CLINICAL RESULTS

EFFICACY OF i-FACTOR® BONE GRAFT VERSUS AUTOGRAFT IN ANTERIOR CERVICAL DISCECTOMY AND FUSION: RESULTS OF THE PROSPECTIVE RANDOMIZED SINGLE-BLINDED FOOD AND DRUG ADMINISTRATION INVESTIGATIONAL DEVICE EXEMPTION STUDY

Arnold PM, Sasso RC, Janssen ME, Fehlings MG, Smucker JD, Vaccaro AR, Heary RF, Patel AI, Goulet B, Kaas R, Kopjar B

– >81% of patients reporting excellent or good relief
– Statistical equivalence between Test and Control arms for primary end points
– Significant improvement in SF-36 scores
– Significant improvement in VAS scores
• No statistical difference in the rate of adverse events
• Pre-operative demographics statistically equivalent

MATERIALS AND METHODS
• Surgeons performed an instrumented anterior cervical discectomy and fusion (ACDF).
  – Test arm: i-FACTOR Putty
  – Control arm: autograft (‘gold standard’)
• 12-month evaluation (blinded, independent third party)
• Primary end points:
  – Fusion
  – NDI
  – Neurological success
  – Safety (adverse events)
• Secondary end points:
  – VAS scores for shoulder, neck and arm pain
  – SF-36 health survey
  – ODAM criteria
• Statistical plan: non-inferior for Test vs. Control arms
• Overall study success: patient meets all four success criteria

RESULTS
• 813 patients: 161 patients in i-FACTOR arm vs. 152 patients in autograft arm
• Pre-operative demographics statistically equivalent
• Primary end points outcome (refer to graph)
  – No statistical difference in the rate of adverse events
• Secondary end points outcome
  – Significant improvement in VAS scores
  – Significant improvement in SF-36 scores
  – Statistical equivalence between Test and Control arms for VAS and SF-36
  – >81% of patients reporting excellent or good relief

CONCLUSION
i-FACTOR clinical performance summary:
• Statistically non-inferior to autograft for fusion rates, NDI and neurological function
• Statistically similar in safety profile to the ‘gold standard’ autograft
• Significant neurological improvement and high fusion rates
• Improvement in patient pain and function outcomes
i-FACTOR yielded statistical superiority compared to autograft in the Overall success criterion

PROSPECTIVE ANALYSIS OF A NEW BONE GRAFT IN LUMBAR INTERBODY FUSION: RESULTS OF A 2-YEAR PROSPECTIVE CLINICAL AND RADIOLOGICAL STUDY

Lauweryns P, Raskin Y

– 97.73% vs. 59.09% at 6 months
– i-FACTOR is statistically significantly superior to autologous bone in facilitating the formation of bridging bone inside the hollow spaces in cage at six months with a p-value <0.01 and at 12 months with a p-value <0.01
– The greatest average decrease in back pain (VAS) was 43 points (85.1%) at three months, in left leg pain, a 27-point decrease (55.1%) at 24 months, and in right leg pain, a 22-point decrease (57.8%) at 24 months
– Functional improvement (ODI) exceeded success criteria at all time points, with the greatest improvement in function at six months (a 30-point decrease in disability on the 100-percentage-point scale, representing a 60.8% improvement from baseline), followed by two years (20-point decrease, representing a 43.4% improvement)

CONCLUSION
This data concludes that i-FACTOR is statistically significantly superior to autologous bone in facilitating formation of bridging bone inside the hollow spaces in PLIF cages at six months and at 12 months. The results of this study confirm the overall efficacy and safety of both materials in PLIF.
CLINICAL RESULTS

CLINICAL OUTCOMES AND FUSION RATES FOLLOWING ANTERIOR LUMBAR INTERBODY FUSION WITH BONE GRAFT SUBSTITUTE i-FACTOR, AN ANORGANIC BONE MATRIX/P-15 COMPOSITE

Mobbs RJ, Rao RJ, Maharaj M

CLINICAL ORTHOPAEDIC DATA
A prospective, non-blinded cohort study designed to investigate the safety and efficacy of the bone graft material P-15/ABM (i-FACTOR) for use in anterior lumbar interbody fusion (ALIF).

MATERIALS AND METHODS
• Surgeons performed anterior lumbar interbody fusion in 110 patients with degenerative spinal disease
• Single-, double- and triple-level fusion were included within the study
• Mean follow-up of 24 months (minimum 15 months)
• Fine-cut, high-resolution CT scans were obtained at three, six and nine to 12 months to assess the progression to fusion.
• Clinical outcomes:
  – Oswestry Disability Index (ODI)
  – 12-Item Short Form Health Survey (SF-12)
  – 10-point visual analogue scale (VAS)
  – Odom’s criteria
• Primary end points:
  – Fusion
  – Safety (adverse events)

RESULTS
• In total, surgery was performed on 142 levels in 110 patients
• All patients who received i-FACTOR demonstrated radiographic evidence of bony induction and early incorporation of bone graft with evidence of fusion as early as three months in some patients
• At a mean of 24 months of follow-up (range 15-43 months), 97.5%, 81%, and 100% of patients, respectively, who had undergone single-, double-, and triple-level surgery exhibited fusion at all treated levels
• The clinical outcomes demonstrated a statistically significant (p < 0.05) difference between preoperative and postoperative Oswestry Disability Index, 12-Item Short Form Health Survey, and visual analogue scores
• A complication rate of 10% was observed; however, all complications were associated with the surgical exposure and approach involved with the ALIF procedure

P-15 SMALL PEPTIDE BONE GRAFT SUBSTITUTE IN THE TREATMENT OF NON-UNIONS AND DELAYED UNION – A PILOT CLINICAL TRIAL

Gomar F, Orozco R, Villar JL

CLINICAL ORTHOPAEDIC DATA
A pilot clinical study was conducted to assess the ability of P-15/ABM, the components of i-Factor, to facilitate healing and bone formation in non-union long-bone fractures. The purpose of this pilot study was to demonstrate the safety and efficacy of P-15 in the treatment of refractive fracture non-unions.

MATERIALS AND METHODS
• A total of 22 patients with non-union fractures were treated from June 2000 to October 2003 by two surgeons at different hospitals
• Adequate fixation of the fracture site along with the placement of i-FACTOR bone graft was achieved

RESULTS
• Full consolidation was achieved in 90% (20 out of 22) of the patients treated with i-FACTOR Bone Graft product
• Of the remaining two patients, one patient had a hardware failure, was retreated and fused. The last patient was lost to follow-up

CONCLUSION
The present study demonstrates a high fusion rate and clinical improvements comparable to the published results for ALIF using autograft or BMP. In addition, i-FACTOR, compared with rH-BMP2 (INFUSE) and rH-BMP-7 (OP-1), is significantly less expensive with the added benefit of fewer complications and similar fusion results.

CONCLUSION
i-FACTOR appears to offer a safe, economical and clinically useful alternative to autograft in the repair of stabilised non-union fractures. The results reported here compare favourably with the published literature as an alternative to autograft.