Original Article

Advancing the design of interspinous fixation devices for improved biomechanical performance: dual *vs*. single-locking set screw mechanisms and symmetrical *vs*. asymmetrical plate designs

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Background: Interspinous devices were introduced in the field of spine surgery as an alternative to traditional pedicle screw fixation in selected patients for treatment of spinal stenosis and fixation. These devices designs have evolved from non-fixated extension blocks to sophisticated interspinous fixation devices (IFDs). There is an absence of literature comparing the biomechanical fixation strength of different IFD plate designs and the role of set screw locking systems. The aim of this study was to evaluate fixation strengths by bench testing static disassembly and pullout strength of two dissimilar IFD designs and locking mechanisms. We hypothesized that the InSpan (InSpan LLC, Burlington, MA, USA) dual-locking symmetrically IFD plate designed will have stronger fixation than the Aspen (ZimVie, Parsippany, NJ, USA) single-locking asymmetric IFD plate design.

Methods: We conducted two biomechanical bench tests to evaluate the load to failure locking characteristics of symmetrical InSpan and asymmetrical Aspen IFD designs. Static pullout testing involved locking each IFD to the stainless steel and 40 pcf cellular polyurethane foam and measuring pullout load and displacement six times. Seven InSpan and two Aspen IFDs (including the "used" IFDs from the pullout testing) underwent static disassembly tests using a pair of disassembly fixtures positioned between the IFD plates to measure disassembly force and displacement. All tests were performed under ambient conditions using an INSTRON 8874 Bi-Axial Tabletop Servohydraulic Dynamic Testing System (INSTRON, Norwood, MA, USA), and data was collected at a 0.2 mm/s displacement control rate until the test was stopped when there was a drop in the continuously increasing force against resistance (gross failure).

Results: The InSpan IFD experienced 94.81% higher resistance to pullout compared to the Aspen IFD in static pullout testing ($P<0.05$), owing to its notably larger footprint area of 69.8%. Gross failure for both IFD implant designs occurred at the foam block-block interface. In static disassembly testing, pristine InSpan required 60.7% higher force over pristine Aspen and 401.3% for "used" IFDs. Gross failure was characterized by the gradual distraction of the plates and material removal at the set screw contact points. Implant failure at the block-implant interface emphasized the pivotal role of teeth design and the contact surface area of the plates in ensuring stability.

Conclusions: The dual-locking symmetrical InSpan IFD outperformed single-locking asymmetric Aspen IFD in both static disassembly and pullout bench tests. This highlights the benefits of InSpan's improved

design and its potential for enhanced long-term stability in spinal fixation applications.

Keywords: InSpan interspinous fixation device (InSpan IFD); interspinous; pedicle screws; fusion; stenosis

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Introduction

Pedicle screw fixation of the spine is successful but can be associated with risks of nerve injury from malpositioned screws, adjacent segment degeneration (ASD) from too much stiffness and failure in elderly osteoporotic patients (1). Interspinous fixation devices (IFDs), such as InSpan (InSpan LLC, Burlington, MA, USA) and Aspen (ZimVie, Parsippany, NJ, USA), are effective by fixating against the spinous processes and distract between the spinal vertebrae by its a central hub to indirectly decompress the neural foramina and the nerves without the risks associated with pedicle screws (2-4). Interspinous fixation has the potential to be an effective alternative to pedicle screws in selected patients if it could achieve strong fixation to the lamina and spinous processes. In this regard, lessons can be learnt from interlaminar hooks that have been shown by Wilke *et al.* (5) to provide similar primary and long-term stability when compared to a pedicle screw system.

Lumbar spinal stenosis (LSS) is prevalent in the aging population and involves degeneration of the spinal segment, including the discs, ligamentum flavum, and facet joints. This degeneration process gradually results in compression of associated neural elements, leading to radiculopathy and claudication (6). Surgical treatment has been shown to be more effective to conservative treatment in LSS patients exhibiting moderate to severe symptoms (7). Lumbar decompression options include laminectomies, laminotomies, foraminotomies and microdiscectomies to remove compression caused by bone, ligaments and disc material. Techniques that require less exposure spine surgery technologies compared to full open laminectomies, such as interspinous process (ISP) device, have been introduced in selected patients to treat spinal stenosis and to achieve spinal fusion. The insertion of non-fixated ISP devices for decompression of the nerve were intended to decrease spinal narrowing associated with lumbar extension, and the motion from flexion into extension (2). Although non-fixated ISPs have achieved some positive outcomes, their popularity has declined due to inconsistent clinical results and failure rates (8).

