Finceramica

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AN OBSERVATIONAL PROSPECTIVE CLINICAL STUDY FOR THE EVALUATION OF A COLLAGEN-HYDROXYAPATITE COMPOSITE SCAFFOLD IN HIP REVISION SURGERY"

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Material: RegenOss is an implantable, resorbable, non-active medical device that acts as a bone substitute. It consists of type I collagen (equine origin) and hydroxyapatite enriched with magnesium ions. Collagen is a fibrous protein and represents the most important structural component of the extracellular matrix of many human connective tissues, while hydroxyapatite is the bone main mineral element (65% by weight). The presence of type I collagen and hydroxyapatite makes the device chemically and structurally biomimetic.

Intented Use IFU: orthopaedic surgery, prosthetic revision, mixed with autologous bone

Keywords paper: hip revision surgery, bone tissue regeneration, collagen-based hydroxyapatite, stemmed cup

Background

One of the greatest challenges for hip revision surgery is managing extensive bone stock 15 loss by creating a stable reconstruction with long-term durability. The present observational, inves-16 tigator-initiated prospective study was carried out to evaluate the clinical and radiological results 17 on the use of a commercial biomimetic collagen-hydroxyapatite composite biomaterial (RegenOss) 18 in hip revision surgery.

Methods

Thirty-three patients who underwent hip revision were included in this study, and 29 received up to 2 years of follow-up. The acetabulum was reconstructed using an uncemented hemispherical shell both with or without an iliac fixation stem. Functional recovery was assessed according to the Harris Hip Score (HHS) at the pre-hospitalisation check-up, and at 6-, 12-, and 24-month follow-ups.

Results

Radiological evaluation consisting of X-ray analyses (6, 12, and 24 month follow-ups) and CT scan exams (within 10 weeks post-surgery and at 12-month follow-up) were performed to evaluate the reduction in bone defect and new bone regeneration. All the patients reported a complete recovery and a considerable improvement in functional outcome assessed by the HHS, which was significantly higher at all the follow-ups than at pre-hospitalisation. Moreover, radiological assessments revealed good scaffold integration

Conclusions

Overall, collected data suggest that RegenOss is a valid and safe alternative to restoring acetabular bone loss in revision hip arthroplasty.

Take home messages: thanks to the particular configuration and biomimetic chemical composition, RegenOss can promote the regenerative processes of orthopaedic surgery.