

Summary

Mg OSTEORETE is a combination of monopotassium phosphate, magnesium oxide, tricalcium phosphate, C/12J/22O/11 mixed with a modified saline that is osteoconductive and biodegradable. The patented, proprietary formula includes critical components to maximize the process of bone health and development.

Objectives

The objective of this study is to evaluate the performance of Mg OSTEORETE when combined with autograft (50:50) in a rabbit posterolateral spine fusion model. The test groups, Mg OSTEORETE and Mastergraft® Putty (Medtronic) were evaluated for spine fusion rate, new bone formation, graft remodeling and inflammatory response using radiographic, microCT, biomechanical and histological endpoints at 4, 8 and 12 weeks following implantation.

Methods

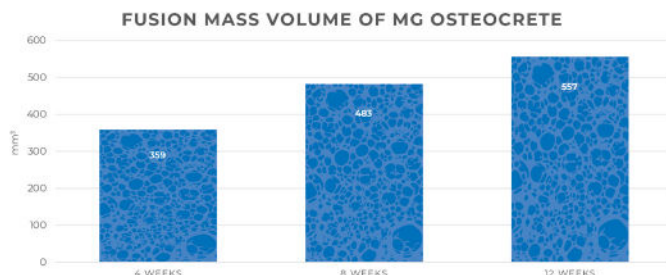
Gross examination of each grafted level demonstrated a normal tissue response to posterolateral grafting in this rabbit model.

Radiographic scoring of the fusion sites indicated a normal healing response in all test groups, with no adverse reactions and similar progressions of new bone formation observed over time.

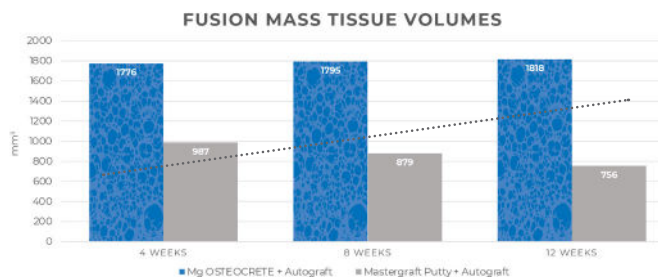
Spine fusion was assessed by manual palpation and micro-CT analysis of the treated motion segments. **Mg OSTEORETE demonstrated fusion in as little as 8 weeks.**

* All claims based on Lapine Posterolateral Fusion and Condyle Defect Models. It is unknown how results from the rabbit models compare with clinical results in humans.

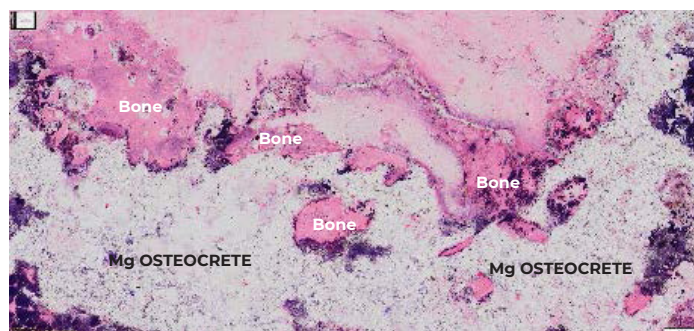
Conclusions



Mg OSTEORETE + Autograft fusion mass (total implant volume) maintained its size during the remodeling period whereas the fusion mass of Mastergraft + Autograft decreased over time.



Mg OSTEORETE continued to remodel at each time point, providing stability during the crucial healing period.



Based on histomorphometry measurements at 12 weeks, Mg OSTEORETE remodeled at a rate of approximately 10% after each 4-week time period. This rate corresponds to approximately 65% remodeling at 26 weeks and complete remodeling by 36-40 weeks.