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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*.

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%).

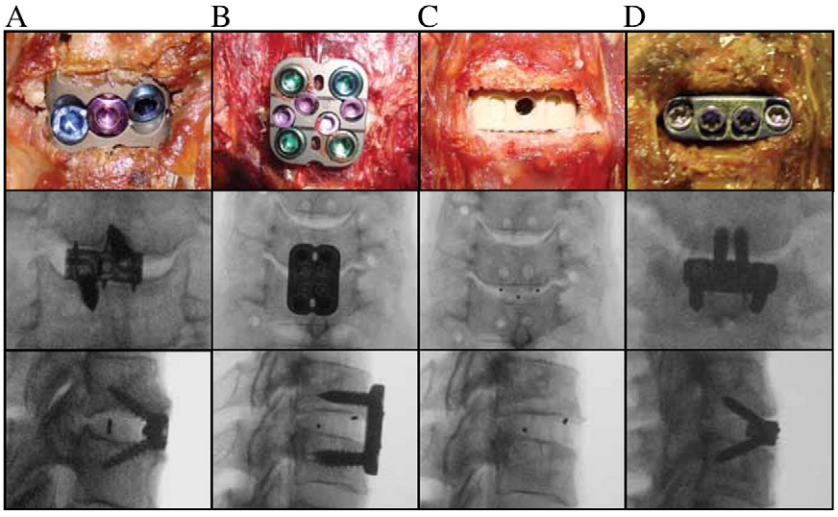

Fig. 1. Surgical constructs. A) Integrated plate-spacer device I (IPS-I); B) traditional interbody spacer and anterior cervical plate (S + P); C) interbody spacer only (S) and; D) integrated plate-spacer device II (IPS-II).