

Report on study number 2008-005645-27 (Sponsor's protocol code number DBM)

## **Vergleich von demineralisierter Knochenmatrix (DBM) und Knochenallograft bei der anterioren lumbale Wirbelkörperfusion (ALIF) mittels Synfix LR**

**Purpose:** The purpose of the present study was to assess the efficacy of  $\beta$ -tricalcium phosphate ( $\beta$ -TCP) as a bone graft substitute in ALIF (anterior lumbar interbody fusion) implants in a patient population with degenerative lumbosacral disorders using thin-slice CT scans.

**Methods:** In a prospective clinical study, ALIF cages were prefilled with  $\beta$ -TCP and additionally fixated with posterior pedicle screw. Computed tomography (CT) and X-rays were performed one year after surgery. Fusion was assessed and functional status was evaluated before and one year after surgery.

**Randomization and study groups:** Fifty patients were enrolled in the study: 33 underwent single level, 13 double-level and four patients triple-level anterior lumbar interbody fusion with Syn cage (Synthes, Oberdorf, Switzerland) filled with TCP, and additional posterior pedicle screw fixation. Patients with lower-back pain and degenerative disc disease (DDD) or degenerative spondylolisthesis between L3 and S1 were included in this study. Patients were enrolled only if symptoms had persisted for more than six months and were persistent despite conservative treatment.

**Inclusion and exclusion criteria:** Inclusion criteria were: patient age between 18 and 80 years; objective radiographically significant evidence of significant disc degeneration at lumbar levels involving L2/L3, L3/L4, L4/L5 and L5/S1, as confirmed by plain films and magnetic resonance imaging (MRI) or computed tomography (CT). Exclusion criteria were presence of spinal infection, past or present, tumor, metabolic bone disease, spondylolisthesis greater than Grade I according to Meyerding, spondylolysis or significant bony defect in the lumbar spine.

**Statistical analysis:** Data were processed using Stata (Stata Statistical Software, Release 11; StataCorp, College Station, TX, USA). In most cases the data were not normally distributed. Therefore we report medians together with first and third quartile (M [Q1; Q3], if not stated

otherwise. For inferential statistics, the Friedman test was used to test for longitudinal differences. P values < 0.05 were considered statistically significant. In case of significant results, Wilcoxon tests were performed for posthoc analyses without correction for multiple testing.

**Results:** Median ODI scores improved significantly, from 55 (44; 64) pre-operatively to 18 (10; 40) at 12 months' follow-up (P < 0.001). VAS pain assessment on a ten-point scale showed a decrease in score for leg and back pain, indicating an improvement (10 = severe, to 1 = none). The median scores, leg 7 (5; 8) and back 8 (7; 9), were significantly improved at 12 months' follow-up, leg 2 (1; 3) and back 2 (2; 4), (leg P < 0.001, back P < 0.001). Median fusion grade assessed by X-ray was 2 (2; 3) at three months' follow-up, 3 (2; 3) at six months' follow-up and 3 (3; 4) at 12 months' follow-up, thus showing a significant improvement over time (P = 0.0037). CT assessment of fusion showed a median of 2 (1; 3) anteriorly, and a mean of 2 (1; 2) posteriorly. X-ray evaluation showed a definite fusion in 85.48 % of treated levels. CT assessment showed anterior and posterior intersegmental bone bridging in 77.78 % of treated levels.

**Conclusions:** The X-ray fusion rate presented is comparable with those published for ALIF procedures with bone graft. Fusion rates  $\beta$ -TCP are similar to autologous bone. ALIF with  $\beta$ -TCP and additional posterior fixation is a safe and effective procedure.