

**Type of presentation:**

Podium willing to present as poster.

**TITLE:**

CLINICAL TRIAL OF BONE MARROW STROMAL STEM CELL IMPLANTATION FOR REFRACTORY FRACTURE NON-UNION. RESULTS FROM THE FIRST PATIENTS.

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**INTRODUCTION:**

This research aims to study the efficacy of Bone Marrow Stromal Stem Cell (BMSSC) implantation on healing of refractory fracture non-union.

**METHODS:**

Twelve patients (9M and 3F), age range 38 to 76 years (mean 49.9) with non-union resistant to multiple previous treatments (mean 3.75 procedures) were included in a study approved by the local Research Ethics Committee. Four had tibial and eight had femoral fractures

The patients were admitted for harvesting of stromal cells by bone marrow aspiration from the iliac bone. BMSSC were culture-expanded for three weeks to an average of  $5 \times 10^6$  cells. At implantation the non-union site was decorticated and BMSSC added to synthetic bone graft substitutes (different types) on one side of the fracture (medial or lateral) according to randomisation. The other side received bone graft substitute alone. The side treated with cells was blinded to patient, surgeons and radiologists.

Standard radiographs were taken and evaluated by experienced musculoskeletal radiologists. The extent of callus formation on each side was recorded. In equivocal cases computerized tomography (CT) was also obtained.

**RESULTS:**

No patient developed systemic complications related to the procedure. On follow-up callus formation was present in 9 of 12 patients. Callus was more marked on the cell implantation side in 6/12 patients (50%), control side in 1/12 (8.3%) and equal in 2 patients. 3 patients showed no change.

**DISCUSSION:**

These findings suggest that implantation of BMSSC can enhance bone formation in persistent nonunion. A larger randomized controlled trial will follow to test this new treatment.