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A comparative biomechanical study of a novel integrated plate spacer for stabilization of cervical spine: An *in vitro* human cadaveric model

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ABSTRACT

Background: Integrated plate-spacer may provide adequate construct stability while potentially lowering operative time, decreasing complications, and providing less mechanical obstruction. The purpose of the current study was to compare the biomechanical stability of an anatomically profiled 2-screw integrated plate-spacer to a traditional spacer only and to a spacer and anterior cervical plate construct. In addition, the biomechanical stability of 2-screw integrated plate-spacer was compared to a commercially available 4-screw integrated plate-spacer.

Methods: Two groups, each of nine cervical cadaver spines (C2–C7), were tested under pure moments of 1.5 Nm. Range of motion was recorded at C5–C6 in all loading conditions (flexion, extension, lateral bending, and axial rotation) for the following constructs: 1) Intact; 2) 2-screw or 4-screw integrated plate-spacer; 3) spacer and anterior cervical plate; and 4) spacer only.

Findings: All fusion constructs significantly reduced motion compared to the intact condition. Within the instrumented constructs, spacer and anterior cervical plate, 2-screw and 4-screw integrated plate-spacer resulted in reduced motion compared to the spacer only construct. No significant differences were found in motion between any of the instrumented conditions in any of the loading conditions.

Interpretation: The application of integrated plate-spacer for anterior cervical discectomy and fusion is based on several factors including surgical ease-of-use, biomechanical characteristics, and surgeon preference. The study suggests that integrated plate-spacer provide biomechanical stability comparable to traditional spacer and plate constructs in the cervical spine. Clinical studies on integrated plate spacer devices are necessary to understand the performance of these devices *in vivo*.

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1. Introduction

Anterior cervical discectomy and fusion (ACDF) is one of the most commonly used spine procedures to treat degenerative conditions of the cervical spine, such as radiculopathy and spondylotic myelopathy (Scholz et al., 2009). ACDF studies have shown a 90–95% success rate in patients with cervical radiculopathy or myelopathy (Bartolomei et al., 2005; Hannallah et al., 2007). First reported by Robinson and Smith (1955), a single level ACDF is now an established surgical treatment for cervical degenerative conditions, with fusion rates ranging from 83% to 97% and 82% to 94%, for autograft and allograft, respectively (Hunter et al., 2011).

The primary objective of ACDF, in addition to neural decompression, is to provide segmental stability and a solid arthrodesis with minimal surgical risks. The establishment of normal cervical lordosis and disk space height are often necessary in order to obtain decompression, relieve present symptoms, and prevent the progression of deformity (Herrmann and Geisler, 2004). One commonly employed technique uses an interbody spacer at the level of degeneration to restore the disk and foraminal height and to provide segmental stability until a bony fusion occurs (Scholz et al., 2009). However, since the anterior longitudinal ligament is resected during ACDF procedures, the interbody spacer provides stability only through tensioning of the remaining ligaments and stability, especially during extension and axial rotation, may be compromised. For this reason, many surgeons prefer to supplement the construct with an anterior cervical plate to further stabilize the segment (Kaiser et al., 2002). Although cervical plates reduce the problem of graft extrusion and collapse, they may be associated with complications such as screw or plate dislodgement, dysphagia, and soft tissue injury (Fujibayashi et al., 2008). Moreover, in spite of low profile plate designs, the process of adding a plate increases the operative (OR) time and may be related to complications involving vital anterior structures, such as the trachea, carotid arteries, and esophagus (Scholz et al., 2009). Recently,

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anatomically profiled integrated plate-spacers (IPSs) have been introduced as an alternative to a traditional spacer and plate (S + P) constructs for ACDF procedures. The use of an integrated plate-spacer device may also be beneficial for revision surgeries by negating the need to remove the original instrumentation, thus lowering the theoretical risk of increased OR time and patient morbidity.

To date, there have been few reports on the biomechanical performance of IPSs. One previously reported cervical IPS has 4 integrated screws and has shown to provide adequate stability compared to spacer only constructs (Scholz et al., 2009). The design of common IPSs may be further streamlined to minimize the surgical incision by reducing the amount of hardware by the use of a 2-screw IPS design (Fig. 1).

This study presents the biomechanical performance of a novel 2-screw PEEK IPS. The objective of this study was to compare biomechanical performance of the novel 2-screw IPS, and a commonly used 4-screw IPS, to the traditional spacer and plate construct following an ACDF in a cervical spine model.

