

BoneSync™ BioActive Bone Void Filler (BVF) In Vitro Bioactivity Test

Abstract

An in vitro bioactivity test was performed to evaluate the apatite-forming ability of predicate device Vitoss® BA versus BoneSync™ BioActive bone void filler.

Objective

Evaluate the ability of BoneSync BioActive filler to induce calcium phosphate layer formation using simulated body fluid (SBF), as compared to Vitoss BA.

Material Methods

BoneSync BioActive filler and Vitoss BA were incubated in SBF for 5 days. Samples were then analyzed to determine the changes in chemical composition and surface morphology by field emission scanning electron microscopy (FESEM) and energy dispersive spectroscopy (EDS).

Results

The bioactivity of BoneSync BioActive filler was demonstrated from the widespread induction of calcium and phosphate growth on the surface of the implant, as shown in **Figure 1**. EDS analysis confirmed the increase in calcium and phosphate content after 5 days of incubation in SBF.

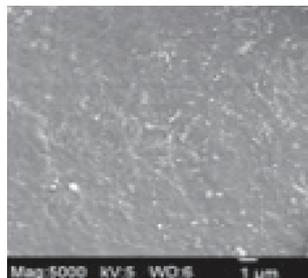
In addition, results from the in vitro bioactivity test demonstrate that BoneSync BioActive filler induces nearly 2.5× more calcium phosphate deposition than Vitoss BA.^{1,2} The bioactivity testing was performed per ISO 23317 for apatite-forming ability of implant materials, as shown in **Figure 2**.

Vitoss is a registered trademark of Stryker.

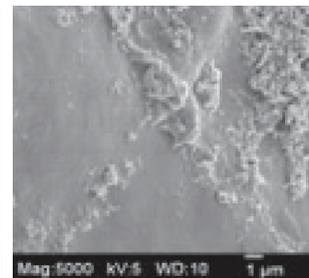
Figure 1. FESEM Images of BoneSync BioActive Cement vs Vitoss BA Incubated in SBF from 0 to 120 hours.

BoneSync BioActive Cement

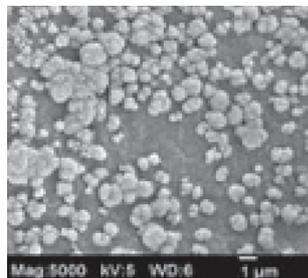
Time: 0 hours



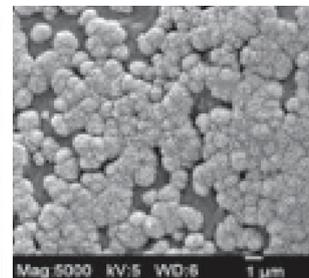
Time: 12 hours



Time: 24 hours

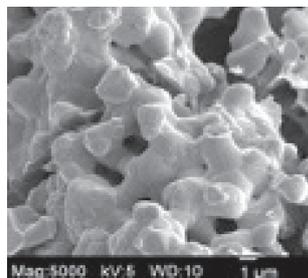


Time: 120 hours



Vitoss BA

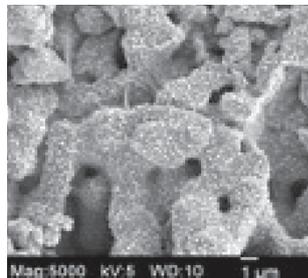
Time: 0 hours



Time: 12 hours



Time: 24 hours



Time: 120 hours

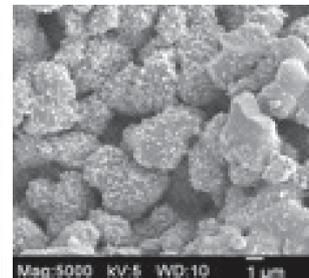
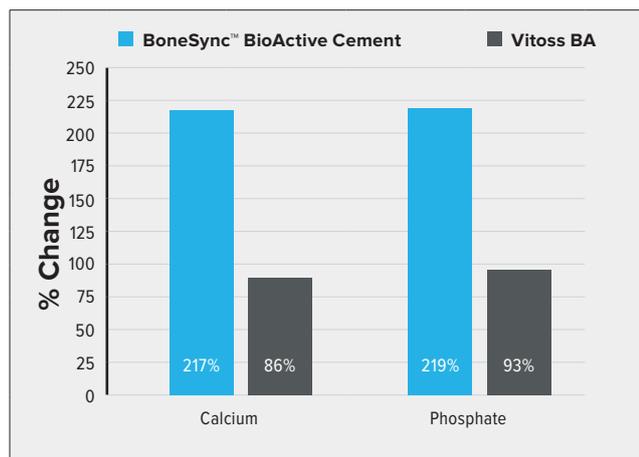


Figure 2. Calcium and Phosphate Percent Changes From 0 to 120 Hours^{1,2}



In vitro preclinical evaluation is not necessarily indicative of human clinical outcomes.

Conclusion

FESEM images reveal apatite layer formation on both BoneSync BioActive filler and Vitoss BA after soaking in SBF for 5 days. EDS analysis confirms the increase in calcium and phosphate content for BoneSync BioActive filler.

References

1. Collagen Matrix, Inc. Data on file. Oakland, NJ.
2. International Organization for Standardization. ISO 23317:2014: Implants for surgery—In vitro evaluation for apatite-forming ability of implant materials. Published June 2014. Updated 2020. Accessed September 7, 2022. <https://www.iso.org/standard/65054.html>