLIF, XLIF) and posterior approaches (PLF, TLIF).

SPINOUS PROCESS STABILITY

The ability of the posterior spinal elements to maintain structural integrity and accommodate stress forces exerted by an interspinous fixation system has been examined in previous studies.¹⁶ Overall, these studies indicate that the posterior spinal elements have sufficient structural integrity to accommodate an interspinous fusion device. Sheperd et al. measured the mechanical force required to fracture the spinous process of 32 specimens with average to below-average bone mineral density.¹⁷ They found a significant linear correlation between bone mineral density and bone strength. A mean load of 339 N was required to cause a spinous process failure with a 95% confidence interval of 257-447 Newtons. Talwar et al designed a study to test the incidence of spinous process fracture during interspinous spacer implantation.¹⁸ This study showed a lateral load of 95-786 N was required to cause failure of the posterior spinal elements and there was no significant difference in load tolerance between the cranial, middle or caudal aspects of the spinous process. An insertional load of 10.5-150.2 Newtons was required for intraoperative device fixation. These results suggest intraoperative fracture of the most osteoporotic patients with the ISP spacers is a highly unlikely but feasible possibility for patients with very low bone density.

ADJACENT LEVEL CHANGES

A study of 76 adult patients by Kim et al. showed significantly more adjacent level angular hypermobility and degenerative changes in the pedicle screw stabilization group.¹³ In the same study, the range of motion for the patients in the ISP group did not significantly change to the pre-operative condition. The number of patients with adjacent segment disease was 60% lower in the ISP group (13 out of 36 and 5 out of 40 for the PS and ISP group, resp. $p=0.029$) which was significantly different. At the same time, the Fisher's exact test revealed that the change in the segmental angle of the adjacent segment was higher in PS group than the IFD group. Additionally, ISP devices have been shown to preserve normal anatomy and not violate adjacent facet joints, resulting in less hardware-related pain or accelerate adjacent facet degeneration.¹¹

INTERSPINOUS FIXATION VERSUS TRANSPEDICULAR CONSTRUCTS (PEDICLE SCREWS)

Traditional posterior spinal fusion constructs utilizing

only transpedicular screws to achieve supplemental fixation allow for high post-operative fusion rates, but are associated with inherent risks. These risks include nerve damage, damage to perineural structures, cerebrospinal fluid leakage, deep wound infection, as well as significant radiation exposure to the surgeon, the patient and the operating room staff during implantation.^{6,19}

The use of rigid interspinous fusion devices as supplemental fixation to achieve stabilization is designed to minimize the risks associated with pedicle screw insertion. Implantation of an interspinous device requires minimal bony exposure without the need for extensive muscle or soft tissue retraction. As a result, Kim et al. reported in a study of 76 adult patients a significantly shorter operation time and 50% lower estimated blood loss (EBL) in patients stabilized with interspinous fixation as supplementation to posterior interbody fusion compared to those that were stabilized using transpedicular fixation.¹³ ISP and pedicle screw groups had comparable improvement in Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS) score outcome scores at 1 year after surgery. However, ISP patients had immediately after ISP procedure more improved VAS score (4.6 ± 3.7) than the pedicle screw group (7.0 ± 3.5) with the difference being statistically significant ($p<0.05$) (Figure 4).^{12,13} Other studies have also shown that ISP surgical technique can clearly be characterized as a minimally invasive spine surgery, as it spares tissue that routinely is disrupted to place pedicle screws, encourages fusion, minimizes complications and may allow for quicker post-operative recovery.^{20,21}

