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EFFICACY AND SAFETY OF THE MAGNESIUM-HYDROXYAPATITE BONE GRAFT SUBSTITUTE IN POSTERO-LATERAL SPINAL FUSION: OBSERVATIONAL, SPONTANEOUS CLINICAL 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 fusion.

Keywords paper: spinal fusion, hydroxyapatite bone graft, magnesium-hydroxyapatite

Background

Iliac Crest Bone Graft (ICBG) is considered the "gold standard" option for achieving fusion in spinal surgical procedures, thanks to its known osteoinductive and osteoconductive properties. However, complications related to harvesting and donor site morbidity have been largely reported in literature, favouring the development of a wide range of alternative products to be used as bone graft extenders or substitutes. Ceramic-based biomaterials are since years employed as bone graft substitutes to replace autograft, due to their similarity with the mineral component of human bone. Recently, new generation of HA biomaterials have been developed with superior properties to promote a faster remodelling and new formation of human bone, and a rapid cell-mediated material resorption. We report here the results of a prospective study aiming to evaluate the degree of fusion obtained by the use of an Mg-doped hydroxyapatite (Mg-HA) product to achieve postero-lateral fusion in degenerative spine diseases. Second aim of the study was to evaluate of the safety profile of the bone graft in spinal arthrodesis procedures.

Methods

A prospective, spontaneous, observational, post-marketing clinical study was conducted. Twenty subjects were included in the study and underwent surgery for postero-lateral fusion with the use of the Mg-HA bone graft.

Results

No early infections occurred in the population treated with antibiotic-combined bone substitutes, compared with 6.7% of patients treated with autologous bone without antibiotics. The relative risk of EIs was 0.33 (P=.49; 95% CI= 0.01–7.58) and the number needed to treat was 15.

Conclusions

The Mg-doped HA bone graft substitue SintLife represents a good alternative to autologous bone graft. The device can be safely used alone performing in a similar manner as the "gold standard" autologous bone.

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 and very good total safety profile.