

PRESS RELEASE



BIOCERA-VET: a promising alternative to autologous bone graft in canine arthrodesis

- *BIOCERA-VET presents similar efficacy and better ergonomics compared to bone autograft while reducing risks of complications.*
- *This conclusion results from the evaluation of data collected in over 40 clinical cases evaluating BIOCERA-VET in target orthopedic surgeries in dogs and cats and the comparison between 13 clinical cases evaluating BIOCERA-VET and 16 bone autograft cases in dog arthrodesis.*

Jumet (Wallonia, Belgium), April 27th, 2021 - **TheraVet S.A.**, a pioneering company in the management of osteoarticular diseases in pets, announces today **the positive efficacy results of BIOCERA-VET, its new generation bone substitute for the treatment of bone surgeries in small companions, in bone fusion in canine arthrodesis.**

A real need for new bone substitute alternatives to replace effectively autologous bone graft in orthopedic surgeries

For orthopedic surgeries, autologous bone graft¹ is still considered as the standard of procedure to fill in cavities or to treat major defects with bone fusion such as arthrodesis². However, the procedure presents some limitations such as donor site morbidities and

¹ Autologous bone graft is defined as the use of bone obtained from the same individual receiving the graft

² Surgical procedure to restore function and alleviate pain in carpal and tarsal joints with ligamentous injuries, bone fractures, joint luxation or subluxations

lameness, limited availability of graft volume, particularly in small size pets, and additional surgical time.

Alternatives to autologous bone graft exist. However, they do not present satisfying characteristics in terms of efficacy, ergonomics and/or co-morbidities involved in order to replace autologous bone graft.

BIOCERA-VET: a new innovative alternative to autologous bone graft

BIOCERA-VET is an injectable synthetic self-hardening calcium-phosphate bone substitute with high porosity and a chemical composition similar to natural bone crystals. TheraVet is evaluating its efficacy, ergonomics and complications related to its use in bone surgery applications requiring a bone graft such as arthrodesis, multi-fragmented fractures, corrective osteotomy and tibial tuberosity advancement in dogs and cats.

In total, results from 44 clinical cases have been collected thanks to TheraVet's network of orthopedic vet surgeons. The 11 participating vets in Belgium and France reported no complications with BIOCERA-VET, and an excellent ergonomics allowing to save up to 45 min in surgical time as compared to gold standard procedure.

In order to evaluate and confirm the efficacy of BIOCERA-VET in the different possible applications, TheraVet evaluated its product in arthrodesis (fusion of carpal or tarsal joint), compared to similar (historical) cases treated with the gold standard, bone autograft.

An independent radiological evaluation then assessed the bone fusion in 13 canine cases of arthrodesis treated with BIOCERA-VET, compared to 16 canine cases treated with autologous bone graft, all in addition to the standard surgical procedure.

Bone fusion was evaluated by a blinded and qualified orthopedic surgeon using a numerical rating scale^{3,4} ranging from 0 (no consolidation) to 3 (solid bone fusion). The comparative analysis, performed at 4⁵ and 8⁶ weeks post-surgery, showed that bone fusion induced by BIOCERA-VET was as good as the one induced by bone autograft (respective mean scores of 1.70 vs 1.41, $p > .05$ at 4 weeks⁷ and of 2.08 vs 1.88, $p > .05$ at 8 weeks).

³ Michal, U., Fluckiger, M., & Schmokelt, H. (2003). Healing of dorsal pancarpal arthrodesis in the dog. *Journal of Small Animal Practice*, 44(3), 109–112.

