

# Bone Augmentation of Atrophic Alveolar Ridges Using a Synthetic Bone Substitute With Mesenchymal Stem Cells: A randomized, Controlled Clinical Trial

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## Introduction

The 3D reconstruction of maxillary bone defects caused by infection, trauma, rare disease or tumor lesions) is a major challenge in oral surgery.

The current standard treatment, based on autogenous bone block graft, has some

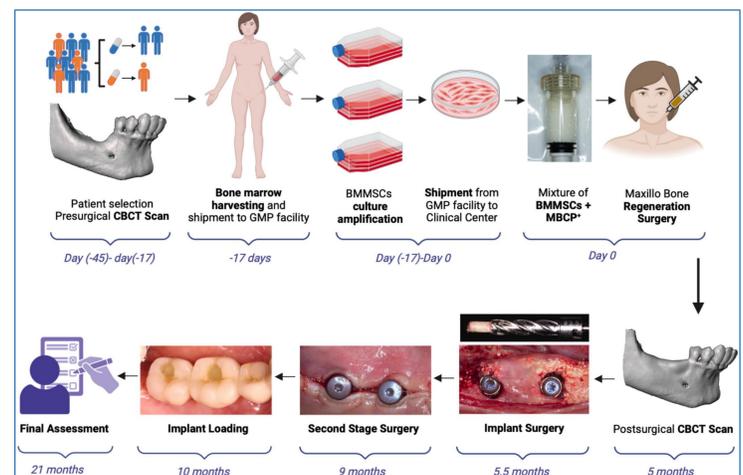
drawbacks:

- increased patient morbidity related to graft harvesting
- intra- or post-operative complications

Objectives:

We aimed to assess the efficacy and safety of a cell based innovative therapy for 3D bone augmentation of severe alveolar bone defects prior to dental implant placement as an alternative to the standard treatment.

## Experimental design of the cell based therapy



## Results

A phase 2 randomized controlled clinical trial to evaluate the bone regenerative innovant cell therapy compared to standard procedure

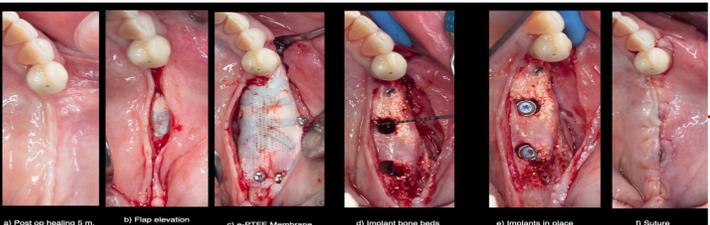
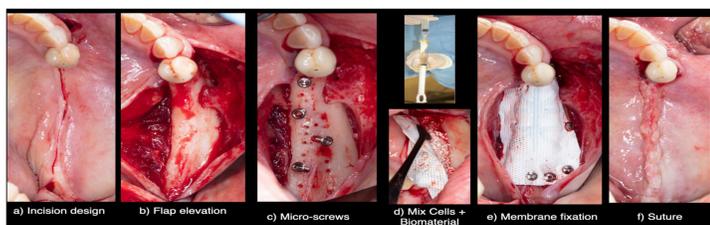
### Test Group

Patients received a graft based on:

- Autologous iliac crest-derived Mesenchymal Stem Cells
- Seeded on a synthetic granular bone substitute biomaterial

### Surgical Interventions:

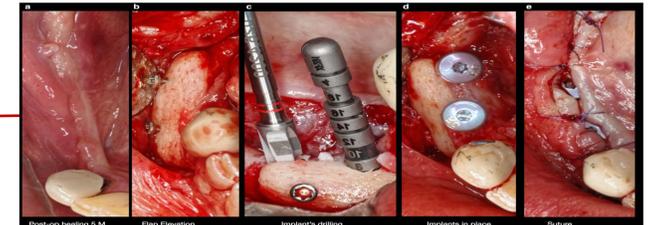
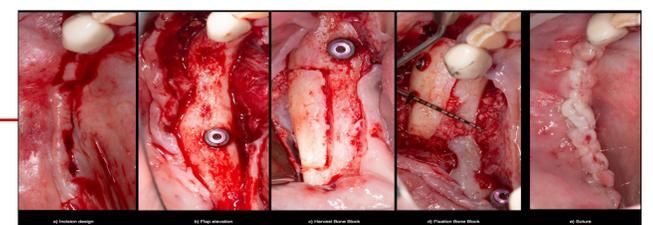
Bone Regeneration Surgery (Day 0)



