PRE-CLINICAL RESULTS

EVALUATION OF P-15/ABM VERSUS AUTOGENOUS BONE IN AN OVINE LUMBAR INTERBODY FUSION MODEL [9]

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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

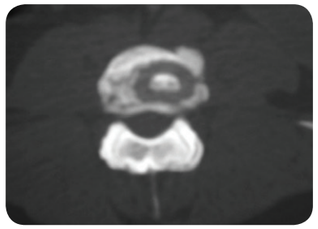
- At 3 months, the CT scans for both treatment groups demonstrated substantial new bone formation inside the PEEK rings, as well as outside the PEEK rings bridging the vertebral bodies
- At 6 months, the CT scans for both treatments demonstrated complete segment-to-segment fusion
- Micro CT scans at 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 [9]

CONCLUSION

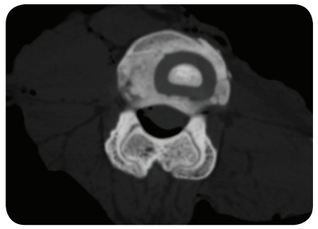
Vertebral fusion and abundant bone formation were achieved in a sheep lumbar fusion model, and the fusion results were equivalent using i-FACTOR Putty compared to the 'gold standard' autogenous bone.

P-15/ABM

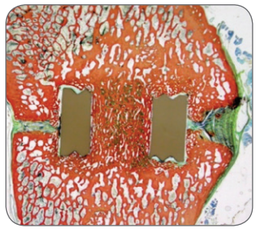
3-month CT



6-month CT

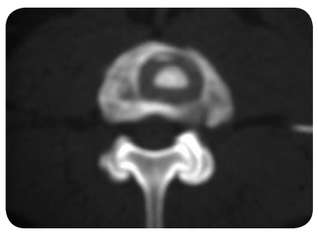


Undemineralised histological section

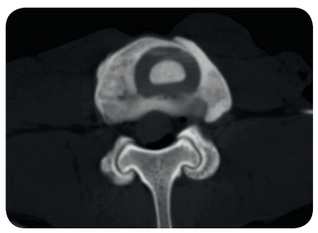


AUTOGRAFT

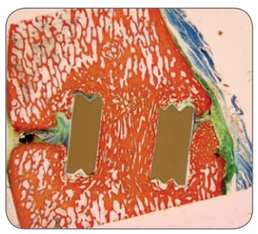
3-month CT



6-month CT



Undemineralised histological section



CASE STUDY

i-FACTOR BIOLOGIC BONE GRAFT COMPARED TO AUTOGRAFT IN POSTERIOR LUMBAR INTERBODY FUSION [3]

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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.

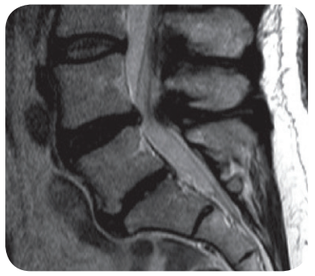


Fig. 1 *Lateral MRI*

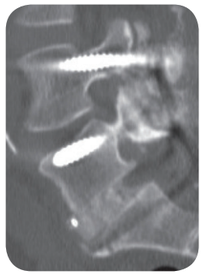


Fig. 2 *Post-op lateral CT, cage with autograft*

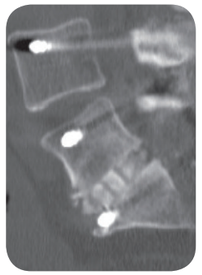


Fig. 3 *Post-op lateral CT, cage with i-FACTOR*

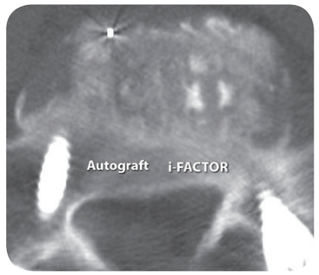


Fig. 4 *Post-op L5-S1 axial CT, cage with i-FACTOR patient left, cage with autograft patient right*

THREE-MONTH FOLLOW-UP

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

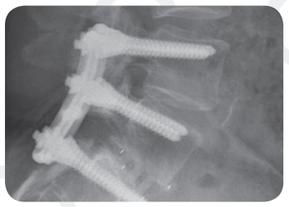


Fig. 5 *3-month anterior-posterior X-ray*

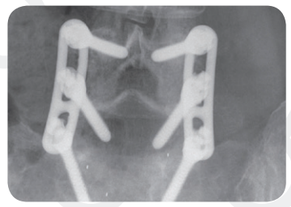


Fig. 6 *3-month lateral X-ray*

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).

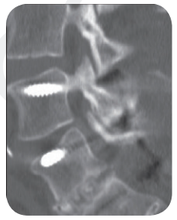


Fig. 7 *6-month lateral CT, cage with autograft*

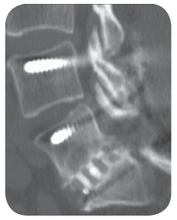


Fig. 8 *6-month lateral CT, cage with i-FACTOR*

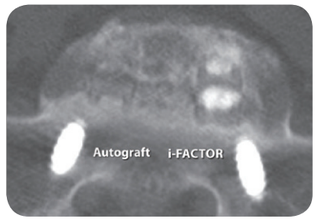


Fig. 9 *6-month L5-S1 axial CT, cage with i-FACTOR patient left, cage with autograft patient right*

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).

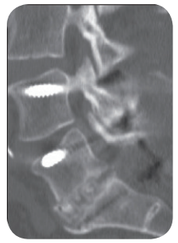


Fig. 10 *12-month lateral CT, cage with autograft*

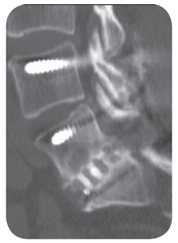


Fig. 11 *12-month lateral CT, cage with i-FACTOR*

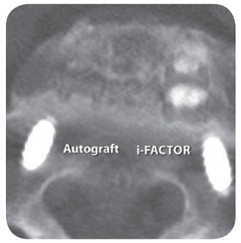


Fig. 12 *12-month L5-S1 axial CT, cage with i-FACTOR patient left, cage with autograft patient right*

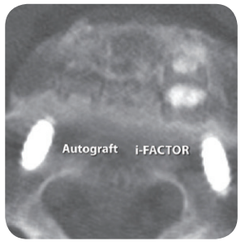
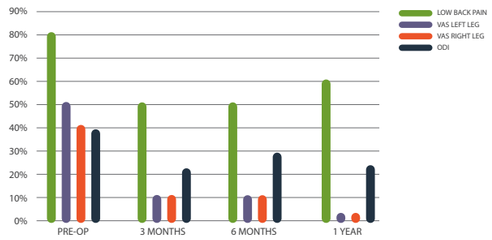


Fig. 13 *12-month CT coronal view*

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 [3]

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

putty
i=FACTOR™
Peptide Enhanced Bone Graft

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

flex FR
i=FACTOR™
Peptide Enhanced Bone Graft

		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.