Biphasic Calcium Sulfate - Chemical Structure and Regenerative Properties

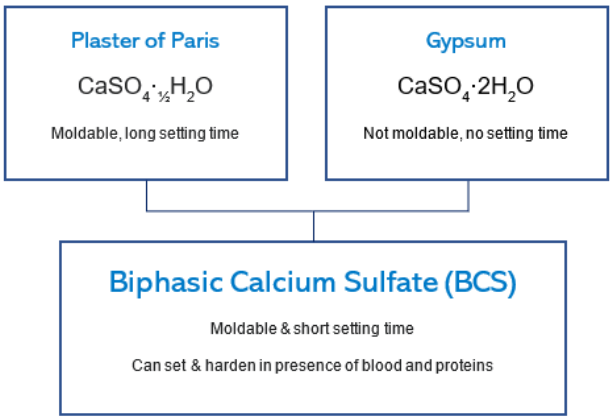
Calcium sulfate (CS) features a unique position among all regenerative bone graft substitutes. With more than 100 years of documented clinical success, (Dreesmann 1892, Thomas and Puleo 2008) it has a longer history of clinical use than most currently available biomaterials.

In an in vivo scenario, proteins and other biological macromolecules may further retard the setting time to up to 200 min. This is impeding the application procedure as well as the clinical performance for a typical dental application significantly (Ricci 2000).

Although Orsini and co-workers have shown that there are no differences in the bone healing pattern between preset CS dihydrate granules and moldable CS-hemihydrate cement. (Orsini 2004), by using preset CS dihydrate the surgeon loses advantageous handling properties of the moldable cement derivative.

By making use of the Biphasic Calcium Sulfate, the previous setting issues can be solved: The CS hemihydrate component is controlling the cement consistency and moldability characteristics. The dihydrate component is regulating the setting properties.

Using this formulation, the setting process can be reduced from about 20 minutes to 3 minutes, also under in vivo conditions in presence of blood and saliva. The key performance criteria of CS-derived graft materials that was shown in numerous studies is the fast and effective vital bone formation as a result of the rapid dissolution in vivo. (Thomas and Puleo 2008, Toloue, Dahlin) These characteristics provoke advantageous clinical results in small and well-contained bony defects like extraction socket filling. (Toloue, Guarnieri).



Biphasic Calcium Sulfate Composition

Bond Apatite®

Bond Apatite® is composed BCS and synthetic hydroxyapatite granules. With this formulation, the concept of a graft cement can be successfully applied for a wider range of indications.

The BCS affects an injectable graft cement and features fast resorption and new bone formation. The hydroxyapatite granules provide a slow-resorbing osteoconductive scaffold to preserve the augmented volume also over a longer time period.

The BCS matrix is supposed to feature complete resorption. The slow-resorbing hydroxyapatite granule matrix serves as longer range space maintainer for optimized volume control.

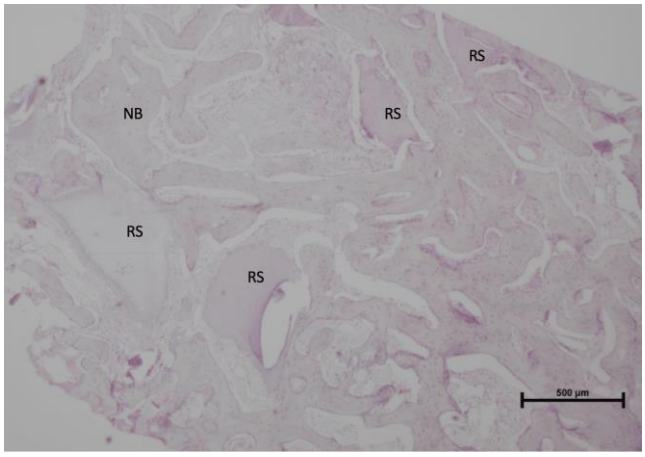
Bond Apatite® is delivered in a specially designed ready-to-use syringe containing the granulated powder and physiological saline. Mixing the powder component with the liquid in the driver results in a viscous composite that is suitable for direct injection into the graft site.

