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Clinical and radiographic outcomes of extreme lateral approach to interbody fusion with β-tricalcium phosphate and hydroxyapatite composite for lumbar degenerative conditions

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Abstract

Background: Historically, iliac crest bone graft has been used as the graft of choice for lumbar spine fusion procedures. Because fusion techniques have become less invasive, the demand for minimally disruptive grafting options has increased. This prospective study was performed to assess clinical and radiographic outcomes of patients treated with an iliac crest bone graft alternative and lateral lumbar interbody fusion.

Methods: Fifty degenerative lumbar patients were treated with the extreme lateral approach to interbody fusion and a β-tricalcium phosphate–hydroxyapatite graft with bone marrow aspirate (BMA) at 1 or 2 adjacent levels. BMA was collected from the iliac crest with a bone aspiration needle and applied to the FormaGraft (NuVasive, Inc., San Diego, California) in a 1:1 ratio. Radiolucent cages were filled with FormaGraft strips, granules, or blocks and implanted in a standard fashion. Clinical data were collected at baseline, 6 weeks, and 3, 6, and 12 months and included visual analog scale, Oswestry Disability Index, and Short Form 36 patient-reported assessments. Fusion assessments were made from neutral anteroposterior/lateral radiographs, lateral flexion/extension radiographs, and computed tomography images taken at least 12 months after surgery.

Results: Forty-four patients treated at 49 levels completed follow-up. The mean patient age was 54.7 ± 10.8 years, and mean body mass index was 30.8 ± 7.7 kg/m^2. Radiographic fusion was observed in 41 of 44 assessed levels (93.2%). Blood loss was less than 100 mL in 95.5% of patients. Of the patients, 93.2% spent 1 night or less in the hospital. By the 6-week follow-up, all clinical outcomes were significantly improved ($P < .05$). Improvements were maintained or increased throughout the course of follow-up.

Conclusions: This report shows that the technique of extreme lateral approach to interbody fusion in combination with FormaGraft and BMA in the interbody space is a safe and effective treatment option for interbody fusion of the lumbar spine when compared with other approaches and biologic options.

Keywords: Obese; Spine; Lumbar fusion; β-Tricalcium phosphate; Synthetic; Graft; BMA

The clinical and radiographic outcomes after a lumbar interbody fusion procedure are influenced by a number of factors, including surgical approach, interbody implant, internal fixation, and application of biologics.

The extreme lateral approach to interbody fusion (XLIF) (NuVasive, Inc., San Diego, California) is a minimally disruptive technique for fusion of the anterior spine. The technique was first described in 2006[1] and has gained widespread acceptance within the spine community.

With decreased morbidity at the surgical site, there has been an increased demand for minimally disruptive grafting options as well. Traditionally, interbody fusion procedures have included the use of iliac crest bone graft (ICBG) to increase fusion success and healing. However, concerns about graft-site morbidity and resultant changes in clinical and financial outcomes have fed a demand for alternatives. Bone marrow aspirate (BMA) has the same osteogenic qualities as ICBG and can be collected from either the vertebral bodies or the iliac crest with a thin aspirate needle. The combination of BMA with osteoconductive materials such as hydroxyapatite (HAp) and β-tricalcium phosphate (β-TCP) can theoretically provide a minimally disruptive alternative to ICBG. HAp and β-TCP graft alternatives have been studied in a number of applications and have been

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shown to perform as well as or better than iliac crest autograft in comparative studies,[2–4] observational studies,[5–8] and a number of animal studies.[9,10]

Methods

Study design

The use of a β-TCP–HAp composite (FormaGraft; NuVasive, Inc.) with BMA as a substitute for iliac crest bone autograft was prospectively studied in 54 nonrandomized patients undergoing the XLIF procedure at 1 or 2 levels between February and November 2008. The study was approved and overseen by an institutional review board. Before enrollment, all patients gave their written consent for participation.

Study participation was limited to patients aged between 18 and 70 years with a primary diagnosis of internal disc disruption at 1 or 2 contiguous lumbar levels between L1 and L5 and persistent back or leg pain for at least 6 weeks. Patients were excluded if they had more than 1 previous failed fusion or active or latent infection of the disc or spine.