⁴ Jennifer J Ree, Wendy I Baltzer, Katy L Townsend, Augmentation of arthrodesis in dogs using a free autogenous omental graft. *Can Vet J*. 2016 Aug;57(8):835-41. 0

⁵ Radiological evaluation performed from 3 to 5 weeks post-surgery

⁶ Radiological evaluation performed from 6 to 8 weeks post-surgery

⁷ At 4 weeks: 10 cases with BCV vs 17 cases of autograft

Furthermore, in the smaller subgroup of the pantarsal arthrodesis⁸, bone fusion induced by BIOCERA-VET was 50% more advanced than the one induced by bone autografts, although not reaching statistical significance (respective mean scores of 2.00 vs 1.00, $p > .05$ at 4 weeks; of 2.67 vs 1.75, $p > .05$ at 8 weeks). These observations suggest that BIOCERA-VET seems to accelerate the bone fusion process at tarsal level as compared to autograft, which should be confirmed later on in larger comparative analysis.

Additionally, whereas no complication reported in the 13 cases treated with BIOCERA-VET, the complication rate in cases treated with autograft was similar to those reported in literature i.e. between 15 to 30%^{9,10,11}.

These results suggest that BIOCERA-VET is at least as effective as autologous bone graft in bone fusion and that it reduces complication rate and surgery time.

Dr Guillaume Ragetly, Head of Department of Surgery at CHV Frégis (France) said: “*BIOCERA-VET induces bone fusion thanks to its interesting properties of osteo-induction, osteo-conduction and osteo-integration. It has real advantages for the veterinary surgeon allowing him to have an alternative to autograft, with less complications while saving significant surgical time*”.

To further validate these observations, TheraVet initiated in November 2020 a prospective multicentric clinical study in November 2020 to evaluate safety, efficacy and ergonomics of BIOCERA-VET. Currently conducted in 10 sites in France and in Belgium, the study will include 30 cases of bone surgeries in dogs proportionally distributed between the indications of arthrodesis, fracture and TTA¹². Results are expected for the second trimester 2021 for TTA indication and later in 2021 for the other two surgical indications.

Sabrina Ena, Chief Operating Officer of TheraVet, concludes: “*By combining excellent efficacy to superior ergonomics and limited risks of complications in bone fusion, BIOCERA-VET is now positioned as a real alternative to autologous bone grafts, the standard of procedure.*”

⁸ Arthrodesis performed at tarsus

⁹ Hoffer, MJ, Griffon, DJ, Schaeffer, DJ, Johnson, AL, & Thomas, MW (2008). *Clinical Applications of Demineralized Bone Matrix: A Retrospective and Case-Matched Study of Seventy-Five Dogs*. *Veterinary Surgery*, 37(7), 639–647

¹⁰ McKee WM, May C, Macias C, Lapish JP (2004) *Pantarsal arthrodesis with a customised medial or lateral bone plate in 13 dogs*. (2004). *Australian Veterinary Journal*, 82(12), 749–749.

¹¹ Tuan, J., Comas, N., & Solano, M. (2019). *Clinical outcomes and complications of pancarpal arthrodesis stabilised with 3.5 mm/2.7 mm locking compression plates with internal additional fixation in 12 dogs*. *New Zealand Veterinary Journal*, 1–16.

¹² TTA: Tibial Tuberosity Advancement



About BIOCERA-VET

BIOCERA-VET is a line of injectable synthetic self-hardening calcium-phosphate bone substitutes. BIOCERA-VET, a new veterinary medical device, presents unique properties combining ideal bone formation and remodeling properties associated to mechanical resistance. BIOCERA-VET targets bone surgeries (such as arthrodesis, fractures) and osteosarcoma in small companions (dogs and cats) and bone cyst in horses.

For more info, www.thera.vet/en/biocera-vet or www.covetrus.be

About TheraVet

TheraVet is a vet company created in November 2017 by Enrico Bastianelli, MD, MBA, and based in Jumet, Belgium. The Company specializes in the treatment of osteoarticular diseases in small companion animals, such as dogs, thanks to its portfolio of biological and synthetic products. TheraVet currently has two product lines: BIOCERA-VET, a line of injectable synthetic self-hardening high porosity calcium-phosphate bone substitutes and VISCO-VET, a versatile line of injectable hyaluronan-based visco-regenerative gel with anti-inflammatory and pro-regenerative properties.

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