### Control group

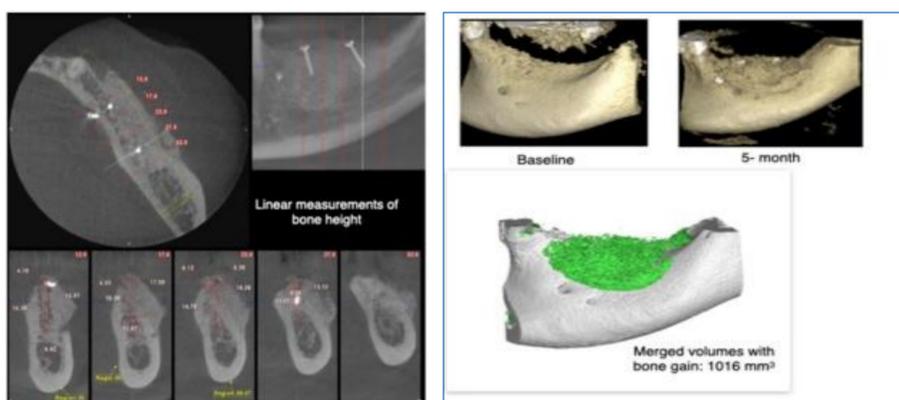
Patients received an:

- Autologous jaw bone block graft
- From the mandibular ramus

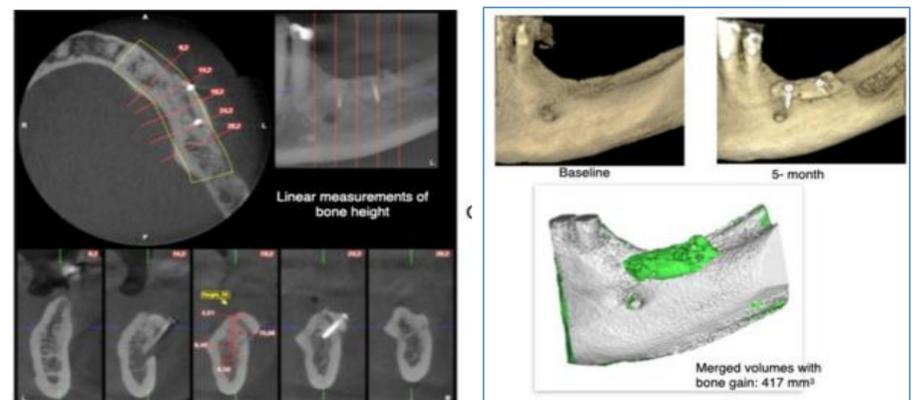


### Radiographic measurements:

#### Test Group

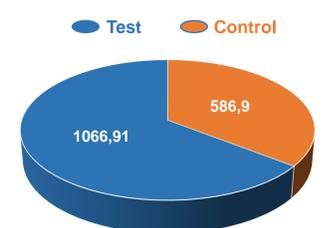


#### Control group



Bone volumetric changes assessment by superimposing two cone-beam computerized tomography (CBCT) scans: one taken prior to the regenerative surgery and other before the implant surgery in both test and control groups.

- The tested intervention demonstrated significant greater gains in bone volume : mean difference of 480 mm<sup>3</sup> (p = 0.032)
- The mean change in bone crest volume from baseline to 5 month was higher in the test group compared to the control group
- Implants were placed on the regenerated bone and were integrated in both groups.
- Adverse reactions and patient morbidity were minor in both groups



Volumetric bone changes between baseline and 5 months post augmentation surgery (mm<sup>3</sup>)

## Conclusions

- The proposed cell based regenerative intervention for three-dimensional maxillary bone volume augmentation prior to dental placement was effective and safe.
- The significant gain of bone volume led to the placement of implants
- This innovative therapy, proven effective in maxillary bone reconstruction, could be extended to other sites requiring bone reconstruction in maxillofacial surgery or general orthopedics.

## Maxibone Study Information

European Project H2020: Personalised Maxillofacial Bone Regeneration, the Maxibone Project

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