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PAPER SUMMARY

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COMPARISON OF BONE INGROWTH AND CLINICAL OUTCOME OF A COLLAGEN HYDROXYAPATITE BONE GRAFT SUBSTITUTE VERSUS AUTOLOGOUS BONE GRAFT IN POSTERIOR LUMBAR INTERBODY FUSION

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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: spinal surgery, intervertebral implants, spinal fusion.

Keywords paper: posterior lumbar interbody fusion (PLIF); bone graft substitute; 18F-fluoride positron emission tomography/computed tomography (18F-fluoride PET/CT); spine; fusion

Background

Posterior lumbar interbody fusion (PLIF) is a surgical procedure to treat painful unstable spinal segments using bone graft filled interbody cages and instrumentation. The graft can be autologous bone or a bone substitute. RegenOss is a porous, 3-dimensional composite bone substitute consisting of collagen fibers including hydroxyapatite. The aim of this cohort study was to evaluate RegenOss as graft material in PLIF patients, as compared to a historical cohort grafted with autologous bone.

Methods

Fifteen patients were enrolled prospectively at the Maastricht University Medical Center between November 2016 and May 2019 in the RegenOss cohort (METC14-1-056) and were compared to 15 matched prospective patients from a historical autologous cohort collected at the Maastricht University Medical Center between October 2011 and January 2014 (METC10-1-025). During PLIF, interbody cages were filled with RegenOss bone substitute in the RegenOss cohort and with local autologous bone in the autologous cohort. Both cohorts were subjected to patient reported outcome measures (PROMs) [including Oswestry Disability Index (ODI), Visual Analogue Scale (VAS), EuroQol-5D (EQ-5D)], 18F-fluoride positron emission tomography/computed tomography (PET/CT) at six weeks and one year.

Interbody fusion was assessed on CT at one year and bone metabolism on 18F-fluoride PET/CT was assessed at six weeks and one year. Differences in patient demographics, clinical outcome, interbody fusion and bone metabolism were assessed between graft cohorts. Bone metabolism was also compared between follow-up moments.

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Results

Patient demographics were comparable between cohorts. At one-year follow-up, clinical outcome in both cohorts was similar (ODI: P=0.12, VAS: P=0.15, EQ-5D: P=0.22). Interbody fusion was considered comparable between cohorts; 7/15 RegenOss patients and 8/15 autologous patients were scored as completely fused on CT at one year. Similar findings in bone metabolism between follow-up moments were found for both cohorts; bone metabolism in the operated segment was significantly lower at one year compared to at six weeks (RegenOss cohort: P=0.003, P=0.005 for the upper and lower endplate respectively, autologous cohort: P=0.001, P=0.001). No differences in bone metabolism were observed between cohorts.

Table 2 Glassman grading on the diagnostic computed tomography scan one year after surgery, for both the RegenOss and the autologous graft cohort. Based on the Glassman grading the patients were classified as incompletely fused (Glassman grade 1, 2 or 3) or completely fused (Glassman grade 4 or 5)

Fusion status	Glassman grades	RegenOss cohort (number of patients)	Autologous graft cohort (number of patients)
Incomplete fusion	Grade 1—no fusion	0	0
	Grade 2—partial or limited unilateral fusion	1	1
	Grade 3—partial or limited bilateral fusion	7	6
Complete fusion	Grade 4—solid unilateral fusion	3	4
	Grade 5—solid bilateral fusion	4	4

Conclusions

Bony bridging, clinical outcome, bone metabolism were comparable for the RegenOss and the autologous bone graft PLIF cohorts.

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