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MAGNESIUM-ENRICHED HYDROXYAPATITE FOR SPINAL INTERBODY FUSION: EXPERIENCE IN 75 CASES

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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, interbody fusion.

Keywords paper: anterior cervical discectomy and fusion, magnesium–enriched hydroxyapatite. hydroxyapatite

Background

Anterior cervical discectomy and fusion (ACDF) is a surgery indicated to remove a herniated or degenerative disc in the neck. Numerous graft extenders are available on the market as alternatives to the patient's own autograft bone. Among all, calcium phosphate salts such as HA and β-TCP can be inserted in cages and allow vertebral fusion. Aim of the present study was to evaluate the safety and efficacy of a new generation biomimetic hydroxyapatite (HA) enriched with magnesium ions (MgHA) inserted in cages for spinal fusion.

Methods

A series of consecutive patients undergoing ACDF was selected to be treated with the use of an Mg-doped HA bone graft material inserted in cage. Clinical and radiologic data were collected immediately after surgery, then up to 2 year after surgery. The primary endpoint (i.e. safety) was considered as lack of any adverse event leading to revision surgery or re-hospitalization during the follow-up period. The secondary endpoint (i.e. performance or evidence of fusion) was considered as lack of cage mobilizations recorded during the follow-up period.

Results

seventy-five patients underwent interbody spinal fusion for the treatment of ACDF. A minimum 2-year follow-up was recorded for all the patients. Radiographic images showed the stability of the implant, as result of successful surgery. No adverse events (cage mobilization, infection, etc.) were recorded.

Conclusions

Mg-hydroxyapatite bioceramics show osteoconductive properties and a safety profile when employed in ACDF procedures.

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 total safety.