

BIOCERA
The next generation bone substitute



BIOCERA-VET

BONE SURGERY

OSTEOSARCOMA



Back to the bone

THERA**Δ**VET



BIOCERA-VET

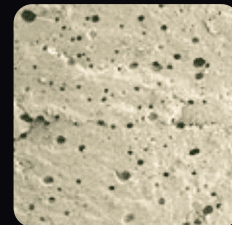
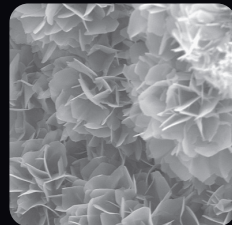
NATURAL COMPOSITION, HIGH POROSITY

BIOCERA-VET® is a synthetic injectable self-hardening calcium-phosphate bone substitute.

BIOCERA-VET is made from tricalcium phosphate (α -TCP) and ortho-phosphate salts that after crystallization give rise to calcium deficient apatite. This is chemically close to the components in natural bone. Therefore, BIOCERA-VET becomes well integrated in the mineral components of the bone matrix, resorbed by osteoclasts and

progressively replaced by newly formed bone. BIOCERA-VET has a full range of micro, meso and macropores that makes it over 50% porous. This supports osteoconduction, facilitates cell colonization and biological fluid penetration, which promotes bone remodeling and formation.

Calcium-deficient apatite crystals, chemically very close to the mineral component in bone⁽⁹⁾.



50% porosity promotes bone cell colonization and biological fluid penetration.

ORTHO-PHOSPHATE SALTS

BIOCERA-VET COMPOSITION

PHOSPHATE SOLUTION

TRICALCIUM PHOSPHATE

Back to the bone

UNIQUE OSTEOINTEGRATION AND BONE FORMATION

Thanks to its unique features, BIOCERA-VET shows excellent osteointegration, which enables the formation of bridges between the bone and the bone substitute.

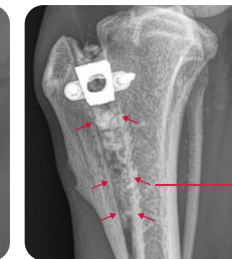
6 weeks after implantation BIOCERA-VET showed:

- bridges with host bone indicative of excellent osteointegration
- osteogenesis within, and around the periphery of the bone substitute thanks to its osteoconductive properties.

POSTOPERATIVE
X-RAY



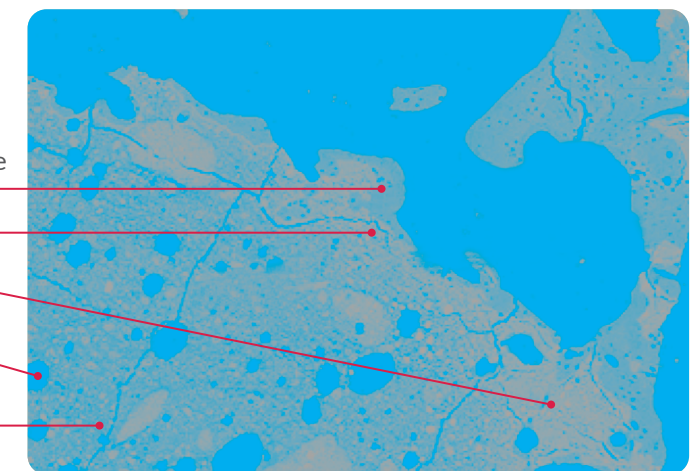
POSTOPERATIVE
X-RAY 6 WEEKS



Postoperative and 6 week follow up radiographs of a tibial tuberosity advancement (TTA) surgery. The tibial osteotomy was filled with BIOCERA-VET. Follow up image at 6 weeks indicates the osteointegration of the bone cement, represented by the smooth transition between the cancellous bone, the new bone formation and BIOCERA-VET. Image courtesy of Prof. Balligand DVM, PhD, Dipl. ECVS, Liège University, Belgium.