2. Methods

2.1. Specimen preparation

Eighteen fresh frozen human cervical cadaver spines (C2–C7), randomized into two groups of nine each, were used in the study. The specimens were obtained from Science Care® (Phoenix, AZ) tissue bank, donated from five women and thirteen men (mean age, 62 years; range 45–84). The medical history of each of the donors was reviewed to exclude trauma, malignancy, or metabolic disease that might otherwise compromise the biomechanical properties of the cervical spine. Furthermore, the spines were radiographed in the anteroposterior and lateral planes to ensure the absence of fractures, deformities, disk narrowing and any metastatic disease. Those with visible flaws were excluded and replaced. Specimens were then separated randomly into two groups of nine and stored in double plastic bags at −20 °C. The spines were dissected by carefully denuding the paravertebral musculature, avoiding disruption of spinal ligaments, joints and disks. Each spine was potted proximally at C2 and distally at C7 in a 3:1 mixture of Bondo auto body filler (Bondo MarHyde Corp, Atlanta, Ga) and fiberglass resin (Home-Solution All Purpose Bondo MarHyde). Three infrared light-emitting diodes, mounted non-collinearly on a plexiglass plate were rigidly attached to the anterior aspect of each vertebral body and served as points for motion measurement. Three dimensional motions were tracked using Optotrak Certus motion analysis system (NDI, Inc. Waterloo, Canada).

2.2. Flexibility testing

Each spine was fixed to the load frame of a custom built six degree of freedom spine simulator and a pure moment was applied to the construct through servomotors (Gabriel et al., 2011; Hunter et al., 2011). Each specimen was maintained moist throughout the test by spraying it with 0.9% saline. All tests were carried out at room temperature of 25 °Celsius. Each of the test constructs were subjected to three load-unload cycles in each of the physiologic planes, generating flexion-extension, right-left lateral bending and right-left axial rotation load displacement curves. This was achieved by programming the motors to apply continuous moments in each physiologic plane. A typical load–unload cycle in the sagittal plane comprised of Neutral − Full Flexion + Full Extension (3 times) − Neutral. Data from the third cycle was used for analysis. The design of the load frame enables unconstrained motion of the spine in response to an applied load. There was no compressive preload applied on the specimen. A load control protocol was used to apply a maximum moment of 1.5 Nm at a rate of 1°/s (Goel et al., 2006; Wilke et al., 1998).

The three dimensional intervertebral rotation was obtained from the motion analysis data files in the form of Euler angles (degrees) about the X, Y and Z axes. $R_x/-R_x$, $R_y/-R_y$ and $R_z/-R_z$ denoting flexion-extension, right–left axial rotation and right–left lateral bending range of motion (RoM), respectively (Hunter et al., 2011).

2.3. Study design

Each spine was tested at C5–C6 level in the following sequence: (1) Intact (n = 18); (2) discectomy and stabilization using integrated plate-spacer [IPS-I or IPS-II] (n = 9 each); (3) stabilization using a traditional spacer and plate [S + P] (n = 18); and (4) with interbody spacer only [S] (n = 18); (Fig. 1). The COALITION® [Globus Medical, Inc., Audubon, PA] 2-screw (IPS-I) and ZERO-P [Synthes, West Chester, PA] 4-screw (IPS-II) integrated plate-spacer devices were used in the study and were assigned to one of the independent cadaveric groups. The COLONIAL® ACDF Spacer [Globus Medical, Inc.] and PROVIDENCE™ anterior cervical plate [Globus Medical, Inc.] were both used. In each tested condition, the specimens were subjected to pure moments of 1.5 Nm in flexion-extension, lateral bending and axial rotation. The data was normalized to the intact specimen (Intact = 100%).

