Biocomposites®		Analytical Report	
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Title:	Compressive Strength of Two Forms of Calcium Sulfate Bone Void Filler		

Study Summary

Two samples of calcium sulfate bone void filler received. Investigate material properties related to strength.

Sample Name	Ref	Lot	Appearance
Synthecure	20-125	RM118904	White Powder, clear liquid
Stimulan Rapid Cure	620-005D	2018-03a	White Powder, clear liquid

Analytical Methods

For this study, the International standard for testing calcium phosphates ISO/DIS 18531:2015 (E) was adapted to also suit the testing of calcium sulfate biomaterials. There is no identified standard for compressive testing of calcium sulfate based biomaterials so this standard was chosen as a 'best fit' for the materials tested here.

For both samples, mixing was conducted according to the manufacturer's instructions for use (IFU) and the resulting pastes were used to produce cylindrical test specimens in a purpose made mould (fig 1.) producing 7.5mm diameter, 10mm height cylinders conforming to the required standard. All samples were prepared at ambient room temperature (approximately 21 °C) and left to cure for 1 hour in the mould.

Whilst pasting the sample materials, care was taken to tap the mould mat on a hard surface to remove any entrapped air bubbles which may have been incorporated during the mixing process to give cavity free, uniformly moulded cylinders.

After one hour, the samples were removed from the mould.

10 Samples of each material were tested to failure and their compressive strength (MPa) determined using a static materials mechanical testing machine (Zwickline Z2.5 TN Serial no. 724285, Zwick/Roell AG) (Bio no. 389) and parallel plate accessories. Fig 2.

Compression testing was conducted with a 2.5kN load cell. A cross-head speed of 0.5mm/min was applied until downward displacement reached 2 mm. The compressive strength (MPa) was calculated using the maximum compressive load for each sample divided by cross-sectional area.

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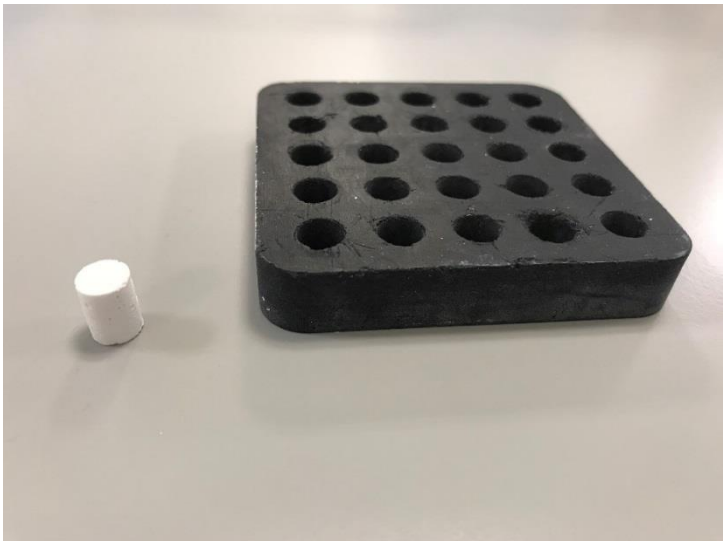

Fig. 1 Cylinder mould mat

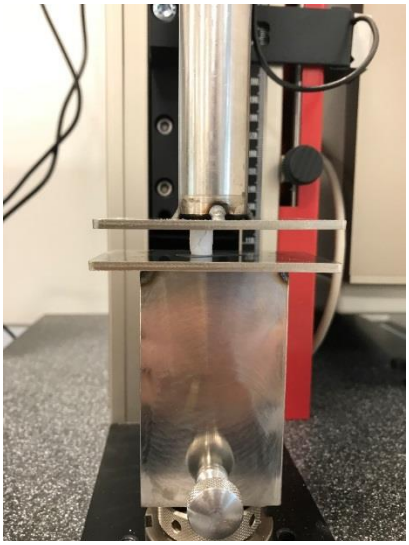

Fig. 2 Testing machine with parallel plate accessory

Results

Stimulan Rapid Cure averaged 14.96 MPa over the 10 samples. The maximum single cylinder strength was recorded as 18 MPa with the lowest recorded as 12.5MPa.

Synthecure averaged 4.58 MPa over the 10 samples. The maximum single cylinder strength was recorded as 6.2 MPa with the lowest recorded as 2.52 MPa.

The results are shown in fig. 3 and fig. 4.

Conclusions

Although both are calcium sulfate materials, Stimulan Rapid Cure is different to Synthecure in terms of compressive strength. Over the 10 cylinder samples tested here, after one hour curing time, Stimulan Rapid Cure is 3 x stronger than Synthecure.

