ELSEVIER

The Spine Journal 14 (2014) 128–136

THE SPINE JOURNAL

Basic Science

Biomechanics of an integrated interbody device versus ACDF anterior locking plate in a single-level cervical spine fusion construct

Matthew I. Stein, MD[a], Aniruddh N. Nayak, MS[b], Roger B. Gaskins, III, MD[b], Andres F. Cabezas, BS[b], Brandon G. Santoni, PhD[b,*], Antonio E. Castellvi, MD[c]

[a]*Department of Orthopaedics and Sports Medicine, University of South Florida, 13220 USF Laurel Dr, Tampa, FL 33612, USA*
[b]*Phillip Spiegel Orthopaedic Research Laboratory, Foundation for Orthopaedic Research and Education, 13020 N. Telecom Parkway, Tampa, FL 33637, USA*
[c]*Center for Spinal Disorders, Florida Orthopaedic Institute, 13020 N. Telecom Parkway, Tampa, FL 33637, USA*

Received 12 March 2012; revised 11 April 2013; accepted 24 June 2013

Abstract

BACKGROUND CONTEXT: No profile, integrated interbody cages are designed to act as implants for cervical spine fusion, which obviates the need for additional internal fixation, combining the functionality of an interbody device and the stabilizing benefits of an anterior cervical plate. Biomechanical data are needed to determine if integrated interbody constructs afford similar stability to anterior plating in single-level cervical spine fusion constructs.

PURPOSE: The purpose of this study was to biomechanically quantify the acute stabilizing effect conferred by a single low-profile device design with three integrated screws (''anchored cage''), and compare the range of motion reductions to those conferred by a standard four-hole rigid anterior plate following instrumentation at the C5–C6 level. We hypothesized that the anchored cage would confer comparable postoperative segmental rigidity to the cage and anterior plate construct.

STUDY DESIGN: Biomechanical laboratory study of human cadaveric spines.

METHODS: Seven human cadaveric cervical spines (C3–C7) were biomechanically evaluated using a nondestructive, nonconstraining, pure-moment loading protocol with loads applied in flexion, extension, lateral bending (right+left), and axial rotation (left+right) for the intact and instrumented conditions. Range of motion (ROM) at the instrumented level was the primary biomechanical outcome. Spines were loaded quasi-statically up to 1.5 N-m in 0.5 N-m increments and ROM at the C5–C6 index level was recorded. Each specimen was tested in the following conditions:

1. Intact
2. Discectomy+anchored cage (STA)
3. Anchored cage (screws removed)+anterior locking plate (ALP)
4. Anchored cage only, without screws or plates (CO)

RESULTS: ROM at the C5–C6 level was not statistically different in any motion plane between the STA and ALP treatment conditions ($p>.407$). STA demonstrated significant reductions in flexion/extension, lateral bending, and axial rotation ROM when compared with the CO condition ($p<.022$).

CONCLUSIONS: In this in vitro biomechanical study, the anchored cage with three integrated screws afforded biomechanical stability comparable to that of the standard interbody cage+anterior plate cervical spine fusion approach. Due to its low profile design, this anchored cage device may

FDA device/drug status: Approved (STALIFC and CSLP).

Author disclosures: ***MIS:*** Nothing to disclose. ***ANN:*** Nothing to disclose. ***RBG:*** Nothing to disclose. ***AFC:*** Nothing to disclose. ***BGS:*** Centinel Spine (D, Paid directly to institution/employer); Grants: Medtronic (D, Paid directly to institution/employer), Globus (C, Paid directly to institution/employer), NIH-NIBIIB (D, Paid directly to institution/employer). ***AEC:*** Grant: Centinel Spine (C, Paid directly to institution/employer); Consulting: Central Spine SAB (A), Alphatec Spine (A), Trans1 (A), Orthokinematics (A); Scientific Advisory Board/Other Office: Alphatec Spine (A), Orthokinematics SAB (A), Crocker SAB (A); Fellowship Support: OREF grant (D, Paid directly to institution/employer).

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

Support: This study was supported in part by a research grant from Centinel Spine Inc. (West Chester, PA).

* Corresponding author. Biomechanics Operations, Phillip Spiegel Orthopaedic Research Laboratory, Foundation for Orthopaedic Research and Education, Tampa, FL 33637, USA. Tel.: (813) 910-3662; fax: (813) 558-6948.

E-mail address: bsantoni@foreonline.org (B.G. Santoni)

http://dx.doi.org/10.1016/j.spinee.2013.06.088

avoid morbidities associated with standard anterior plating, such as dysphagia.

