Vertebral fusion

Vertebral fusion is performed in order to stabilize the spine in the presence of degenerative, traumatic or oncological pathologies that alter its stability. The autologous bone, harvested from the patient's iliac crest or from the lamina during surgery, is still considered the "gold standard" for spine fusion due to its osteogenic, osteoinductive and osteoconductive properties. However, several biological and synthetic bone substitutes have been introduced as alternatives for regenerating bone tissue.

Barbanti Bròdano et al., studied in particular the use of ceramic biomaterials prepared from hydroxypatite (HA), starting from in vitro analysis, through an in vivo study on ovine animal model and a post-market surveillance analysis, to finally design and perform a clinical study, which is ongoing in our Department. In the first step, HA-derived biomaterials were tested in vitro in the presence of bone marrow-derived human mesenchymal stem cells (hMSCs) and evaluated for their ability to activate precursor cells. In the second step, the biomimetic bone graft substitute SintLife® putty (MgHA) was evaluated in vivo. A posterolateral fusion procedure was applied on 18 sheep, where a fusion level was treated with MgHA, while the other level was treated with autologous bone. Microtomography and histological/histomorphometric analysis were performed six months of after surgery. In the third step, we reported the results of a post-market surveillance study conducted on 4 independent cohorts of patients (total 115 patients), in which HA-derived biomaterials were used as bone graft substitutes or extenders. Finally, a clinical study has been designed and approved by the Ethics Committee of our Institute and is currently ongoing. This study aims to evaluate the efficacy of the ceramic biomaterial SintLife® putty for bone replacement in patients treated by posterolateral fusion for degenerative spine disorders. HA biomaterials were effective in promoting the in vitro growth of hMSCs and their osteogenic differentiation. In the animal model, SintLife® putty has been effective in generating neo-formed bone tissue with morphological and structural features similar to those of the pre-existing bone. The post-market surveillance analysis has not reported any intra-operative nor early or late post-operative adverse events. Seven patients are currently recruited for the clinical trial designed to evaluate Sintlife efficacy for spine fusion (FU range: 1-7 months). No adverse events have been recorded. The first CT analysis performed at 6 months FU showed a good spine fusion. The study is ongoing. Our results, obtained from in vitro, preclinical and clinical studies, suggest that biomaterials derived from hydroxyapatite could be a valid alternative to autologous bone graft for vertebral fusion. This would potentially avoid or reduce the need of autologous bone harvesting and therefore, the risk of drawback-related side effects [1].

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Barbanti Bròdano G, Griffoni C, Nataloni A, Manfrini M, Giavaresi G, Bandiera S, Gasbarrini A, Terzi S, Ghermandi R, Tedesco G, Girolami M, Tognon M, Fini M. Biomaterials as bone graft substitutes for spine surgery: from preclinical results to clinical study. J Biol Regul Homeost Agents. 2017 Oct-Dec;31(4 suppl 1):167-181. PubMed PMID: 29188680.