

PliaFX[®] Prime

Scientific Summary: Advantage of 100% Bone



First-generation DBM putties contain a carrier, such as glycerol or reverse phase medium (RPM), solely to improve handling characteristics of the graft. The proportion of bone content in first-generation DBM putties can be as low as 17% by weight.¹ PliaFX Prime is 100% bone; the graft's advanced fiber technology provides optimized handling without the need for a carrier. In a weight-to-weight comparison, PliaFX Prime consistently demonstrated better *in vitro* performance than a first-generation DBM with a carrier.

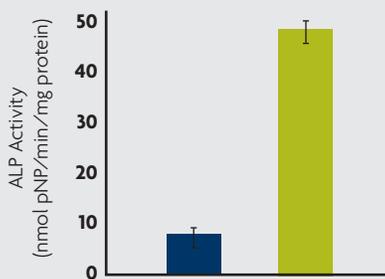
PliaFX Prime Has Greater Osteoinductive Potential than DBM with a Carrier

Osteoinductive potential is the ability to induce new bone growth. PliaFX Prime is comprised of 100% bone that has been demineralized, ensuring there is no dilution of osteoinductive potential.

6.8x

Higher expression of ALP activity

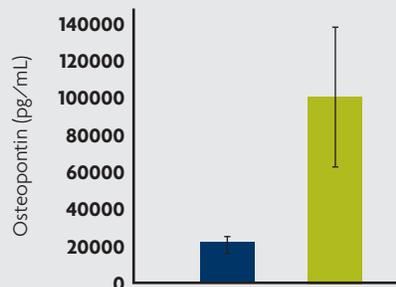
A marker of the early stages of new bone formation commonly used as one measure for osteoinductive potential.²



4.9x

More osteopontin

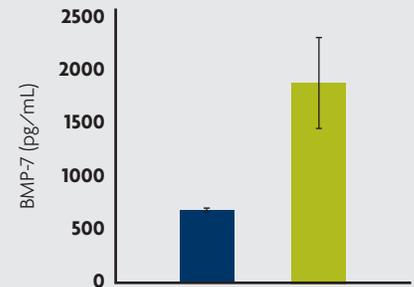
Involved in the mineralization of bone and essential to the bone remodeling process.^{4,5}



2.7x

More BMP-7

A growth factor naturally occurring in bone that provides signals for bone remodeling.³



■ Demineralized Fibers with Glycerol Carrier ■ PliaFX Prime Demineralized Fibers 100% Bone

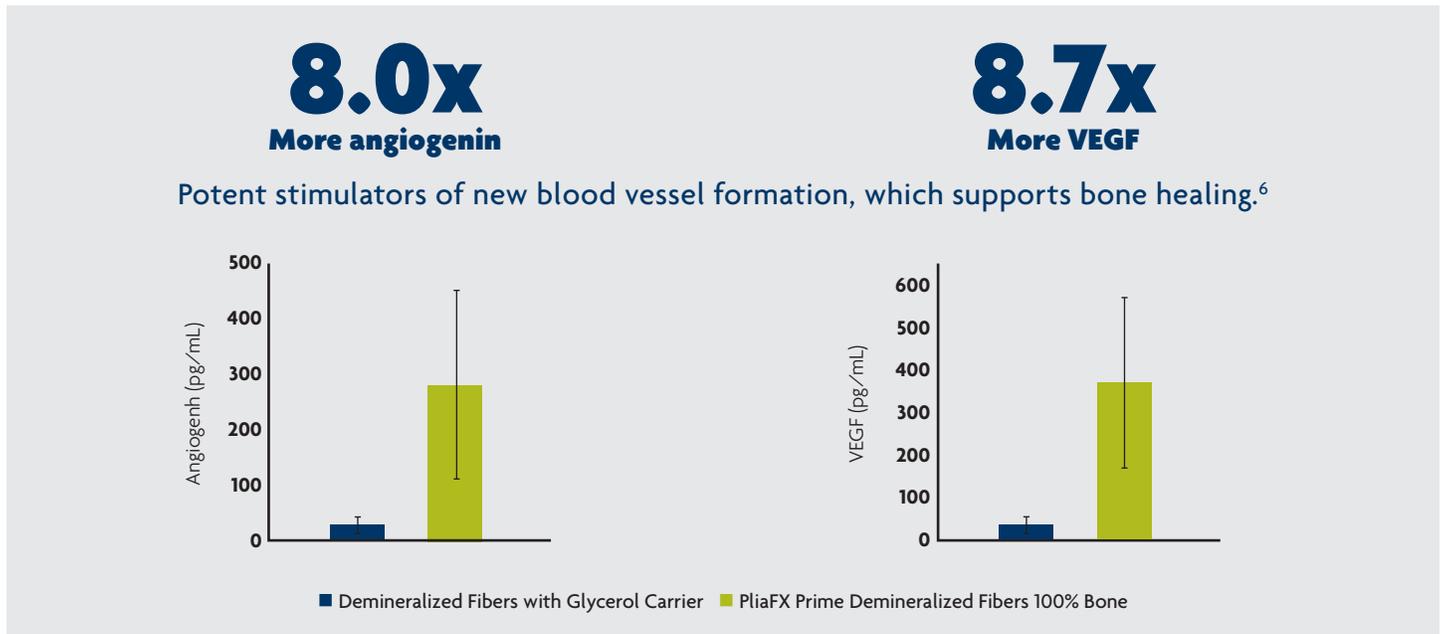
ALP activity. *In vitro*, PliaFX Prime stimulated the release of more alkaline phosphatase compared to demineralized fibers with a glycerol carrier. Three equal-weight samples of each graft were measured (six replicates of each sample) four days after the cells were incubated with DBM. On average, PliaFX Prime exhibited 6.8x more ALP activity than DBM with a carrier.

Osteopontin Content. Protein samples were prepared from three donors for each graft based on weight, and the resulting solutions were analyzed using MAGPIX[®] Protein Multiplexing system. On average, PliaFX Prime contained 4.9x more osteopontin than DBM with a carrier.

BMP-7 Content. Samples from three donors for each graft based on weight were digested with collagenase enzymatic solution, and the resulting solutions were analyzed using a Quantikine enzyme-linked immunosorbent assay (ELISA) from R&D Systems, Minneapolis MN. On average, PliaFX Prime contained 2.7x more BMP-7 than DBM with a carrier.

PliaFX Prime has Greater Angiogenic Potential than DBM with a Carrier

Angiogenesis is the growth of blood vessels from the existing vasculature. Blood vessel formation supports bone healing by bringing oxygen, nutrients, and bone precursor cells to the injury site.⁶ PliaFX Prime is comprised of 100% bone that has been demineralized, ensuring there is no dilution of angiogenic factors naturally occurring in bone.



Angiogenin and vascular endothelial growth factor (VEGF) content. Protein samples were prepared from three donors based on graft weight and the resulting solutions were analyzed using the MAGPIX® Protein Multiplexing system. The VEGF samples were diluted 1:10 while angiogenin was tested in undiluted samples. On average, PliaFX Prime contained 8.0x more angiogenin and 8.7x more VEGF than DBM with a carrier.

References

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6. Hankenson KD, Dishowitz M, Gray C, Schenker M. Angiogenesis in bone regeneration. Injury. 2011. 42(6): 556-561.

68-20-297.00

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