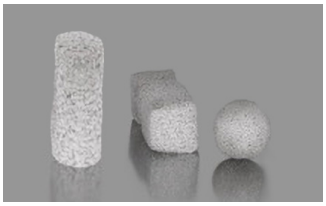
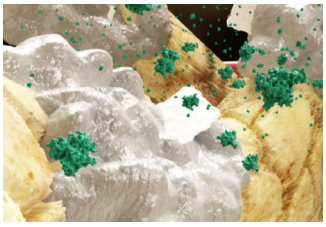
NanoBone Patient Information



NanoBone is a bone graft substitute that harnesses the body's own capacity to heal bone without the complications and post-surgical pain of harvesting your own bone graft



NanoBone attracts the body's own proteins that are critical for new bone formation

NanoBone is used as a bone graft substitute in major orthopaedic surgeries

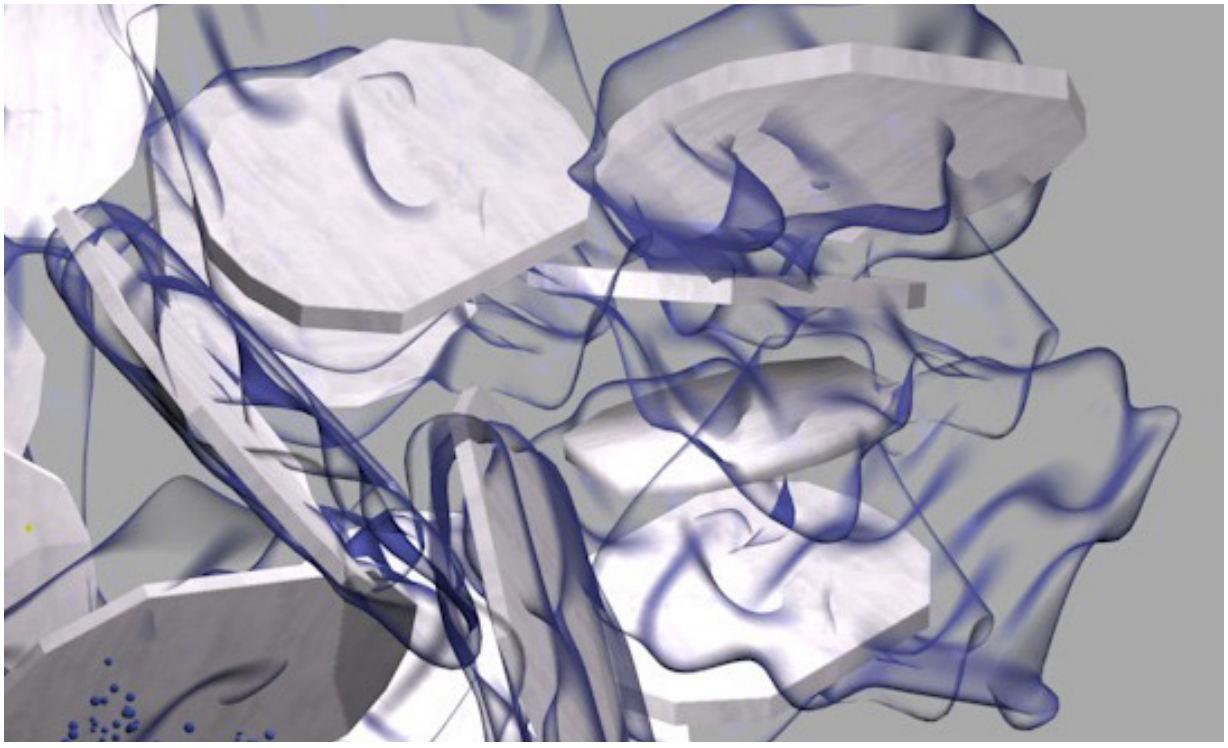


Fig. 1. NanoBone consist of nanocrystals of hydroxyapatite, the same mineral as your bones (white) and an amorphous silica matrix (blue).

NanoBone Patient Education Monograph

Frequently Asked Questions:

What is NanoBone?

NanoBone is a bone graft substitute for use in orthopaedic surgeries in place of a patient's own bone (autograft) harvested in a separate procedure. NanoBone consists of two parts:
NanoBone consists of 1.) nanocrystals of hydroxyapatite (HA) dispersed in 2.) amorphous silica gel matrix (ASG). HA is the mineral found in the human body that makes up bone and helps bone growth and healing. ASG attracts proteins which facilitates the bone healing process. NanoBone harnesses the body's own capacity to heal bone, heals as well as autograft with lower risks and less pain, and is a standalone product to facilitate bone growth in many orthopaedic procedures.

Where does bone graft come from for orthopaedic procedures?

Autograft comes from the patient's own body, typically involving surgical harvesting of bone graft from the iliac crest. Allograft bone graft is bone obtained from cadavers and is treated with different techniques of sterilization for surgical use. Additionally, it has different storage techniques, such as fresh frozen or freeze-dried. There are other bone graft substitutes that are synthetic and do not come from a patient's own body or a cadaver. Of these, NanoBone is the most able to heal like human bone heals itself.

Is NanoBone safe?

The U.S. FDA has determined that NanoBone may be a safe and effective alternative to autogenous iliac crest bone graft (autograft). NanoBone facilitates bone growth and fusion at a rate equivalent to or greater than traditional bone grafts, such as the patient's own autograft bone.

How does NanoBone work?

