

5.3.3.3 Choice of Control and Surgical Model

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Choice of Control

Spinal fusion is a surgically created bony union across the involved vertebrae and approximately 70,000 posterolateral lumbar spinal fusions are performed annually. The use of bone graft to stimulate bone growth is a standard surgical technique in spinal fusion with and without instrumentation. Bone graft stimulates new bone formation and acts as a matrix or scaffold into or over which new bone can grow. Currently, autologous bone (autograft) is considered the most successful bone grafting material and it is preferred over allograft bone. The most common site for harvesting autograft material is the iliac crest. However, this increases operative time, blood loss, and the morbidity associated with spinal fusion.

In recent years, there has been focus on BMPs as osteoinductive agents. OP-1 is one such BMP. Implants containing OP-1 and collagen matrix have been shown to be osteoinductive and osteoconductive, to speed the rate of bone healing and to improve the performance of autograft in animals. Implants containing OP-1 and collagen matrix have also been shown to promote stable spinal fusions in a significantly more rapid fashion than autograft. Safety and efficacy of other BMPs in spinal applications have also been reported in animal models.

It was therefore postulated that OP-1 Putty could substitute for iliac crest autograft for the treatment of patients requiring decompression and lumbar spinal fusion, thereby eliminating the pain and morbidity associated with harvesting autograft bone from the iliac crest. A clinical study program was therefore designed to evaluate the safety and effectiveness of OP-1 Putty as a replacement to autograft in posterolateral fusion of the lumbar spine in patients with degenerative spondylolisthesis with spinal stenosis.

Reference

16. Lombardi JS, Wiltse LL, Reynolds J, Widell EH, Spencer C. Treatment of degenerative spondylolisthesis. *Spine*. 1985;10(9) 821-827.

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(Content from P060021 Original PMA, CSR S01-01US, Section 9.4.1)

Surgical Model

All patients received posterior decompression with concomitant posterolateral intertransverse process arthrodesis. Multiple-level decompression was permitted, however, only 1 level could be fused. The product under investigation or autogenous bone graft from the iliac crest was implanted using standard surgical procedures for lumbar spinal fusion. All participating investigators and co-investigators received instruction on appropriate use of the investigational product. Any question concerning the surgical aspects of use of the investigational product was answered by the Principal Investigator (PI), T. Patel, MD, Commonwealth Orthopaedics & Rehabilitation, P.C., Virginia and/or Co-PI, J. Fischgrund, MD, William Beaumont Hospital, Royal Oak, Michigan in conjunction with Stryker Biotech.

Prophylactic antibiotic treatment, pre- and post-operatively, was recommended. The following standard post-operative rehabilitation schedule was used by all investigators: Walking was encouraged on the first post-operative day, progressive walking (10-to-20 minutes twice daily) was started during the first 4 to 6 weeks postoperatively, exercises on a stationary bicycle or in water were begun at 6 to 8 weeks, and exercises for gentle flexion of the spine and strengthening of the abdominal muscles were started at 8-to-12 weeks. Exercise was monitored through physical therapy or individualized through a therapist. Use of a corset or brace for 3 months was required.