

# Early Experience with a New Interbody Fusion Device (OptiMesh<sup>®</sup>)

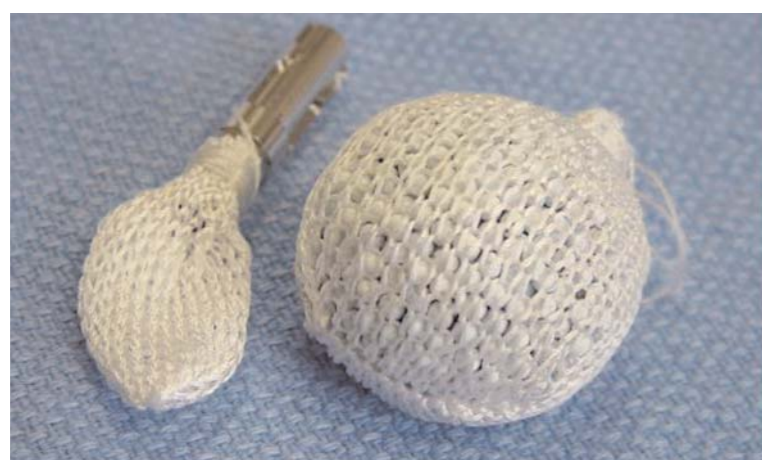
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## Introduction

A prospective FDA-IDE study is being conducted to evaluate OptiMesh 1500S (Spineology, St. Paul, MN) as a new interbody fusion device. This report illustrates the experience of one investigator within that study.



## Methods

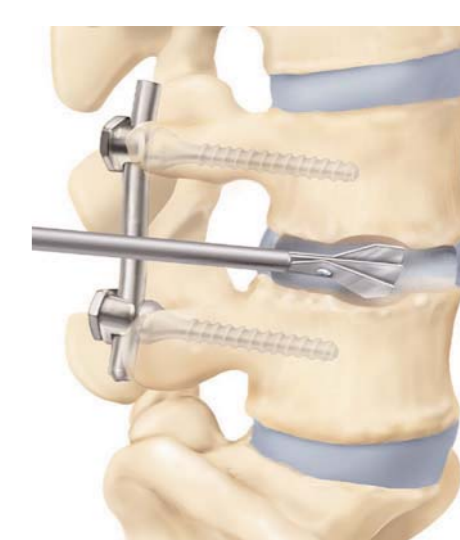
OptiMesh<sup>®</sup>, a conformable, porous, polymeric containment device, is inserted into the evacuated disc space and filled through an 8mm portal with a mixture of cortico-cancellous allograft with DBM (Musculoskeletal Transplant Foundation, Edison, NJ), autograft, and bone marrow aspirate. Graft is packed tightly into the mesh container, creating sufficient force to separate the vertebrae, increasing lordosis. Based on principles of granular mechanics, the filling process creates a structural, load-bearing construct. All fusions were performed through a PLIF or TLIF approach, supplemented with pedicle screw instrumentation and posterolateral grafting. Inclusion criteria include single level DDD (L2-S1), not greater than Gr. 2 spondylolisthesis, no previous fusion attempted at same level, failure of conservative treatment, and LBP VAS  $\geq 4$ . Primary endpoints include: fusion (AP/lat/flex/ext x-rays at 6, 12, and 24-mo), pain (VAS), function (Oswestry), and complications.

## Technique

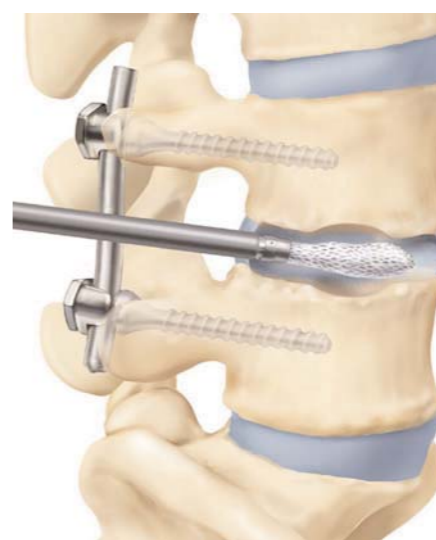
- **Approach:** midline (PLIF) or parasagittal (TLIF)
- **Pedicle screws:** inserted; distracted to open disc space; fluoroscopic guidance
- **Neural decompression:** done if appropriate
- **Discectomy:** thorough, using curettes & rongeurs, to allow large implant size
- **Shaper:** allows controlled decortication and intimate contact of OptiMesh and graft with host endplates and cancellous bone
- **Optimesh placement:** size chosen to fill disc space; inserted empty through 8mm diameter portal
- **Graft material:**
  - 30% autograft (milled)
  - 70% allograft (80% bone granules; 20% demineralized bone matrix)
  - 8-10cc bone marrow aspirate



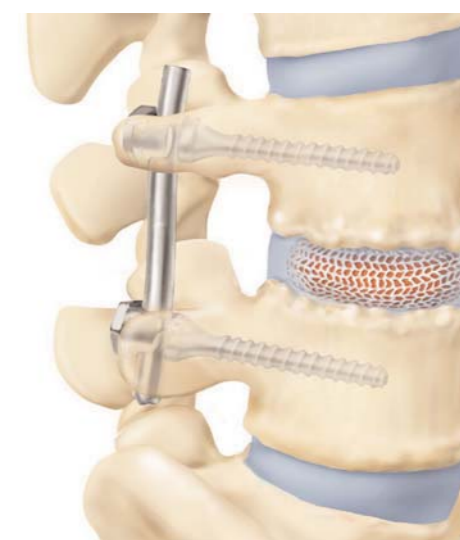
1. Pre-op



2. Discectomy and endplate shaping



3. OptiMesh inserted empty



4. OptiMesh filled with graft

## Results

Total number of patients implanted is 29. Follow-up has been 6 months for 23 patients and 12 months for 12 patients. Motion measured on digitized flexion/extension films (Medical Metrics, Houston, TX) averaged 1.02 deg at 6 months and 0.94 deg at 12 months. Fusion status at 6 months: 13 fused, 1 indeterminate, 2 not fused. Fusion status at 12 months: 11 fused, 0 indeterminate, 0 not fused.

Complications include 1 deep tissue infection, 4 transient lateral femoral cutaneous neuropathies related to intra-operative positioning, and 0 nerve root irritations. There was 1 non-union at 6 month follow-up, based on return of pre-op symptoms and motion on flexion/extension x-rays. This patient had subsequent surgery with addition of both interbody graft around the OptiMesh and posterolateral graft.

MEAN SCORES	Pre-op	6-month	12-month
VAS	6.7	3.8*	2.8*
Oswestry	49.3	31.3*	24.3*

\* p < .001



Pre-op



6 weeks



12 months

47-year-old female with L5-S1 spondylolisthesis. X-rays at 12-months post-op demonstrate apparent graft incorporation, maintenance of disc height, and absence of motion on flexion/extension x-rays (not shown).

## Conclusions

The use of the OptiMesh implant allows placement of a large, conforming graft mass under compression through a small round portal. This appears to have the benefit of facilitating fusion, improving lordosis, and avoiding nerve root irritation. The effectiveness and safety of OptiMesh to assist in lumbar fusions are sufficiently encouraging to justify performance of a prospective, randomized, controlled, multicenter trial, which is now in progress.