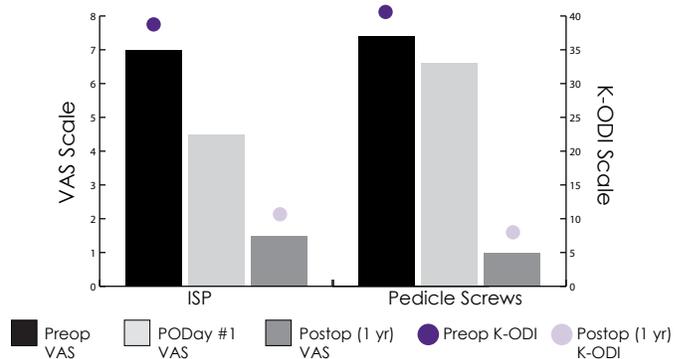


Figure 4: Clinical outcome in the interspinous fusion device group and pedicle screw group one year after surgery ($p<0.05$) for VAS and KDI. Preop: preoperation, Postop: postoperation, ISP: Interspinous fusion device.¹³

A study on 32 patients (21 ISP and 11 bilateral PS) from Wang et al. found that the ISP plate is not only easy to implant but is also associated with minimal operative risk.¹¹ Compared with bilateral PS/rod constructs, the ISP plate fixation lead to less EBL and shorter operative time, without an increase in the rate of pseudarthrosis. Hospital length of stay (LOS) was also shorter, which aligned well with the goals of minimal access spinal

technologies (Figure 5).¹¹ Tatsumi et al. reported results on 55 consecutive patients with posterior fusion at a single center that the spinous process fixation group demonstrated clinically and statistically significant improvement in ODI scores at 6 weeks and 3 months.²²

Richard et al. found that a dynamic interspinous process implant prevents narrowing of the spinal canal and foramina in extension.²³ Similar results were found in 26 patients based on MRI analysis by Saddiqui et al.²⁴ He found that there was a significant increase in the dimensions of the neural foramen and canal area after surgery with a dynamic ISP device. In another study on 17 distraction levels, it has been shown that the ISP device increased the cross-sectional area of the dural sac and exit foramina without causing changes in posture.²⁵ Due to the similarity in design and attachment of dynamic and rigid ISP devices, it can be assumed that a rigid ISP device will also lead to improved degree of central and foraminal stenosis.

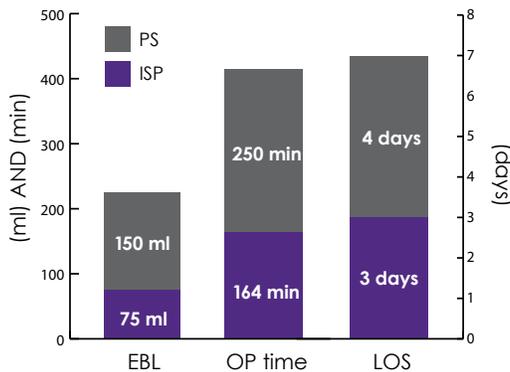


Figure 5: Clinical outcome in the interspinous fusion device group and pedicle screw group after surgery for EBL, OP time and LOS. EBL: estimated blood loss, OP time: duration of the operation, LOS: Length of hospital stay.¹¹

COMPLICATIONS

Potential causes of poor clinical outcome after interspinous fixation have been rare for rigid ISP devices. Most literature is pertaining to dynamic systems. Tamburrelli et al. retrospectively evaluated several patients with persistent post-operative low back pain, radiculopathy, or neurogenic claudication after interspinous fixation.²⁶ Three major causes of failure for those dynamic ISP systems were identified: incorrect surgical indication, device failure and technical error. Device failure was a rare complication and was likely secondary to improper maneuvers during implantation. Technical errors occurred when the interspinous device was not implanted deep enough into the interspinous space, likely secondary to facet hypertrophy and osteophyte obstruction. The majority of failures were secondary to an incorrect surgical indication.

However, there is a clear distinction between ISP spacers

and ISP fixation. Complications associated with the former have not been reported in the latter. Wang et al. found in his study of 32 patients with rigid ISP fixation that there were no instances of major surgery induced complications, pseudarthrosis, or hardware failure during mean follow-up periods of 5.5 months.¹¹ Future analysis of larger cohort studies with longer follow-ups are still needed to confirm his findings. However, due to the nature of the implant, its geometry and positioning, it is very unlikely that serious complications can be expected.

