

# BIOLOGIC BONE GRAFT

The safe, biological way to stimulate natural bone growth



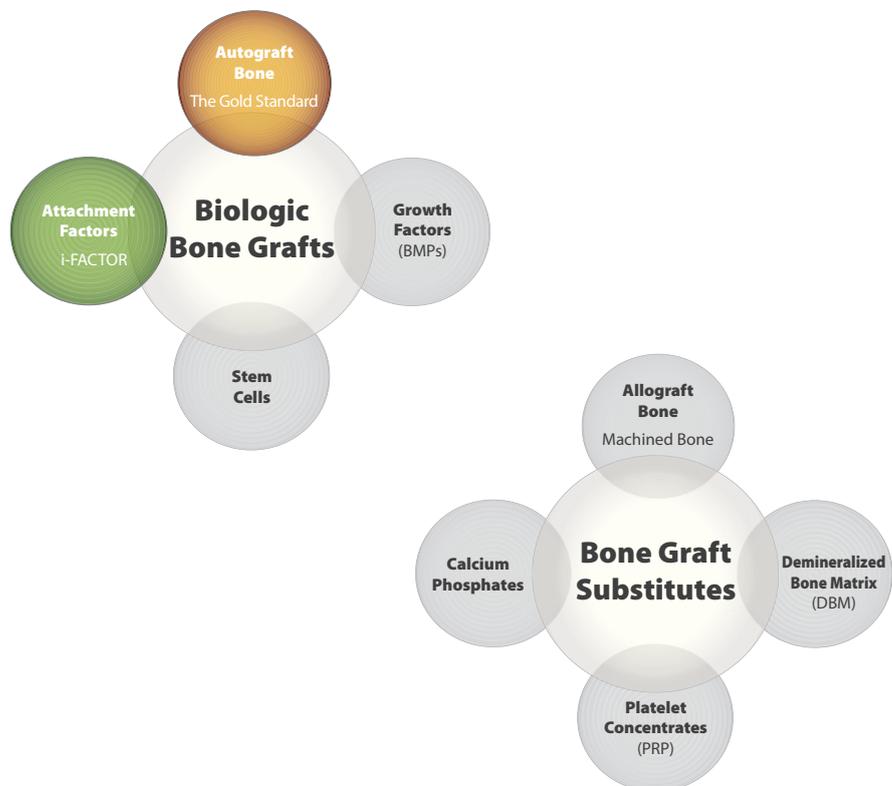
# OVERVIEW OF ORTHOBIOLOGICS

## VARIETY OF BONE GRAFT SUBSTITUTES

The number and types of commercially available bone graft substitutes continue to grow. Today, surgeons can choose products from machined bone, demineralised bone matrix (DBM), synthetics, stem cell therapy, attachment factors and growth factors (all of these products attempt to replicate autograft bone with varying degrees of success).

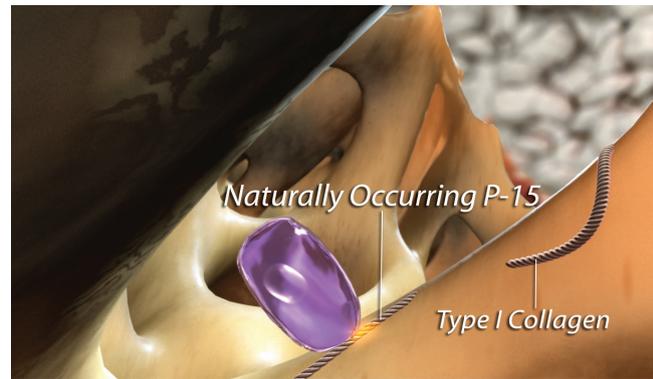
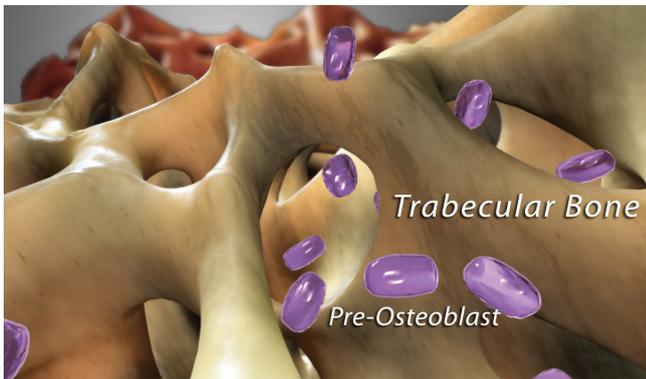
The two categories of bone graft products frequently used in spinal fusion and orthopaedic applications are bone graft substitutes and biologic bone grafts. The industry-accepted 'gold standard' bone graft is autograft, a patient's own bone with all the properties needed for fusion: cells, scaffold and biological signals.