Osteointegration

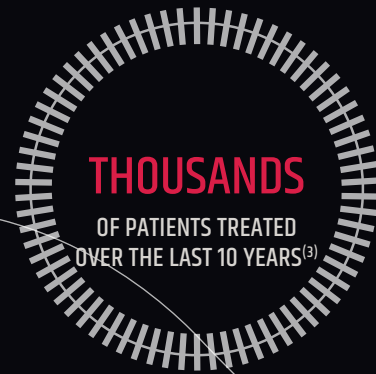
Newly formed bone
Host bone
BIOCERA-VET remaining bone substitute
Pores



Scanning electron micrography of a transverse section of calcium-deficient apatite crystals implanted in a rabbit femur, twelve weeks after implantation⁽¹⁾. Image adapted from Mellier et al. Acta Biomateriala 2017.



BIOCERA-VET



TESTED ON HUMANS, APPROVED FOR PETS

Orthopedic surgeons have been confidently using the human equivalent of BIOCERA-VET registered and marketed for over 10 years on more than 10,000 patients, ensuring a proven safety track-record⁽³⁾.

Use of BIOCERA-VET by specialist veterinary surgeons around the globe, in over 100 canine and feline patients, demonstrated an excellent safety profile with no adverse effects reported.



Back to the bone

THE HUMAN TREATMENT



BONE SURGERY

In human orthopaedic surgery, synthetic bone substitutes are used in the majority (50-60%) of procedures requiring grafts, whilst in veterinary orthopaedics, autografts remain the default for bone substitution^(5,6).

With BIOCERA-VET you now have the latest generation of bone substitute at your disposal, preventing unnecessary complications, without compromising on efficacy and making your surgery shorter and more enjoyable. Also in veterinary orthopedics, the patient deserves the highest standard of care!

NON-AUTOGRAFTS IN BONE SURGERY

HUMAN 50-60% vs VETERINARIAN 19%



OSTEOSARCOMA

In human oncology, cementoplasty is commonly used to consolidate bones affected by tumors or bone cysts. With this technique bone substitute is injected in the affected bone resulting in bone consolidation and pain relief^(7,8).

With the development of a specific osteosarcoma indication for the new generation bone substitute BIOCERA-VET, the technique is now available to veterinary surgeons providing a novel, minimally-invasive and cost-effective management option for dogs suffering with osteosarcoma.

