

PMCF Report, 26th May 2022

#DS6LM



SpherHA (Synthetic bone substitute)

Based on bio-mimetic nano-structured hydroxyapatite; available in dense granules, porous chips, injectable paste, and moldable crunch in a wide range of sizes. Produced by Tiss'You.



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Collygen

Collagen membrane made from highly pure type I atelocollagen of equine origin, produced by Tiss'You.



Post-extraction sockets

Guided Bone Regeneration



31 patients

26-66 years



Bone defects

Surgical cleaning, bone filling, and membrane application



Up to 6 months

of follow-up



Probing depths and X-rays

outcomes

Background

Regenerative therapy in dentistry involves the replacement and/or regeneration of oral tissues altered as a result of disease or injury. Furthermore, traumatic extraction has also been associated with additional loss of bone. In the healing phase after extraction, alveolar bone undergoes additional atrophy as a result of the natural remodelling process. This begins immediately after extraction and may result in up to 50 % resorption of the alveolar ridge with impact on dental implant placement.

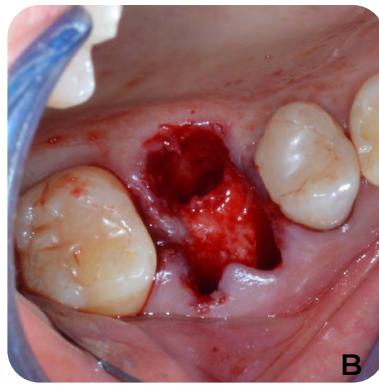
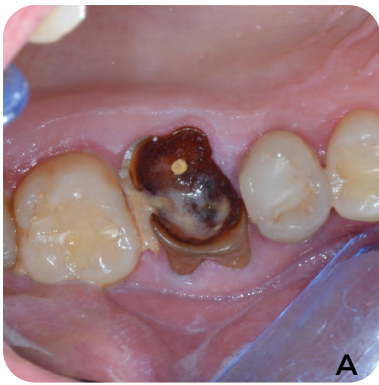
Post-extractive socket preservation procedures aim to prevent alveolar ridge atrophy and maintain adequate dimensions of bone in order to facilitate implant placement. Here we report the clinical results of a guided bone regeneration strategy tackled with a synthetic biomimetic nanostructured hydroxyapatite, and an absorbable equine-derived collagen membrane.

Methods

In this prospective study, we aimed to comprehensively address the treatment outcomes for post-extractive sockets in 31 patients. The chosen intervention encompassed a multi-faceted approach involving meticulous surgical cleaning, augmentation with SpherHA synthetic bone granules (Tiss'You), and the utilization of Collygen, an absorbable collagen membrane (Tiss'You). The membrane was securely affixed using a criss-cross suture technique applied to the mucosal flaps. A photo-

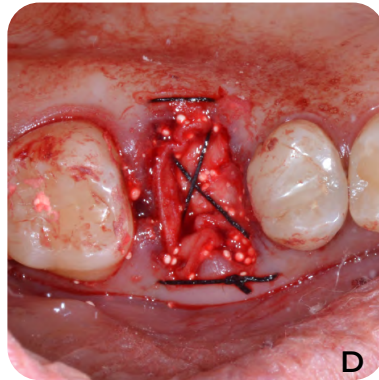
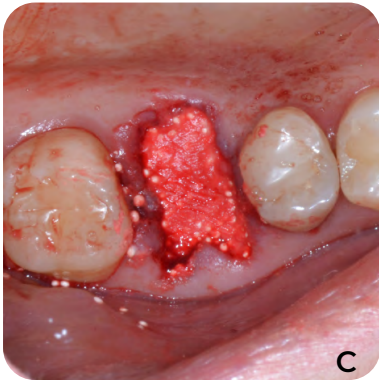
graphic section showing the treatment protocol is available in the next page.

Primary objective was to assess bone remodeling by measuring probing depths at various distances (central, medial, distal, lingual/palatine, and vestibular) at baseline, 3 months, and 6 months. X-ray images were also obtained at these time points to further understand changes in bone density and structure.



A. Defect before tooth extraction.

B. Post-extraction site and surgical cleaning.



C. Bone filling with synthetic nanostructured hydroxyapatite*.

D. Collagen membrane application†.

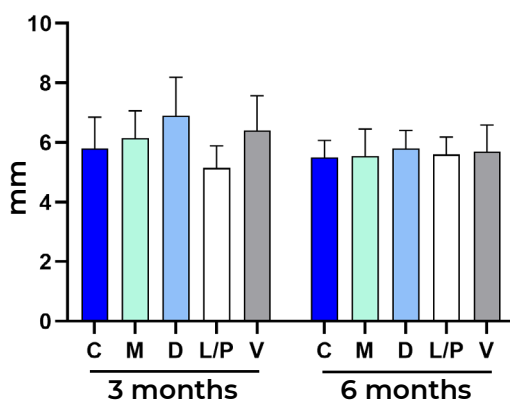
* either dense granules, porous chips, injectable paste, or mouldable crunch

† the membrane is held with a criss-cross suture of the mucosal flaps

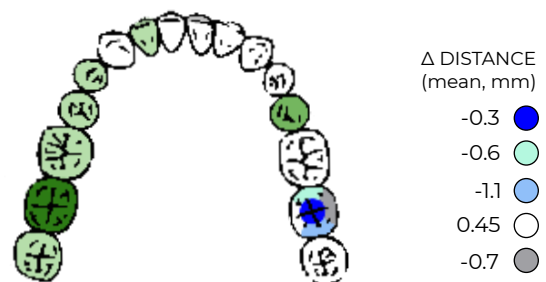
Results

The study revealed no adverse effects, ensuring the safety of the treatment. Post-operative pain averaged 3.2 ± 1.1 at 15 days, demonstrating manageable discomfort. Encouragingly, no patients reported pain at the 3 and 6-month follow-ups. Additionally, early-stage soft tissue

healing was observed and confirmed at 3 months, while X-Rays indicated successful bone regeneration at 3 and 6 months. Probing depths consistently affirmed optimal bone regeneration throughout the study duration.



Probing in central (C), medial (M), distal (D), lingual/palatin (L/P), and vestibular (V) sites.



Graphic representation of (left) treated teeth prevalence (darker stands for higher number of sites) and (right) mean distance change in probing sites between 3 and 6 months.