Spine Deformity
www.spine-deformity.org

Spine Deformity 6 (2018) 28−37

Factors Predictive of Outcomes in Vertebral Body Stapling for Idiopathic Scoliosis

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Received 8 August 2016; revised 10 March 2017; accepted 20 March 2017

Abstract

Study Design: Retrospective review.
Objectives: To identify factors associated with successful outcomes in patients treated with vertebral body stapling (VBS) for idiopathic scoliosis.
Summary of Background Data: The standard of care for moderate scoliosis (20°−45°) consists of observation and bracing with the goal of halting curve progression. Although several recent studies have confirmed the efficacy of bracing in altering the natural history of scoliosis, bracing is not universally effective. Recent studies have demonstrated that VBS is a safe and viable treatment for some young patients with scoliosis at risk for progression. The identification of factors associated with successful outcomes in VBS for idiopathic scoliosis would better define the population likely to benefit from VBS.
Methods: We retrospectively reviewed all patients from a single institution treated with VBS who met previously defined inclusion criteria. Successful treatment was defined as avoidance of a fusion and a final Cobb angle no more than 10° greater than the pretreatment Cobb angle.
Results: We identified 63 patients who met inclusion criteria. The patients underwent VBS at a mean age of 10.78 years and had a mean follow-up of 3.62 years (minimum 2 years). The mean pre-op Cobb angle for stapled thoracic curves was 29.5°. Seventy-four percent of the patients who had VBS of the thoracic curve have avoided progression and/or fusion, and the mean Cobb angle at most recent follow-up was 21.8°. The mean preoperative Cobb angle for lumbar curves was 31.1°. Eighty-two percent of the patients who had VBS of the lumbar curve have avoided progression and/or fusion, and their mean Cobb angle at follow-up was 21.6°.
Conclusion: VBS is effective at preventing progression and fusion for moderate idiopathic scoliosis in immature patients. The complication rates are low.

Keywords: Vertebral body stapling; Moderate idiopathic scoliosis; Juvenile idiopathic scoliosis; Adolescent idiopathic scoliosis

Level of Evidence: Level IV

Author disclosures: PJC (other from AAOS, POSNA, SRS, JBJS-A, and Spine Deformity, outside the submitted work); MA (none); ED (none); JPG (none); AFS (personal fees from DePuy Synthes Spine, Ethicon, Globus Medical, Misonix, Stryker, and Zimmer Biomet, outside the submitted work); JMP (personal fees from DePuy Synthes Spine and Globus Medical, outside the submitted work); RRB (personal fees from DePuy Synthes Spine, Globus Medical, Medtronic, and Zimmer Biomet; personal fees and other from Abyrx, Apifix, and SpineGuard; other from Advanced Vertebral Solutions, MiMedx, Orthobond, and Medovex, outside the submitted work).

The device(s)/drug(s) that is/are the subject of this manuscript is/are not FDA-approved for this indication and is/are not commercially available in the United States.

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2212-134X/$ - see front matter
http://dx.doi.org/10.1016/j.jspd.2017.03.004

Introduction

The current standard of care for moderate idiopathic scoliosis greater than or equal to 25° is a thoracolumbosacral orthosis (TLSO). The advantages of bracing include its noninvasiveness and preservation of growth, motion, and function of the spine. Bracing is generally well tolerated [1]. The goal of TLSO bracing is to prevent further curve progression, but studies have demonstrated incomplete efficacy [2-5], especially in patients in whom moderate deformity is present prior to peak height velocity [6,7]. Furthermore, compliance shortfalls with prescribed wearing schedules are present in almost all studies of bracing [1,6,8]; studies using a manometer or temperature gauge have indicated that compliance averages no better than 60% [9].

Vertebral body stapling, or VBS, is a surgical adjunct to fusionless management of moderate idiopathic scoliosis that may address the shortcomings of TLSO bracing. VBS, an anterior fusionless technique, was designed to correct spinal deformity and prevent scoliosis progression. Staples have been in use for decades as a method of spanning physes of long bones and correcting limb malalignment [10,11]. Animal models demonstrated that such techniques could be adapted to the spine to modulate vertebral growth and ultimately correct experimental scoliosis [12,13].

