

# Clinical Evidence

With over 50 technical publications and 32 clinical publications in peer reviewed journals, NB Putty has consistently proven to regenerate bone in various osseous defects including ridge augmentations, sinuses, sockets, periodontal defects, etc. Most studies suggest approx. 80%-90% graft absorption in 4-6 months, while regenerating bone at the same time.

NB Putty with its unique cartridge delivery system has redefined sinus augmentation surgeries facilitating minimally invasive surgical approaches and improvisations. NB Putty with its handling characteristics acts as an excellent carrier for guided bone regeneration surgeries in combination with NovaBone Morsels or Allograft bone (1:1).



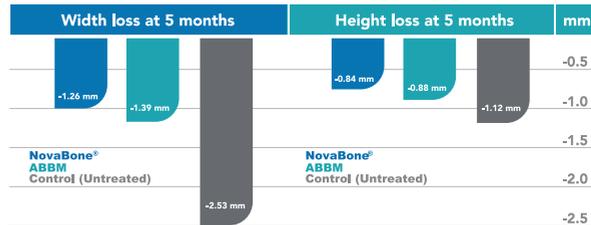
## Comparison with Bovine Bone

2015 JOI article by Lanka et al., evaluated both NB Putty & Bovine xenograft histomorphometrically. They concluded that ridge preservation using a putty calcium phosphosilicate alloplastic bone substitute results in more timely graft substitution and increased bone regeneration when compared to an anorganic bovine bone xenograft.

In a 2014 JOMI article, Kotsakis et al., published data from a blinded randomized controlled trial comparing dimensional changes at 5 months following socket preservation using NovaBone Dental Putty (PUT) or anorganic bovine bone mineral (ABBM), both groups showed a statistically significant reduction in ridge width loss. NovaBone® treated sites showed comparable results to sites treated with ABBM in both width and height changes. The maximum implant insertion torque (MIT) was measured as an index of primary implant stability.

MIT for PUT was <35 N/cm<sup>2</sup> (MIT grade 4) for seven of the nine implants.

MIT values in the ABBM group ranged from grade 1 (10 to 19 N/cm<sup>2</sup>) to grade 4, which was statistically significantly lower than the PUT group. The overall implant success rate was 94.1% (16 of 17 implants were successful). They concluded that Putty was good to preserve ridge dimensions and had favorable bone density values for implant placement.



## Histomorphometry

In four separate studies, histomorphometric evaluation of cores taken from extraction sockets grafted with NovaBone Dental Putty showed vital bone regeneration and significant graft resorption.<sup>1,2,3,4</sup>

Year	Author	Number of Sites	Average Re-Entry Time	Mean Vital Bone Content	Mean Residual Graft
2015	Lanka et al. <sup>1</sup>	N=10	4.9 months	47.15%	17.4%
2014	Kotsakis et al. <sup>2</sup>	N=17	5.7 months	31.76%	11.47%
2012	Lanka et al. <sup>3</sup>	N=20	4.9 months	49.57%	4.3%
2011	Gonshor et al. <sup>4</sup>	N=22	5.4 months	48.2%	2.4%

1. Lanka M, et al. Alveolar ridge preservation with the socket-plug technique utilizing an alloplastic putty bone substitute or a particulate xenograft: a histological pilot study. J Oral Implantol 2015 Apr; 41(2):178-83  
 2. Kotsakis GA, et al. Histomorphometric evaluation of a calcium-phosphosilicate putty bone substitute in extraction sockets. Int J Periodontics Restorative Dent. 2014 Mar-Apr; 34(2):233-9  
 3. Lanka M, et al. Socket grafting with calcium phosphosilicate alloplast putty: a histomorphometric evaluation. Compend Contin Educ Dent. 2012 Sep;33(8):e109-15.  
 4. Gonshor A, et al. Histologic and Clinical Evaluation of a Bioactive Calcium Phosphosilicate Bone Graft Material in Postextraction Alveolar Sockets. Int J Oral Imp and Clin Res. 2011;2(2): 79-84.



# NovaBone Dental Putty

The next generation Calcium-Phosphosilicate bone substitute engineered for enhanced handling and improved performance

# Product Characteristics

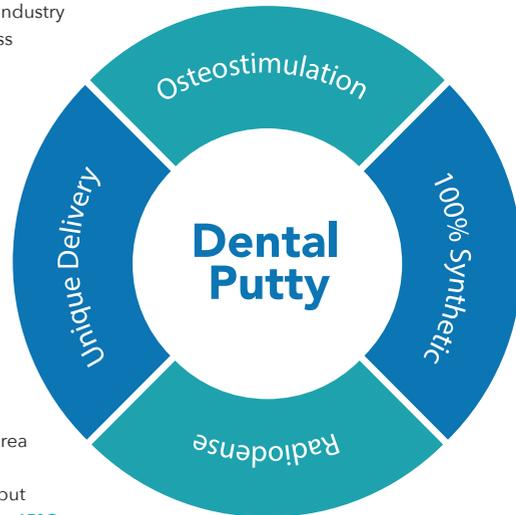
NovaBone Dental Putty was introduced after extensive market research which suggested that clinicians did not expect great strides in the rate of bone formation but rather in delivery, handling and performance of bone graft substitutes without a significant cost increase.

