# 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 [4]

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

### CLINICAL ORTHOPAEDIC DATA

A prospective, randomised, controlled, multi-centre trial was designed to investigate the efficacy of P-15 peptide against an autologous bone control group. The hypothesis was that the P-15 Putty (Test arm) was non-inferior to the 'gold standard' autologous bone (Control arm) as determined by fusion rate, NDI scores, and neurological success. A blinded, independent third party was utilised to assess safety, radiologic outcomes and neurologic outcomes.

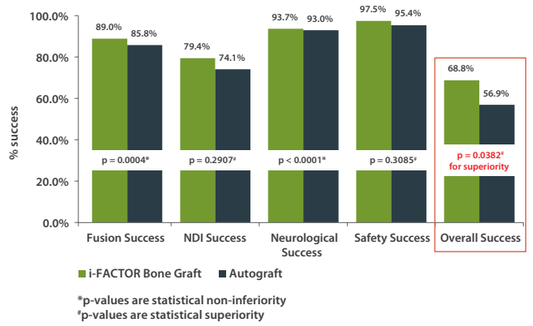
#### MATERIALS AND METHODS

- 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
  – Odoms criteria
- Statistical plan: non-inferior for Test vs. Control arms
- Overall study success: patient meets all four success criteria

#### RESULTS

- 313 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

Clinical efficacy and safety of i-FACTOR bone graft putty vs 'gold standard' autograft.




### 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 [3]

Lauweryns P, Raskin Y

### CLINICAL ORTHOPAEDIC DATA

A prospective, controlled, long-term trial designed to investigate the efficacy and safety of bone graft material P-15/ABM (i-FACTOR) for use in posterior lumbar interbody fusion. Each patient was used as a control with local autograft bone placed inside one cage and i-FACTOR bone graft in the other cage for each vertebral level treated. The study hypothesised non-inferiority of i-FACTOR efficacy and safety compared to autograft for use in PLIF.

#### MATERIALS AND METHODS

- Surgeons performed posterior lumbar interbody fusion with pedicle screw fixation (one to four levels) in 40 patients
- Each patient was used as the control:
  – Test cage: i-FACTOR
  – Control cage: local autograft (the 'gold standard')
- 24-month evaluation with assessment of fusion rate (CT scans), VAS and ODI
- Primary end points:
  – Fusion
  – Safety (adverse events)
- Secondary success criteria were improvement in back pain, right leg / left leg pain, function, and amount and ease of use of i-FACTOR
- Statistical significance was determined using the chi-square test

#### RESULTS

- Intra-cage bridging bone occurred earlier with i-FACTOR than autograft:
  – 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 (65.1%) 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 [23, 24]

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

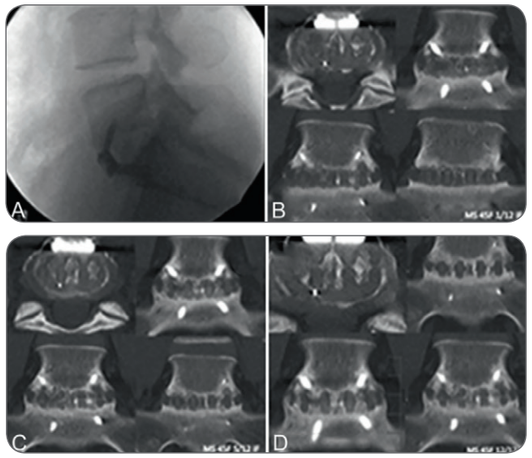



*Fig. 1. Images demonstrating progression of interbody fusion in a 45-year-old woman treated for DDD without radiculopathy. A: Radiograph of the L5-S1 level one day postsurgery. B: Coronal CT images obtained one month postoperatively. C: CT images obtained five months postoperatively. D: CT images obtained 12 months postoperatively demonstrating solid fusion.*

### 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 rhBMP-7 (OP-1), is significantly less expensive with the added benefit of fewer complications and similar fusion results. [18]

## P-15 SMALL PEPTIDE BONE GRAFT SUBSTITUTE IN THE TREATMENT OF NON-UNIONS AND DELAYED UNION – A PILOT CLINICAL TRIAL [25]

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
- The average time for full consolidation was 5 months for patients in Series I and 3.3 months for patients in Series II
- Histological assessment of the fracture callus in five of the 24 patients confirmed osteosynthesis

### 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.

*1 month* *3 months* *15 months*