

Summary of Biphasic Mineral Use in Spine Fusion Clinical Trials

Clinical Performance Summary

- The biphasic mineral used in BioStructures' OsteoMatrix™, OsteoPlus™ and Signafuse™ bone graft products has an established history of safe and effective clinical use in a variety of spine fusion procedures.
- Biphasic mineral as shown to be equivalent to the “gold standard” **iliac crest bone graft (ICBG)** in prospective spine fusion studies.
- Biphasic mineral has been verified via human biopsy histology to resorb and support new bone formation in fusion defects.

Published Studies Assessing Biphasic Mineral in Spine Fusion Procedures

Procedure	Study Design	Test Groups	# Patients	Duration	Endpoints	Results Summary
Cervical Fusion [1]	Prospective, Randomized	Biphasic mineral vs. ICBG ^a	58	24 months	Radiography	Biphasic mineral fusion rate statistically equivalent to ICBG fusion rate
Lumbar Fusion [2]	Retrospective	Biphasic mineral	20	2-56 months	Biopsy/Histology	Biphasic resorption and new bone formation found in all biopsies
Cervical Fusion [3]	Prospective, Randomized	Biphasic mineral vs. ICBG	100	6 months	Radiography	100% fusion rate in both Biphasic mineral & ICBG groups
Scoliosis [4]	Prospective, Randomized	Biphasic mineral vs. ICBG	58	24 months	Radiography	Biphasic mineral fusion rate statistically equivalent to ICBG fusion rate
Lumbar Fusion [5]	Prospective	Biphasic mineral w/ BMA ^b	106	24 months	Radiography	Biphasic mineral w/ BMA = 94% fusion rate (100/106 patients)
Scoliosis [6]	Prospective, Randomized	Biphasic mineral vs. ICBG	341	24 months	Radiography, Biopsy/Histology	Biphasic mineral fusion rate statistically equivalent to ICBG fusion rate; Biphasic resorption and new bone formation found in all biopsies
Scoliosis [7]	Prospective	Biphasic mineral vs. Biphasic/ICBG	12	18 months	Radiography, Biopsy/Histology	Complete fusion in all patients; Biphasic resorption and new bone formation found in all biopsies

^aIliac Crest Bone Graft, ^bBone Marrow Aspirate

References

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