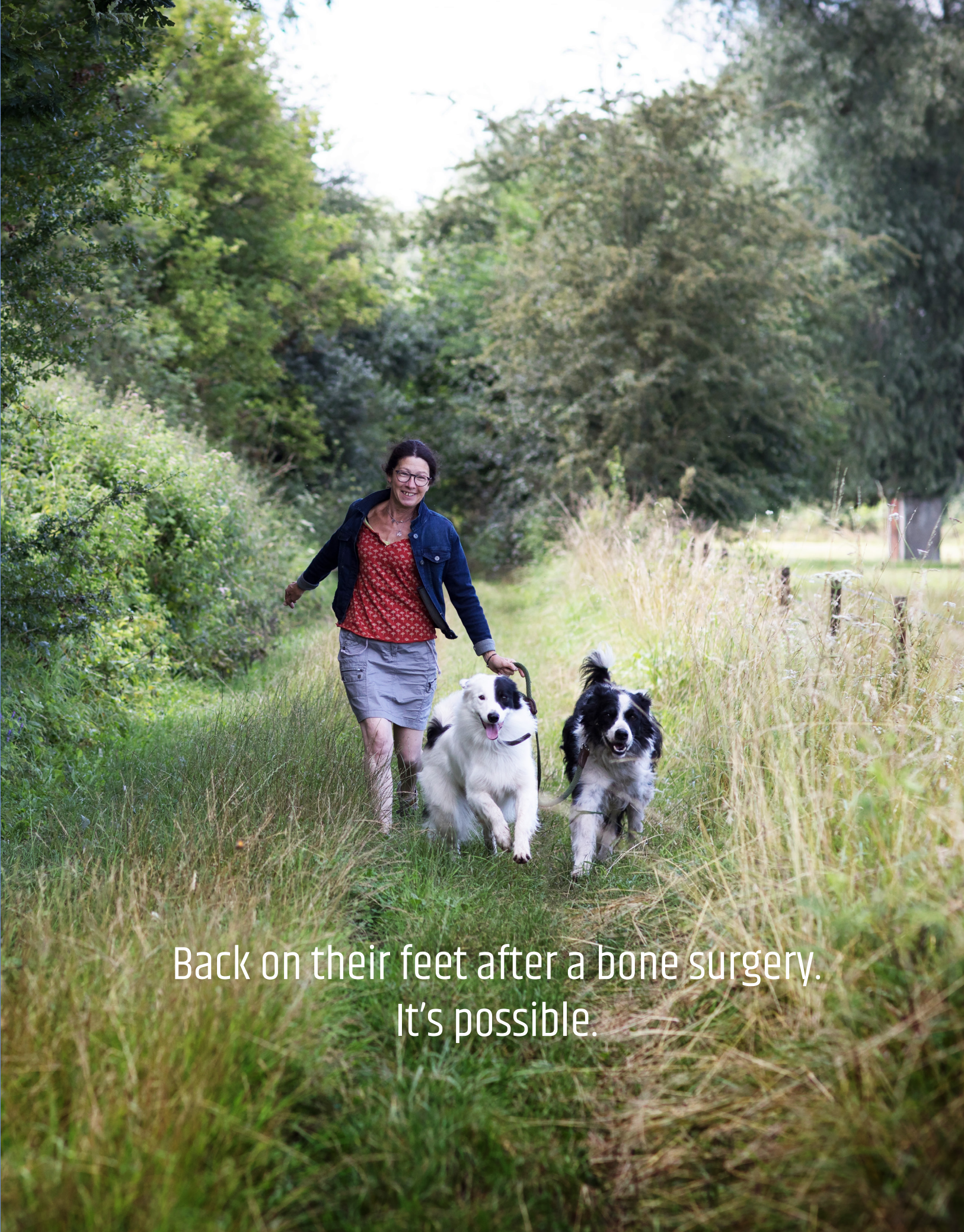


BIOCERA-VET FOR BONE SURGERY



“BIOCERA-VET promotes bone fusion thanks to its unique characteristics that combine interesting osteoconductive properties and outstanding osteointegration. Compared to autografts it has at least a comparable efficacy while reducing the risk of complications and significantly reducing surgery time. In addition to its efficacy and safety, its ergonomics and ease of use make it a promising alternative to autografts.”

G. Ragetly DVM, DipACVS, DipECVS
Surgery Specialist
CHV Frégis, France



Back on their feet after a bone surgery.
It's possible.



Back to the bone



BIOCERA-VET

AS-GOOD-AS AUTOGRAFTS

In a recent study⁽⁹⁾ the efficacy of BIOCERA-VET has been assessed for carpal and tarsal arthrodesis, and compared to similar cases treated with bone autograft.

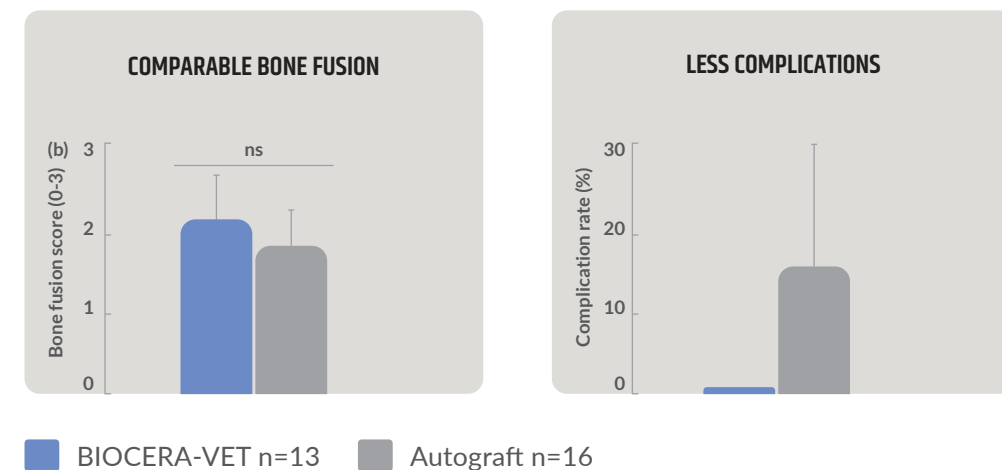
- independent and blinded radiological analysis by specialist veterinary orthopaedic surgeons
- BIOCERA-VET (n=13) vs. autologous bone graft (n=16); both groups followed the standard surgical procedure