When inserted via the classically minimally invasive midline posterior techniques, IFD provides good resistance to flexion and extension and moderate resistance to lateral bending and axial rotation; thus, these devices are good for spinal fusion and stabilization (6). An added benefit to these IFD is that their insertion increases foraminal height, leading to symptomatic relief for patients with foraminal stenosis (6). Non-fixated ISPs on the other hand act dynamically and thus risk failures from dislodgement, spinous process erosions and fractures (8,9). Clinical studies have demonstrated the safety of spinous process plate fixation (2,8). There is limited literature looking at the factors that would increase fixation and decrease the risk of complications.

This biomechanical study aimed to evaluate fixation

Highlight box

Key findings

- The InSpan interspinous fixation devices (IFDs) experienced 94.81% increase resistance to pullout compared to the Aspen IFD, which could be attributed to its larger footprint area.
- During static disassembly testing, pristine InSpan required 60.7% greater force compared to pristine IFDs and 401.3% for "used" IFDs.
- Noted failures in both InSpan and Aspen designs occurred specifically at the foam block-block interface, which emphasizes the importance of teeth design and contact surface area.

What is known and what is new?

- It is known that IFDs have declined in popularity due to inconsistent clinical results and failure rates.
- InSpan's IFD dual-locking symmetrical design resists pullout and disassembly over Aspen.

What is the implication, and what should change now?

- InSpan's design should be considered due to its enhanced fixation strength when selecting an IFD for spinal surgeries.
- InSpan IFD could lead to further research into the design and development of IFD devices, which could ensure greater stability and reliability.

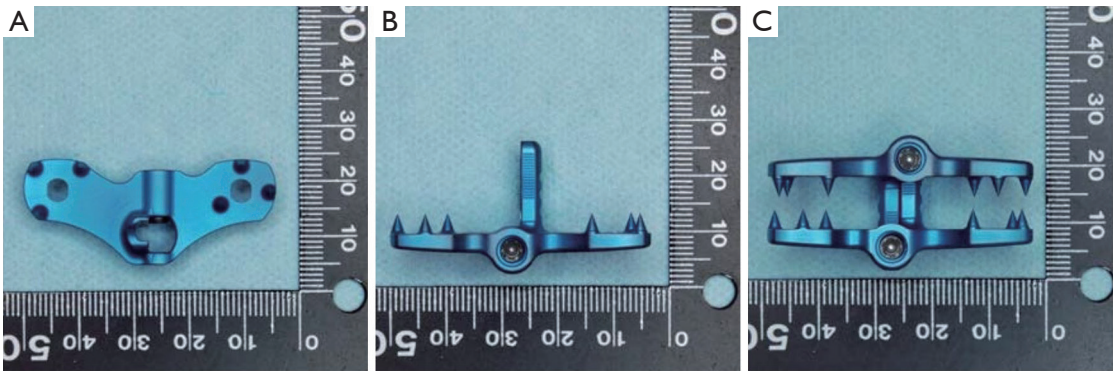

Figure 1 InSpan IFD, illustrating (A) staggered teeth and central hub cut-out on a single plate, (B) central hub and a single set screw on a single plate and (C) final symmetrical dual-locking construct of two plates. IFD, interspinous fixation device.