- Bone graft substitutes are primarily osteoconductive products, sourced from human cadavers or made of synthetic materials that provide a scaffold where new bone may grow
- Biologic bone grafts are products that actively influence bone growth, contributing properties such as growth factors or cells, in addition to the basic osteoconductive (i.e. scaffold) elements



## THE OSTEOBLAST AND BONE FORMATION

Osteoblasts originate from local pluripotent mesenchymal stem cells, either bone marrow stromal stem cells (endosteum) or connective tissue mesenchymal stem cells (periosteum). With the right stimulation, these precursor cells proliferate and differentiate into preosteoblasts. At this point they are committed to an osteogenic lineage and differentiate into mature osteoblasts, which is the key component for successful orthopaedic fusion procedures.<sup>1</sup>



*i-FACTOR* plays an integral role in stimulating these precursor cells to proliferate and differentiate into mature osteoblasts in a manner unlike any other osteobiologic or bone graft substitute.<sup>2</sup>

## i-FACTOR IS AN 'ATTACHMENT FACTOR'

i-FACTOR Biologic Bone Graft is categorised as an 'attachment factor'. i-FACTOR uses a novel mechanism of action based on the cell binding of osteogenic precursor cells via integrins, or signal receptors, to a patented synthetic protein segment (GTPGPQGIAGQRGVV), simply called P-15. i-FACTOR possesses three unique characteristics that allow it to compete effectively against other biologic bone grafts:

1. i-FACTOR has demonstrated superiority to autograft<sup>3,4</sup>
2. i-FACTOR is a biologically active medical device that enhances cellular attachment to stimulate natural bone growth<sup>2,5,6,7</sup>
3. The technology in i-FACTOR (P-15/ABM) has been used clinically for more than a decade in the dental and now orthopaedic markets, in an estimated 500,000 cases, with a solid safety profile

# i-FACTOR BIOLOGIC BONE GRAFT

i-FACTOR Biologic Bone Graft is the only bone graft that combines a unique anorganic bone mineral (ABM) and small peptide (P-15) to act as an attachment factor for specific integrins on osteogenic precursor cells. This novel mechanism of action enhances the body's natural bone healing process, resulting in safe, predictable bone formation. P-15/ABM has been in human clinical use for more than 17 years in an estimated 500,000 patients worldwide.