DISCUSSION

InterSpinous Process (ISP) fixation for fusion has gained recent attraction as a less invasive option for patients undergoing lumbar fusion surgery for the treatment of degenerative disc disease, spinal stenosis, spondylolisthesis and/or instability of the lumbar spine.²⁶ ISP devices have been shown to be a safe and efficacious alternative to traditional methods of posterior spinal fixation adjunctive to interbody fusion.. With reliable fusion rates combined with low complication rates, ISP fixation is a safe and effective minimally invasive technique in lumbar fusion surgery. Multiple clinicians have published their successful experience with a variety of ISP fixation devices as a minimally invasive alternative to traditional fixation.^{9,11,13,14}

Rigid interspinous fixation devices provide excellent biomechanical stability in flexion-extension and are sufficiently rigid in axial rotation and lateral bending at the instrumented level while preserving adjacent segments. Multiple studies have found patient outcomes after interspinous fixation to be comparable or superior to traditional transpedicular fixation methods. Additionally, ISP devices are easy to implant and associated with essentially no risk of dural tear or neurological injury. The fixation provided is comparable in stability with pedicle screw instrumentation, but exposes the patient to much less attendant risk. These qualities make ISP fixation an attractive alternative to PS systems for selected patients requiring instrumentation-augmented fixation. In particular, when used as an adjunct to an interbody fusion construct, the use of ISP fixation offers an effective and less invasive option compared to the traditional pedicle screw fixation.^{9,11,13,22}

Besides those primary advantages, ISP devices are also popular due to their easy maneuverability. It has been shown that reduction in estimated blood loss (EBL), operative time, hospital stay and fluoroscopic use can be achieved with these devices.^{11-13,22} Additionally, minimal blood loss, and reduced soft tissue dissection in an increasingly elderly population requiring lumbar decompression and fusion will lead to fewer post-op complications such as prolonged pain, anemia,

infection, and exacerbation of co-morbidities. . These inherent benefits have been shown to lead to less postoperative discomfort and immediately improved postoperative VAS scores in the ISP patients and although PS patients show significant improvement they require longer rehabilitation periods.¹³ In an increasingly cost restrictive medical system these improvements may lead to decreased healthcare costs making the use of ISP devices even more attractive.

However, as with all surgical techniques, interspinous fixation must be utilized for the correct surgical indication to achieve clinical success. Patients with mild to moderate stenosis and a stable low grade spondylolisthesis undergoing interbody fusion may benefit from interspinous fixation. ISP fixation should be avoided in patients with pars interarticularis defects or any bony incompetence between the anterior and posterior spinal columns.^{11,13} In addition, patients with advanced degenerative spondylolisthesis (\geq Grade II), with severe osteoporosis or significant translational instability may not be good candidates for interspinous fixation.

This review has some limitations. Most of the studies included in this systematic review are of a retrospective unrandomized design and cannot exclude all the of the factors that affect the results. While a prospective, randomized trial with a long-term follow up period is needed to confirm the efficacy of rigid one level ISP fixation as an adjunct to interbody fusion, the present review indicates that there is a wide base of evidence for the use of ISP devices in the future.

CONCLUSION

Minimally invasive fixation utilized with current rigid ISP devices such as ZIP Ultra™ from Aurora Spine Inc. have been shown to provide immediate rigid fixation of destabilized motion segments. Combined with interbody fusion, ISP fixation is comparable to pedicle screws in terms of fusion and clinical outcome assessment. ISP devices do not violate adjacent facet joints, decreasing the chances for adjacent segmental degeneration. The ISP adjunct to interbody fusion including anterior (ALIF), lateral (DLIF, LLIF, XLIF) and posterior approaches (PLIF, TLIF) is a valuable alternative technique for patients requiring single level lumbar interbody fusion.

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