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Clinical Study

A prospective, multi-center clinical and radiographic outcomes evaluation of ChronOS strip for lumbar spine fusion

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ABSTRACT

This prospective clinical study evaluated the use of a composite bone void filler (ChronOS Strip, DePuy Synthes, West Chester, PA, USA), combined with bone marrow aspirate plus local autologous bone, in a series of patients undergoing instrumented posterolateral spinal fusion with interbody support. Seventy-six patients were enrolled and treated per protocol at 13 clinical sites. At 24 months, 55/76 patients (72%) were evaluated, with 49/76 (65%) having sufficient data to determine the primary endpoint. The primary endpoint, posterolateral fusion success, was achieved in 48/54 (88.9%) patients at 12 months and in 45/49 (91.8%) patients at 24 months. At all follow-up time points, statistically significant improvements were observed when compared to baseline in back and leg pain and functional status as measured by visual analog scale, Oswestry Disability Index and 12-Item Short Form health surveys. This prospective multi-center series provides evidence that the composite bone void filler, when applied posterolaterally with instrumentation, bone marrow aspirate and/or local autologous bone and concomitant interbody support, can be used to achieve a successful posterolateral fusion, resulting in improvements in clinical outcomes in patients with degenerative disc disease.

1. Introduction

Iliac crest bone graft has been considered the gold standard for the induction of spinal fusion due to its osteogenic, osteoinductive, and osteoconductive attributes. Harvesting autologous bone graft from the iliac crest can be associated with significant morbidity, including harvest donor site pain (19%), femoral nerve and superior gluteal artery injury, hernia, hematoma, infection and fracture [1–3]; as a result, alternatives to iliac crest bone graft harvesting have been pursued.

As an alternative to autologous iliac crest bone, graft substitutes may be used in spinal fusion surgery in combination with bone marrow aspirate and/or local bone to provide cell anchorage sites, a structural framework, and mechanical stability.

Synthetic osteoconductive materials provide a porous scaffold for new bone in-growth. These include beta-tricalcium phosphates (β-TCP), hydroxyapatite, and calcium sulfate. In the current study, we evaluated a porous, osteoconductive, three-dimensional composite bone void filler (CBVF) manufactured from β-TCP granules and a resorbable polymer (polylactide-co-ε-caprolactone) (chronOS Strip; DePuy Synthes, West Chester, PA, USA). When combined with autologous blood, bone marrow aspirate or local autograft obtained from the posterior spinal elements, the CBVF can be used to promote posterolateral spinal fusion as it is resorbed and ultimately replaced with bone [4,5].

The purpose of this prospective, multi-center clinical case series was to evaluate posterolateral fusion rates and clinical outcomes in a prospective series of patients with degenerative disc disease. The surgical procedure consisted of instrumented posterolateral fusion with interbody support. The CBVF, combined with bone marrow aspirate and local bone, was applied to the posterolateral gutters. This report summarizes the premise that patients receiving this treatment would have comparable clinical and radiographic fusion success to patients treated with iliac crest autograft alone.

2. Methods

This study is registered at www.clinicaltrials.gov (NCT00943384). Institutional review board approval was obtained

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and patients screened/enrolled at 13 clinical sites according to strict inclusion/exclusion criteria. Informed consent was obtained from all study participants. Specific inclusion variables included radiographic evidence of degenerative disc disease with symptomatic back and/or leg pain, >3 mm or >5 degrees of dynamic instability between L2 and S1, an Oswestry Disability Index (ODI) score >30, and failure of a minimum 6 months of conservative therapy. Additional variables as well as exclusion criteria are outlined in Table 1. All patients received an interbody spacer and instrumented fixation support with pedicle screws and rods in addition to the posterolateral placement of the CBVF at up to two contiguous spinal levels between L2 and S1. If local bone graft was additionally utilized, a 1:1 ratio was used. The chronOS Strip was trimmed and saturated with autologous iliac bone marrow aspirate and applied posterolaterally in a subperiosteal manner (that is, in direct contact with healthy decorticated bone).

Patients were evaluated preoperatively and followed postsurgery until discharge. Follow-up visits were conducted at 6 weeks, 6 months, 12 months and 24 months. Demographic variables and prognostic factors (such as age, sex) were recorded prior to treatment. Intraoperative metrics including estimated blood loss, operative time, surgical approach, and levels treated were additionally collected. Neurological examinations and patient self-assessments were recorded to evaluate back and leg pain on a visual analog scale (VAS), satisfaction, ODI, and 12-Item Short Form (SF-12) health survey. Patients also self-reported medication usage, employment/recreational status, and satisfaction with surgery at each follow-up visit. Adverse events were collected throughout the study, including any revision surgery or medical intervention.