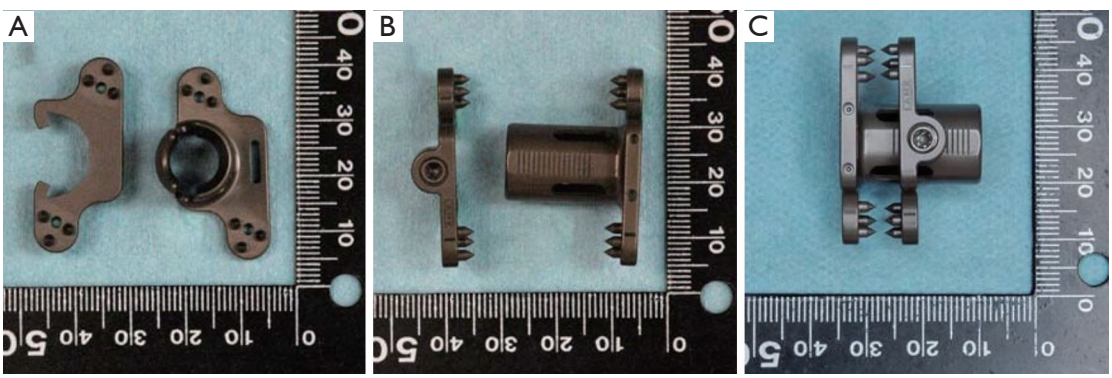

Figure 2 Aspen IFD, illustrating (A) dissimilar plate designs, (B) dissimilar plate with a central hub and a single set screw and (C) final asymmetrical single-locking construct. IFD, interspinous fixation device.

strength by bench testing static disassembly and pullout strength of two dissimilar IFD designs and locking mechanisms. We hypothesized that the InSpan (InSpan LLC) dual-locking symmetrically IFD plate design will have stronger fixation than the Aspen (ZimVie) single-locking asymmetric IFD plate design.

Methods

The symmetric InSpan IFD design consists of a pair of symmetrical plates featuring a single set screw and tall, staggered teeth at both ends of the plate (*Figure 1A,1B*). Two of these individual plates are positioned facing each other to yield the symmetric dual-locking IFD InSpan design (*Figure 1C*). The asymmetric Aspen IFD design, on the other hand, comprised of dissimilar plates, united by a single set screw (*Figure 2*). The InSpan and Aspen IFD designs were biomechanically bench tested using static pullout and disassembly testing. All tests were performed in ambient conditions using an INSTRON 8874-Biaxial Tabletop Servohydraulic Dynamic Testing System (INSTRON, Norwood, MA, USA) equipped with a 25 kN axial and 100 Nm torsional load cell (10). No preload was applied prior to the testing. Data collection occurred at a 0.2 mm/s displacement control rate and was recorded using INSTRON's Wavemaker Software. Testing stopped at gross failure defined as a drop in the applied continuously increasing force against resistance.

Static pullout test

One size 8 mm InSpan and one 14 mm Aspen IFD underwent static pullout testing. The superior ends of each IFD plate were aligned with a stainless-steel removable insert featuring spike-accommodating holes. An 8 mm wide block of 40 pcf cellular polyurethane foam (Sawbones,

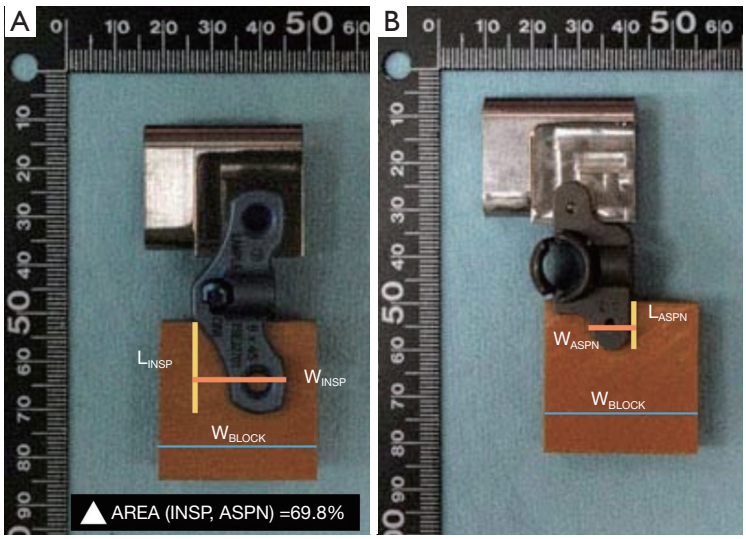

Figure 3 Lateral view of IFD set up and contact area surface measurements of InSpan (A) and Aspen (B) for static pullout test. INSP contact area 69.8% greater than ASPN (black rectangle). INSP, InSpan; ASPN, Aspen; L_{INSP}, length of the contact surface of InSpan; W_{INSP}, width of the contact surface of InSpan; L_{ASPN}, length of the contact surface of Aspen; W_{ASPN}, width of the contact surface of Aspen; W_{BLOCK}, width of the polyurethane foam block; IFD, interspinous fixation device.

