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Superiority of Bone Marrow Derived-Osteoblastic Cells (ALLOB®) over Bone Marrow Derived-Mesenchymal Stem Cells

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Abstract : Bone Therapeutics is a bone cell therapy company addressing high unmet medical needs in the field of bone fracture repair, more specifically in non-union and delayed-union fractures where the bone repair process is impaired. The company has developed a unique allogeneic osteoblastic cell product (ALLOB®) derived from bone marrow which is currently tested in humans in the indication of delayed-union fractures. The purpose of our study was to directly compare ALLOB® vs. non-differentiated mesenchymal stem cells (MSC) for their in vitro osteogenic characteristics and their in vivo osteogenic potential in order to determine which cellular type would be the most adapted for bone fracture repair. Methods: Healthy volunteers' bone marrow aspirates (n=6) were expended (i) into BM-MSCs using a complete MSC culture medium or (ii) into ALLOB® cells according to its manufacturing process. Cells were characterized in vitro by morphology, immunophenotype, gene expression and differentiation potential. Additionally, their osteogenic potential was assessed in vivo in the subperiosteal calvaria bone formation model in nude mice. Results: The in vitro side-by-side comparison studies showed that although ALLOB® and BM-MSC shared some common general characteristics such as the 3 minimal MSC criteria, ALLOB® expressed significantly higher levels of chondro/osteoblastic genes such as BMP2 (fold change (FC) > 100), ALPL (FC > 12), CBFA1 (FC > 3) and differentiated significantly earlier than BM-MSC toward the osteogenic lineage. Moreover the bone formation model in nude mice demonstrated that used at the same cellular concentration, ALLOB® was able to induce significantly more (160% vs.107% for control animals) bone formation than BM-MSC (118% vs. 107 % for control animals) two weeks after administration. Conclusion: Our side-by-side comparison studies demonstrated that in vitro and in vivo, ALLOB® displays superior osteogenic capacity to BM-MScs and is therefore a better candidate for the treatment of bone fractures.

Keywords : gene expression, histomorphometry, mesenchymal stem cells, osteogenic differentiation potential, preclinical
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