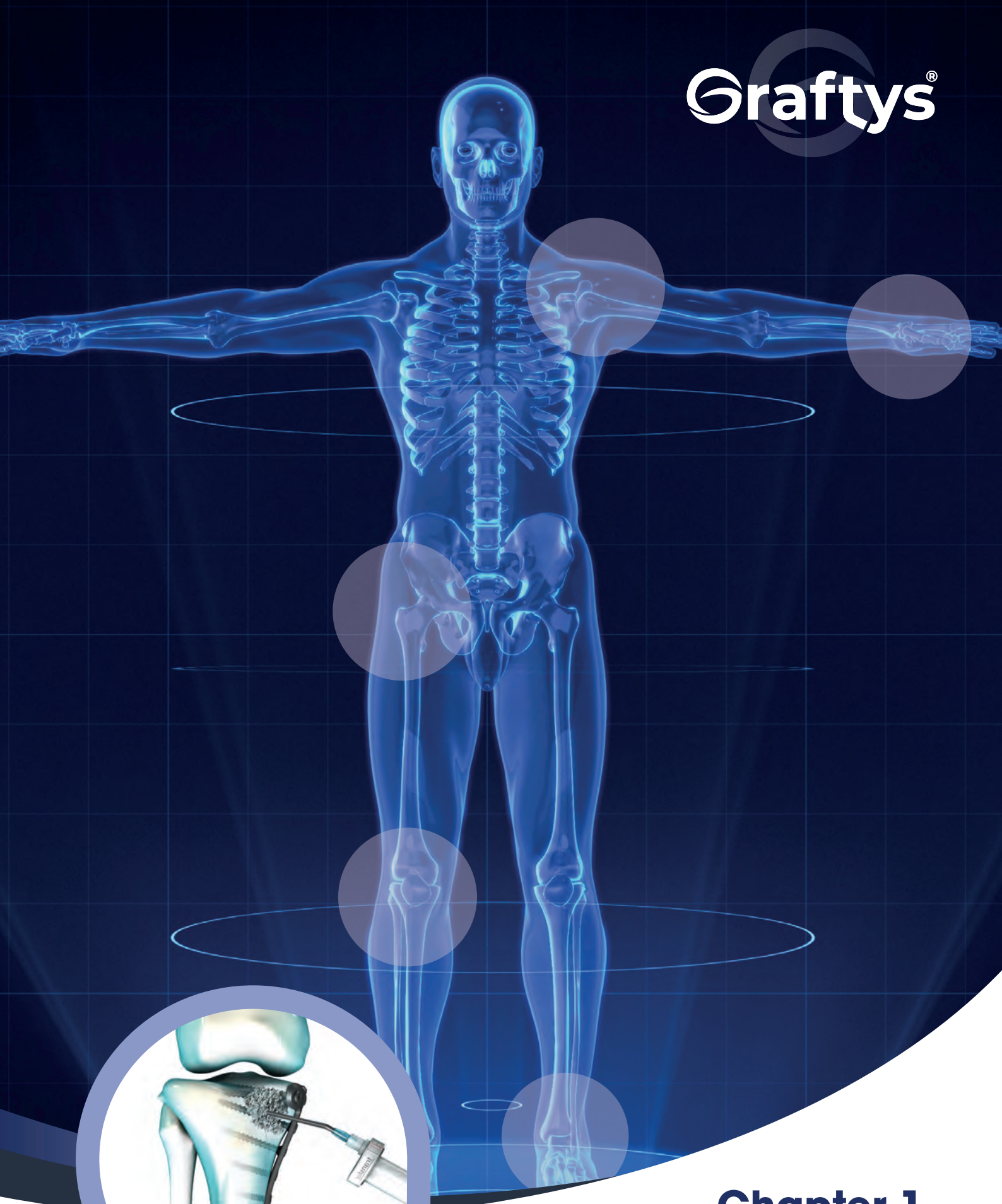
Graftys®



Chapter 1

Ortho-trauma Fracture

GraftysQuickSet & HBS

Calcium Phosphate Cement: A Safe Alternative of Autograft

BACKGROUND

Since the first development of CPC in 1980s, its application in various orthopaedic surgeries have been preferred over other calcium phosphate-based biomaterials due to its resorption ability under physiological conditions. CPCs clinical potential is further increased, as the apatite crystals resulted to be biocompatible, osteoconductive, and bioresorbable, while they offer an intrinsic microporous structure for the transport of nutrients and metabolic waste products.[1]