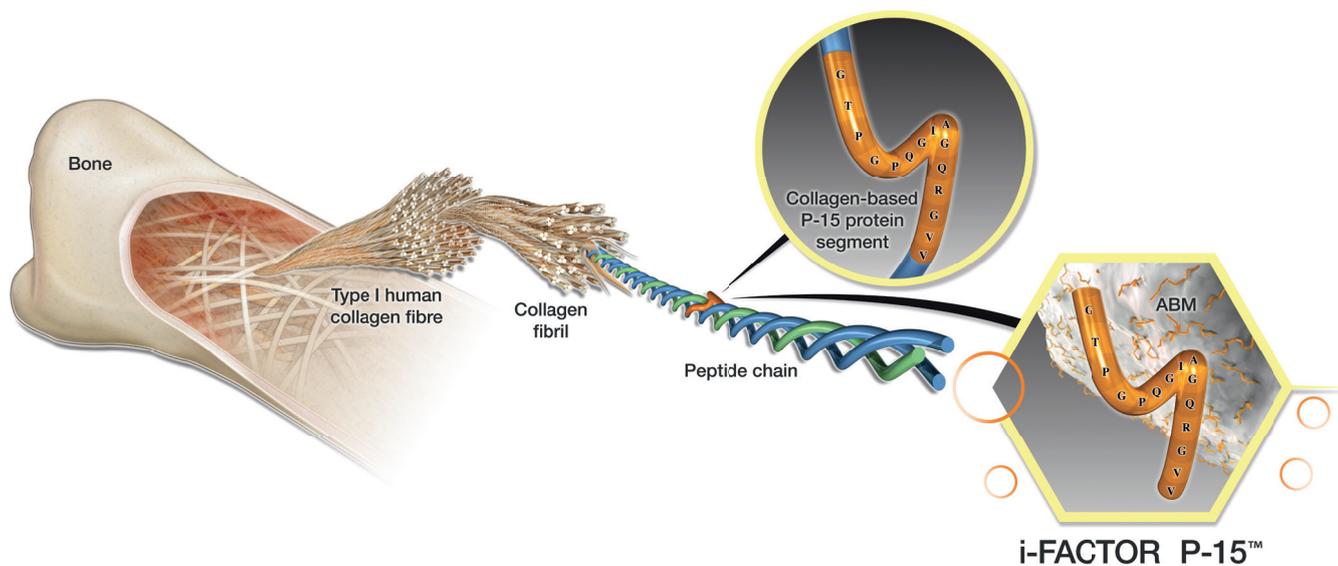
*i-FACTOR Putty is ideal for contained areas such as interbody fusion devices*



*i-FACTOR Flex FR can be cut or shaped to fit the particular dimensions of an osseous defect or interbody fusion device*

## SYNTHETIC REPLICATE OF P-15

i-FACTOR technology is based on the biological activity of a 15 amino acid peptide naturally found in Type I human collagen. Type I collagen is the primary organic component making up autograft bone. This protein segment (P-15) is responsible for the attachment and proliferation of osteogenic cells. These cells bind to the synthetic P-15 found in i-FACTOR the same way they would bind to Type I collagen.<sup>8</sup>



## ANORGANIC BONE MINERAL (ABM)

One component of i-FACTOR Biologic Bone Graft is anorganic bone mineral. ABM particles are a natural form of hydroxyapatite [ $\text{Ca}_{10}(\text{PO}_4)_6\text{OH}_2$ ] that contains crystal lattice defect sites.

ABM provides an ideal scaffold for bone growth because of its:

### COMPOSITION

It is composed of natural calcium phosphate bone mineral.

### RESORPTION

It is capable of effective cellular mediated resorption properties.<sup>9,10</sup>

### MANUFACTURABILITY

After processing, ABM shows a high affinity and capacity for binding the P-15 protein segment.<sup>11</sup>

## SAFE, NATURAL, PREDICTABLE

- i-FACTOR Biologic Bone Graft offers surgeons the efficacy of autograft while avoiding the long-term morbidity issues associated with harvesting iliac bone graft<sup>3,4,12</sup>
- i-FACTOR Biologic Bone Graft actively triggers cellular attachment of osteogenic precursor cells, resulting in production of natural amounts of bone morphogenic proteins and growth factors. Unlike growth factor products, i-FACTOR only stimulates bone growth in the presence of bone forming cells<sup>2,5,6,7,13</sup>

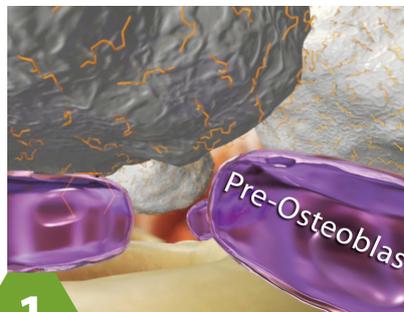
## HOW i-FACTOR WORKS

# MECHANISM OF ACTION

## ATTRACT, ATTACH, ACTIVATE

i-FACTOR increases the opportunity for cell binding in the fusion site by making an abundance of P-15 available to osteogenic cells. The ability of P-15 to enhance cell binding hastens the process of new bone formation and closely resembles the natural process of bone regeneration. Once cells attach to the P-15 immobilised on the ABM substrate, the cascade of events leading to new bone formation commences.