NanoBone consists of nanocrystals of hydroxyapatite (HA) in an amorphous silica gel matrix (ASG). The HA nanocrystals have similar size, shape, and chemistry to the HA in human bone. Following implantation, the ASG is rapidly replaced by the body's own organic matrix. Once the organic matrix is in place, the process of cell-mediated bone formation occurs, with clinical and radiological healing taking place within 8 weeks.

Are there any limitations or restrictions after surgery?

There are typically restrictions for the first 6-8 weeks after surgery regarding avoiding certain movements, lifting, pushing or pulling objects greater than 5 lbs. Usually activity restrictions are gradually removed as the healing process takes place. Although NanoBone demonstrates clinical and radiological healing within 8 weeks, it is recommended that you consult with your physician to determine when it is appropriate to return to normal daily activities.

Does bone grow back after procedure using bone graft substitute?

Bone grafts, whether autograft (from your own body), cadaveric donor, or synthetic may fill an area where bone has been removed or to help provide structural stability. Typically a bone graft material is used to fill a void or stabilize an implant. The bone used in a bone graft can come from your body or a donor, or it can be entirely synthetic. It can provide a framework where new, living bone can grow if it's accepted by the body. Bone grafts differ in their healing rate, with NanoBone providing rapid bone formation and healing with clinical and radiographic healing within 8 weeks.

NanoBone Cases

Here are clinical case examples of where NanoBone has been used successfully

Spine Case:

Pain from slipped lumbar vertebrae treated with posterior fusion and application of NanoBone

J. Cummings, MD

Pre-surgery:
- Patient is a 70-year-old male with low back pain and unable to walk more than 50 feet.
- X-rays showed L5-S1 slipped vertebrae and disc bulge pressing on the left L5 nerve root.

Surgery:
- Pedicle screws were placed at L5 and S1 using live X-ray.
- 5 ml of NanoBone was placed with bone chips on both sides.

Post-surgery:
- At 4-months after surgery, X-rays confirmed the fusion well-healed, with patient back to normal activities, no pain medication, with pain score 0/10.

Talk to your doctor about whether NanoBone is right for you

Fig. 2.a. Pre-surgery lateral X-ray

Fig. 2.b. Post-surgery lateral X-ray

Fracture Case:

Application of NanoBone in an open tibial fracture

G. Ortega, MD

Pre-surgery:
- 20-year-old male athlete presented with sports-related injury, an open right tibial fracture with bony defect.

Surgery:
- Patient underwent fixation of his tibia with an implant and the bony defect was not initially filled.
- At 8-weeks, he underwent bone defect filling in a second surgery of his right tibia in an outpatient setting with 10 ml of NanoBone.

Post-surgery:
- Patient continued weight-bearing as tolerated, at 3-months post-grafting with NanoBone, he was clinically and radiographically healed.

Discussion:
- Our patient returned to competitive sports after he healed and was satisfied with his outcome.

Talk to your doctor about whether NanoBone is right for you

Fig. 3.a. Pre-surgery lateral X-ray

Fig. 3.b. Post-surgery lateral X-ray 3-months healed with NanoBone

Oncology Case:

Benign tumor of the proximal tibia treated with internal fixation and NanoBone

J. Cummings, MD

Pre-surgery:
- 30-year-old female with right knee pain with X-rays revealing benign tumor; recommended hardware and bone grafting treatment due to impending fracture.
- Biopsy was performed confirming diagnosis of giant cell tumor.

Surgery:
- Live X-ray used to identify extent of the tumor, remove tumor, cavity was treated with laser, and void filled completely with 90 ml of NanoBone.
- Live X-rays confirmed complete filling of the void.

Post-surgery:
- At 3-months after surgery, patient continues to improve, NanoBone shows progressive healing, and there is no evidence of tumor recurrence.

Talk to your doctor about whether NanoBone is right for you

Fig. 4.a. Pre-surgery X-ray

Fig. 4.b. Post-surgery X-ray 3-months

Resources

1. Bone and Joint Burden - The Burden of Musculoskeletal Disease in the US
https://www.boneandjointburden.org/fourth-edition/ib0/prevalence-select-medical-conditions

2. American Academy of Orthopaedic Surgeons (AAOS) OrthoInfo
https://orthoinfo.aaos.org

3. Understand Spine Surgery Patient Education
https://www.understandspinesurgery.com

4. Osteoporosis Fast Facts from National Osteoporosis Foundation
https://cdn.nof.org/wp-content/uploads/2015/12/Osteoporosis-Fast-Facts.pdf

5. About Fractures by MediNiche
https://www.mediniche.com/fracture.html

6. Trends in Fracture Incidence: A Population-Based Study Over 20 Years
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3929546/

7. Bone and Joint Burden – Fracture Trends
https://www.boneandjointburden.org/2014-report/via23/fracture-trends

8. Key Statistics About Bone Cancer – American Cancer Society
https://www.cancer.org/cancer/bone-cancer/about/key-statistics.html

9. American Academy of Orthopaedic Surgeons (AAOS) Musculoskeletal Oncology Education Resources
https://www.aaos.org/education/specialty-resources/musculoskeletal-oncology/

10. American Academy of Orthopaedic Surgeons (AAOS) OrthoInfo – Bone Tumor
https://orthoinfo.aaos.org/en/diseases--conditions/bone-tumor/

11. Foot Health Facts – American College of Foot & Ankle Surgeons (ACFAS)
https://www.foothealthfacts.org/foot-ankle-conditions/browse-foot-ankle-conditions

12. Foot Care MD - American Orthopaedic Foot & Ankle Society (AOFAS)
https://www.footcaremd.org

Please consult your doctor for more information regarding your condition and potential procedures and factors that may impact surgical results. U.S. Federal Law restricts NanoBone to sale by or on the order of a physician or hospital.

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