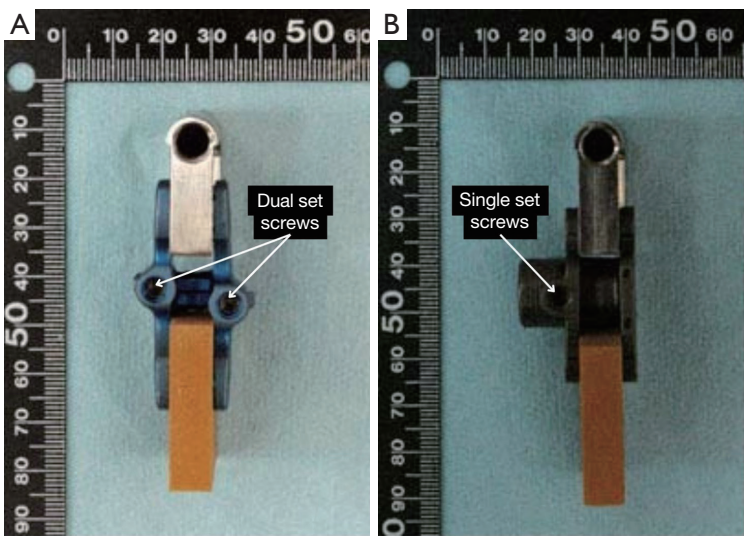

Figure 4 Posterior view of IFD set up for dual set screws for InSpan (A) and single-locking set screw for Aspen (B) for static pullout test. IFD, interspinous fixation device.

Pacific Research Laboratories, Vashon, WA, USA) was positioned between the inferior ends. Polyurethane foam is validated in published reports as a synthetic bone substitute material in testing (11,12). We chose to use it as a model for the benefit that it eliminates bone density variables for more reproducible results. The plates were compressed using a vice until the spikes were fully seated into the removable insert and the polyurethane foam block. The set screw(s) were torqued to 30 in-lb using a Proto 6106 Torque Screwdriver (Stanley Proto Industrial Tools, Covington, GA, USA). This resulted in the finalized test constructs and the effective contact surface area of the symmetric InSpan and the asymmetric Aspen IFD plate designs were measured (*Figures 3,4*). The removable insert was securely fastened

Table 1 InSpan versus Aspen IFD: static pullout load and displacement at pullout to failure mode

Test	Pullout load (N)			Displacement at pullout (mm)		
	InSpan	Aspen	% Diff.	InSpan	Aspen	% Diff.
1	2,383.81	1,082.83	120.15	2.67	0.57	368.42
2	2,409.29	830.02	190.27	3.16	0.43	634.88
3	2,410.97	1,424.83	69.21	2.68	0.97	176.29
4	2,411.35	1,376.89	75.13	3.11	0.78	298.72
5	2,458.93	1,241.82	98.01	2.94	0.87	237.93
6	2,411.69	1,258.63	91.61	2.94	0.79	272.15
Median	2,411.16	1,250.22	94.81	2.94	0.79	285.44
Range	75.12	594.81		0.49	0.54	
95% CI	2,388.75–2,439.93	973.74–1,431.27		2.70–3.13	0.53–0.94	

IFD, interspinous fixation device; N, Newton; mm, millimeter; % Diff., percentage difference; CI, confidence interval.

to a detachable faceplate fixture using a shoulder bolt, while the foam block was firmly clamped within a vice. The static pullout tests were performed six times for each IFD, and data for pullout load (N), displacement at pullout load (mm) and load to failure mood were recorded (*Table 1*). The ramp waveform was applied until a continuous force was no longer detectable, indicating the cellular polyurethane foam test blocks experienced gross failure and met the failure criteria.

Static disassembly test

Seven InSpan IFDs and two Aspen IFDs (sizes 8 and 14 mm) were subjected to static disassembly testing. Among them, six InSpan and one Aspen were pristine (never used), while one InSpan and one Aspen were "used" in the prior static pullout testing. The disassembly fixtures consisted of 5 mm thick plates with precisely engineered holes to accommodate spikes and the central hub of each IFD. For the testing procedure, two disassembly fixtures were positioned between the IFD plates, and subsequent compression of the plates was accomplished by tightening the set screw(s) to a torque of 30 in-lb using a Cedar Digital Torque Screwdriver (Imada Inc., Northbrook, IL, USA). These disassembly fixtures were then securely attached to the testing frame, as shown in *Figure 5*. Static disassembly tests were conducted on each IFD to measure disassembly force (N), displacement at disassembly force (mm), and record load to failure. Data was collected until reaching permanent IFD deformation or experiencing gross failure.

