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# Impact of screw location and endplate preparation on pullout strength for anterior plates and integrated fixation cages

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**Abstract**

**BACKGROUND CONTEXT:** Numerous integrated fixation cages (IFCs) have recently been introduced to the market with “zero-profile” designs that incorporate screw fixation through the vertebral endplate. It is unclear whether differences in bone quality and quantity in this insertion location may affect fixation compared with screws used in traditional anterior plate (AP) fixation. Moreover, endplate preparation for IFC implantation may affect fixation strength.

**PURPOSE:** This study aimed to compare pullout strength of screws used in IFCs with screws used for AP implantations.

**STUDY DESIGN:** A biomechanical cadaveric study.

**METHODS:** $T_{12}$ and $L_1$ vertebrae from 13 human cadaver spines were prepared for pullout testing. End plates in $T_{12}$ vertebrae were scraped according to surgical practice for fusion procedures. Conversely, endplates in $L_1$ vertebrae were kept intact (unscraped). Integrated fixation cage screws were implanted at a 45° angle into the endplate and AP screws were implanted horizontally into the same vertebral body. Pullout testing was performed on all screws, and peak pullout force (PPF) and work were compared between groups to determine fixation strength. In addition, micro-CT imaging was used to assess bone quantity and quality parameters such as trabecular bone volume fraction, endplate and anterior cortex thickness at screw insertion location, endplate mineralization, and anterior cortex mineralization.

**RESULTS:** Peak pullout force for IFC screws (176±68 N) with scraped endplates was similar (p=.26) to AP screws (192±84 N). However, PPF for IFC screws (231±75 N) with unscraped endplates was significantly greater (p<.01) than AP screws (176±50 N). Peak pullout force for IFC screws with scraped endplates was significantly lower (p=.03) than IFC screws with unscraped endplates. Scraped endplates group (0.17±0.05 mm) were thinner (p=.05) than unscraped endplates (0.21±0.06 mm) by approximately 40 μ on average.

**CONCLUSIONS:** These data indicate that IFC and AP screws exhibited similar fixation behavior when the endplate is prepared according to common surgical practices. However, endplate scraping reduces endplate thickness by 20% on average, resulting in a decrease in fixation strength when compared with the unscraped endplates and provides bounds for IFC screw fixation strength. Published by Elsevier Inc.

*Keywords:* Anterior plate; End plate thickness; Integrated fixation; Intervertebral cageScrew pullout; Spine

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## Introduction

Half of all individuals over 40 years of age have some degree of disc degeneration [1,2]. Disc degeneration is associated with increased back pain and disability in patients, costing approximately $100 billion in treatment per year in the United States [3–5]. The past decade has seen a two-fold increase in disc degeneration-related surgeries, where spinal fusion is considered the gold standard treatment [6,7]. Anterior approaches such as anterior lumbar interbody fusion access a wide region of the endplate, with discectomy resulting in a large surface area for fusion. Intervertebral body fusion cages are used in this procedure to distract the disc space and neural foramina. Lumbar cages are often implanted along with supplemental fixation which can include pedicle screws, anterior plates (APs), facet screws, or spinous process plates. These supplemental fixation techniques are intended to provide additional segmental rigidity to aid in fusion and prevent cage migration; however, each technique has drawbacks such as additional posterior surgery or increased anterior profile requiring additional exposure.

