ELSEVIER

The Spine Journal 11 (2011) 1002–1008

THE SPINE JOURNAL

Clinical Study

Bioabsorbable anterior cervical plate fixation for single-level degenerative disorders: early clinical and radiographic experience

Darren R. Lebl, MD[a], Christopher M. Bono, MD[b], Umesh S. Metkar, MD[c], Brian E. Grottkau, MD[c], Kirkham B. Wood, MD[c,*]

[a]*Hospital for Special Surgery, 535 East 70th St, New York, NY 10021, USA*
[b]*Department of Orthopaedic Surgery, Brigham and Women's Hospital, 75 Francis St, Boston, MA 02115, USA*
[c]*Department of Orthopaedic Surgery, Massachusetts General Hospital, Yawkey Center for Outpatient Care, 32 Fruit St, Boston, MA 02114, USA*

Received 5 March 2011; revised 25 May 2011; accepted 7 September 2011

Abstract

BACKGROUND CONTEXT: Increased fusion rates have been reported with the addition of an anterior cervical plate (ACP) to anterior cervical discectomy and fusion (ACDF). Bioabsorbable implants have become increasingly used in orthopedic and spine surgical procedures. There are limited data regarding the outcomes of bioabsorbable ACP (bACP) with ACDF.

PURPOSE: To compare the clinical and radiographic outcomes of patients undergoing ACDF for single-level degenerative disorders with a bACP versus a conventional metal ACP (mACP).

STUDY DESIGN: Retrospective comparative cohort study.

PATIENT SAMPLE: Thirty-one patients undergoing ACDF for a single-level degenerative disorder (ie, disc herniation or spondylotic neural compression).

OUTCOME MEASURES: Incidence of early (within 2 weeks) complications, postoperative sagittal alignment, Odom's criteria, and pseudarthrosis rate.

METHODS: The authors retrospectively reviewed the results of a consecutive series of patients undergoing ACDF for symptomatic single-level disc herniation or spondylotic neural compression with either a bACP or an mACP over a 3-year period. Operative notes, clinical charts, and radiographs were analyzed. Radiographic outcomes were assessed for intersegmental alignment, graft subsidence, fusion rate, prevertebral soft-tissue shadow, and graft containment. Clinical outcome was evaluated by Odom's criteria.

RESULTS: Fourteen patients underwent ACDF with a bACP and 15 with an mACP. Radiographic outcomes at the most recent follow-up demonstrated pseudarthrosis in 4 of 14 patients (29%) in the bACP group and 0 of 15 patients in the mACP group. Graft extrusion and anterior displacement was present in three of four pseudarthroses (75%). Comparing preoperative and final radiographs, cervical lordosis was maintained at the operative segment in only 3 of 14 bACP patients (21%) compared with 8 of 15 patients (53%) in the mACP group. The mean Cobb angle was $2.4^\circ \pm 1.9^\circ$ lordosis in the mACP group and $-2.7^\circ \pm 2.5^\circ$ kyphosis in the bACP group ($p=.12$). In the mACP group, 14 of 15 patients had good or excellent results. In the bACP group, only 7 of 14 patients had good or excellent results.

CONCLUSIONS: Bioabsorbable ACP fixation was associated with a high rate of graft extrusion and early loss of intersegmental cervical alignment. Inferior clinical outcomes were observed in patients in the bACP group compared with the mACP group. Based on these findings, continued use of the bACP used in this study cannot be recommended.

Keywords: Bioabsorbable; Cervical; Fusion; Spinal instrumentation

FDA device/drug status: Approved (Inions S1 anterior cervical plate).

Author disclosures: ***DRL:*** Nothing to disclose. ***CMB:*** Royalties: Wolters Kluwer (B), Informa Healthcare (B); Other Office: Barricaid (Financial), Applied Spine (B); Other: JAAOS (B), The Spine Journal (Nonfinancial, Deputy editor). ***USM:*** Nothing to disclose. ***BEG:*** Relationships Outside the One-Year Requirement: Biomet Corporation (D, Royalties). ***KBW:*** Stock Ownership: TranS1 (10,000 shares, 100%); Grants: Scoliosis Research Society (C, Paid directly to institution/employer), Synthes Corp. (E, Paid directly to institution/employer), NIH (E, Paid directly to institution/employer), Medtronic, Inc. (D); Fellowship Support: OREF (E), Globus, Inc. (E), AO Spine; Synthes (E).

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

* Corresponding author. Department of Orthopaedic Surgery, Massachusetts General Hospital, Yawkey Center for Outpatient Care, 32 Fruit St, Boston, MA 02114, USA. Tel.: (617) 724-8636; fax: (617) 726-7587.

