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Imaging Evidence of Tissue Regeneration with Cultured Mesenchymal Cells (CMC): Results from Clinical Trials and Authorised Personalised Treatments

Cultured Mesenchymal Cells (CMC) constitute an Advanced Therapy Medicinal Product (ATMP) subject to validation through clinical trials for demonstration of efficacy, differentiating them from other products obtained by processing bone marrow or adipose tissue, as well as from synthetic products such as exosomes or secretomes, which should equally undergo clinical trials as they are considered medicinal products. The purpose of this study is to present imaging evidence of structural tissue regeneration achieved with CMC across multiple musculoskeletal indications. ITRT has developed a complete circuit comprising bone marrow aspiration, cell isolation and expansion in a clean room under GMP standards, release of the medicinal product with specifications for cell dose, viability, production date, expiry date, and phenotypic characterisation, clinical application, and cryopreservation of surplus cells. Treatments were performed under clinical trial protocols authorised by the AEMPS or through individual compassionate use authorisations, employing autologous, allogeneic, and cryopreserved formulations. The clinical trial in patellar tendinopathy demonstrated excellent results in both clinical parameters and structural tissue regeneration. Compassionate use treatments for Achilles tendon, supraspinatus tendon, and hamstring tendon showed clinical improvement accompanied by tissue regeneration objectifiable by magnetic resonance imaging. Additionally, cases of regeneration in bone, intervertebral disc, and articular cartilage are presented. In conclusion, CMC manufactured as a medicinal product in a clean room, with certified quality control and clinical trial validation, provide objective evidence of structural tissue regeneration across multiple musculoskeletal indications.

Keywords

Cultured Mesenchymal Cells, ATMP, structural regeneration, clinical trial, GMP manufacturing,musculoskeletal

Biography

Mr Francesc Malagelada is a Trauma and Orthopaedic surgeon at The Royal London Hospital NHS Barts Trust and Clinical Associate at ITRT London. He has particular expertise in sports injuries, foot deformities and complex trauma cases. He has a keen interest in non-surgical treatments, minimally invasive surgery and arthroscopy, practising in orthobiologics and stem cell treatments. He holds a PhD in minimally invasive surgery of the foot and has published extensively with over 80 papers and book chapters. He serves as Honorary Senior Lecturer at Queen Mary University of London, teaching on a Masters degree in orthopaedic trauma sciences.

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