Histological Evidence | Complete Regeneration 8 Months Post-Op

At 12 weeks after placing the Bond Apatite®, nearly 90% is replaced by the patient's own bone.

The HA particles occupying 1/3 of the composite graft are intended to slow down the overall resorption rate of the graft. The HA particles do not integrate with the bone, they are first encapsulated by connective tissue, slowly resorb, and later on, the remaining connective tissue under goes ossification.

3 Months Post-Op | Nearly 90% Bone Regeneration

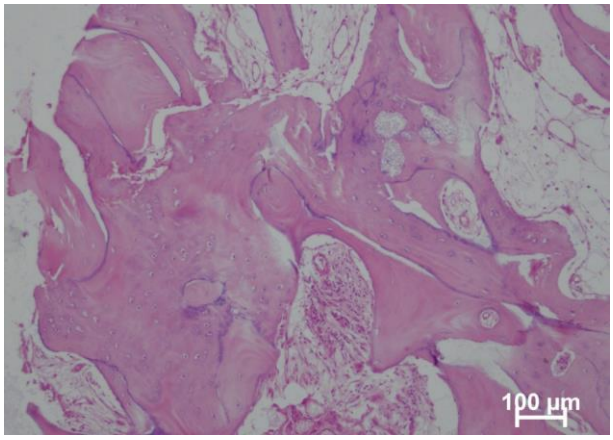


Properties and Clinical Applications of Biphasic, Calcium Sulfate, Yahav et al, April 2020.

8 Months Post-Op | Complete Bone Regeneration

After eight months of healing time, the Bond Apatite® graft is almost entirely resorbed with no encapsulated materials remaining due to the complete transformation of the graft into the new vital bone.

The small and medium-sized HA particles resorb in 3-4 months. In contrast, the larger size particles, which comprise less than 10% of Bond Apatite®, will remain for a prolonged period, almost fully resorbed after eight months, and continues its resorption process up to a complete regeneration.



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More information and references can be found at: https://www.augmabio.com/abca/e-book/

CALCIUMSULFAT

Mehr als 100 Jahre dokumentierter klinischer Erfolg in der Knochenregeneration

Seit 1982 wird CS stets als gut-toleriertes Knochen-Regenerationsmaterial beschrieben. Nach der vereinfachten Augmentation fungiert CS als hoch-biokompatible, osteokonduktive Matrix und wird praktisch komplett resorbiert.[2,3,9,10,11,12,13]

Calciumsulfat medizinischer Güte wird klinisch in 2 verschiedenen Formen verwendet:[14]
a) Calciumsulfat-Hemihydrat ($CaSO_4 \cdot ½\ H_2O$), auch bekannt als "Plaster of Paris"
b) Calciumsulfat-Dihydrat ($CaSO_4 \cdot 2\ H_2O$), auch bekannt als "Gypsum"

Wenn das CS-Hemihydrat mit Wasser angemischt wird, entsteht eine formbare Paste (Zement), der nach einer gewissen Zeit abbindet und aushärtet. Hierdurch entsteht die andere Calciumsulfat-Form CS-Dihydrat:

$$CaSO_4 \cdot ½\ H_2O + 1½\ H_2O \rightarrow CaSO_4 \cdot 2\ H_2O$$

Durch die Verwendung des innovativen biphasischen Konzepts bei 3D Bond™ kann eine optimale Handling-Performance erzielt werden:
Die CS-Hemihydrat-Komponente kontrolliert die Zementkonsistenz und die pastösen Eigenschaften des Materials. Die Dihydrat-Komponente reguliert die Aushärte-/ Abbindeigenschaften. Mit dieser Formulierung kann die Abbindezeit auf ca. 3 Minuten eingestellt werden, auch bei Anwesenheit von Blut oder Speichel.

