SAFETY AND EFFICACY OF AUTOLOGOUS BONE MARROW CLOT AS A MULTIFUNCTIONAL BIOSCAFFOLD FOR INSTRUMENTAL POSTERIOR LUMBAR FUSION: A ONE-YEAR FOLLOW-UP PILOT STUDY

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INTRODUCTION: Bone marrow aspirate (BMA) in association to graft substitutes has long been introduced as a promising alternative to iliac crest bone graft in spinal fusion. However, BMA use is limited by the absence of a standardized technique, of a physical texture and by the possibility of dispersion away from the implant site. Recently, the potential use of a new formulation of BMA, named BMA clot, has been preclinically described. We report the results of a prospective pilot clinical study designed to assessing the safety and efficacy of autologous vertebral BMA (vBMA) clot as three-dimensional and multifunctional bio-scaffold in instrumental posterior lumbar fusion (Figure 1).
METHODS: Clinical outcomes were evaluated by the Visual Analog Scale (VAS), Oswestry Disability Index (ODI), and EuroQoL-5L (EQ-5L) preoperatively and at 3 and 12 months after spinal fusion. Bone fusion quality was evaluated at 12 months of follow-up by Brantigan classification on radiography (XR) imaging. Bone density was measured on computed tomography (CT) scans at 6 and 12 months of follow up visits and expressed in Hounsfield Unit (HU).
RESULTS SECTION: Results show a degree of fusion of about 100% (considering the levels with C, D, and E grades, Brantigan classification) at 12-month follow-up and an increase in bone density from 6 to 12 months follow-up. An enhancement of quality of life and health status following surgery, as assessed by clinical scores (ODI, VAS, and EQ-5L) was also observed already at 3 months follow-up. No adverse events associated to the vBMA clot were reported.
DISCUSSION: Preliminary data from this study demonstrated a satisfactory safety profile in post-lateral instrumented fusions evaluated over different follow-ups. No patient displayed systemic toxicity and/or ectopic bone formation. Radiographically, the Brantigan classification showed fusion success rate was approximately 100% at 12 months of follow-up, considering the levels with C, D, and E grades of the Brantigan classification, as well as a significant increase of bone density by CT from 6 to 12 months of follow-up. The limitations of the study stemmed from the low number of subjects enrolled, which was exacerbated by the worldwide COVID-19 pandemic that severely reduced surgical activities during 2020-2021. However, the results from this pilot study permitted the provision of reliable considerations in terms of performance and safety of vBMA clot in comparison to other graft substitutes used alone or in combination with un-clotted BMA.
SIGNIFICANCE/CLINICAL RELEVANCE: This prospective pilot study shows the efficiency and the safety profile of vBMA clot as advanced bio-scaffold able to achieve posterior lumbar fusion in the treatment of degenerative spine diseases, laying the groundwork for a larger randomized clinical study.

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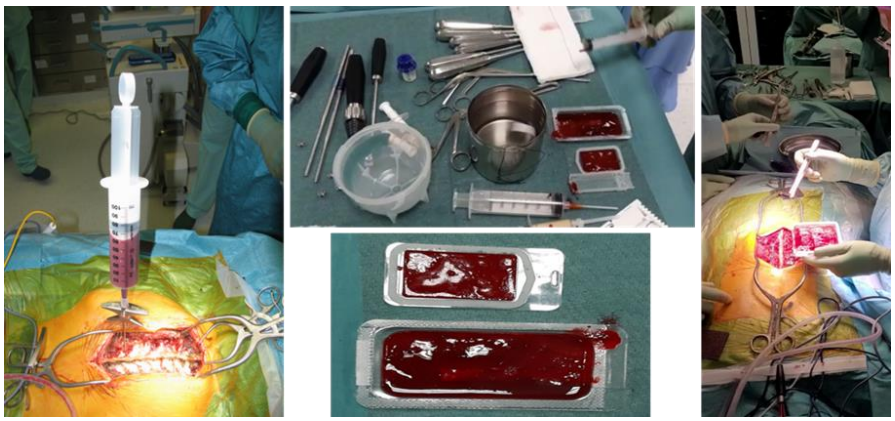

Figure 1: Method used to clot and use the vBMA in the clinical scenario.