Comparative analysis at 8 weeks post-implantation showed:

- bone fusion with BIOCERA-VET similar to that induced by autograft
- no complications with BIOCERA-VET compared to a 15-30% complication rate with autografts

BIOCERA-VET BONE SURGERY COMPARABLE EFFICACY IN BONE FUSION AND LESS COMPLICATIONS **VS AUTOGRAFTS**

ARTHRODESIS BIOCERA-VET VS AUTOGRAFTS - RADIOLOGICAL ANALYSIS^(a)

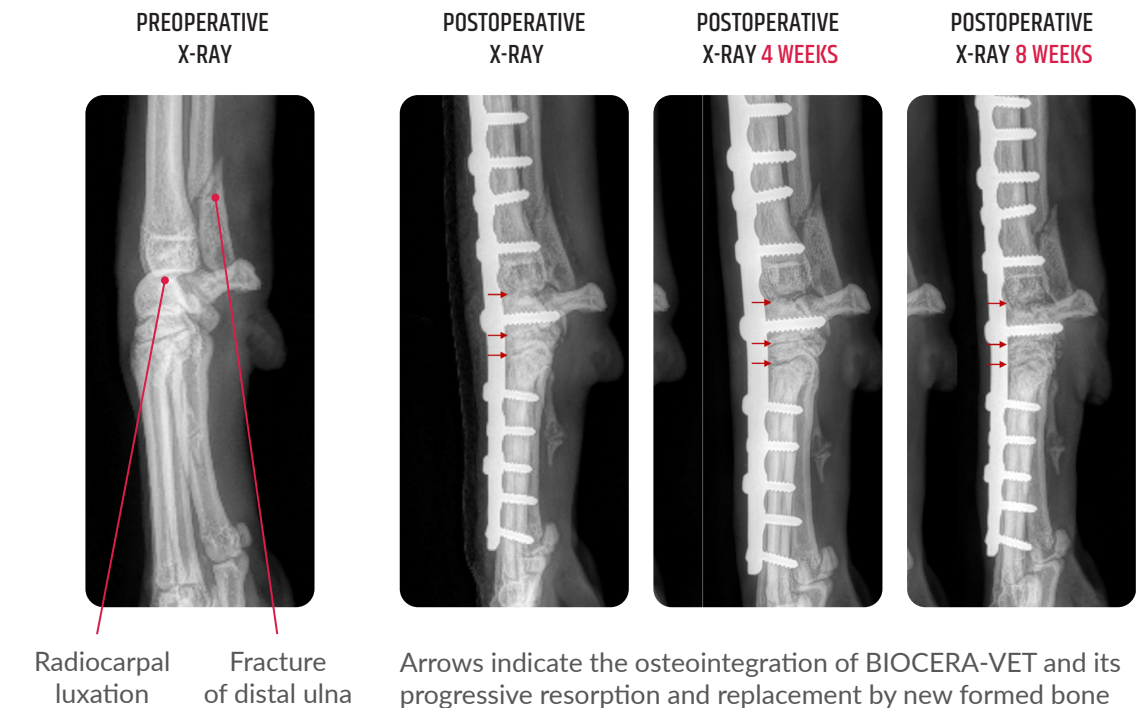


BIOCERA-VET - Comparative analysis report for arthrodesis. Apr 2021 Data-on-file. Collaborating veterinary surgeons Belgium: Dr Bouvy, Dr Flasse, Dr Van Ommen, Dr Stiévenart. France: Dr Ragetly. (a) Independent radiological analysis following bone fusion score, as described by Michael et al., 2003 Ree et al. 2016.



Back to the bone

ARTHRODESIS TREATED WITH BIOCERA-VET



Radiocarpal luxation and fracture of distal ulna, treated by pancarpal arthrodesis.

