Biocomposites®		Analytical Report	
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Title:	Dissolution Analysis of Two Forms of Calcium Sulfate Bone Void Filler		

Study Summary

Two samples of calcium sulfate bone void filler received. Investigate material degradation properties in solution.

Sample Name	Ref	Lot	Appearance
Intersep	CS-05CC	016371	White Powder, clear liquid
Stimulan Rapid Cure	620-005D	2018-03a	White Powder, clear liquid

Analytical Methods and Results

Sample Degradation Assay

Investigate the rate of degradation of each material in a physiological solution. The total volume of solution was exchanged and replenished at 24 hour intervals.

Method

Each material was prepared according to the instructions for use (IFU) and were prepared into 6mm hemispherical beads and weighed to 4 decimal places. Sample quantities were n=10 for Stimulan and n=8 for InterSep. The beads were saturated with Phosphate Buffered Saline (PBS) for 1 minute and the saturated weight was recorded. The beads were then placed into individual sealed containers of 10ml of 0.01M PBS solution and incubated at 37°C. Samples were removed from the solution at regular intervals, surface dried and weighed. At each interval, the PBS was replenished with fresh solution.

Results

Table 1. Weight increase on soaking

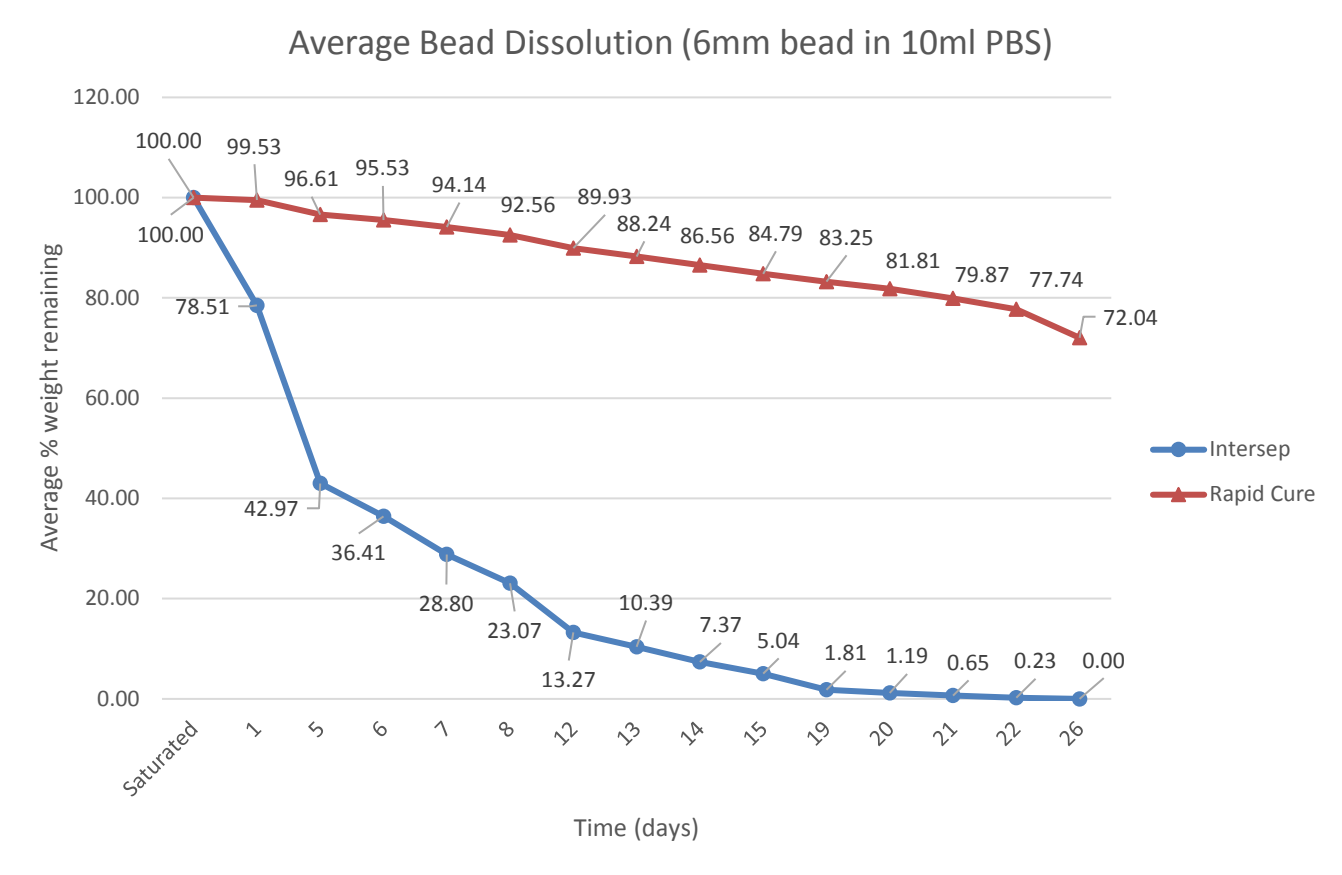
	Lot Number	Average Initial Weight of bead (n=10)	Average Saturated weight of bead (n=10)	Average Weight increase	Average Weight increase %
Intersep	016371	0.1548g	0.1627g	0.0079g	4.86%
Stimulan Rapid Cure	2018-03a	0.1800g	0.1858g	0.0058g	3.22%

The Intersep beads produced a greater increase in average bead weight indicating higher porosity.

Table 2. Dissolution rate data

Day	**% Bead Remaining**	
	Intersep 016371	Stimulan Rapid Cure 2018-03a
Saturated	100.00	100.00
1	78.51	99.53
5	42.97	96.61
8	23.07	92.56
12	13.27	89.93
15	5.04	84.79
20	1.19	81.81
26	0.00	72.04

Fig 2. Dissolution rate



Conclusions

Intersep beads were observed to degrade at a much higher rate than Stimulan Rapid Cure beads in the same assay.

The 4.86% increase in weight on soaking with PBS indicates a higher porosity of Intersep

Of the 8 bead samples of Intersep, 7 remained at the 16 daytime point and 3 at the 22 day time point. All InterSep samples had dissolved by day 26.

All 10 samples remained for Stimulan Rapid Cure at the 26 day time point.