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A preliminary comparative study of radiographic results using mineralized collagen and bone marrow aspirate versus autologous bone in the same patients undergoing posterior lumbar interbody fusion with instrumented posterolateral lumbar fusion

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Abstract

BACKGROUND CONTEXT: Multiple bone graft substitutes for spinal fusion have been studied with varying results.

PURPOSE: The purpose of this study was to assess the effectiveness of a mineralized collagen matrix combined with bone marrow, versus autologous bone, in the same patients undergoing a posterior lumbar interbody fusion and an instrumented posterolateral lumbar fusion.

STUDY DESIGN/SETTING: A prospective, comparative study.

PATIENT SAMPLE: Patients indicated for one-level posterior lumbar interbody fusion and instrumented posterolateral lumbar fusion, serving as self-controls.

OUTCOME MEASURES: Thin-cut computed tomographic scans with sagittal reconstruction and plain radiographs, including lateral flexion/extension views were performed and assessed at 12 and 24 months after surgery. Oswestry Disability Index and Visual Analog Scale questionnaires were completed by all patients preoperatively and at 12 and 24 months after surgery.

METHODS: After informed consent and failure of nonoperative treatment, 25 consecutive patients requiring one-level instrumented posterolateral fusion combined with posterior interbody fusion were enrolled in the study. Mineralized collagen bone graft substitute combined with bone marrow aspirate was used on one side of the posterolateral fusion, with iliac crest autograft on the contralateral side.

RESULTS: A fusion rate of 84% (21/25) was achieved for the autologous bone grafts and 80% (20/25) for the bone graft substitute. The interbody fusion rate was 92% (23/25). Mean Oswestry Disability Index (ODI) scores decreased 57.2% at 12 months and 55.6% at 24 months, compared with baseline.

CONCLUSIONS: Mineralized collagen bone graft substitute exhibited similar radiographic results compared with autograft in this model. Further trials incorporating bilateral fusion, as well as posterolateral fusion alone without interbody fusion are warranted to confirm the results of this study.

Keywords: Lumbar spine; Posterior fusion; Bone graft substitute

Introduction

Autologous bone harvested from the iliac crest is the gold standard in grafting materials for lumbar spinal fusion. However, significant rates of postoperative donor site pain and morbidity have been reported in the literature, with some reported rates as high as 30% [1–7]. In addition, many patients underreport the incidence and intensity of postoperative donor site pain to their surgeons [1], suggesting donor site pain may be higher than conventional wisdom suggests. Local autologous bone available after a posterior decompression is an alternative to iliac crest graft. Yet local autologous bone graft is often infiltrated with soft-tissue material [8,9]. This source of bone graft is not available for anterior fusion procedures.

FDA device/drug status: approved for this indication (Healos Bone Graft Substitute).

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The primary alternative to autologous bone is allograft, but allograft by itself is widely recognized as an ineffective material as a posterior onlay graft except in cases of instrumented fusion for pediatric deformity [10–16]. Though successful for fusion in some applications, the slight risk of disease transmission from allograft remains, and incorporation and fusion rates in smokers tend to be lower when compared with nonsmokers [17–19]. Bone morphogenetic protein has been approved for use as a bone graft substitute in a cage for anterior lumbar interbody fusion, but bone morphogenetic protein has only been approved for posterior lumbar use as part of a Humanitarian Device Exemption [20].

The ideal bone graft substitute for spinal fusion would have the following characteristics: osteoconductivity; osteoinductivity or osteogenicity; easily formed to custom shapes and sizes; resorbable; easily transported (does not require refrigeration); nonimmunogenic; and provides equivalent rates of fusion when compared with iliac crest bone graft [21]. A commercially available Type I bovine collagen fibrous matrix (DePuy Spine, Raynham, MA) is uniformly coated with hydroxyapatite through a patented mineralization process. The final product is approximately 30% hydroxyapatite by weight and completely radiolucent on plain radiographs. It has an interconnected pore size of 4–200 microns, similar to human cancellous bone. The collagen fibers combined with the pore size provide an osteoconductive matrix for new bone growth (Fig. 1). The hydroxyapatite coating provides protein binding capability similar to the composition of immature human bone. In addition to it being osteoconductive and resorbable, this mineralized collagen meets all of the criteria for an ideal bone graft replacement with the exception that is had no inherent osteoinductive or osteogenic properties. Therefore, in order to realize its full potential as a bone graft replacement, it should be combined with an osteogenic component.