### ATTRACT



P-15 facilitates and expedites ingrowth of bone by promoting the immigration of reparative cells from the surrounding tissues.<sup>7</sup>

### ATTACH



The high affinity between cells and P-15 supports the physiological mechanism in which cells bind to collagen via the domain simulated by P-15 and continue to organize the matrix by tractional forces. Cells attach to and migrate on Type I collagen by haptotactic mechanisms.<sup>8, 14, 15</sup>

### ACTIVATE



P-15 enhances bone formation by facilitating cellular attachment with subsequent increase in cell binding, proliferation, and differentiation of cells increasing TGFb-1, BMP-2, and BMP-7 levels that positively influence all processes of new bone formation.<sup>16</sup>

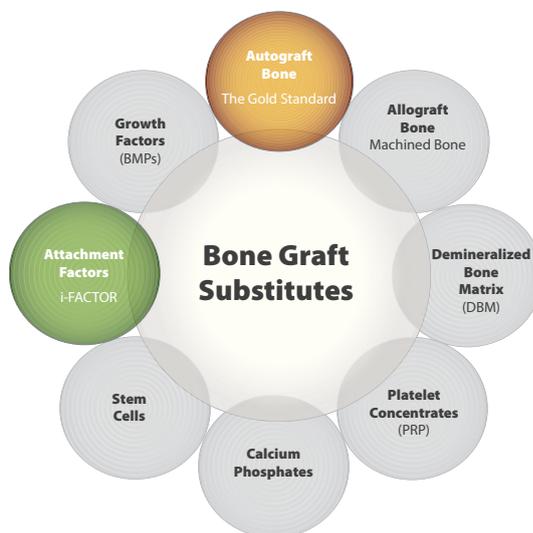
## COMPARATIVE METHOD OF ACTION FOR ORTHOBIOLOGICS

**AUTOGRAFT** is the 'gold standard' of bone grafts because it provides all the necessary elements for bone growth: namely bone mineral, osteogenic precursor cells and biological signals. However, most autograft bone graft originates from the iliac crest, and has variable quality, is limited in availability and causes secondary surgical site morbidity.<sup>12</sup>

**GROWTH FACTORS (BMPs)** are osteoinductive products, manufactured through recombinant gene technology. These exogenous growth factors are not synthesised by the body's natural mechanism of action for osteogenesis. BMPs direct cells to become bone cells regardless of the cells' lineage, predisposition or early developmental stage. Due to their potent nature, BMPs can also come with complication rates and adverse events, as BMP is a soluble molecule free to migrate to local tissues.<sup>17,18</sup>

**DBM (DEMINERALISED BONE MATRIX)** products are derived from human cadaver bone. DBMs are subjected to an acid process to extract mineral, leaving trace amounts of osteoinductive proteins and growth factors. The biologic aspects of DBMs are largely influenced by original donor properties, product processing and storage. The amount of BMPs in DBM products is low and varies between commercial products and even between lots from the same manufacturer.<sup>19</sup>

**PLATELET CONCENTRATES (OR PLATELET-RICH PLASMA)** use blood harvested from patients to bring cytokines and growth factors to the surgical site, similar to the blood clotting stage of bone repair. Platelet gel preparations vary in quality based upon patient factors and preparation techniques. Platelet concentrates have been shown not to enhance fusion rates, even when added to autograft bone.<sup>20</sup>



**STEM CELL-BASED ALLOGRAFTS** are marketed as an alternative to autograft and consist of mesenchymal stem cells with cancellous bone or DBM. After six years in the marketplace, no peer-reviewed, randomised, controlled trial exists to support the efficacy of stem cell bone grafts.

**ALLOGRAFT BONE, CALCIUM PHOSPHATES** and synthetic hydroxyapatites comprise the majority of products in the bone graft substitute market, acting as simple osteoconductive scaffolds that provide a surface that permits bone growth. These bone graft substitutes have little active influence on bone growth, often relying on bone marrow aspirate for biologic activity.<sup>21</sup>

**SILICATED CALCIUM PHOSPHATE** products have the osteoconductive properties of traditional calcium phosphate bone fillers. These products, marketed as osteostimulatory, rely on the silicate ions and the subsequent negative surface charge of the released Si ions to enhance cellular activity. However, the evidence of this being effective in the clinical setting is lacking at this time.<sup>22</sup>

# 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 <sup>4</sup>

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.