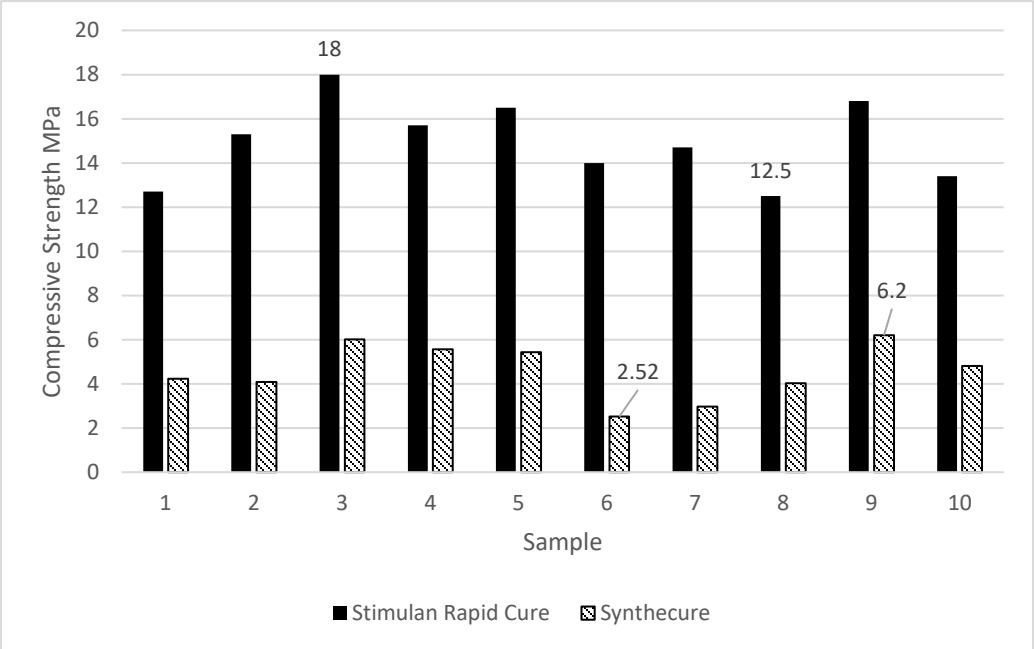

Fig. 3 Compressive strength of each cylinder tested.

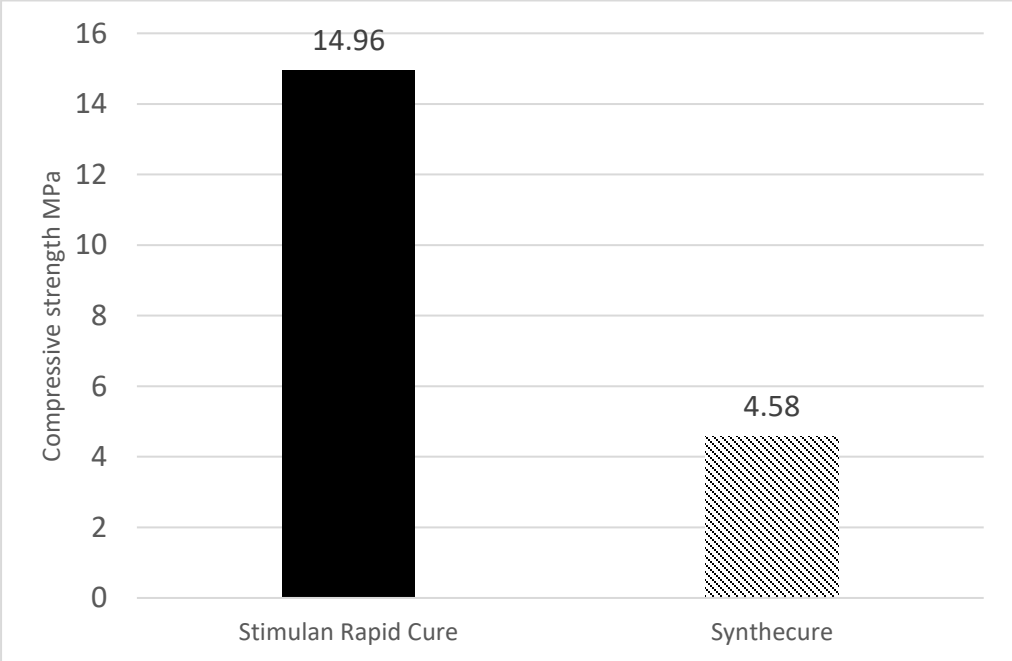

Fig. 4 Average Compressive strength (n=10).