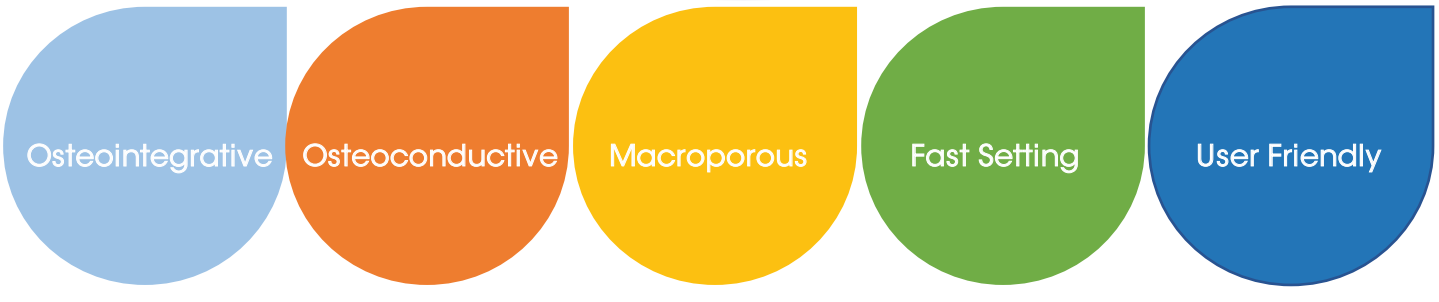
Keeping this need in mind the Graftys® HBS and QUICKSET are developed after immense research by a multidisciplinary team of scientists, engineers and surgeons. The Graftys® HBS and QUICKSET materials are designed to have multi-functional characteristics which can fulfil the biomechanical and biological prerequisites of the bone.

Although CPCs are considered as the most suitable injectable biomaterials to accommodate narrow and irregular bone defects. The lack of macropores is considered a major limitation for the widespread use of CPCs.[1] Graftys® R&D team has addressed this problem by introducing macroporous structures which can facilitate bone regeneration and aid in fast resorption of CPCs.

TREATMENT OPTIONS

Surgeons often face challenging situation, where they have to utilize combination therapies to treat difficult fractures. Nowadays in a variety of surgical procedures, use of biologically safe, non-toxic, macroporous, osteoconductive and synthetic bone calcium-phosphate cements (CPC's) is considered a minimally invasive and safe alternative of autografts.

Owing to their ease of use, injectability in minimally invasive and remote manner, being sterile, safe and with perfect integration into host bone due to high degree of osteoconductivity and ability to fill or reinforce variety of bony voids or defects, GRAFTYS®HBS and QUICKSET are suitable for an array of surgical procedures.



Preclincial Study of Graftys® HBS

IN VIVO STUDY

An in vivo study compared Graftys® HBS with a comparable product (Norian cement) and investigated the extent of porosity and permeability of injectable apatitic cements. Hence, the two CPCs were implanted in critical-sized defects created in the distal lateral femoral condyle of rabbits.[2]

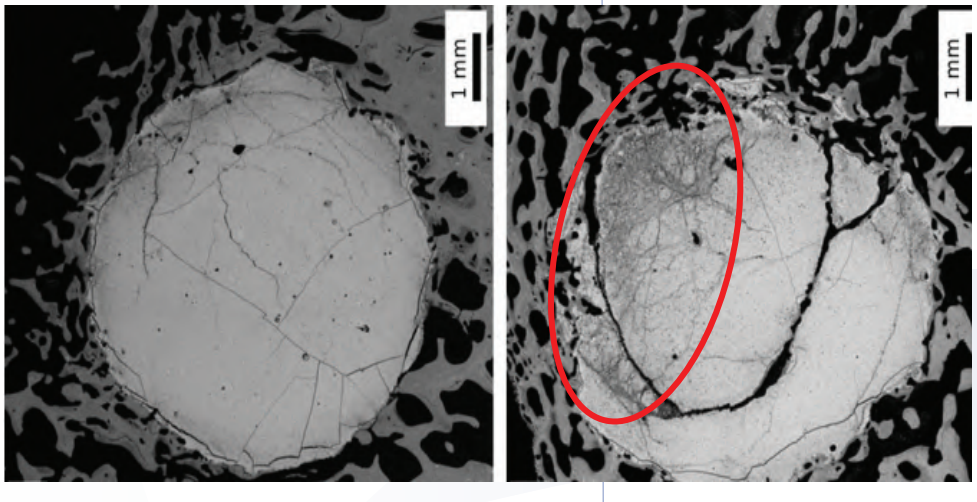


Fig. 1: SEM images (x35 magnification) of HBS after 8 weeks of implanatation in animal model (red encircled area shows growth of bone after 8 weeks of tranplantation)

Histmorphometrical analysis confirmed a significantly lower cement area density after 8 and 12 weeks of Graftys® HBS implantation (Table 1 and Figure 1). The histological images show the specific microstructure of HBS which generates a diffused interface with the newly formed bone tissue, giving evidence of a more dynamic remodeling process than the comparator (Norian cement). [2]

Graftys® HBS cement showed faster osteoconduction and material degradation than the comparator (NORIAN cement) at all implantation times (Table 1).

