Study of guided bone regeneration at implant sites using a new native bilayer collagen membrane

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**Background:** Collagen membranes are used in Guided Bone Regeneration (GBR) to enhance osteogenesis by excluding faster-growing epithelial tissue from the treatment site. Australia's geographical isolation and stringent animal health regulations reduce the risk of zoonoses from xenographic materials. We have developed an Australian-sourced native bilayer porcine collagen membrane with suitable physical characteristics for GBR treatment in dental and maxillofacial applications.

**Aim/Hypothesis:** To characterise the physical-chemical properties of CelGro™, a newly-developed native bilayer porcine collagen membrane, and to evaluate its clinical performance in guided bone regeneration treatment of bone defects surrounding dental implants.

**Material and Methods:** The native bilayer collagen structure of the porcine source material was preserved during the patented purification process that removed lipids, nucleic acids, & other cellular impurities. Purity was assessed by imaging and chemical analysis. Patients (N = 10) who fulfilled the eligibility criteria were enrolled in the clinical study. Study participants received two-stage dental implant treatment with simultaneous GBR using CelGro™ & void-filling material (natural bone mineral). Implant sites were allowed to heal for 6 months before re-entry surgery. Mucosal tissue conditions and evidence of wound dehiscence or membrane exposure were recorded during the healing period. Quality of newly formed bone (QT scale) was assessed at the time of re-entry surgery. Vertical (defect height) & horizontal (facial bone wall thickness) dimensions of the implant site were measured immediately after implant placement (baseline) and prior to re-entry surgery by CBCT scan.

**Results:** Porcine lipids, DNA, and α-Gal epitope were not detected in CelGro™ samples. Western blotting & imaging (SEM, micro-CT) of CelGro™ showed pure type I collagen bundles in a bilayer structure, with two distinct surface topologies. Aligned collagen bundles form a barrier structure on one side, with the other being composed of loosely packed collagen bundles, facilitating cell migration & tissue integration. In the clinical study, a total of 16 implants were placed in 10 participants. CelGro™ demonstrated excellent handling characteristics during surgery. Mucosal healing was successful at all sites, with no adverse tissue reactions, adverse events, or membrane exposures observed. Void filling material was fully integrated into the newly formed bone with (mean QT score = 4.6) and each implant demonstrated sufficient bone volume to proceed to completion of implant therapy. Defect height was significantly reduced and facial bone wall thickness increased at re-entry compared to baseline.

**Conclusions and Clinical Implications:** CelGro™ is an Australian-sourced native porcine collagen membrane with excellent biocompatibility and handling characteristics. High quality bone was regenerated at all implant sites, resulting in increases in bone volume in both vertical and horizontal dimensions. The results of this study indicate that CelGro™ collagen membrane can be used in GBR treatment to preserve or restore bone volume required for successful functional and aesthetic outcomes in dental implant treatment.