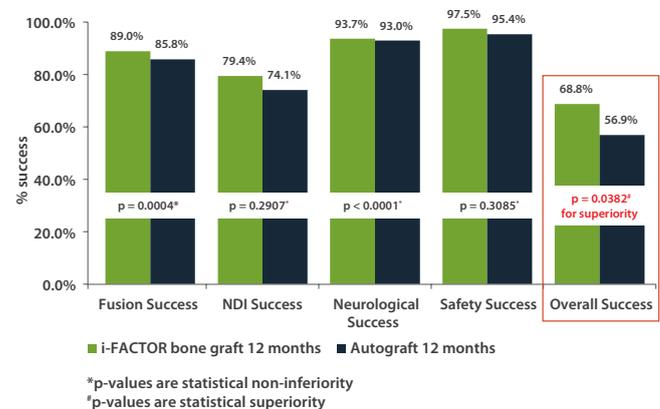
#### MATERIALS AND METHODS

- 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 <sup>3</sup>

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<sup>23, 24</sup>

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

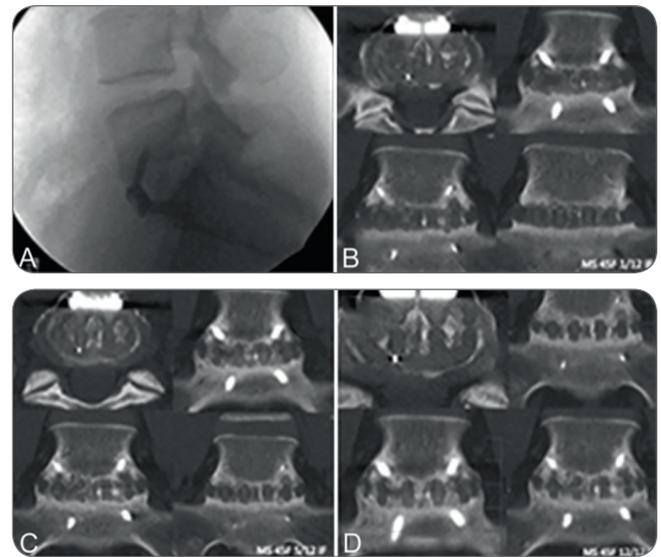


Fig. 1. Images demonstrating progression of interbody fusion in a 45-year-old woman treated for DDD without radiculopathy. A: Radiograph of the L5-S1 level one day postsurgery. B: Coronal CT images obtained one month postoperatively. C: CT images obtained five months postoperatively. D: CT images obtained 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.<sup>18</sup>

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

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

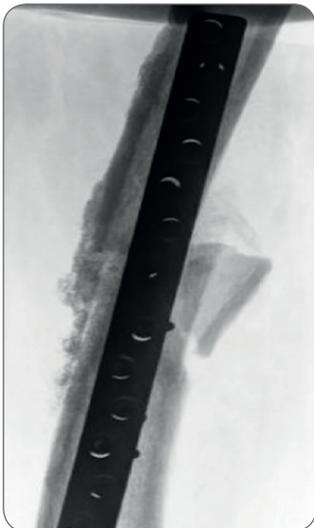
- Full consolidation was achieved in 90% (20 out of 22) of the patients treated with i-FACTOR Bone Graft product
- Of the remaining two patients, one patient had a hardware failure, was retreated and fused. The last patient was lost to follow-up

- 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

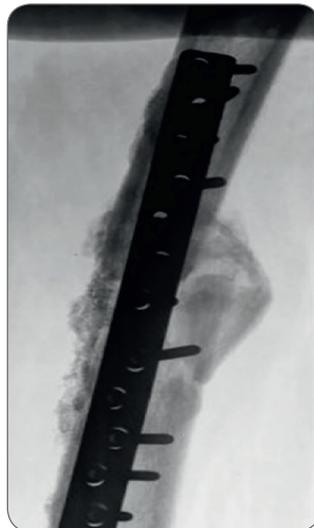
### CONCLUSION

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.

