



FREGIS

# EFFICACY AND SAFETY ASSESSMENT OF A SELF-SETTING BONE SUBSTITUTE ( $\alpha$ -TCP) AS AN EFFICIENT ALTERNATIVE TO AUTOGRAFTS

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## INTRODUCTION

Bone grafts are used in orthopedic surgery to accelerate and promote bone regeneration<sup>1</sup>, including:

- Autograft, which is the gold standard because of its osteoconductive, osteo-inductive and osteogenic properties<sup>2</sup>. Its limitations include donor site morbidity (pain, surgical site infection, fractures<sup>3</sup>), limited access, increased surgical time and a lack of biomechanical strength<sup>3,4</sup>.
- Allografts, which have good osteo-inductivity properties but has limited availability and presents an increased risk of infection<sup>1</sup>.
- Synthetic bone grafts, which are commonly used in human orthopedics<sup>4</sup>. However, few osteo-regenerative options are available in veterinary medicine.

**Calcium phosphate-based synthetic grafts** offer a high potential as bone substitute<sup>4,5</sup>: with a similar composition to natural bone; they are osteointegrative, osteoconductive, highly soluble, and provide advantageous mechanical properties<sup>5</sup>.

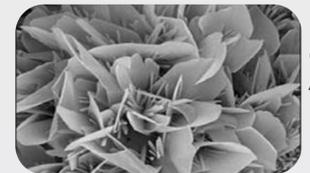
This comparative study aimed to assess the efficacy and safety of an  $\alpha$ -TCP (tricalcium phosphate) self-setting bone substitute compared to autografts.

## SELF-SETTING BONE SUBSTITUTE

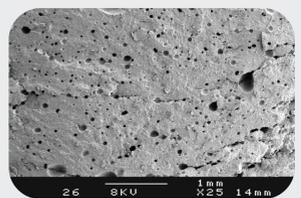
( $\alpha$ -TCP) and ortho-phosphate salts crystallize into **calcium deficient apatite**, chemically close to the components of natural bone.

The graft is **well integrated** in bone matrix, **resorbed by osteoclasts** and progressively **replaced by newly formed bone**.

Its porosity promotes bone cell colonization and biological fluid penetration. A full range of micro, meso and macropores makes BIOCERA-VET® Bone Surgery over 50% porous **promoting osteo-conduction and bone remodelling**.



Calcium-Deficient Apatite Crystals



Porous structure

## MATERIAL AND METHODS

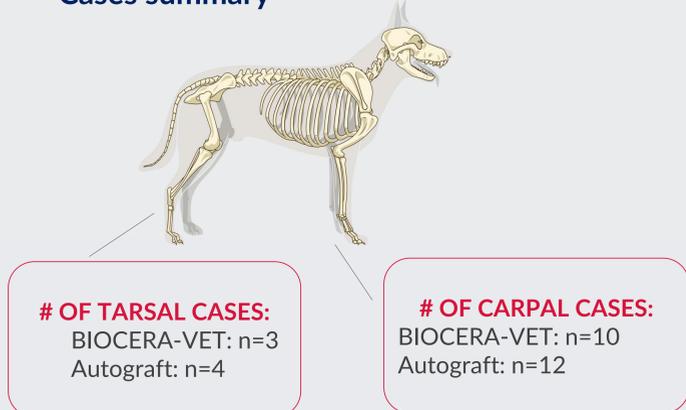
Data from a total of 29 total of arthrodesis cases (7 tarsus and 22 carpus) performed by 5 veterinary surgeons were collected.

- **STUDY DESIGN:** Comparative study of cases treated with a  $\alpha$ -TCP bone substitute to historical of tarsal and carpal arthrodesis using autograft, performed between 2015 and 2020,
- **TREATMENT:** Standard tarsal and carpal arthrodesis procedures associated to the use of  $\alpha$ -TCP bone substitute (BIOCERA-VET®BS) or autograft.
- **SAFETY ASSESSMENT:** A general physical examination was performed at each follow-up visit by the surgeon.
- **RADIOLOGICAL SCORING:** A blinded radiological analysis was performed by an independent surgeon evaluating 4 and 8 weeks post-operative radiographs. Radiographs were scored from 0 to 3<sup>6,7</sup>, with 0 being the absence of mineralised tissue (bone) visible in the joint space, and 3 a solid fusion of adjacent bones with modelling of bone and loss of subchondral bone plate.