E-mail address: kbwood@partners.org (K.B. Wood)

1529-9430/$ - see front matter © 2011 Elsevier Inc. All rights reserved.
doi:10.1016/j.spinee.2011.09.010

Introduction

Fusion rates for single-level uninstrumented anterior cervical discectomy and fusion (ACDF) with an allograft spacer have been reported to be 90% or greater [1–3]. In recent years, the addition of a metal anterior cervical plate (mACP) to ACDF has become a widely accepted adjunct in the treatment of cervical disc herniations and spondylotic neural compression. Fusion rates for a single-level construct have been reported to be as high as 96% [2]. A significant decrease in graft-related complications, such as collapse [3], subsidence, extrusion, and postoperative kyphosis [2], has also been reported with the addition of an mACP.

Unfortunately, the use of mACPs has not eliminated the risk of complications. Static fixed-angle locked plates can lead to axial stress shielding of the graft that has been implicated as the cause of pseudarthroses, plate loosening, breakage [4], and/or pullout [5]. Although semistatic and dynamic mACPs can enable greater axial stress sharing of the graft [6,7], the advantages over locked plates remain to be clearly established. Unrelated to plate design, esophageal erosion [8] and screw migration [9] into the gastrointestinal tract have been reported years after surgery.

With these concerns, interest in a bioabsorbable ACP (bACP) has arisen. Intuitively, a bACP could decrease the chance for late plate-related complications as the device would eventually be resorbed. Furthermore, the material may more closely match the elastic modulus of bone and thus minimize stress shielding of the graft. Although bACPs are currently available and being marketed, there are few clinical data available about their performance [10,11]. In the present study, the authors present their early experience with a bACP for the treatment of single-level cervical degenerative disorders.

EVIDENCE & METHODS

Context
In an effort to avoid the placement of long-term or permanent metallic devices, resorbable fixation devices are being used in the spine and elsewhere. The authors assess outcomes using one such device for anterior cervical plate fixation (ACDF).

Contribution
In this retrospective study, the authors compared results of ACDF using a resorbable plate to those using a metallic plate. Patients with the resorbable plate had higher pseudathrosis rates (29% vs. 0%); graft extrusion in 75% of pseudarthroses; lesser ability to maintain segmental lordosis (21% vs. 53%); and poorer clinical outcomes (50% good/excellent vs. 93%).

Implication
The methodology is not ideal—the study was neither randomized nor the control carefully matched—so confounders might account for some of the differences seen between the two groups. That said, the profound differences seen and the fact that the findings fit well with our background knowledge on resorbable plates used elsewhere suggests likely validity. Certainly, the findings raise enough concern to limit equipoise and dissuade consideration for a randomized controlled trial or matched cohort for this particular resorbable plate. To regain equipoise, future resorbable plates should demonstrate improved biomechanical and biological characteristics prior to clinical use in humans.

—The Editors

Materials and methods

After obtaining the approval of the institutional review board, a retrospective review of the charts and imaging studies of a consecutive series of patients who underwent ACDF with a bACP for single-level degenerative disease was performed. To serve as a control, records of a cohort of consecutive patients undergoing single-level ACDF with a titanium mACP plate were also reviewed. All patients had a symptomatic single-level disk herniation or spondylotic neural compression that failed to improve with nonoperative treatment that included physical therapy, anti-inflammatory medications, activity modification, chiropractic care, and/or epidural steroid injections.

Surgical technique

Patients underwent routine ACDF through a left-sided anterior Smith-Robinson approach. Decompression was affected via removal of the pathological disc fragment or osteophytic bone. Structural allograft was used in all bACP cases. In control cases, a titanium mesh cage filled with morcelized allograft bone was inserted and stabilized by a titanium plate (Synthes, Paoli, PA, USA; Aesculap, Center Valley, PA, USA; and DePuy Spine, Raynham, MA, USA). Patients were immobilized postoperatively in a rigid cervical orthosis for 2 weeks.

Bioabsorbable plate

The bACP was a 70:30 L-polylactic acid (PLA):D, L-PLA implant (Inion Ltd, Weston, FL, USA) that measured 25 to $27\times19\times2$ mm. Intraoperatively, the plates were customized to match the anterior surface of the cervical vertebral bodies by pretreatment in a thermal water bath for 1 minute before insertion. Plates were secured to the vertebral bodies using 4.5-mm bioabsorbable screws (length, 12–16 mm).

Clinical and radiographic evaluation

Clinical records and postoperative radiographs were reviewed. Bony fusion was determined by evaluating lateral