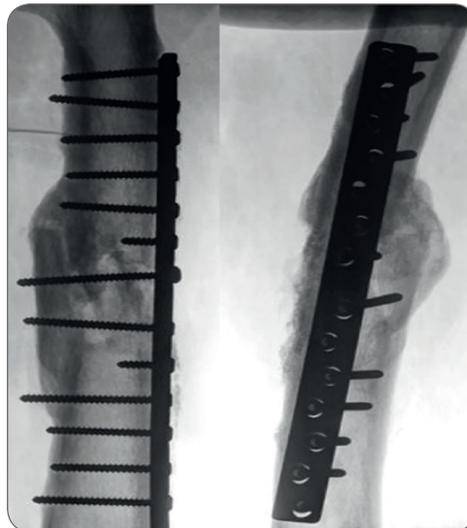
1 month



3 months



15 months



# PRE-CLINICAL RESULTS

## EVALUATION OF P-15/ABM VERSUS AUTOGENOUS BONE IN AN OVINE LUMBAR INTERBODY FUSION MODEL<sup>9</sup>

Blake P. Sherman, Emily M. Lindley, A. Simon Turner, Howard B. Seim III, James Benedict, Evalina L. Burger, Vikas V. Patel

### CLINICAL ORTHOPAEDIC DATA

A prospective, randomised study was performed in an ovine model that compared the efficacy of using i-FACTOR Biologic Bone Graft to autogenous bone harvested from the iliac crest to facilitate lumbar interbody fusion.

#### RESULTS

- At 3 months, the CT scans for both treatment groups demonstrated substantial new bone formation inside the PEEK rings, as well as outside the PEEK rings bridging the vertebral bodies
- At 6 months, the CT scans for both treatments demonstrated complete segment-to-segment fusion
- Micro CT scans at 6 months demonstrated the newly formed fusion bone was most dense inside the PEEK ring compared to outside the ring for both treatments

- Bone measurements at 6 months showed no statistical difference between the fusion area of the i-Factor Putty segments and the autograft segments
- After 6 months, the ABM had largely reabsorbed 94%, with the remaining ABM particles surrounded by or embedded in bridging bone<sup>9</sup>

### CONCLUSION

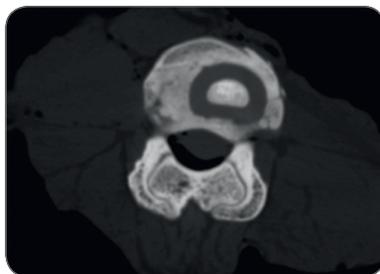
Vertebral fusion and abundant bone formation were achieved in a sheep lumbar fusion model, and the fusion results were equivalent using i-FACTOR Putty compared to the 'gold standard' autogenous bone.

#### P-15/ABM

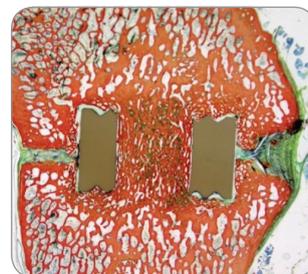
3-month CT



6-month CT



Undemineralised histological section

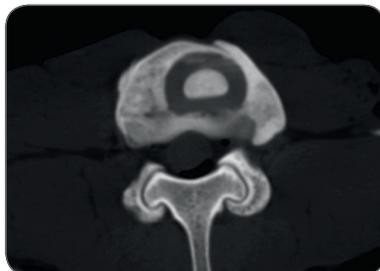


#### AUTOGRAFT

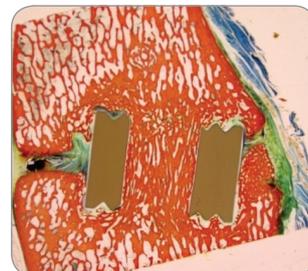
3-month CT



6-month CT



Undemineralised histological section



# CASE STUDY

## i-FACTOR BIOLOGIC BONE GRAFT COMPARED TO AUTOGRAFT IN POSTERIOR LUMBAR INTERBODY FUSION<sup>3</sup>

Philippe Lauweryns, MD, PhD, Orthopaedic Department, Regional Ziekenhuis Sint-Trudo (RZST), Sint-Truiden, Belgium and Faculty of Medicine, Hasselt University, Hasselt, Belgium

### INTRODUCTION

A 57-year-old female presented with the primary complaint of chronic low back pain in addition to left sciatica on posterior aspect of the leg. Clinical examination revealed painful range of motion. Straight leg raising was positive on the left at 65° and negative on the right side. Motor and sensory findings were normal.