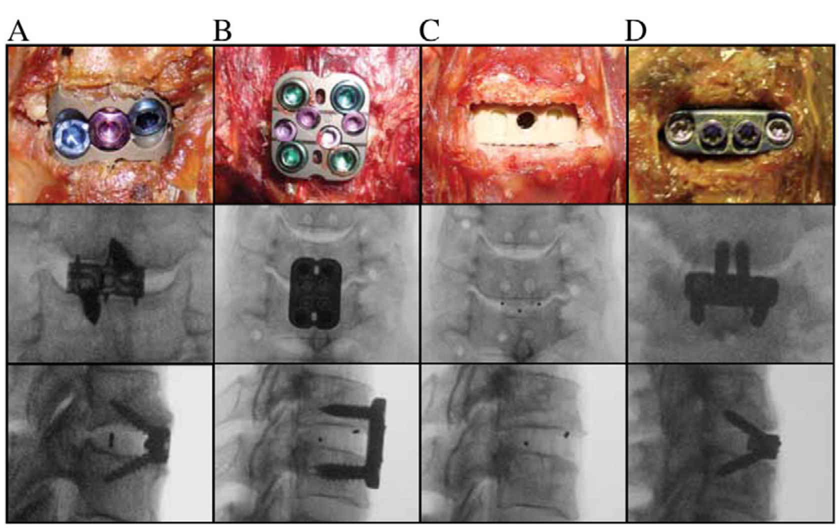

Fig. 1. Surgical constructs. A) Integrated plate-spacer device I (IPS-I); B) traditional interbody spacer and anterior cervical plate (S + P); C) interbody spacer only (S) and; D) integrated plate-spacer device II (IPS-II).

Table 1
Mean range of motion (standard deviation) in degrees at C5–C6.

Loading parameter	Intact	S	S + P	IPS-I	IPS-II
	n = 18	n = 18	n = 18	n = 9	n = 9
Flexion	1.4 (1.1)	0.8 (0.8)	0.7 (0.8)	0.6 (0.6)	0.2 (0.1)
Extension	1.6 (1.9)	0.6 (0.8)	0.4 (0.5)	0.5 (0.7)	0.3 (0.1)
Lateral bending	2.4 (1.4)	0.9 (0.7)	0.7 (0.6)	0.5 (0.4)	0.6 (0.7)
Axial rotation	4.4 (2.2)	2.6 (2)	1.9 (2.1)	1.6 (1.2)	1.7 (1.7)

Statistical analysis was performed on raw data using a repeated measures analysis of variance for independent samples followed by Tukey's post-hoc analysis for multiple comparison procedures, where RoM within each group and in each instrumented condition (S, S + P, IPS-I/IPS-II) were compared to one another. In addition, the IPS-I, and IPS-II constructs were compared using Independent samples *t* test. Significance was accepted at $P<0.05$. RoM values for intact, S and S + P constructs were averaged over two groups for the purpose of graphical representation.

3. Results

The constructs were examined after testing and none showed any visible signs of damage, loosening, or breakage. The means (standard deviations) for RoM in flexion-extension, lateral bending, and axial rotation are presented in Table 1 and Fig. 2.

3.1. Flexion

The RoM was significantly ($P<0.05$) reduced in flexion for all instrumented constructs compared to the intact condition. The spacer only (S) construct reduced the motion significantly by 47%, while addition of an anterior plate (S + P) further reduced motion significantly by 6% compared to the intact condition. For integrated plate-spacer constructs, the IPS-I reduced the motion significantly by 73% and IPS-II by 75%, compared to intact condition. RoM for the S construct was higher compared to the S + P, IPS-I, and IPS-II constructs but was not statistically significant. Furthermore, there was no significant difference between IPS-I and IPS-II constructs.

3.2. Extension

Similar to flexion, all fixation constructs significantly reduced motion compared to the intact condition. The spacer only (S), spacer and plate (S + P), IPS-I and IPS-II constructs reduced the motion significantly by 46%, 67%, 68%, and 64%, respectively. There was no significant difference in the stability between the instrumented constructs.

3.3. Lateral bending

All instrumented constructs reduced motion significantly ($P<0.05$) compared to the intact condition and trended as follow: S > S + P > IPS-I > IPS-II. The RoM in lateral bending for the S, S + P, IPS-I, and IPS-II constructs was reduced by 59%, 69%, 70% and 73%, respectively compared to the intact condition. In addition, there was no significant difference in the range of motion between IPS-I and IPS-II constructs.

3.4. Axial rotation

The RoM for all instrumented constructs decreased significantly ($P<0.05$) compared to the intact condition and followed a trend similar to lateral bending: S > S + P > IPS-I > IPS-II. The motion significantly reduced by 45% with spacer only (S) constructs and further decreased by 17% with the addition of an anterior plate (S + P). Within the integrated plate-spacer constructs, IPS-I and IPS-II, motion reduced by 63% and 69% respectively, compared to the intact condition. There was no statistical significant difference between S + P, IPS-I and IPS-II constructs in any of the loading conditions.