To avoid implant failure from motion encountered across intervertebral discs, novel metallurgies are utilized. Nitinol is a biocompatible shape memory alloy (Medtronic, Memphis, TN) that imparts a dynamic force (Fig. 1). The Nitinol staple was tested in a goat scoliosis model by Braun and colleagues and shown to be safe and effective [14,15]. Betz and colleagues [16] utilized the Nitinol staple in skeletally immature patients with idiopathic scoliosis and found the procedure to be safe and effective in humans. Data reported by the same group in 2010 [17] suggested a more narrowly defined patient population most likely to benefit from VBS: patients with lumbar curves less than 45° and thoracic curves less than 35° at time of stapling.

The goal of the current study is to provide updated results of VBS for those patients meeting the indications suggested by Betz and colleagues in 2010 [17], including additional patients on whom the surgery was performed and longer follow-up than previously reported. An additional goal was to further elucidate complication rates and to identify factors associated with successful clinical and radiographic outcomes in VBS for idiopathic scoliosis.

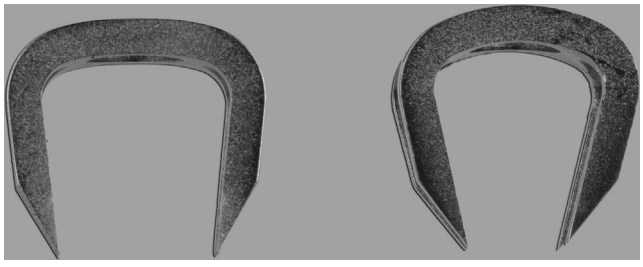

Fig. 1. Staple prongs are straight when cooled but clamp down into the bone in a "C" shape when the staple returns to body temperature.

Materials and Methods

The data for this report were collected retrospectively from patient images and medical records. The study was approved by the institutional review board of the Lewis Katz School of Medicine at Temple University, Philadelphia, PA. The implants used were Nitinol staples (Medtronic Memphis, TN) which were used in a surgeon-directed manner ("off-label"). Following IRB approval, we retrospectively reviewed our records and identified 127 patients who underwent VBS and identified 63 who met our inclusion criteria: (1) diagnosis of idiopathic scoliosis; (2) age 7–15 years at time of surgery; (3) preoperative coronal curve magnitude of 20°–35° for thoracic curves and 20°–45° for lumbar curves; (4) preoperative Risser sign of 0 or 1; and (5) minimum of 2-year follow-up.

Data collection included a variety of clinical and radiographic variables. Radiographic measurements were made by an independent physician not involved in the patients' care. Measurements were made on preoperative, first erect, 1 year, 2 year, and most recent follow-up (if greater than 2 years) radiographs. Preoperative supine bending films were also analyzed.

Follow-up radiographs were examined to assess the change in Cobb angle measurements over time. Any change was identified as improvement, no change, or progression [18]. "Improvement" was defined as a decrease in the preoperative Cobb angle of greater than 10°. "No change" was defined as a +10° to −10° change in the preoperative Cobb angle (both values inclusive). "Progression" was defined as an increase of the curve by greater than 10°. These assessments allowed for the classification of success versus failure, with "success" defined as either improvement or no change and "failure" defined as progression. These assessments were made on the most recent follow-up radiographs, which in all cases was greater than or equal to 2 years' follow-up, unless a spinal fusion had been performed earlier than 2 years' follow-up, because fusion clearly indicated failure of VBS.

For each radiograph, Cobb angles predicted both the stapled curve magnitude and the worst curve magnitude for each stapled thoracic and lumbar curve. Both measurements were analyzed at each time point so that we could track the effect on the instrumented levels and also that we may be able to report on overall spinal deformity because this is germane to future surgical decision making. The worst of the two curves' data were used for statistical analysis of treatment success.

We also report on those patients who reached skeletal maturity, defined as Risser stage 4 or 5. Consistent with prior reporting on VBS [17,19], thoracic curves and lumbar curves were analyzed separately, since thoracic curves and lumbar curves have been shown to respond differently.