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OBSERVATIONAL, SPONTANEOUS CLINICAL STUDY ON THE PERFORMANCE AND SAFETY OF THE MAGNESIUM-HYDROXYAPATITE BONE GRAFT SUBSTITUTE SINTLIFE IN SPINE INTERBODY FUSION

Progress in Neuroscience, Vol. 7, 19-26, N. 1-4, 2023 (https://www.researchgate.net/publication/3762599) - (OPEN ACCESS)

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, spinal fusion.

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

Background

Iliac Crest Bone Graft (ICBG) is considered the "gold standard" for achieving fusion in spinal surgical procedures due to its osteoinductive and osteoconductive properties. Because of complications related to harvesting and donor site morbidity, alternative products such as bone graft extenders or substitutes have been developed. Ceramic-based biomaterials can be used as bone graft substitutes in order to replace autograft, due to their similarity with the mineral component of human bone. Recently, a new generation of hydroxyapatite biomaterials were developed with superior properties to promote faster remodeling, new formation of human bone, and a rapid cell-mediated material resorption. The purpose of this study was to evaluate the fusion degree obtained with the use of an Mg-doped hydroxyapatite (Mg-HA) product to achieve postero - lateral fusion in degenerative spine disease. Additionally, the safety profile of the bone graft in spinal arthrodesis procedures was evaluated.

Methods

In this, observational, clinical study, twenty participants were originally included. After inclusion and exclusion criteria were applied, 17 participants remained. All participants underwent surgery for postero - lateral fusion with the use of the Mg-HA bone graft.

Results

At 12 months follow-up, more than 94,1% of fusion was reached. A statistically significant improvement was observed for clinical parameters related to the quality life improvement following spinal fusion. Mg-doped HA bone graft substitute SintLife represents a good alternative to autologous bone graft. The device can be safely used and has a similar performance to the "gold standard", which is autologous bone.

Conclusions

Mg-doped HA bone graft substitute SintLife represents a good alternative to autologous bone graft. The device can be safely used alone performing similarly 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.