NB Putty has bimodal particle distribution of Calcium Phosphosilicate (CPS) (active ingredient), with Polyethylene Glycol (PEG) as an additive and Glycerin as the Binder. The volume of the active ingredient is approximately 70%. The Putty format allows easier manipulation due to its format and eliminates the need for any preparation prior to placement. NB Putty offers clinicians various delivery systems (Shells, Cartridges & Syringes) in various sizes with benefits of consistent, reliable bone regeneration. Putty received its FDA & CE approval for dental indications in 2006-07.

NB Putty is available in unique uni-dose cartridges - an industry first; ideal for minimally invasive surgeries, hard to access defects, immediate implant surgeries, osteotome sinus surgeries, etc. Each cartridge holds 0.25-0.5cc of putty.

Putty does not set like a cement. CPS has a transient hemostatic effect providing a comfortable environment for the clinician to work with. It encourages clot stabilization and promotes healing. Putty has good retention and can adapt to the defect shape.

Putty is **radio-dense** and can be visualized on radiographs. Upon implantation, it appears as a mass at the defect site which can be differentiated from surrounding bone by the lack of trabecular pattern. Over time, with bone remodeling, the grafted area appears analogous to the natural bone in the region. Putty has a **4 year shelf life** does not need refrigeration but caution should be exercised at temperatures higher than **45°C**.



## Superior Delivery System

NovaBone Dental Putty is available in multiple delivery options: trays, pre-filled syringes and a unique cartridge delivery system. The diameter of the cannula is 2.8mm which is ideal for dispensing of the graft, especially in minimally invasive techniques such as gaps in immediate implant and crestal approach sinus lifts. Cartridges are available in various sizes and are used in conjunction with cartridge dispenser.

# Smart Science™ - Osteostimulation

Unlike other synthetic grafts that are bioinert, NB Putty belongs to the class of bioactive regenerative materials that not only acts as an osteoconductive scaffold but also interacts with the surrounding tissues and imparts an osteostimulatory effect. NB Putty is not osteoinductive but a number of in vivo studies have demonstrated an accelerated bone formation with CPS particles. Also, the viability and proliferation potential of osteoblasts has been shown to be accelerated in the presence of CPS particles. Studies also demonstrate increased osteocalcin and alkaline phosphatase levels in the presence of CPS particles providing a favorable environment for bone formation.

Osteostimulation is an active process. NovaBone Dental Putty acts as a bone matrix and encourages differentiation of new bone cells at the site. This phenomenon results in faster bone regeneration than exhibited by osteoconduction alone while simultaneously increasing the resorption rate of the graft material.

## Biologic Interpretation

- Immediately upon implantation, silicon and calcium ion release initiates a cascade of events that signals and recruits undifferentiated cells to the site
- Several genes are regulated, resulting in proliferation and differentiation of undifferentiated cells into osteoblasts
- The osteoblasts mature into osteocytes (mature bone cells) at the terminal stage
- This process continues resulting in bone regeneration at a much faster pace than osteoconduction

## Clinical Interpretation

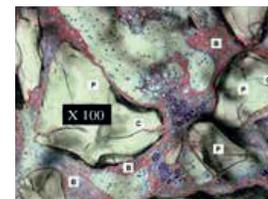
- Upon implantation, the binder gets absorbed within 24-72 hrs, creating a 3-dimensional porous scaffold that facilitates active movement of blood and tissue fluids through the matrix
- Smaller CPS particles interact with blood providing the initial burst of calcium and phosphate ions
- This provides a favorable area for bone regeneration as it creates numerous calcium phosphate nodules that mature individually to form bone throughout the defect
- Subsequently, the larger particles react and continue the process of bone regeneration

## Histologic Interpretation

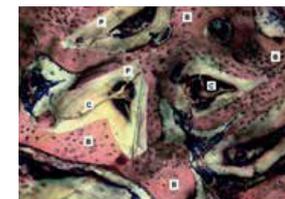
Rabbit Histology at 3 and 6 weeks helps visualize the osteostimulation phenomenon. At 3 weeks, cracks developing through individual particles can be noticed with bone growing through them. Pink areas of bone formation are also seen around the putty particles along with areas of cartilaginous cells & giant cells (purple).

At 6 weeks, abundant bone around each particle can be seen (pink areas). The cracks have progressed completely into the center of each particle, and an area of bone regeneration (pink) is seen within each individual particle. This is very unique to CPS products and results in the creation of multiple foci of bone regeneration resulting in enhanced bone regeneration and consequently faster material absorption!

3 Weeks



6 Weeks



B-Bone, P-Graft Particle, C - Cracks