Bone Graft Scaffolds: It's All About the Mineral

Bone grafts scaffolds comprising mineral granules suspended in a carrier matrix are commonly used in spinal fusion procedures as they provide superior surgical handling characteristics over stand-alone granule implants, and facilitate biological augmentation with autogenous factors such as autograft bone and bone marrow aspirate [1,2]. The mineral component of these grafts is typically in the form of hydroxyapatite (HA), beta tricalcium phosphate (β-TCP) or a mixture of the two, referred to as biphasic mineral. These materials generally differ in terms of composition, structure and solubility, all of which affect bone bonding, osteoconductivity and remodeling at the defect site. The ultimate goal with all of these biomaterials is to better control of implant resorption and bone substitution such that bony fusion can be reliably achieved [3].

HA is similar in composition to human bone, however is largely insoluble with bioactivity limited to the material surface. The slow resorption rate can ultimately result in sub-optimal remodeling, creating a defect site susceptible to focused mechanical stress [1,4]. β-TCP is similar in composition to amorphous bone precursors, and readily undergoes remodeling through osteoclastic resorption and osteoblastic new bone formation, stimulated by the material's calcium phosphate-rich surface layers [4,5]. However, complete remodeling of β-TCP depends on the rate of new bone formation, which may not match the rapid resorption rate, resulting in the formation of non-mineralized fibrous tissue at the implant site [1,4,5]. Despite enhanced configurations of β-TCP, such as the "highly purified β-TCP" featured in the Integra Mozaik Osteoconductive Scaffold, that tout optimized structure, resorption profile and osteoconductivity, the resorption of β-TCP has been largely reported to be unpredictable in biological environments [1,4,6].

Biphasic mineral combines the solubility of β-TCP with the long term stability of HA in optimal ratios to provide controlled implant resorption and sustained bioactivity, which can result in more reliable bone remodeling at the defect site. Dissolution of biphasic mineral in biological fluids produces a direct bonding interface with host bone through the release of calcium and phosphate ions and subsequent formation of carbonate hydroxyapatite (CHA) on the surface, which is similar to bone mineral [7]. After surface bonding, the controlled resorption rate, porosity and microstructure result in a stable scaffold that allows sustained bioactivity and osteoconductivity during the healing process.

Specifically, macroporous biphasic mineral in a 60:40, HA to β-TCP ratio, such as that featured in the Signafuse Bioactive Bone Putty (BioStructures), has shown advantageous bone remodeling properties. The unique 60:40 mineral ratio has shown to be in the optimal range for resorption and bioactivity (cell growth & bone bonding) and scaffold stability (cell maturation & bone formation) in bench testing as well as in clinically relevant animal models [3,7,8,11]. Additionally, the biphasic granulate structure comprises optimal ranges of macroporosity (>100 μm) to facilitate osteoconduction, and microporosity (>10 μm) needed for penetration of biological fluids [7]. Clinical studies have demonstrated the efficacy of micro and macroporous biphasic mineral in posterolateral spinal fusion procedures, across a range of patient demographics, indicating that biphasic mineral is a safe alternative to autograft and allograft materials [6,9,10].

The biphasic mineral component of the Signafuse Bioactive Bone Graft Putty provides distinct advantages over the highly purified β-TCP of the Integra Mozaik Osteoconductive Scaffold in terms of implant resorption, bioactivity and long term bone remodeling, indicating its potential for more predictable healing of spinal fusion defects and a safe and effective alternative to autograft and allograft materials.

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