Recently, numerous integrated fixation cages (IFCs) have been developed that incorporate screws or other bone anchors into the cage. A search of product code OVD (Intervertebral Fusion Device with Integrated Fixation, Lumbar) in the FDA's 510(k) Premarket Notification database revealed 80 cleared 510(k) submissions for lumbar IFC devices to date. Integrated fixation cage designs with screws often involve insertion of the screw at an angle through the front face of the cage through the vertebral endplate into the vertebral body (VB). These designs may have the benefit of being lower profile than anterior plating while also reducing the number of devices needed for implantation. This reduced exposure associated with IFC implantation may potentially reduce complications, surgical costs, and morbidity. However, there have been few clinical reports in literature on the safety and performance of lumbar IFC devices [8–11]. These studies demonstrated fusion rates of 85–90% at 2–3 years follow-up; however, there were also reports of subsidence (up to 32%), device loosening, and bone fracture post implantation. Previous biomechanical cadaver studies have compared IFC devices to cages with traditional supplemental fixation to assess initial segmental rigidity or range of motion (ROM) [12–14]. Two of these studies specifically compared IFC devices to a cage and AP [13,14]. They demonstrated that IFC cages have similar ROM in lateral bending and torsion, but greater ROM in flexion/extension motions. Only Beaubien and colleagues evaluated the fixation strength of IFC devices. They showed that peak pullout forces (PPFs) of their IFC device were significantly greater than threaded cages, but did not compare to AP devices.

Integrated fixation cage devices have different characteristics that could affect stability and fixation strength as compared to cages with traditional supplemental fixation. For example, screws used in IFC implants have different insertion location (eg, through the vertebral endplate) and trajectory (30°–60° from the vertebral endplate) from screws of traditional supplemental fixation devices such as anterior plating. In addition, performance of IFC devices is highly dependent on how well the device interfaces with the surrounding environment. Screws in IFC devices rely heavily on the quantity and quality of trabecular bone and endplate for fixation strength [15]. End plate preparation for IFC implantations may also be an important factor in the fixation strength as screws are inserted through the endplate. In osteoporotic individuals with low bone mineral density (BMD), thin endplates, and reduced trabecular bone volume fraction (BVF), stand-alone IFC implantations may result in poor segmental stabilization and pseudarthrosis. Therefore, it is unclear if the fixation strength of IFC screws is comparable to that of traditional anterior supplemental fixation (anterior lumbar plates). The overall goal of this study was to evaluate pullout strength of screws inserted through the vertebral endplate for IFC devices compared with screws inserted horizontally through the cortical wall as performed in AP implantations. A secondary goal was to understand the effects of endplate preparation on the pullout strength of the IFC screws.

## Materials and methods

### *Specimen preparation*

Thirteen fresh-frozen human cadavers, six male and seven female specimens (mean age: 71±12 years) were procured from an accredited tissue processing institution (National Disease Research Interchange and Maryland State Anatomy Board). The medical history of each donor was reviewed to exclude trauma, malignancy, or metabolic disease that might otherwise compromise the mechanical properties of the lumbar spine. Each specimen was radiographically screened to exclude osteolysis, fractures, or other abnormalities. After careful removal of connective tissue, fat, and musculature, the lumbar portion of these specimens was scanned using Dual-energy X-ray absorptiometry (DEXA, Hologic, Bedford, MA, USA) in the anterioposterior direction to assess BMD. Average BMD and T-score for these cadaver specimens was 0.72±0.10 mg/cm$^3$ and −2.9±0.7, respectively (Table 1). $T_{12}$ and $L_1$ VBs were isolated from the spinal column and cleaned of soft tissues. These VBs were prepared for mechanical testing by inserting wood screws into the spinous process and lamina of the VB to improve fixation. The inferior of the VB was potted in rapidly curing epoxy (Bondo, 3M Corp., St. Paul, MN, USA) and allowed to cure at room temperature. These cadaver specimens were wrapped in saline soaked gauze and stored at −20°C before use. Although IFC devices are typically indicated for fusion of the lumbosacral region ($L_2$–$S_1$), the vertebrae used in this study had similar BMD ($T_{12}$–$L_1$: 0.72±0.10 mg/cm$^3$, $L_2$–$L_5$: 0.88±0.22 mg/cm$^3$) and trabecular BVF ($T_{12}$–$L_1$: 9.9±1.8%, $L_2$–$L_5$: 8. 2±1.8%) compared with $L_2$–$L_5$ levels in the same cadaver spines. Therefore, we expect screw pullout testing in this study to be applicable to the lower lumbar vertebrae.