Bond Apatite® setzt sich aus Biphasischem Calciumsulfat und synthetischem Hydroxylapatit-Granulat zusammen. Durch diese Konfiguration kann die Indikationsbreite des Knochenzements ausgeweitet werden.
Das BCS ermöglicht eine pastöse Konsistenz zur direkten Injektion sowie die schnelle Resorption und Knochenneubildung. Das HA-Granulat fungiert als langsam resorbierende Matrix zur besseren Volumenkontrolle des augmentierten Defekts, auch über einen längeren Zeitraum hinweg.

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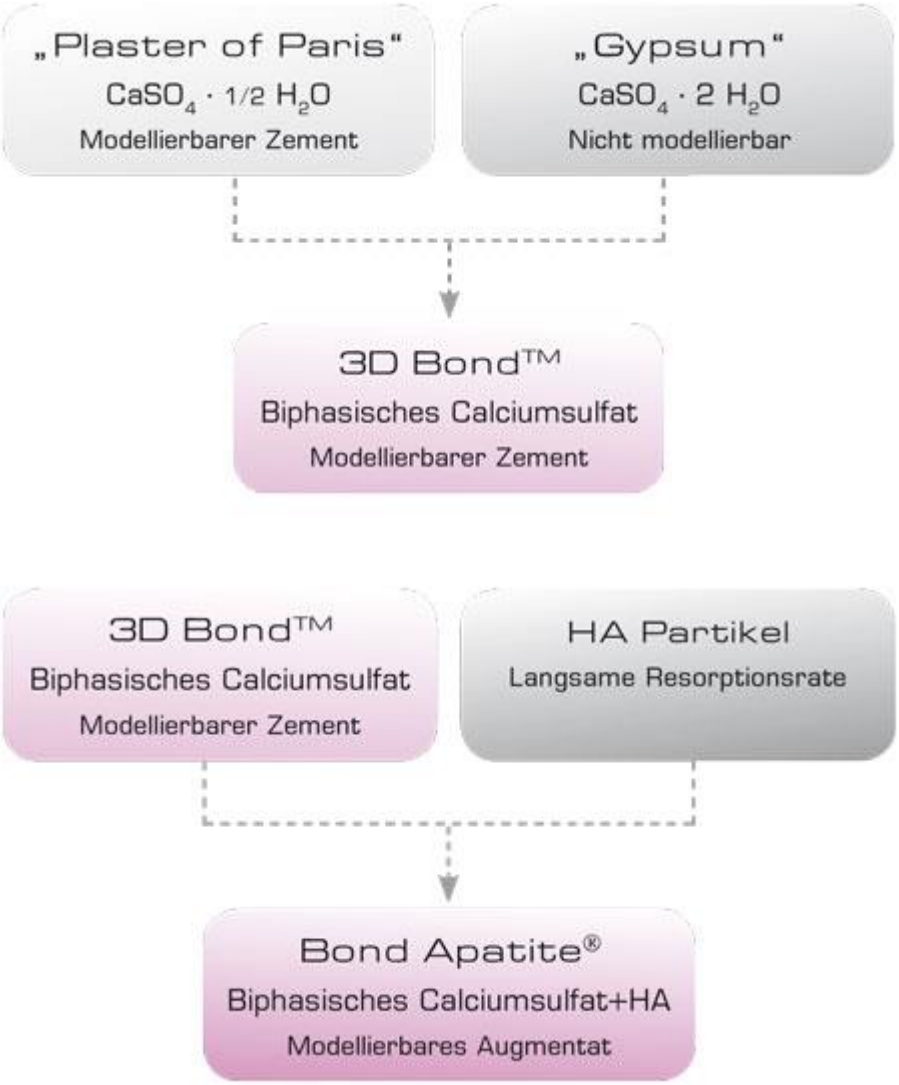
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Modellierbarer Zement
HA Partikel
Langsame Resorptionsrate
Bond Apatite®
Biphasisches Calciumsulfat+HA
Modellierbares Augmentat