The arrows indicate the presence of BIOCERA-VET at the level of the radiocarpal, intercarpal and carpometacarpal joints. At the 4 week follow-up, one can observe a transition from the radiopaque bone substitute visible in the immediate postoperative image, towards a less radiopaque new bone formation. At 8 weeks, the consolidated joint has progressive remodelling and a reduced quantity of BIOCERA-VET as it is replaced by new bone.

Arthrodesis of the carpal joint using BIOCERA-VET in a 3-year-old Sighthound dog. May 2020. Images at the courtesy of G. Ragetly DVM, DipACVS, DipECVS - Surgery Specialist -CHV Frégis, France





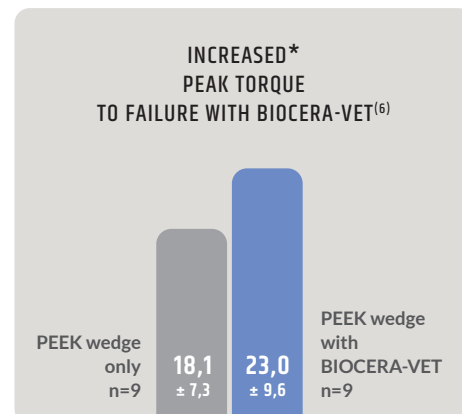
BIOCERA-VET

STRONGER

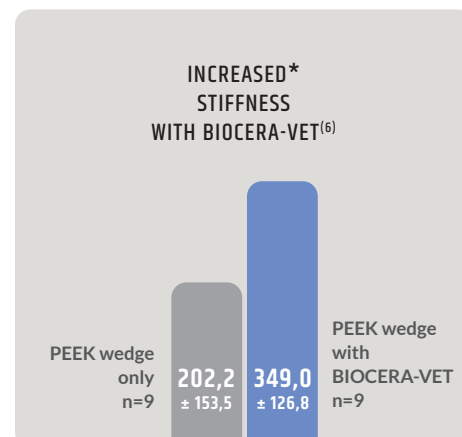
A critical factor for a successful bone grafting and defect repair is mechanical stability.

Studies⁽⁶⁾ performed with BIOCERA-VET on cadaver bone specimens in an opening wedge high tibial osteotomy (owHTO) showed a significant improvement in the mechanical properties with an increased torsional peak to failure and stiffness (compared to the cadaver bone without substitute)⁽⁶⁾.

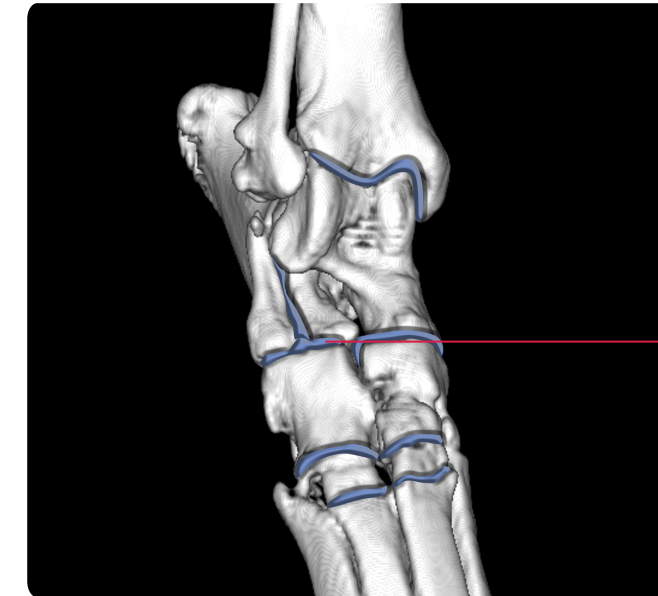
BIOCERA-VET is self-setting and fast-hardening (after 4-8 minutes), reaching its complete and isothermal hardening after 24 hours, thus contributing to the structural stability and improving biomechanics, whilst maintaining its porosity and bone remodeling properties.



Peak torque to failure (Nm +/- SD); *significant



FILLING-THE-GAP



CT-scan of canine tarsal arthrodesis representing the filling with BIOCERA-VET.

