Spine


**Study Design:**
- Prospective; 40 patients, 53 levels
- PLF with pedicle screws; single level (27), 2 level (13)

**Test Materials:**
- VITOSS Foam Strips with BMA from the Iliac crest or pedicle + local bone (approx. 50:50 mix)
  - 2 strips (25 x 100 x 4 cm) for 1 level; 3 strips for 2 level
- 10cc/side/level - single level
- 7.5cc/side/level - 2 levels
- No control

**Outcome Measures:**
- F/E X-rays (Dynamic X-rays) - Blinded fusion assessment
- CT scans - Fusion assessment
- SF-36 Outcome Analysis
- Odom’s Criteria
- 3, 4.5, 6, and 12 months post-op follow up

**Results:**
- Successful fusion for 26/27 single level (1 pseudoarthrosis)
  and 11/13 two-level (2 pseudoarthroses)
- Only 1 pseudoarthrosis required re-operation


**Study Design:**
- Prospective; 60 patients
- Non-instrumented PLF
- Average age = 70 years

**Test Materials:**
- VITOSS Foam Strips with BMA from the Iliac Crest or pedicle + local bone (approx. 50:50 mix).
  - 2 strips (25x100x4cm) for level 1, and 3 strips for 2 level
- 10cc/side/level - single level
- 7.5cc/side/level - 2 levels
- No control

**Outcome Measures:**
- CT scans - Fusion assessment
- Dynamic X-rays
- Fusion assessed separately by 2 neuroradiologists blinded to the treatment
- Post-operative outcomes using SF-36
- 3, 6, 12, and 24 months follow up

**Results:**
- Successful fusion in 85% of patients (51/60) when judged by CT and F/E
- 9 pseudoarthrosis occurred
- 2 were asymptomatic
- On average, these 9 patients were older (76 vs. 70 years)
- On average, these 9 patients had more smokers (4/9 vs. 23/60)
Spine


Study Design:
- Prospective study; 100 patients with lumbar spinal stenosis
- Multisegment laminectomies (avg. 3.6 segments) and one segment (78 patients) or two segment (22 patients) posterolateral instrumented fusion
- Document radiographic arthrodesis/pseudoarthrosis rates using lamina autograft and β-TCP

Test Materials:
- VITOSS Foam Strips with BMA from the iliac crest or pedicle + local bone (approx. 50:50 mix)
  - 2 strips (25 x 100 x 4cm) for 1 level: 3 strips for 2 level
  - 10cc/side/level - single level
  - 7.5cc/side/level - 2 level
  - No control

Outcome Measures:
- Dynamic X-rays
- 2D-CT Scans
- Postoperative outcomes using SF-36
- Fusion assessed separately by 2 independent neuroradiologists blinded to the treatment
- Patients were followed-up on 3, 4.5, 6, and 12 months, with a minimum of 2.5 years and a maximum of 5.0 years (avg. 3.1 years)

Results:
- Successful fusion in 95% of patients (95/100) when judged by CT and Dynamic X-ray
- Single level fusion was performed in 79 patients; 74 of those patients fused “early” (6.5 postoperative months) 93.7%; Two-segment arthrodesis was performed in 21 patients and 90.5% fusion
- The average age of the patients was 48.3 years old
- Of interest, 6 of 7 patients with arthrodesis, and all 5 patients with pseudoarthrosis were 2 packs/day smokers
Spine


Study Design:
- Prospective; 30 patients, 44 levels
- Non-instrumented PLF; single level (16), 2 level (14)
- Average age = 71.4 years (only 2 patients below 65 years)

Test Materials:
- VITOSS Foam Strips with BMA from the iliac crest or pedicle + local bone (approx. 50:50 mix)
  2 strips (25 x 100 x 4cm) for 1 level: 3 strips for 2 level
- 10cc/side/level - single level
- 7.5cc/side/level - 2 level
- No control

Outcome Measures:
- F/E X-rays (Dynamic X-rays)
- CT scans - Fusion assessment
- Fusion assessed separately by 2 neuroradiologists blinded to the treatment
- SF-36 Outcome Analysis
- Odom's Criteria
- 3, 4.5, 6, and at least 12 months post-op follow up (average follow up 20 months)

Results:
- Successful fusion in 90% of patients (27/30) when judged by CT and F/E
- Only 1 pseudoarthrosis required re-operation (patient with both motion on F/E and lack of fusion on CT)
- 2 patients had lack of motion on F/E but did not appear to be fused on CT. These patients did not require re-operation
- Recovery utilizing Odom's Criteria showed: Excellent (26), Good (3), Fair (1) outcomes


Study Design:
- Case studies; 11 patients
- PLF

Test Materials:
- VITOSS with ICBG

Outcome Measures:
- Establishing safety and efficacy of graft material (complications)

Results:
- No bone graft related complications at time of report
Extremities

Study Design:
- Retrospective; 40 patients
- Repair of benign tumor or cyst

Test Materials:
- VITOSS with either blood or saline (average graft volume = 42cc; range = 2-10cc)
- No control

Outcome Measures:
- X-rays
- Clinical success determined by return to unrestricted activities of daily living and recreation within 3 months
- Follow up at 6 weeks, 3, 6, and 12 months

Results:
- All patients had satisfactory clinical outcomes
- All patients had unrestricted return to activities of daily living and recreational activities within 3 months in all but 1 patient (who was rehabilitated prior to the end of this study)
- In defects less than 43cc, VITOSS was resorbed and replaced by trabecular bone by 1 year
- In defects greater than 43cc there was still some VITOSS remaining in the defect after 1 year
- When comparing to historic controls for Calcium Sulphate, HA, allograft, and autograft materials, VITOSS results appeared to be favorable


Study Design:
- 6 case studies in trauma
- Proximal tibial bone graft donor site (1), Tibial Plateau Fracture (1), Subcapital Humerus Fracture (1), Calcaneal Fractures (3)

Test Materials:
- VITOSS alone or with blood

Outcome Measures:
- Consolidation of bone graft
- Follow up range = 2-9 months

Results:
- Consolidation of bone graft occurred (or was occurring) in all patients
Extremities


Study Design:
- Retrospective; 60 consecutive patients treated over a 3 year period for cavitary defects

Test Materials:
- VITOSS with BMA (1cc BMA / 5cc of graft)

Outcome Measures:
- X-rays (resorption and trabeculation over time)
- Return to daily activities

Results:
- Patients progressed to unrestricted activity in 51 of 60 patients by 6 weeks and 59 of 60 by 12 weeks
Study Design:
- Randomized, controlled; 30 patients
- Iliac crest backfill (ACDF)

Test Materials:
- VITOSS backfill
- GelFoam (control)

Outcome Measures:
- McGill Pain Index
- 6 weeks and 3 months
- 3 and 6 months post-op follow up

Results:
- Significant improvement in pain with use of VITOSS for Iliac crest backfill at 6 weeks and trend toward improvement at 3 months. (5 patients in the control group experienced severe pain at 6 weeks vs. 0 patients in the VITOSS group at 6 weeks. 2 experienced severe pain in the control group at 3 months vs. 0 patients in the VITOSS group at 3 months)