### Cases summary

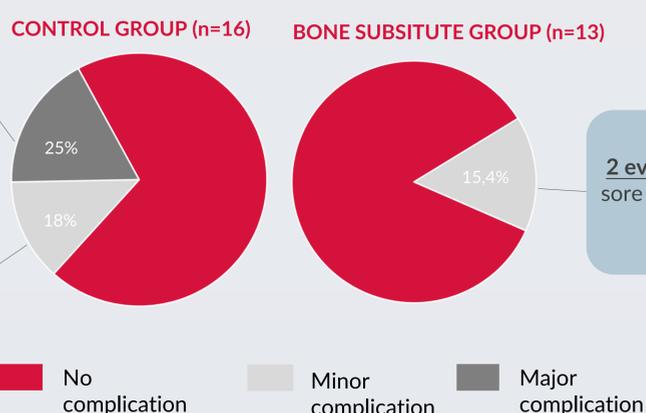
**CONTROL GROUP**  
16 dogs treated with autologous bone graft (historical cases from 2015 to 2019)

**EXPERIMENTAL GROUP**  
13 dogs treated with the self-setting bone substitute (BIOCERA-VET®)



## RESULTS

### Complication percentage comparison

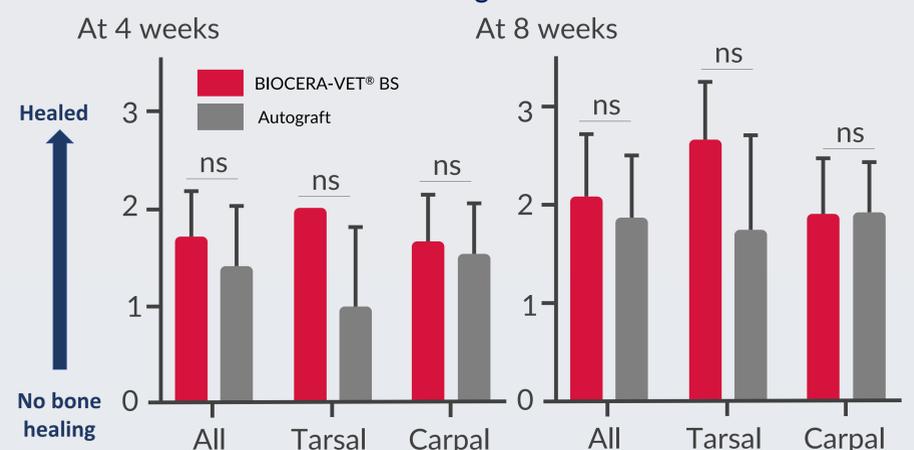


4 events:  
- 2 cases: infection (confirmed)  
- 1 case: fracture  
- 1 case: infection combined with a fracture

3 events:  
- 2 cases: infection (suspicion)  
- 1 case: fixation failure

Safety evaluation showed a lower rate of complications compared to the autograft group.

### Mean score of radiological evaluation



The blinded radiological evaluation resulted in mean scores of 1,7 (SD ± 0,48) and 1,41 (SD ± 0,62) at 3 to 4 weeks follow-up and 2,08 (SD ± 0,64) and 1,87 (SD ± 0,62) at 6 to 8 weeks follow-up for the self-setting bone substitute and autograft groups respectively. No statistical difference was observed between these scores. A similar healing process was observed when comparing both set of images at 4 weeks after the surgical procedure and its progression was visible at the 8-week follow-up.

## CONCLUSION

A **lower prevalence of complications** was reported when the bone substitute was implemented. This is likely due to the shorter surgical time resulting of the absence of cancellous bone harvest.

The radiological analysis showed **no statistical difference between the results of the autograft and the new self-setting bone substitute**. A similar healing process was observed when comparing both groups 4 and 8 weeks after the surgical procedure. The self-setting bone cement showed thus comparable efficacy to promote bone healing than autograft.

Further studies with a higher number of patients should be performed to confirm the findings of this comparative study.

**CONFLICT OF INTEREST:** BIOCERA-VET® Bone Surgery, 3 cc, was provided free of charge by the company TheraVet®

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