Statistical analysis

All statistical analysis was performed using Excel data analysis tool. Descriptive statistics were described as median and range. Welch's *t*-test was used to compare the groups of non-normally distributed variables. Tests were considered significant if $P<0.05$.

Results

Static pullout test

The symmetric dual-locking InSpan IFD plate design exhibited approximately 69.8% greater effective contact area coverage by the locked plates compared to the asymmetrical single-locking Aspen IFD plate design (*Figure 3*). The InSpan IFD device experienced 94.81% higher resistance to pullout compared to Aspen with 95% confidence (*Table 1*), showcasing the superior retention strength of InSpan IFD.

According to *Table 2*, Welch's *t*-test was conducted to look for significance in comparing the median pullout between InSpan and Aspen IFDs at the point of gross failure. An alpha (α) value of 0.05 was applied. InSpan was significantly stronger in pullout over Aspen and required much larger displacement before failure ($P<0.05$). The foam block-block interface was the site of gross failure for both IFD implant designs.

Static disassembly test

The static disassembly tests produced load (N) versus

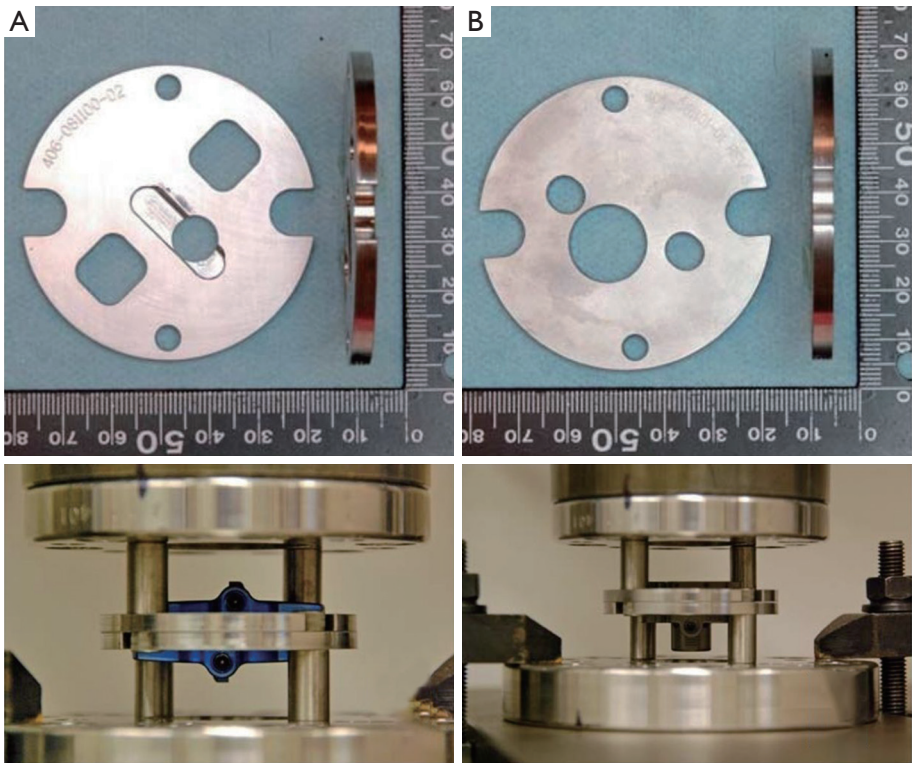

Figure 5 Disassembly fixtures and set up construct of InSpan (A) and Aspen (B) for static disassembly test.

Table 2 Welch's *t*-test results of InSpan versus Aspen IFDs for pullout load and displacement at pullout to failure mode

Pullout load (N)	Displacement at pullout (mm)
$P=3.31\times10^{-5}$	$P=4.47\times10^{-9}$

IFD, interspinous fixation device; N, Newton; mm, millimeter; P, P value.

displacement (mm) curves for seven InSpan IFDs (six pristine and one used) and two Aspen IFDs (one pristine and one used), depicted in *Figure 6*. In static disassembly testing, pristine InSpan required 60.7% higher force over pristine Aspen and 401.3% for "used" IFDs (*Figure 7*). All IFDs experienced gross failure by a gradual distraction of the plates and removal of material at the set screw contact points.