BIOCERA-VET becomes - once mixed - a malleable paste, making it possible to fill bone and articular gaps. In this way the bone substitute makes close contact with the adjacent bone, providing mechanical resistance and promoting new bone formation.



DVM B. Flasse,
Centre Vétérinaire Beumont, Belgium

"BIOCERA-VET is a wonderful product, very easy to prepare and faster in filling in compared to other products available on the veterinary market. Its integration at the bone gap level (including radiological appearance on postoperative and follow-up views is faster than a «classical» autologous autograft."



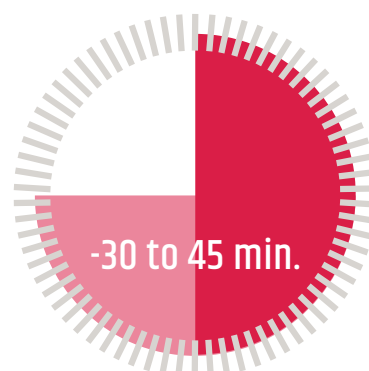
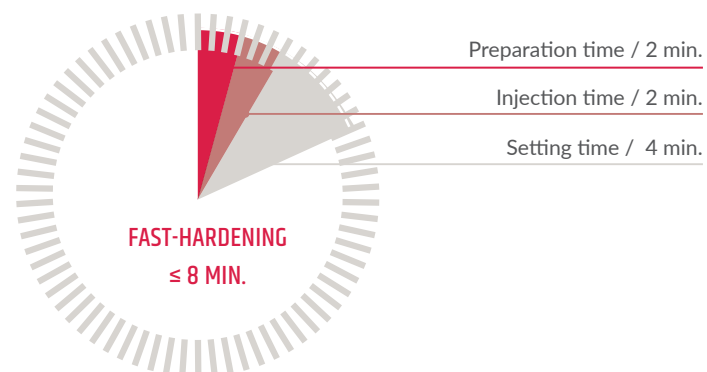
Back to the bone



BIOCERA-VET

EASIER

BIOCERA-VET is easy to prepare, meeting the needs of modern orthopedic surgery: simple, intuitive and fast-hardening (< 8 min.).



REDUCE SURGERY TIME BY 30 TO 45 MINUTES

Surgeries become easier and faster when harvesting of autogenous bone grafts is not needed. Better results are achieved when the bone defect is well and completely filled^(7,8).



Back to the bone

BIOCERA-VET, THE NEXT GENERATION BONE SUBSTITUTE

**UNIQUE
IN VETERINARY
ORTHOPEDICS**

- ▶ High clinical performance thanks to its unique composition
- ▶ Safe
- ▶ Less complications
- ▶ Easy to prepare
- ▶ Highly injectable
- ▶ Time-saving
- ▶ Avoids autograft harvesting
- ▶ Rapid setting time provides mechanical strength

INDICATIONS

- ▶ Canine and feline bone surgery



BONE SURGERY
3cc



- ▶ Arthrodesis
- ▶ Fractures
- ▶ Corrective osteotomy
- ▶ TTA (Tibial Tuberosity Advancement)
- ▶ All indications that require bone grafting

BIOCERA-VET Bone Surgery is
available through www.thera.vet



BIOCERA-VET FOR OSTEOSARCOMA



“With BIOCERA-VET, the technique of cementoplasty comes to the disposal of veterinary surgeons. Treatment of carefully selected patients suffering from osteosarcoma with BIOCERA-VET improves quality of life and significantly reduces lameness and pain through a minimally-invasive and cost-effective technique. It provides a new option in the palliative treatment of osteosarcoma as an alternative to amputation, which is highly appreciated by pet owners.”

DVM O. Gauthier
Professor of Veterinary Surgery,
College of Veterinary Medicine ONIRIS Nantes, France



Back to the bone



Live more comfortably with bone cancer.
It's possible.



BIOCERA-VET

THE NEW GENERATION FOR PALLIATIVE CARE OF DOGS WITH OSTEOSARCOMA

Osteosarcoma, a sad diagnosis for pet owner and vet.

Osteosarcoma is the most common bone cancer in dogs, with about 40,000 cases annually in Europe and the United States. It accounts for about 90% of all canine bone cancers. If left untreated, the average survival time of a dog with osteosarcoma is usually no more than 4-5 months.