Keywords: No-profile interbody device; Anterior locking plate; ACDF; Biomechanical evaluation; Cervical spine

Introduction

Anterior cervical discectomy and fusion (ACDF) has been the standard surgical treatment for degenerative conditions of the cervical spine, including degenerative disc disease, cervical spondylotic myelopathy, and cervical disc prolapse [1]. Since the description of the anterior approach for cervical discectomy and fusion by Robinson and Smith in 1955, anterior cervical procedures have become quite common with generally good clinical results [2]. Although motion-preserving disc arthroplasty procedures have been recently described, ACDF remains the standard surgical treatment, particularly for more elderly patients or those with a contraindication to disc prosthesis [3].

Studies have shown that the addition of an anterior plate with screws to an interbody cage/spacer provides enhanced stability and increased fusion rates [4,5]. Although successful in achieving fusion, anterior plating is not without complications. Dysphagia is the most common postoperative complication, and although its mechanism is poorly understood, it has been linked to the anterior prominence associated with plate and screw constructs, the adhesions that form in response to the plate [2,6,7], and retraction of the pharynx/esophagus during the anterior approach and instrumentation of the cervical spine [8,9]. Although the profile of current anterior plates is smaller than prior designs, 2% to 60% of patients complain of dysphagia in the early postoperative period [7,10]. Although in many patients these symptoms eventually disappear, not all become asymptomatic subsequent to ACDF, as the incidence of chronic dysphagia has been reported to range from 3% to 21% [6,11–13]. In addition to prolonged surgical time, other potential risks associated with anterior plating include screw pullout, subsequent cage migration, and a potentially higher rate of adjacent-level degeneration [14–18], manifested as adjacent-level ossification due to placement of the anterior plate near the adjacent level disc.

The STALIFC (Centinel Spine, West Chester, PA, USA), from this point on referred to as the ''anchored cage,'' is a radiolucent cervical integrated interbody fusion device constructed of polyether-ether-ketone (PEEK) with three integrated cancellous screws designed to provide lag compression between the adjacent vertebral bodies and confer anterior column fixation, bridging the index levels. The design avoids the need for any additional internal fixation devices and theoretically circumvents the aforementioned morbidities associated with anterior plating while providing the segmental rigidity necessary for cervical spinal fusion.

The purpose of this study was to biomechanically evaluate, in a single-level fusion construct (C5–C6), the stabilizing properties of the anchored cage and compare this with the standard cage+anterior plate ACDF construct, which has been shown to provide excellent rigidity and fusion outcomes [3,4]. We hypothesized that the anchored cage would provide similar stability to that of the cage+anterior plate and screws. This biomechanical evaluation could provide clinicians with an anterior cervical fusion device that affords adequate segmental rigidity, without the anterior prominence implicated as a cause for multiple surgical morbidities.

Materials and methods

Specimen preparation

Seven cervical spines (C3–C7) were dissected from fresh-frozen, human cadaveric specimens (three male, four female) (mean age: 56.6 years; range: 50–64 years). The medical history of each donor was reviewed to exclude trauma, malignancy, or significant metabolic disease. Anterior-posterior and lateral radiographs were taken to confirm that the procured specimens were free of significant deformity or prior instrumentation. Bone mineral density (BMD) values were assessed at each C6 vertebral level by using dual energy X-ray absorptiometry (DEXA) (Lunar Prodigy Advance; GE Healthcare, Madison, WI, USA) using an approach previously described for assessing bone quality in cadaveric tissue specimens denuded of extraneous soft tissues published by Wahnert et al. [19] Specimens with BMD values indicating obvious osteoporosis were excluded and replaced. The average BMD value at the C6 level of the seven cadaveric specimens was 0.980 g/cm^2 (range 0.786–1.159 g/cm^2).

Specimens were cleaned of musculature and adipose tissue and all ligamentous structures were retained. The specimens were then rigidly potted at the cephalad and caudal (C3 and C7) ends using interference screws and high-strength resin. All cadaveric specimens were kept hydrated throughout dissection, instrumentation, and biomechanical evaluation by wrapping with saline-soaked gauze or spraying with 0.9% saline at regular intervals. Before biomechanical testing, all specimens were thawed overnight (8–10 hours) at room temperature (approximately 25°C).

Implants

To control for interspecimen variability, each specimen was tested in each of the following conditions: (1) intact (INT); (2) following discectomy, decompression, and insertion of the anchored cage (STA); (3) anchored cage without screws+anterior locking plate (ALP); and (4) anchored cage only (CO) with screws and anterior plate removed. The test