Discussion

Recognizing the broad spectrum of complications associated with the evolution of pedicle screws, it's evident that not all patients are suited for such stabilization techniques. Hence, the development of the InSpan device reflects an ongoing endeavor to innovate more effective IFDs for spinal fixation in selected patient groups. This study, in examining Aspen as a contrast to InSpan, seeks to learn from design improvements, informing future iterations of IFDs. With a rich clinical history using InSpan since its United States Food and Drug Administration (FDA) approval, we aim to continue evaluating its performance and comparing it with pedicle screws in suitable patients. The design of the InSpan IFD also evolved from the continuous innovation spurred by the limitations of past devices such as pedicle screws, which have seen significant advancements over decades. This evolution has been driven by a need for alternative solutions for patients where traditional pedicle screws and interbody cages may not be ideal, particularly in interventional pain management scenarios for elderly patients with osteoporotic bone or those with low demands.

From the tests performed on this limited sample size, we documented biomechanical disparities between the dual-locking symmetric InSpan IFD and the single-locking asymmetric Aspen IFD. In studying multiple InSpan IFDs, there was consistent demonstration of the need for higher pullout forces before the occurrence of failure in both static disassembly and pullout bench tests

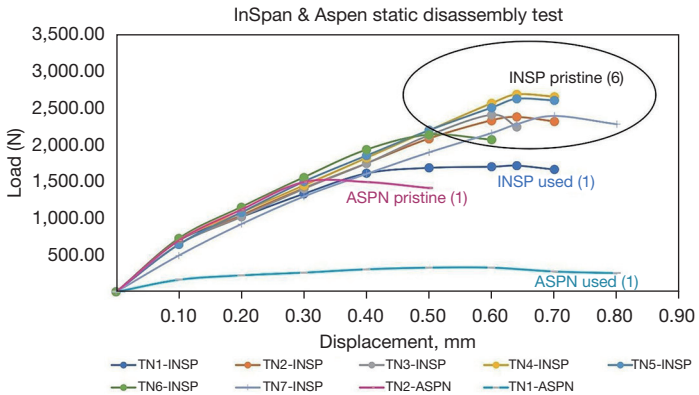

Figure 6 InSpan and Aspen IFD static disassembly tests showing load (N) *vs.* displacement (mm) curves. The turning point of the curve represents the disassembly force. INSP, InSpan; ASPN, Aspen; TN, test number; N, Newton; mm, millimeter; IFD, interspinous fixation device.

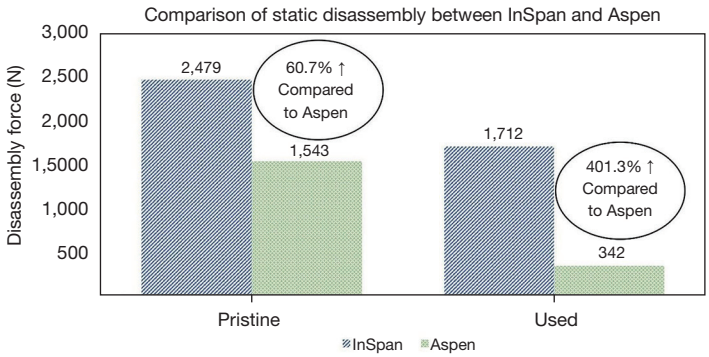

Figure 7 Comparisons of static disassembly force (N) between pristine and "used" InSpan and Aspen interspinous fixation devices. N, Newton.

for InSpan versus Aspen. The InSpan IFD displayed a 94.81% increase in static pullout force over the Aspen IFD during testing. This result can be attributed, in part, to the InSpan's larger footprint area covered by the locked plates (approximately 69.8% greater than that of the Aspen IFD), thereby contributing to a more effective distribution of load. The resultant augmented stability of the InSpan translated to a heightened threshold for axial displacement. Consequently, this increased stability accounted for the more significant displacement observed at the attachment site upon separating the InSpan IFD from the block. The disassembly testing results further supported InSpan IFD's design robustness, as it required greater disassembly forces of 60.7% for pristine IFD compared to Aspen. To simulate a scenario relevant to surgical practice where a device may be re-implanted after being used, we extended our investigation to include a disassembly study involving previously "used" InSpan and Aspen IFD devices. When comparing single "used" InSpan and Aspen, we documented a significantly higher disassembly strength for InSpan over Aspen. If this can be further substantiated with repetitive studies, it provides an insight into the potential design improvement of the InSpan dual-locking set screws. This could also mean InSpan has the potential to maintain stability over time, a crucial factor for long-term implant success. The failure mechanism observed during disassembly testing, characterized by the gradual distraction of plates and material removal at set screw contact points, provided valuable insights into potential weak points in the design. The failure mode at the block-implant interface highlighted the pivotal role of teeth design and contact surface area in ensuring overall stability.