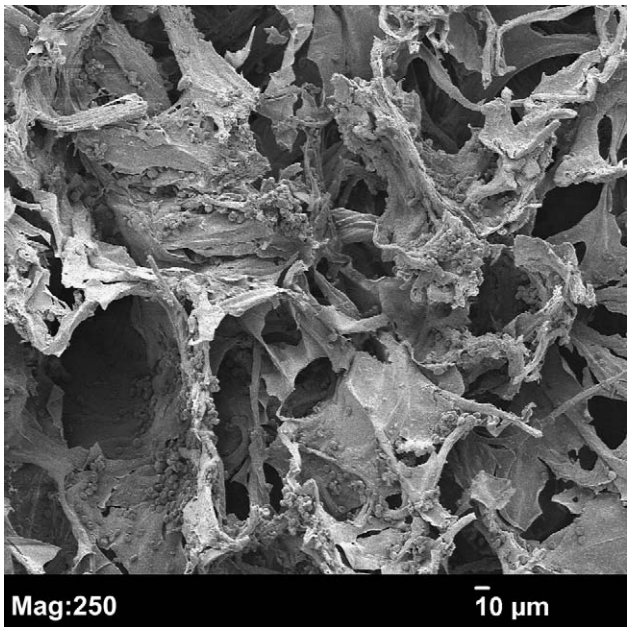

Fig. 1. The collagen fibrous matrix is uniformly coated with hydroxyapatite through a patented mineralization process. The final product is approximately 30% hydroxyapatite by weight and completely radiolucent on plain radiographs. It has an interconnected pore size of 4–200 microns, similar to human cancellous bone.

The osteogenicity of bone marrow was first identified by Burwell in 1964 [22]. Burwell demonstrated that the two main sources of new bone formed from ectopically implanted iliac crest bone graft (ICBG) included osteoblasts from the surfaces of grafted bone, and bone marrow cells. The importance of a support matrix for bone marrow cells was further explored by Nade in the 1970s [23–26]. Nade's studies in a rat model led to the conclusion that osteogenesis required an osteoconductive environment with optimal spatial and chemical configurations for attachment of osteogenic cells. Other bone [27] and synthetic matrices [28–31] designed to mimic the configuration of bone have been shown to support bone formation when seeded with bone marrow cells.

Tay et al. [32] described mineralized collagen (MC) combined with bone marrow aspirate (BMA) in a rabbit posterolateral fusion model with a fusion rate 100% (10/10) 8 weeks after surgery. The fusion rate with mineralized collagen alone in this model was 18% (2/11) highlighting the important role that bone marrow plays as a source of osteogenic progenitor cells. In a rabbit long bone critical defect model with MC/BMA, Spiro et al. [33] reported a fusion rate of 100% (20/20) at 24 weeks. In a baboon anterior interbody fusion model with MC/BMA, Griffith et al. [34] reported identical biomechanics, amount of trabecular bone, and fusion rates at both 3 and 6 months when compared with autologous bone.

In humans, Grosse et al. [35] reported a randomized study of MC/BMA versus autograft for instrumented posterolateral lumbar fusion. At 12 months the fusion rate was 76.9% (10/13) in the MC/BMA group and 81.3% (13/16) in the autograft group. There was no statistical difference between the groups with respect to fusion rate ($p=1.00$), and no complications in either group. With the experience in animals and humans as background, a prospective pilot study of 25 patients was designed to ascertain the efficacy of MC/BMA as a bone graft substitute in a one-level, self-controlled, instrumented posterolateral lumbar fusion model.

Materials and methods

After local institutional review board approval and informed consent, 25 consecutive patients indicated for one-level instrumented posterolateral fusion combined with interbody fusion were enrolled in the study. Primary diagnoses included: degenerative disc disease, isthmic-lytic spondylolisthesis, degenerative spondylolisthesis, and