Radiographs (anteroposterior, lateral, flexion/extension and Ferguson view if required) were obtained. A CT scan at 12 and/or 24 months was obtained for patients in whom fusion assessment was dubious. An independent radiologist assessed available radiographs at the 6, 12 and 24 month visits. The primary composite endpoint of posterolateral fusion status (Table 2) was dependent upon four criteria: bridging bone as per the Lenke scale [6], posterior hardware condition, and angular and translational motion. Successful posterolateral fusion required all four components to be met at all levels under investigation. Failure to meet any one of the four components was designated a posterolateral fusion failure. Fusion status around the interbody spacer was additionally assessed by the independent radiologist. The observed fusion rate was compared qualitatively to those reported in prior studies for patients undergoing posterolateral fusion with iliac crest autograft alone. Clinical outcomes (VAS pain intensity, ODI, and SF-12 physical/mental component summaries) are presented as mean and standard deviation (SD), with changes from baseline evaluated using paired *t*-tests ($\alpha = 0.05$).

3. Results

A total of 76 patients from 13 sites satisfied all inclusion criteria and were included in the study. At 12 months, 65 of 76 (86%) patients were evaluated, and 61 of 76 (80%) patients had fusion related data available for review; the composite radiographic endpoint was available for 71% (54/76) of these patients. At 24 months, 55 of 76 (72%) patients were evaluated, and 52 of 76 (68%) had fusion related data available for review; the primary composite radiographic endpoint was available for 49/76 (65%) patients.

Table 1
Study inclusion/exclusion criteria

Inclusion criteria	Exclusion criteria
1. Indication for posterolateral fusion (transverse process and facet fusion) with posterior rod and screw fixation: degenerative disc disease, with or without stenosis. Diagnosis of degenerative disc disease requires back and/or leg (radicular) pain along with: (a) Instability ($\geqslant$3 mm translation or $\geqslant 5^\circ$ angulation); or (b) MRI confirmation of Modic Type 1 or Type 2 changes; or (c) High intensity zones in the disc space. 2. One or two motion segment(s) to be fused between L2 and S1; 3. Skeletally mature adult, at least 18 years of age at the time of surgery; 4. Oswestry Low Back Pain Disability Questionnaire score $\geqslant$ 30 (out of 100); 5. At least 6 months of conservative therapy, which may include physical therapy, bracing, systemic or injected medications; 6. Psychosocially, mentally and physically able to fully comply with protocol including adhering to scheduled visits, treatment plan, completing forms, and other study procedures; 7. Personally signed and dated informed consent document prior to any study-related procedures indicating that the patient has been informed of all pertinent aspects of the study.	1. Three or more motion segments to be fused; 2. Degenerative scoliosis, defined as Cobb angle >10° at any level in lumbar spine; 3. Previous interbody fusion or posterolateral fusion attempt at any level of the lumbar spine; 4. Active systemic or local infection; 5. Known or documented history of communicable disease, including acquired immune deficiency syndrome and human immunodeficiency virus; 6. Active hepatitis (receiving medical treatment within 2 years); 7. Active rheumatoid arthritis, non-controlled diabetes mellitus, or any other medical condition(s) that would represent a significant increase in surgical risk or interfere with normal healing; 8. Immunologically suppressed, or has received systemic steroids, excluding nasal steroids, at any dose daily for >1 month within last 12 months; 9. Known history of Paget's disease, osteomalacia, or any other metabolic bone disease; 10. Osteopenia or osteoporosis: A screening questionnaire for osteoporosis, Simple Calculated Osteoporosis Risk Estimation (SCORE), was used to screen patients who required a DEXA bone mineral density measurement. If DEXA was required, exclusion was defined as a DEXA bone density measured T score less than or equal to −1.0. 11. Morbid obesity defined as a body mass index >40 kg/m^2 or weight more than 100 pounds over ideal body weight; 12. Active malignancy. A patient with a history of any invasive malignancy (except non-melanoma skin cancer), unless treated with curative intent and with no clinical signs or symptoms of the malignancy for more than 5 years; 13. Current or recent history (within last 2 years) of substance abuse (for example, recreational drugs, narcotics, or alcohol); 14. Pregnant or planning to become pregnant during study period; 15. Involved in study of another investigational product that may affect outcome; 16. History of psychosocial disorders that could prevent accurate completion of self reporting assessment scales; 17. Patients who are incarcerated.

DEXA = dual-energy X-ray absorptiometry.