4. Discussion

Historically, cervical plates have been associated with various intraoperative and postoperative complications, despite their ability to increase the biomechanical strength of the construct and increase fusion rates (Shimamoto et al., 2001). Coe and Vaccaro (2005) presented a literature review on complications of anterior cervical plating, with up to 15% screw and plate loosening, 6.7% plate fracture, 21.4% plate and graft displacement, and 12.5% implant malfunction. With the advancement of device technology, implants with low profile and locking screws have been designed to minimize these complications. However,

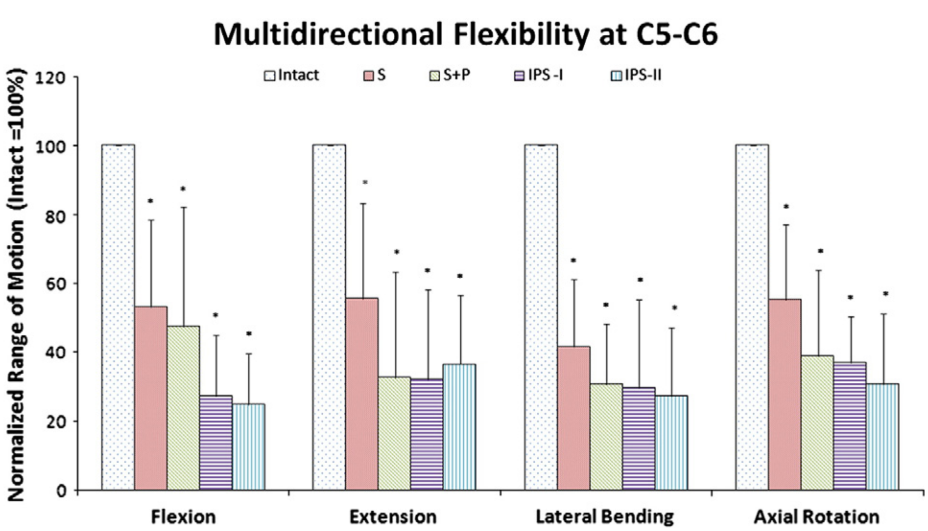

Fig. 2. Comparison of C5–C6 RoM (% of intact specimen) in flexion, extension, lateral bending, and axial rotation. The intact RoM is set to 100%. The figure shows comparison between, 1) interbody spacer only (S); 2) traditional interbody spacer and anterior cervical plate (S + P); 3) integrated plate-spacer device I (IPS-I); and 4) integrated plate-spacer device II (IPS-II). * represents significance w.r.t to the intact condition.

the risk involved with these newer designs is still present, as reported by Lowery and McDonough (1998) in their review of 109 patients with 3 different types of anterior cervical plates. A device with no profile and a blocking set screw would potentially minimize these plate and screw-related complications. However, the biomechanical performance of an anatomically profiled 2-screw IPS (IPS-I) has not been investigated. The IPS-I was designed for ease in clinical use, based on a 2-screw design, while retaining adequate biomechanical performance in comparison to a similar 4-screw design currently available in the market.

One of the potential advantages of IPS-I is that it encompasses a less invasive approach that allows for a smaller surgical incision and less soft tissue retraction compared to a traditional S + P, in addition to having an anatomical profile and fewer procedural steps that may potentially reduce OR time and dysphagia rates. The IPS-I design may be particularly useful for adjacent level treatment whereby removal of the original plate is not necessary. Other advantages may also include less esophageal retraction during instrumentation, reduced intraesophageal pressure (Tortolani et al., 2006), correction of cervical kyphosis, and restoration of disk height. When comparing the IPS-I 2-screw design (medially converging) to the IPS-II 4-screw design, there is potentially less risk of screw placement near the vertebral arteries coursing lateral to the uncinate processes.

The data obtained in this study demonstrated that all the instrumented constructs reduced motion significantly compared to the intact condition but did not show any significant difference in the kinematic behavior among the instrumented constructs. In the present study, the spacer and plate construct reduced the RoM by 24% during flexion-extension, 45% during lateral bending, and 26% during axial rotation compared with spacer only construct. These results although not consistent with other studies, a trend similar to those observed in previous studies have been noticed with spacer only construct being the least stable construct. Freeman et al. (2006) in an *in vitro* biomechanical study showed that titanium plates reduced the RoM by 69% during flexion-extension, 45% during lateral bending, and 27% during torsion compared with a spacer only construct. In another biomechanical study, Greene et al. (2003) showed that a one-level titanium plate reduced RoM by 84% during flexion-extension, 68% during lateral bending, and 55% during torsion compared with a spacer only construct. On the other hand, Crawford et al. (2011) demonstrated that rigid 4-screw plate reduced the RoM by 65% during flexion-extension, 61% during lateral bending, and 60% during torsion compared with a spacer only construct.

