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Ceramic bone graft substitute (Mg-HA) in spinal fusion: A prospective pilot study

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Material: SINTlife is an implantable, resorbable, non-active medical device, acting as bone substitute. SINTlife consists of biomimetic hydroxyapatite, enriched with magnesium ions that make the product, due to its chemical-physical properties, similar to the mineral component of human bones. In addition, due to their chemico-physical features, hydroxyapatite-magnesium composites are acknowledged to provide intrinsic antibacterial propertiesy, which in turn provide higher resistance to microbial infections.

Intented Use IFU: spinal surgery applications, intervertebral implants, postero-lateral spinal fusion.

Keywords paper: lumbar degenerative disc disease, spinal fusion, bone graft substitute, Brantigan score, bioceramics

Background

Iliac crest bone graft (ICBG) is considered the gold standard for spine surgical procedures to achieve a successful fusion due to its known osteoinductive and osteoconductive properties. However, complications related to harvesting procedure and donor site morbidity have been largely reported in the literature, favoring the development of a wide range of alternative products to be used as bone graft extenders or substitutes for spine fusion. Among all, ceramic-based biomaterials have been widely studied and employed in the last years as bone graft substitutes.

Methods

We report here the results of a prospective pilot study aimed to evaluating the grade of ossification obtained by the use of an Mg-doped hydroxyapatite (HA) product to achieve postero-lateral fusion in degenerative spine diseases.

Results

Results show a successful degree of fusion of about 62% at the 12-month follow-up and an improvement of quality of life and health status following surgery, as evaluated by clinical scores (ODI, VAS, and EQ-5L). No adverse events related to the material were reported.

Conclusions

The present pilot study shows the effectiveness and the safety profile of an Mg-doped HA bone graft substitute used to achieve postero-lateral fusion in the treatment of degenerative spine diseases, laying down the basis for further larger clinical investigations.

Take home messages: thanks to the specific biomimetic chemical composition and microstructural features, SINTlife medical devices are able to promote new bone formation in spinal fusion, thereby showing high regenerative processes.