The MRI scan showed spinal stenosis at L4-L5 and disc degeneration at L5-S1, (Figure 1).

All her symptoms were chronic, incapacitating and refractory to conservative treatment, including physiotherapy, medication and infiltration techniques. It was therefore decided to perform an L4-L5 posterolateral fusion and decompression together with an L5-S1 posterior interbody fusion.

### PRE-OPERATIVE HISTORY

Patient had a previous microdiscectomy at L5-S1 on the right side. She is a non-smoker and of normal height and weight.

### SURGICAL PROCEDURE – POSTEROLATERAL

Fusion L4-L5 and Posterior Lumbar Interbody Fusion L5-S1 Posterior approach with exposure of posterior aspects of L4, L5 and S1 was performed. Bilateral pedicle screw instrumentation was implanted at L4, L5 and S1. Decompression and posterolateral fusion at L4-L5 was performed using local autograft bone from the decompression.

At L5-S1, decompression and interbody fusion was performed using two carbon composite interbody fusion cages. The left cage was filled with i-FACTOR Putty and the right cage was filled with local autograft bone. In addition, local autograft bone was placed lateral to right cage and around left cage (Figures 2-4).

### POST-OPERATIVE COURSE

Physical therapy with exercises and reconditioning started six weeks post-operation.



Fig. 1 Lateral MRI



Fig. 2 Post-op lateral CT, cage with autograft



Fig. 3 Post-op lateral CT, cage with i-FACTOR

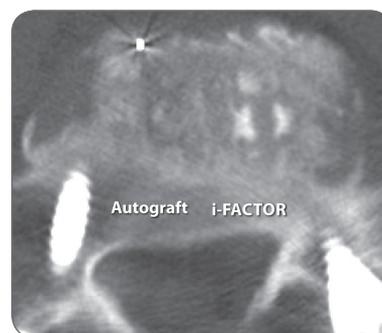


Fig. 4 Post-op L5-S1 axial CT, cage with i-FACTOR patient left, cage with autograft patient right

### THREE-MONTH FOLLOW-UP

Clinical examination and X-ray findings are normal (Figures 5-6).

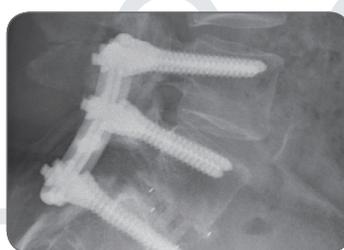


Fig. 5 3-month anterior-posterior X-ray



Fig. 6 3-month lateral X-ray

# CASE STUDY

## SIX-MONTH FOLLOW-UP

CT scan, as interpreted by independent radiologist, shows bridging bone in several of the i-FACTOR cage compartments.

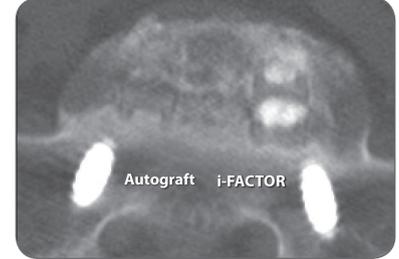
The cage with autograft is not judged to be fused at this six-month interval (Figures 7-9).



**Fig. 7** 6-month lateral CT, cage with autograft



**Fig. 8** 6-month lateral CT, cage with i-FACTOR



**Fig. 9** 6-month L5-S1 axial CT, cage with i-FACTOR patient left, cage with autograft patient right

## 12-MONTH FOLLOW-UP

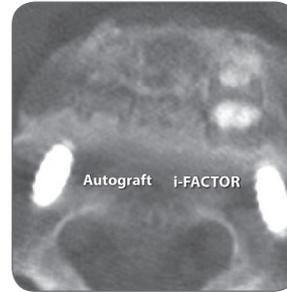
CT scan, as interpreted by independent radiologist, shows bridging bone in several compartments of both cages and fusion at both levels (Figures 10-13).