In the case of appendicular osteosarcoma in dogs, amputation of the primary tumor remains the mainstay of treatment. However, amputation is not always feasible due to the weight of the dog, the presence of other osteoarticular or neurological diseases and/or owners' refusal. Other treatment options are potentially more invasive, expensive and not always effective.

Cementoplasty with BIOCERA-VET provides a palliative treatment, improving the quality of life for the animal suffering from osteosarcoma. Minimally invasive, percutaneous injection of BIOCERA-VET into bone that has been weakened by tumour, reduces the risk of pathologic fracture, relieves pain and improves patient comfort and quality of life.

BIOCERA-VET offers the veterinarian:

- low-trauma, minimally invasive procedure
- short procedural time
- rapid post-operative recovery
- reduced analgesic treatment post-op
- limited costs (compared to amputation)

Navy, a 3-year-old, male, Newfoundland. Treatment by cementoplasty using BIOCERA-VET led to a significant reduction in pain and lameness for 8 months postoperatively.



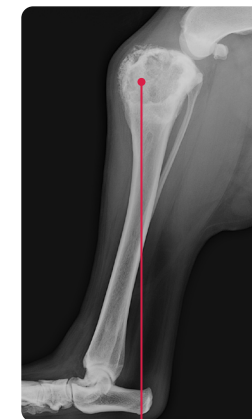
Back to the bone



DVM O. Gauthier
Professor Veterinary Surgery at College of Veterinary Medicine
ONIRIS Nantes, France

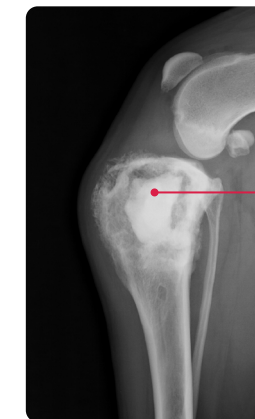
"The cementoplasty procedure with BIOCERA-VET is an interesting alternative to amputation because it allows, through a low-traumatic surgical procedure, an improvement in the animal's welfare, an improvement in lameness and significant pain relief"

PREOPERATIVE X-RAY



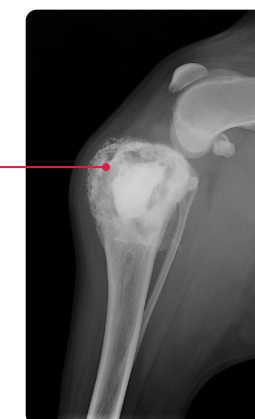
Osteosarcoma
right tibia

POSTOPERATIVE X-RAY



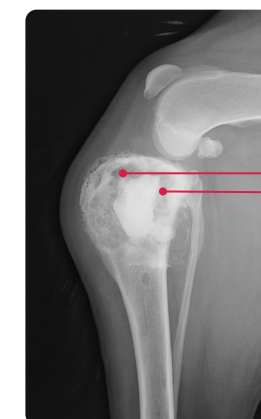
Cementoplasty
with BIOCERA-VET
(radio-opaque)

POSTOPERATIVE X-RAY
3 MONTHS



New bone
formation

POSTOPERATIVE X-RAY
6 MONTHS



Bone remodeling
around the cement.
No pathological
fracture.

Images courtesy of Prof Olivier Gauthier,
Université de Nantes, France (Oniris)



BIOCERA-VET

BIOCERA-VET osteosarcoma is perfectly suited to cementoplasty providing:

- complete hardening and maximum mechanical strength within 24 hours of injection
- ease of use because of its rapid preparation and ease of injection
- monitoring of percutaneous injection by fluoroscopy and assessment of postoperative radiographs due to its inherent radiopacity

Patient eligibility criteria for the use of BIOCERA-VET osteosarcoma:

- tumor preferably located in an appendicular bone
- well-circumscribed tumor with preserved surrounding cortical bone
- preferably early stage tumors with no lung nor bone metastasis

Practical use of BIOCERA-VET osteosarcoma:

- minimally invasive procedure
- limited post-operative care
- reduced analgesic treatment after cementoplasty

