ARTICLE IN REVIEW:

Tgf-β activity within allograft demineralized bone matrix

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TITLE: TGF-β Activity of a Demineralized Bone Matrix.[1]

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STUDY DESIGN: In vitro molecular study (non-clinical).

SUMMARY: Similar to bone morphogenetic proteins (BMPs), transforming growth factor-beta (TGF-β) is a molecular signal known to promote formation of bone-forming cells. TGF-β signals work in tandem with BMPs and enhance their effects, resulting in as much as a 5-fold increase in bone deposition compared with BMPs alone.[2] While the BMPs in demineralized bone matrix (DBM) have been widely studied, this study aimed to demonstrate the presence and activity of TGF-β in allograft DBM, specifically within LifeNet Health's particulate and moldable demineralized fibers (known as OraGraft® and OraGraft/PliaFX® Prime). Using a series of in vitro molecular assays, the authors demonstrate that TGF-β exists at consistent levels in extracts of OraGraft and OraGraft Prime (see Image A below), that it dependably activates TGF-β receptors in gingival fibroblast cells in culture, and that this activation can be blocked by adding an inhibitor known to suppress TGF-β receptor activity. Further, the authors illustrate that this receptor activation results in activity within the fibroblast cell nucleus that is consistent with TGF-β-induced transformation into bone-forming cells, and that this nuclear activity can also be suppressed by a TGF-β receptor inhibitor (see Image B below). The authors conclude that TGF-β activity is consistently preserved and released following processing of OraGraft and OraGraft Prime, and that it remains biologically active. However, it is important to note that this study is non-clinical, and its clinical implications are unknown.

LifeNet Health's Processing Retains TGF-β:

Not only was TGF-β retained in all samples, but there was also lot-to-lot consistency among OraGraft and OraGraft Prime samples (Image A). Levels of TGF-β appear lower in OraGraft Prime because its enhanced absorption of the test solution required more liquid, causing it to be diluted to a lower concentration.

Further Evidence of Osteoinductive Potential:

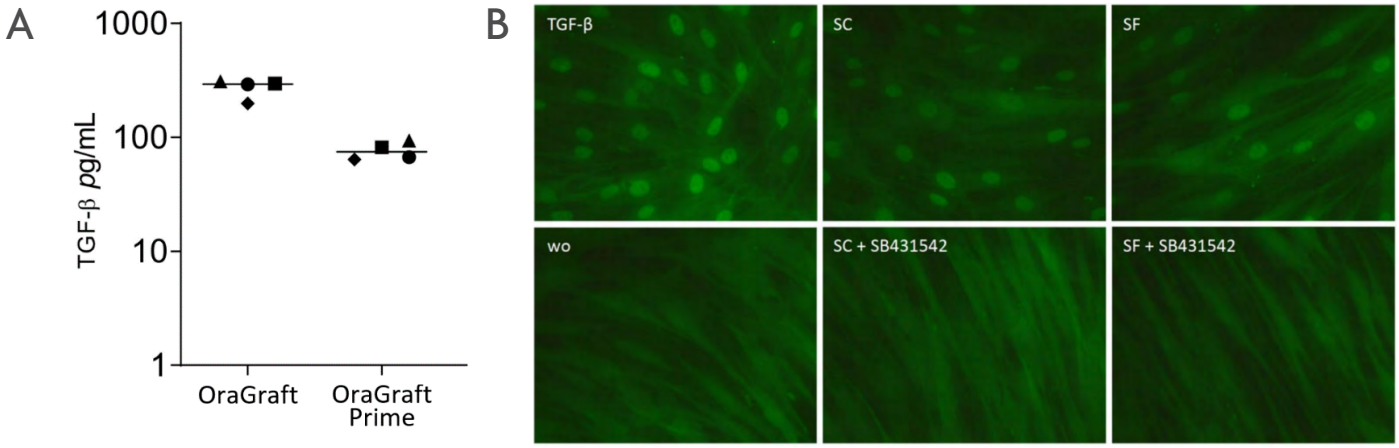
LifeNet Health's particulate and moldable DBMs showed biologically active TGF-β (Image B), an important signaling molecule for osteoinductivity.

Important Foundational Evidence:

While this study is non-clinical and its clinical implications are unknown, it does help confirm the basic science behind the quality and consistency of LifeNet Health's processing of DBMs and moldable DBMs.

References:

1. Panahipour L, Omerbasic A, Nasirzade J, Gruber R. TGF-β Activity of a Demineralized Bone Matrix. Int J Mol Sci. 2021; 22(2). doi: 10.3390/ijms22020664
2. Chen G, Deng C, Li YP. TGF-β and BMP signaling in osteoblast differentiation and bone formation. Int J Biol Sci. 2012; 8(2):272-288. doi: 10.7150/ijbs.2929



(A) Consistent levels of TGF-β were found in 4 samples each of OraGraft and OraGraft Prime processed from separate research-authorized donors. Levels of TGF-β appear lower in OraGraft Prime because its enhanced absorption of the test solution required more liquid, causing it to be diluted to a lower concentration.
(B) Evidence was found of biological activity within the fibroblast cell nuclei that is consistent with TGF-β-induced transformation into bone-forming cells following exposure to a positive control (TGF-β), OraGraft (SC), and OraGraft Prime (SF). No such activity is visible with the negative control (wo) or when a TGF-β receptor inhibitor is added (SC/SF+SB431542 images). Images adapted with permission under an open access license.[1]

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