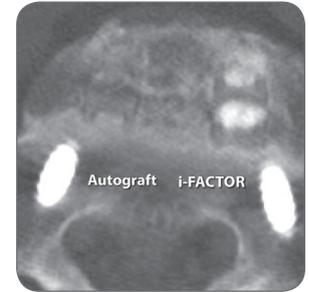
**Fig. 10** 12-month lateral CT, cage with autograft



**Fig. 11** 12-month lateral CT, cage with i-FACTOR



**Fig. 12** 12-month L5-S1 axial CT, cage with i-FACTOR patient left, cage with autograft patient right

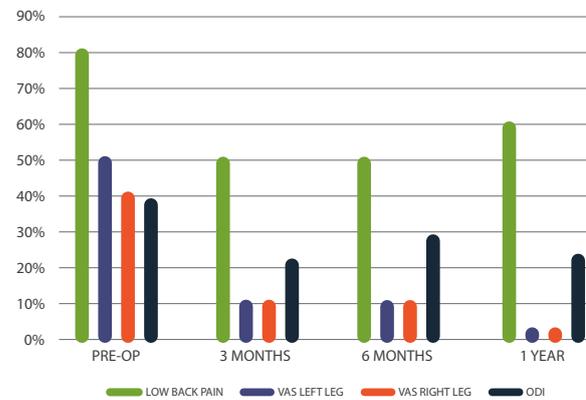


**Fig. 13** 12-month CT coronal view

## PATIENT OUTCOMES

The patient was administered Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) Questionnaire Forms pre-operatively and at 3 months, 6 months and 12 months, post-operatively.

All measurements show improvement over the 12-month follow-up period, and the patient at all follow-up intervals reports to be extremely happy with the surgical outcome, reporting no back pain and no leg pain.



## CONCLUSION

### i-FACTOR PEPTIDE ENHANCED BONE GRAFT IS STATISTICALLY SIGNIFICANTLY SUPERIOR TO AUTOLOGOUS BONE IN FACILITATING FORMATION OF BRIDGING BONE INSIDE PLIF CAGES <sup>3</sup>

Findings suggest that i-FACTOR has equal or greater efficacy than autologous bone in PLIF at 6 and 12 months with statistical significance and equivalence at 24 months. This study provides independent radiographic evidence as well as self-reported outcomes from patients. Patients in the study experienced a statistically higher degree of fusion earlier (at 6 and 12 months) with i-FACTOR than with autograft. Pain and function improvements met or exceeded success criteria at all time points.

# i-FACTOR BIOLOGIC BONE GRAFT

**i-FACTOR BIOLOGIC BONE GRAFT PRODUCTS ARE INTENDED TO REPLACE OR AUGMENT THE USE OF AUTOGRAFT BONE COMMONLY UTILISED IN ORTHOPAEDIC PROCEDURES SUCH AS: SPINAL FUSION INCORPORATING INTERBODY FUSION DEVICES, TREATMENT OF NON-UNION OR TRAUMATIC FRESH FRACTURES, AND AS A BONE VOID FILLER ASSOCIATED WITH JOINT RECONSTRUCTION.**

i-FACTOR products are not intended to provide load-bearing structural support during the healing process. i-FACTOR products are terminally sterilised, can be stored at room temperature and have a three-year shelf life. i-FACTOR Biologic Bone Graft is a standalone product that does not require bone marrow aspirate or other additives for efficacy, although it can be mixed with local autograft if available.

## SIZING INFORMATION



900-010	i-FACTOR Putty	1.0cc
900-025	i-FACTOR Putty	2.5cc
900-050	i-FACTOR Putty	5.0cc
900-100	i-FACTOR Putty	10.0cc



		LENGTH		WIDTH		THICKNESS
950-025	i-FACTOR Flex FR	25mm	x	25mm	x	4mm
950-050	i-FACTOR Flex FR	50mm	x	25mm	x	4mm
950-100	i-FACTOR Flex FR	100mm	x	25mm	x	4mm

**CAUTION:** i-FACTOR Flex FR is not commercially available in the USA.

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