These biomechanical test results might not predict clinical outcomes when selecting an IFD device for a

patient. While the Aspen IFD asymmetric single set screw design demonstrated inferior biomechanical strength compared to the symmetric dual set screw InSpan, their clinical suitability could still be valid in appropriately selected cases. Aspen IFD was found to provide strong fixation when used with anterior lumbar interbody cages (13). Aurora ZIP (Aurora Spine, Carlsbad, CA, USA), a symmetrical IFD design without a set screw, showed no revisions when used by interventional pain management physicians in short-term clinical follow-up (14). Although InSpan demonstrated high strength against disassembly and pullout forces, it should not be implied that it is more robust than other IFDs not tested in this study. Pedicle screws provide strong fixation but result in more significant stresses on the adjacent levels, increasing ASD. Fixation strength provided by InSpan was not tested against pedicle screws, and thus no inference can be made to compare InSpan to pedicle screws or the risk of ASD. The stronger symmetrically designed InSpan theoretically is potentially associated with increased osteopenia of the spinous process secondary to stress-shielding. However, the InSpan design is replacing the interspinous and supraspinous ligaments but will act as load bearing mostly in extension and load sharing in all other planes of motion as it resists forces to separate the spinous processes.

From the literature, spine surgeries employing IFDs have shown a decrease in patient Visual Analog Scale (VAS) scores, indicating successful outcomes with reduced complications and shorter recovery times (2,15). IFDs have also proven effective in reducing direct and indirect costs associated with LSS compared to prolonged conservative treatments or laminectomies (16). However, a study from 2014 examining various ISDs and IFDs drew a less promising conclusion, suggesting inconsistent clinical results and underwhelming long-term outcomes (8). It was against this backdrop that the InSpan design underwent a significant transformation to become symmetrical with dual set screws, a departure from the previous ISD and IFD designs. InSpan's clinical data has revealed the absence of device failures when used as a standalone treatment for patients with L4–5 spinal stenosis, which could be attributed to the biomechanical strength demonstrated in this study (2).

We confirmed our hypothesis that the dual-locking symmetrically designed InSpan IFD plate demonstrated biomechanically stronger fixation than the single-locking asymmetric Aspen IFD plate design. This resilience highlighted the potential of InSpan to maintain stability over time, which is a critical factor for the long-term success of implants. From a clinical perspective, the significance lies in that the InSpan design represents a significant advancement in IFD strength. Surgeons could have had more confidence in using this device to restore interspinous and supraspinous ligaments following decompression and fusion procedures.

This study has important limitations including a small, uneven sample size that may bias results and limit generalizability. The use of cellular polyurethane foam, a synthetic bone substitute, does not accurately represent the variability in human bone quality. Additionally, laboratory conditions do not replicate the dynamic biological environment of the human body, potentially impacting the IFD's performance. The statistical power of the tests was not confirmed to meet the optimal level of 0.80, which might affect the confidence in detecting true differences between the IFD designs. These factors underscore the need for further research with larger, balanced samples and more clinically representative models to validate these biomechanical findings in clinical settings.

Conclusions

Our study demonstrates that the dual-locking symmetrical InSpan IFD significantly outperforms the single-locking asymmetric Aspen IFD in biomechanical pullout and disassembly testing, highlighting its potential for enhanced long-term stability in spinal fixation applications.

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Footnote

Data Sharing Statement: Available at https://jss.amegroups.com/article/view/10.21037/jss-24-13/dss

Peer Review File: Available at https://jss.amegroups.com/article/view/10.21037/jss-24-13/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jss.amegroups.com/article/view/10.21037/jss-24-13/coif). K.R.C. reports that he is the cofounder and CEO of KIC (Kingsley Investment Company) Ventures and has ownership shares in the company. V.L. is an employee of LESSpine, a for-profit medical device company. E.S. and W.M.C. have ownership shares in (Kingsley Investment Company) Ventures. The

other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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