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The role of Osteocel Plus as a fusion substrate in minimally invasive instrumented transforaminal lumbar interbody fusion

Joshua M. Ammerman[a,b,*], Joseph Libricz[b], Matthew D. Ammerman[a,b]

[a] Department of Neurological Surgery, George Washington University School of Medicine, Washington, DC, United States
[b] Department of Surgery, Sibley Memorial Hospital, Washington, DC, United States

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ABSTRACT

Background: Instrumented lumbar fusion has become an accepted and effective surgical technique used to address a wide variety of conditions of the lumbar spine. Iliac crest autograft remains the gold standard with regards to bony fusion substrate. Unfortunately there are significant potential disadvantages associated with autograft harvest, including pain, infection, iatrogenic fracture and bleeding. Osteocel Plus (OC+) is an allograft cellular bone matrix containing mesenchymal stem cells (MSCs) and osteoprogenitor cells combined with DBM and cancellous bone. OC+ is designed to mimic the osteobiologic profile of human autograft bone, thereby eliminating the risks of autograft harvest.
Methods: A retrospective chart review was conducted to identify all patients who had undergone a MITLIF with OC+ for degenerative lumbar conditions. Patient demographics including age, sex, history of risk factors for nonunion including: osteoporosis documented on DEXA scanning, diabetes mellitus, smoking or steroid use were examined and recorded. Successful arthrodesis was judged based on post-operative X-ray imaging.
Results: 23 patients at 26 spinal levels underwent a MITLIF with OC+. Twenty-one patients (91.3%) and 24 levels (92.3%) went on to achieve radiographic evidence of solid bony arthrodesis by 12 months post-op. Six patients (26%) demonstrated clear evidence of early interbody bone growth within 6 months of surgery.
Conclusion: OC+ results in robust and reproducible lumbar interbody fusion, in both young and older patients.

1. Introduction

Instrumented lumbar fusion has become an accepted and effective surgical technique used to address a wide variety of degenerative, traumatic, congenital and neoplastic conditions of the lumbar spine. While there remains controversy regarding the optimal location for bone graft placement during instrumented lumbar fusion; interbody versus posterolateral, iliac crest autograft remains the gold standard with regards to bony fusion substrate. Unfortunately there are significant potential disadvantages associated with autograft harvest, including pain, infection, iatrogenic fracture and bleeding.

In an effort to eliminate the risks associated with autograft donor harvest; while maintaining high rates of bony arthrodesis, numerous allograft/bone marrow/synthetic options have been developed. One such option is Osteocel Plus (OC+) (Nuvasive, San Diego, CA), a minimally manipulated human cellular and tissue allograft that maintain active concentrations of osteoprogenitor stem cells. The purpose of this article is to discuss the authors' experience with Osteocel Plus as an interbody fusion substrate during instrumented, minimally invasive, transforaminal lumbar interbody fusion (MITLIF).

2. Patients and methods

A retrospective chart review was conducted to identify all patients who had undergone a MITLIF with OC+ for degenerative lumbar conditions. Patient demographics including age, sex, number of levels fused and a history of risk factors for nonunion including: osteoporosis documented on DEXA scanning, diabetes mellitus, smoking or steroid use were examined and recorded.

2.1. OC+

Osteocel Plus is an allograft cellular bone matrix containing mesenchymal stem cells (MSCs) and osteoprogenitor cells combined with DBM and cancellous bone. OC+ is designed to mimic

* Corresponding author at: 5215 Loughboro Rd., Suite 510, Washington, DC 20016, United States. Tel.: +1 202 966 6300; fax: +1 202 364 4362.
E-mail address: jmawna@gmail.com (J.M. Ammerman).

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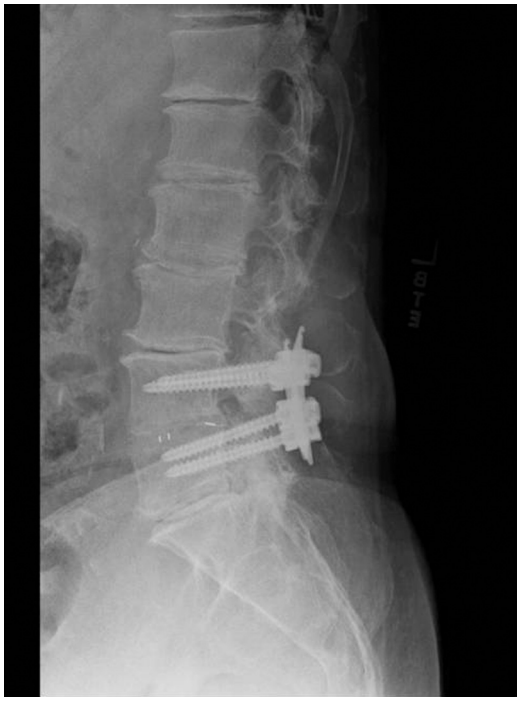

Fig. 1. Lateral lumbar spine X-ray showing dense bony interbody in-growth at L4-L5.

the osteobiologic profile of human autograft bone. MSCs have been demonstrated in both preclinical and clinical studies to promote bony fusion [1–3]. The combination of MSCs, DBM and cancellous bone allograft provide an osteoconductive, osteogenic and osteoinductive environment for bone growth. As such, Osteocel Plus has the potential to replicate autograft without the risks associated with the iliac crest harvest.