	HBS		NORIAN	
Implantation time	Cement area density (%)	Bone area density (%)	Cement area density (%)	Bone area density (%)
4 weeks	88.6 ± 13.2	5.6 ± 1.7*	99.0 ± 0.9	0.6 ± 0.2
8 weeks	76.9 ± 15.5*	13.5 ± 4.1*	98.9 ± 0.9	0.8 ± 0.2
12 weeks	79.1 ± 15.7*	11.0 ± 3.3*	97.5 ± 0.9	1.5 ± 0.5

Table 1: Histomorphometrical results of the Cement area density (%) and bone area density (%) in the region of interest ROI 2, as a function of the implantation period (*p < .05 compared to the NORIAN cement) (ROI: region of interest)

Clinical Study: Treatment of Complex Tibial Plateau Fracture with Graftys® QuickSet & HBS

Patient Background

- A 35 years old active female;
- Complex tibial plateau fracture;

Surgical Procedure

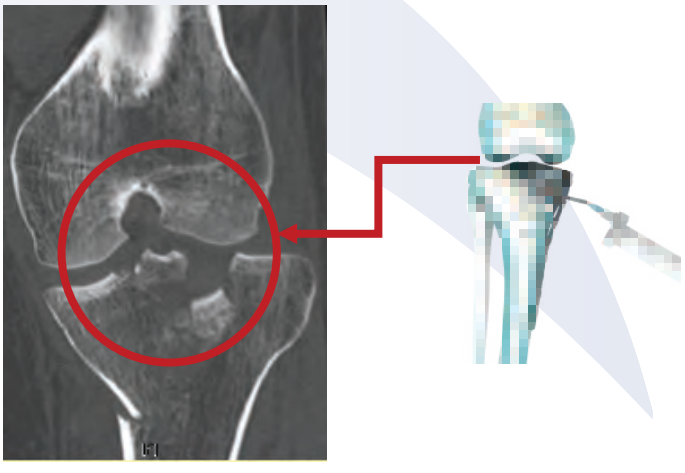
- ORIF with plate, screws and wire;
- Filling of the defects with Graftys®Quickset & HBS;
- Bracing using a custom-made articular bracing;

Treatment Outcome

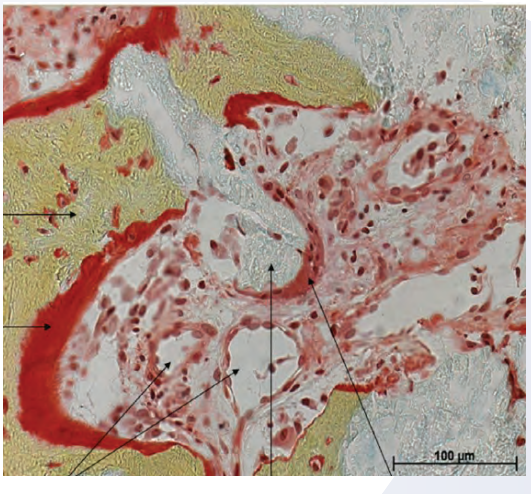
- Within 8 months of surgery patient returned to a normal pain free active life style;
- Cycling and leg flexion (120°) and extension (0°) without pain
  Good healing confirmed by radiological scans;
- Restoration of the articular congruency.

Clinical data show a safe and efficient [3] use of GRAFTYS®HBS and QUICKSET without any related serious adverse event [4, 5]. Furthermore, the GRAFTYS®HBS and QUICKSET are demonstrated to improve mid-term radiological outcomes [6], pain (per KOOS score [6] and VAS scale [7]), functional capacity [7], recovery rate [5], rate of anatomic reduction [4] and also enabling outpatient treatment in many cases [5].

Pre-operative Scan

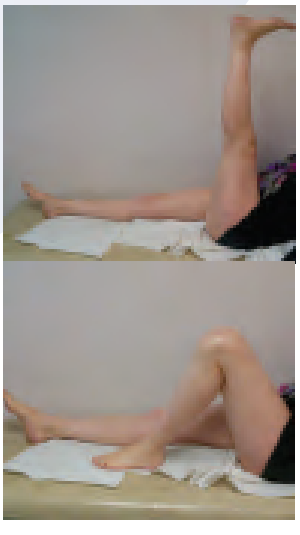


4 Month Biopsy



1 Year Follup-up

Compete Recovery after 2 Years



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