Value Analysis Brief – Anterior Cervical Discectomy and Fusion: Use of a Narrow, Midline Plate

Methods

This value analysis brief summarises biomechanical, clinical, and economic data on the UNIPLATE® and UNIPLATE® 2 Anterior Cervical Plate System relative to a traditional four-screw anterior cervical plate for anterior cervical discectomy and fusion (ACDF). Information presented in this document was obtained from biomechanical studies, case reports, and economic data available to DePuy Spine. These sources were supplemented with a search of PubMed and Google Scholar through July, 2011 for articles mentioning “UNIPLATE”. One full-text publication and two abstracts were identified through this search.

Background

Anterior cervical discectomy and fusion, known as ACDF, is a surgical procedure used to treat damaged discs in the neck (cervical spine). ACDF is typically performed by initially removing the damaged disc and any bone spurs pressing on the nerves exiting the spinal cord. Once the surgeon removes the cervical disc, he/she places bone graft into the disc space and may insert a metal plate and screws into the vertebral body as a means to stabilise the cervical spine.

UNIPLATE and UNIPLATE 2 Anterior Cervical Plate Systems were designed to simplify ACDFs through the use of a narrow midline plate and streamlined surgical technique. This system features one point of midline fixation per level (one screw per vertebral body) for improved screw visualisation, easier screw placement, and minimised lateral retraction, compared to conventional anterior cervical plate construct (two-screws per vertebral body). The following performance characteristics have been observed with UNIPLATE or UNIPLATE 2:

- In two cadaveric studies, UNIPLATE offered the same kinematic stability as traditional four-screw constructs
- In one biomechanical study, UNIPLATE demonstrated pullout resistance comparable to that of a traditional cervical plate
- UNIPLATE 2 may allow re-instrumentation for patients in whom placement of a traditional double-screw plate would be impossible
- As reported in an abstract from one single-arm study, 93% patients who received ACDF with UNIPLATE experienced an excellent (79%) or good (14%) outcome
- UNIPLATE 2 may simplify the ACDF procedure, potentially reducing operative time
In two cadaveric studies, UNIPLATE offered equivalent kinematic stability as a traditional four-screw construct.

In cadaveric testing, the kinematic stability of UNIPLATE was found to be statistically equivalent to that of a double-screw construct (SLIM-LOC® Anterior Cervical Plate System) in both one-level (C4-5) and two-level (C4-6) ACDF constructs. The intact stiffness of the one-level construct averaged 0.6 Nm/deg in flexion/extension, 1.1 Nm/deg in lateral bending, and 0.9 Nm/deg in axial rotation.

When plated with either anterior cervical plate system, the stiffness significantly increased nearly 4x in flexion/extension, 4.5x in lateral bending, and 1.6x in axial rotation (Figure 1). The intact stiffness of the two-level construct averaged 0.6 Nm/deg in flexion/extension, 1.4 Nm/deg in lateral bending, and 1.1 Nm/deg in axial rotation. When plated with either anterior cervical plate system, the stiffness significantly increased at least 6.8x in flexion/extension, 6.9x in lateral bending, and 1.6x in axial rotation (Figure 2). Differences between the UNIPLATE and the double-screw construct were not statistically significant in either construct.

In an abstract from a separate study of UNIPLATE versus ORION (double-screw plate), cadaveric cervical fixation with UNIPLATE was similar or superior to that with ORION. The study’s authors concluded single-level stability of ACDF with UNIPLATE to be satisfactory.

In one biomechanical study, UNIPLATE demonstrated comparable pullout resistance comparable to that of a traditional cervical plate.

The 4.6 mm diameter of UNIPLATE screws provide greater thread depth and surface contact with bone, compensating for the single-screw per vertebra design. In biomechanical testing, the UNIPLATE construct, consisting of one plate and two screws, had a mean pullout force of 603N with a standard deviation of 37N. The competitive plate constructs, consisting of one plate and four screws, obtained a mean pullout force of 698N with a standard deviation of 64N (Figure 3). Based on these results, a UNIPLATE Anterior Cervical System construct provides 86% of the pullout resistance achieved by the competitive cervical plate.
Clinical Experience

UNIPLATE 2 may allow re-instrumentation for patients in whom placement of a traditional double-screw plate would be impossible.

Patients who require revision of an ACDF pose a unique challenge for surgeons, given the need to consider the anatomical impact of previously placed hardware (e.g., the location and size of original screw holes). By allowing placement of one larger, midline screw per level, UNIPLATE 2 may be a solution for patients in whom double-screw options would violate the integrity of the vertebral body. As noted in a case report by Alexander Jones, MD, “Because of the location of the original screw holes and the retained screw portion in C7, re-instrumentation with a cervical plate with 2-screws per level fixation was not feasible. UNIPLATE was utilised because of the ability to gain fixation with a single larger midline screw per level”.

As reported in an abstract from one single-arm study, 93% patients who received ACDF with UNIPLATE experienced an excellent (79%) or good (14%) outcome.

Fifty-seven patients requiring ACDF for cervical disease of varying etiology received ACDF with UNIPLATE. Average follow up was 9.25 ± 2.13 months. No patients experienced failed fusion, loosing, dislocation, or breakage of screws or plates. According to Odom's classification, excellent outcome was seen in forty-five patients, good in eight patients, fair in three patients and poor in one patient. The study's authors concluded that UNIPLATE is an ideal approach for anterior cervical internal fixation given its ease of use and the observed patient outcomes.

Economics

By simplifying the ACDF procedure, UNIPLATE 2 may reduce operative time.

In a description of surgical technique with UNIPLATE, Patrick Fransen, MD, observed that removal of caspar pins prior to plate insertion in a traditional ACDF increased operative time and the number of manipulations, potentially causing unnecessary bleeding. In his manuscript he noted that UNIPLATE provides a, “simplified version of the classical anterior cervical fusion technique saves surgical time, facilitates screw insertion, and obviates the need for manipulations to stabilise the plate before the screws are inserted.”

Citations