Surgical protocol

The procedure was performed by standard surgical technique as previously described,[1] with optional internal fixation. BMA was collected from the iliac crest with a bone aspiration needle during the primary procedure. A maximum of 2 mL of BMA was collected per aspiration site, for a total of 15 to 20 mL on average. The FormaGraft was prepared by applying BMA to the graft in a 1:1 ratio by volume. Radiolucent cages were filled with synthetic graft strips, granules, or blocks and implanted in a standard fashion.

Outcome measures

Baseline demographics were collected at the preoperative visit. Surgical outcomes, including estimated blood loss, surgical time, method of graft application, and intraoperative complications, were captured during surgery.

Clinical outcome measures were collected at each visit and included complication assessments, work status, and visual analog scale (VAS), Oswestry Disability Index (ODI), and Short Form 36 patient-reported assessments. Outcome measures were completed by patients preoperatively and postoperatively at 6 weeks and 3, 6, and 12 months.

Anteroposterior and neutral lateral radiographs were collected at every visit. Flexion and extension lateral radiographs were collected preoperatively and postoperatively at 3, 6, and 12 months. Computed tomography (CT) scans were performed after the 12-month visit to assess fusion. Radiographic assessment of interbody fusion was conducted by an independent board-certified orthopedic surgeon using a modification of the Lenke grading system,[11] where grade I and grade II levels were classified as fused and grade III and grade IV levels were classified as unfused. In addition to the Lenke scale, a secondary scale was used to describe the volume of bone present in the disc space. The Lenke scale and volume scales are defined in Table 1.

Table 1
Radiographic evaluation scales

	Description
Lenke scale	
Grade I	Fused with remodeling and trabeculae
Grade II	Graft intact, not fully remodeled and incorporated throughout; no lucencies
Grade III	Graft intact but definite lucency at top or bottom of graft
Grade IV	Definitely not fused with resorption of bone graft and with collapse
Volume scale	
Grade I	0%–25% of available space occupied by bone
Grade II	26%–50% of available space occupied by bone
Grade III	>50% of available space occupied by bone

Results

Patient demographics

A total of 55 levels were treated in 50 patients at a single center. Two patients died of causes unrelated to their spine condition or procedure, and 4 patients were lost to follow-up. At the end of the study, 44 patients (31 women and 13 men) had completed a clinical evaluation and/or radiographic evaluation at least 12 months after surgery: 36 had both clinical and radiographic records, 5 had CT scans without 12-month clinical outcomes, and 3 had 12-month clinical outcomes without radiographs. Baseline and procedure data are reported for all 44 patients, clinical data are limited to those patients who completed a 12-month clinical assessment, and the fusion assessment is limited to those patients with CT evaluations at least 12 months after surgery.

At baseline, the mean patient age was 54.7 ± 10.8 years (range, 24–70 years) and mean body mass index was 30.8 ± 7.7 kg/m^2. Significant comorbidities included smoking (n = 21, 42.0%), obesity (n = 24, 48.0%), and diabetes mellitus (n = 4, 8.0%). Before surgery, 13 patients (26.0%) were working, 17 (34.0%) were retired voluntarily, 6 (12.0%) were retired because of illness, 7 (14.0%) were medically disabled, and 2 (4.0%) were homemakers.

Indications for surgery included 1 or more of the following: spondylolisthesis (n = 26, 52.0%), degenerative disc disease (n = 22, 44.0%), stenosis (n = 22, 44.0%), lateral listhesis (n = 8, 16.0%), adjacent segment disease (n = 7, 14.0%), instability (n = 7, 14.0%), scoliosis (n = 7, 14.0%), herniated nucleus pulposus (n = 4, 8.0%), and post-laminectomy instability (n = 2, 4.0%). On average, patients were treated at 1.1 levels. L4-5 was included in 28 procedures (63.6%) and accounted for over half of levels treated. L1-2 was included in 2 procedures (4.5%), L2-3 in 5