2.2. Radiographic evaluation

Patients were deemed to have achieved a solid bony arthrodesis if there were without back or radicular complaints and plain X-ray showed evidence of bridging bone at the fusion site without evidence of movement at the level(s) of surgery on flexion-extension views (Fig. 1) [4]. For patients with new or residual symptoms, CT scanning was obtained to confirm hardware position and osseous union.

Plain X-ray remains the traditionally accepted method to confirm a solid arthrodesis. The Food and Drug Administration has stated that "for lumbar spinal systems, successful fusion should be based on all of the following radiographic endpoints being demonstrated on roentgenographic examination (A/P, lateral, flexion and extension). Evidence of bridging trabecular bone between the involved motion segments, translational motion <3 mm; and angular motion <5°. The FDA acknowledges that the radiographic assessment of many of the novel spinal systems is confounded by the presence of opacifying hardware. Therefore, it is tempting to turn to other imaging modalities to assess the area in question. Regarding the use of other radiographic modalities to demonstrate fusion (CT scan, MRI, etc.), the sponsor should demonstrate the validity and reliability of these modalities prior to using these measures as primary study endpoints. FDA generally expects sponsors to use a more traditional method of assessing the fusion status in addition to any proposed method that has not yet been validated" [5]. As well, multiple recent authors have chosen to assess for successful bony fusion via plain X-ray alone, without the aid of supplemental CT scanning [6–8]. Additionally, we are unsponsored, independent investigators who believe that routine CT scanning would be cost prohibitive in the general clinical setting.

Table 1
Number of patients undergoing MITLIF stratified by age and associated nonunion rates.

Age (years)	Total # of Pts	Nonunions
20–29	1	0
30–39	2	1
40–49	5	1
50–59	4	0
60–69	7	0
70–79	4	0

2.3. Indications and surgical technique

All patients had failed a minimum of 12 weeks of conservative treatment including, physical therapy, anti-inflammatory or muscle relaxer medications and/or spinal blocks for symptomatic degenerative lumbar spinal disease with or without radiculopathy.

A MITLIF was performed utilizing the technique previously described by Foley [9]. PEEK interbody devices were used in all cases and packed with 1 cc of OC+ per level. Autograft harvested from the facet joint was placed anterior to the interbody device in all cases. No associated posterolateral/intertransverse fusion was performed. All patients were maintained in a lumbar corset for 12 weeks post-op. Patients with a history of osteoporosis, diabetes mellitus, tobacco or steroid use were also given an external bone stimulator to wear 2 h per day for the first 12 weeks post-op.

3. Results

Between January 2010 and January 2011, 23 patients underwent a MITLIF with OC+ comprising 26 total levels, 11 women and 12 men. Patient age ranged between 26 and 79 years of age, mean 56.9 years of age. One patient had osteoporosis, 3 were diabetics, 1 was a smoker and 1 required chronic steroid administration. Twenty patients underwent a single level fusion and 3 patients underwent a 2 level fusion. Eight procedures were performed at L5-S1, 11 at L4-L5, 4 at L3-L4 and 3 at L2-L3.

Twenty-one patients (91.3%) and 24 spinal levels (92.3%) went on to achieve radiographic evidence of solid bony arthrodesis by 12 months post-op. Six patients (26%) demonstrated clear evidence of early interbody bone growth within 6 months of surgery (Fig. 2). The presence of osteoporosis documented on DEXA scanning, diabetes mellitus, smoking, steroid use did not predict radiographic non-union. Increasing patient age did not predict nonunion (Table 1). One patient, a single level fusion, had failed to develop clear radiographic evidence of a solid interbody fusion by 12 months post-op and was placed in an external bone stimulator. He was subsequently lost to follow-up and was therefore labeled a non-union. The other radiographic non-union was observed at the L5-S1 level in a patient who had undergone an L4-S1 fusion with successful arthrodesis at L4-L5; she declined revision surgery. No complications attributives to OC+, such as heterotopic bone formation or osteolysis, were identified.

4. Discussion

4.1. Fusion substrate options

Numerous options exist for fusion substrate including, autograft, allograft and synthetic products. Iliac crest autograft remains the gold standard, but can be associated with significant donor-site morbidity. Kim et al. examined 110 patients undergoing elective posterior lumbar spinal fusion utilizing autologous iliac crest bone