(1) Adapted from Mellier et al. Acta Biomaterialia 2017 - (2) Close-up X-ray of iatrogenic incision of a canine tibia filled with BIOCERA-VET 6 weeks post-implantation. Image courtesy of Prof. Balligand DVM, PhD, Diplo. ECVS, University Liège, Belgium. (3) Graftys and its partner las Brasil cross the milestone of 10,000 Graftys® HBS units sold in Brazil® - (4) Data on file Belgium/France 2019-2021, >100 cases of use of BIOCERA-VET in cats & dogs gathered from prospective multicentric non-controlled clinical trails and compassionate use. - (5) Medistrat Market Research Orthopedic surgeons n=20 BE - (6) <https://www.fortunebusinessinsights.com/bone-graft-substitutes-market-103106> & Bone Grafts and Substitutes 2011-2020 Global Data - (7) Katsanos, T. Sabharwal, and A. Adam, "Percutaneous cementoplasty," Semin. Intervent. Radiol., vol. 27, no. 2, pp. 137-147, 2010 - (8) Thesis Lena BLANCHOT "Traitement palliatif de l'osteosarcome appendiculaire par cimentoplastie chez les chiens de grande race et de race géante : étude clinique et fonctionnelle" to obtain diploma of Docteur Vétérinaire at the Ecole nationale vétérinaire, agroalimentaire et l'alimentation Oniris Nantes, 2020 - (9) BIOCERA-VET - Comparative analysis report for arthrodesis indication. Apr 2021 Data-on-file. Collaborating veterinary surgeons Belgium : Dr Bouvy, Dr Flasse, Dr Van Ommen, Dr Stiévenart. France : Dr Ragetly. - (10) case Ragetly AR - (11) Adapted from Scordino et al. 2015 Calcium phosphate cement enhances the torsional strength and stiffness of high tibial osteotomies. Knee Surg Sports Traumatol Arthrosc. European Society of Sports Traumatology, Knee Surgery, Arthroscopy (ESSKA) - (7) St John TA, Vaccaro AR, Sah AP, Schaefer M, Berta SC, Albert TA, Hilibrand A. Physical and monetary costs associated with autogenous bone graft harvesting. Am J Orthop. Jan 32(1):18-23, 2003 - (8) DeVries WJ, Runyon CL, Martinez SA, Ireland WP. Effect of volume variations on osteogenic capabilities of autogenous cancellous bone graft in dogs. Am J Vet Res. Oct 57(10):1501-1505, 1996 (9) Sergey V. Dorozhkin, "Self-Setting Calcium Orthophosphate Formulations: Cements, Concretes, Pastes and Putties", International Journal of Materials and Chemistry, Vol. 1 No. 1, 2011, pp. 1-48. doi: 10.5923/j.ijmc.20110101.01.



Back to the bone

BIOCERA-VET OSTEOSARCOMA, THE NEW GENERATION OF PALLIATIVE CARE FOR OSTEOSARCOMA

NEW
IN OSTEOSARCOMA
MANAGEMENT

- ▶ Reducing risk of pathologic fracture & relieving pain
- ▶ Low trauma, minimally-invasive
- ▶ Rapid recovery
- ▶ Cost-effective

INDICATIONS

- ▶ Cementoplasty for palliative treatment of canine and feline osteosarcoma



OSTEOSARCOMA
2 X 8CC

BIOCERA-VET OSTEOSARCOMA KIT

- ▶ 2 pre-loaded 8 cc syringes
- ▶ Disposable gun
- ▶ 2 luer-lock disposable canulas



BIOCERA-VET osteosarcoma is
available through www.thera.vet

THERA△VET

TheraVet® is a vet company headquartered in Belgium. Its mission is to develop innovative, safe and effective treatments to improve the well-being and quality of life of companion animals suffering from osteoarticular diseases. By developing unique solutions, our commitment is to improve the level of care allowing companion animals to live healthier. In order to fully meet the needs of veterinarians, TheraVet's goal is to provide local – safe & effective treatments with a superior functional design. TheraVet is listed on Euronext Growth® Brussels and Paris.

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