

# Osteoinductivity of MTF Flexible Cancellous Sheet with Bone Marrow Aspirate

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## INTRODUCTION:

The use of bioactive factors to enhance the healing potential of musculoskeletal tissue offers intriguing possibilities to the orthopaedic surgeon, especially in the area of bone repair. Bone marrow aspirate (BMA) is an autologous source of bioactive factors used as an adjunct to stimulate new bone formation. The objective of this study was to determine the osteoinductivity level of the ENHANCE<sup>®</sup> Flexible Cancellous Sheet, a demineralized bone matrix (DBM) commercially available from MTF when combined with BMA in an athymic mouse model.

## MATERIALS AND METHODS:

Samples of the Flexible Cancellous Sheet soaked in BMA and heat-inactivated demineralized bone powder (negative control) were implanted in the hind limb musculature of athymic mice as previously described in literature.<sup>1</sup> At 28 days histologic evidence was evaluated using a scoring system consistent with proposed industry standards (see Table 1).<sup>2</sup>

Score	Criteria
0	No evidence of new bone formation
1	1 – 25% of the section is covered by new bone
2	26 – 50% of the section is covered by new bone
3	51 – 75% of the section is covered by new bone
4	> 75% of the section is covered by new bone

Table 1: Osteoinductivity Scoring Scale and Criteria

## RESULTS:

The Flexible Cancellous Sheet with BMA was consistently osteoinductive in this model; 100% of the samples were osteoinductive, with an average osteoinduction score of  $3.94 \pm 0.23$  (see Table 2).

As expected, the heat-inactivated negative control DBM Powder was not osteoinductive in this model; 0% of the samples were osteoinductive (see Table 2).

## DISCUSSION & CONCLUSIONS:

When characterizing demineralized bone matrices it is imperative to assess both the average OI score and the variability in osteoinductive response which is reflected in the number of osteoinductive samples relative to the total number of samples (see Table 2). There is minimal variability in the osteoinductive response of the Flexible Cancellous Sheet with BMA, with every sample demonstrating osteoinductivity and presenting robust new bone formation including bone marrow.

In conclusion, these results suggest that under the conditions of this study, and for the batches (donors) tested, that the ENHANCE Flexible Cancellous Sheet with BMA is consistently osteoinductive with every sample demonstrating osteoinductivity in the athymic mouse model.

Summary Statistics	Osteoinduction Score (0-4 Scale)		# Ranked Samples	Osteoinductive (Numbers & Percentages) Samples
	Mean	Std Dev		
Enhance + BMA	3.94	0.23	36	36/36 (100%)
Negative Control	0.00	0.00	3	0/3 (0%)

Table 2: OI scores of the Flexible Cancellous Sheet w/ BMA and the negative control.

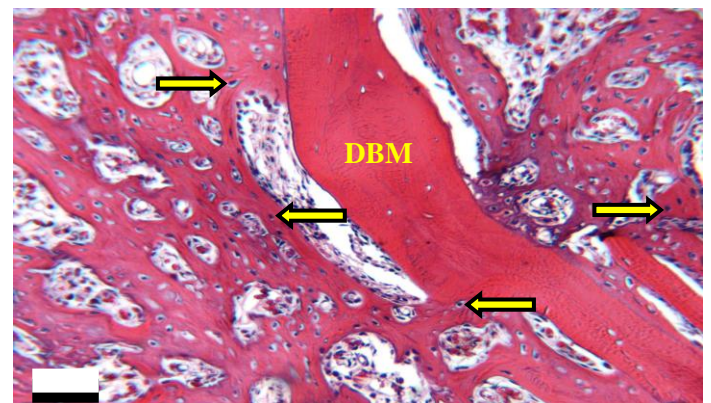


Figure 1: ENHANCE Flexible Cancellous Sheet + BMA demonstrating residual demineralized bone (DBM), the presence of bone marrow and new bone formation (arrows). H&E stain; 100X magnification; BAR = 100  $\mu$ m.

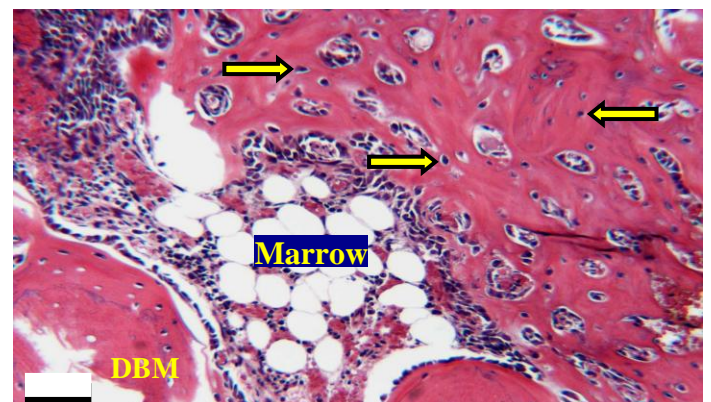


Figure 2: ENHANCE Flexible Cancellous Sheet + BMA demonstrating residual demineralized bone (DBM), the presence of bone marrow and new bone formation (arrows). H&E stain; 100X magnification; BAR = 100  $\mu$ m.

## REFERENCES:

- Schwartz, et al., J. Periodontol Surg. 69: 470 – 478, 1998.
- Draft Standard: **Standard Guide for the Assessment of Bone Inductive Materials**, ASTM F04.4 Division, Draft by Barbara Boyan, Univ. of Texas Health Science Center at San Antonio, downloaded from ASTM website 5-8-2000  
ENHANCE is a registered trademark of MTF.