Furthermore, previous biomechanical studies comparing 2-screw plate versus 4-screw plate constructs have been performed. Crawford et al. (2011) conducted a multidirectional flexibility test comparing 2-screw versus 4-screw plate and concluded that the rigid 2-screw plate performed comparably to conventional rigid 4-screw plate. In another similar biomechanical study, Scholz et al. (2009) compared 4-screw integrated plate-spacer to rigid 4-screw plate and spacer only constructs and found both integrated plate-spacer and rigid 4-screw plate to reduce motion significantly compared to spacer only construct. The findings of the present study show that there are no significant differences between spacer only construct compared to integrated plate-spacer and spacer and plate constructs. This is in contrast to the studies previously mentioned where significant differences between stability offered by spacer only and those augmented with plate were found. The opposite findings may be attributed to the different plate and spacer designs and bone quality of the specimens used in these studies.

Biomechanically, the IPS-I construct demonstrated comparable stability to that of a traditional spacer and plate construct and IPS-II. However there are differences in the design of the two integrated plate-spacers. The IPS-I screws are not threaded into the integrated plate unlike the IPS-II. This allows for a lag effect in which the device is press fitted tightly to the vertebral body using the screws. On the other hand, the IPS-II design relies on being initially well inserted; however an initial gap may exist between the implant and bone and the screws may lock into the plate without lagging the spacer any further. Nevertheless, the results of this study show no statistical differences in stability offered by this new integrated plate-spacer device compared to that offered by IPS-II with 4 integrated screws. Furthermore, the results of this study demonstrate that the stability of this new device is equivalent to that provided by an anterior spacer stabilized by additional anterior cervical plating.

The current *in vitro* study has certain limitations. Firstly, isolated cadaver spines with removed spinal musculature were used. Therefore, the stability offered by muscle forces and the incorporation of bone graft material is not considered. However, as the data was normalized to the intact condition, the findings of the study may not be affected. Also, the size and bone mineral density of each specimen vary according to age and may also affect the data presented here.

Secondly, compressive load arising from head weight and muscle was not simulated. An axial compression across the implanted segment would have presumably enhanced stability during intact and instrumented conditions (Crawford et al., 2011 and Patwardhan et al. 2000). Since no significant differences were observed without preload among instrumented constructs it can be presumed that there would probably have been no noticeable differences if compression had been applied. Furthermore, this study did not evaluate the correlation between bone mineral density and range of motion. Previous studies have shown that degree of stabilization achieved is dependent on the bone mineral density of the vertebral body. Crawford et al. (2011) in a biomechanical study comparing 2-screw versus 4-screw cervical plate found that rigid 4-screw cervical plates are less dependent on bone quality in its ability to limit the range of motion. In contrast, Dvorak et al. (2005) found a strong correlation between bone mineral density and range of motion using the same rigid 4-screw plate. It would have been interesting to see the correlation between change in stability and bone mineral density of different instrumentation and could have probably explained some of the opposite findings observed in the present study. Perhaps in a future study this will be investigated.

Establishment off normal cervical lordosis and disk space height is often necessary to decompress the spine and prevent re-occurrence of the deformity. A quantitative measurement of the changes in the alignment with the insertion of an interbody device and subsequent application of the screws would have given an insight into how well different instrumentation has re-established the initial neutral alignment. The study is limited in this regard. However, all the implants used in the testing come in various sizes and with selectable amounts of lordotic correction at both the superior and inferior ends that allowed for visual restoration of normal lordosis and disk space height.

5. Conclusion

The application of IPSs for ACDF is based on several factors including surgical ease-of-use, biomechanical characteristics, and surgeon preference. This study suggests that IPSs provide comparable biomechanical stability to traditional spacer and plate constructs in the cervical spine. Moreover, the IPS-I provides comparable biomechanical stability to the IPS-II. The IPS-I is also expected to provide more ease-of-use and require less OR time due to its 2-screw based design. Ultimately, IPSs with less overall hardware may provide adequate biomechanical stability to the cervical spine compared to traditional methods. Consequently, the IPS-I, with its no profile design, may potentially reduce reported OR time, dysphagia rates, and complications while maintaining high fusion rates when compared to traditional spacer and plate methods. However, clinical studies are required to confirm these potential benefits.

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