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IMPLANT THERAPY OUTCOMES, PERI-IMPLANT BIOLOGY ASPECTS

Clinical case series study of a new bilayer collagen membrane for guided bone regeneration

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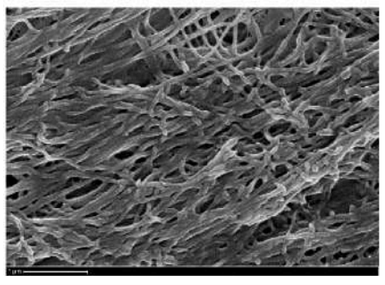
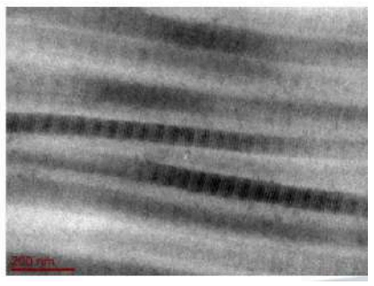
Abstract

Loss of bone volume through resorption is a natural consequence after tooth loss or extraction. Preservation or restoration of bone volume may be necessary for successful functional and aesthetic outcomes after implant placement. In resent study and technique, guided bone regeneration (GBR) is used to preserve or augment bone volume around dental implants. Technically, there are 2 main components in GBR materials: Void-filling material (e.g. autogenous bone, natural bone mineral) and Barrier membrane (usually collagen). Collagen membrane acting as a barrier membrane has been accepted but the source and purification is still the concern that might affect the clinical outcomes. Here the highly purified porcine type I collagen, sourced from and manufactured in Australia by Orthocell Ltd was utilised in this study to evaluate the guided bone regeneration capacity.

CE *Awarded for dental guided bone regenerati (GBR) in November 2017*





Background and Aim

Background: Collagen membranes are used in Guided Bone Regeneration (GBR) to enhance osteogenesis by excluding faster-growing epithelial tissue from the treatment site. Purification processes can disrupt native collagen structure, reducing resistance to biodegradation. Increasing degradation resistance may lead to higher quality or quantity of regenerated bone. The CelGroTM manufacturing process was developed to preserve the natural stability & strength of collagen, without compromising biocompatibility.

Aim: To evaluate the clinical performance of CelGroTM, a native bilayer porcine collagen membrane, in guided bone regeneration for bone defects surrounding dental implants.

Methods and Materials

A prospective case series study enrolled patients who required dental implant treatment with GBR. Patients who fulfilled the eligibility criteria (N=20) received dental implant treatment with simultaneous GBR using CelGroTM & void-filling material (natural bone mineral) (Fig. 1). Implant sites were allowed to heal for approximately 6 months before re-entry surgery (two stage) or restoration (single stage). Mucosal tissue conditions and evidence of wound dehiscence or membrane exposure were recorded during the healing period. The quality of newly formed bone was assessed using the QT scale or CBCT scan at the end of the healing period (two stage or single stage implants, respectively). Vertical (defect height) & horizontal (facial bone wall thickness) dimensions of the implant site were measured using CBCT scan immediately after implant placement (baseline) and at the end of the healing period (Fig. 2).

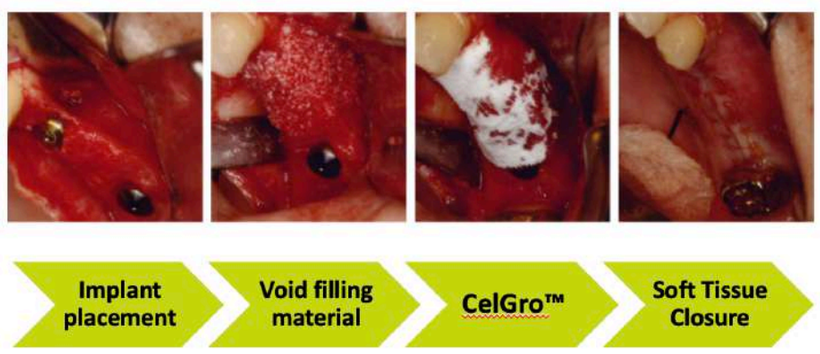


Figure 1. Surgery procedure with CelGro.

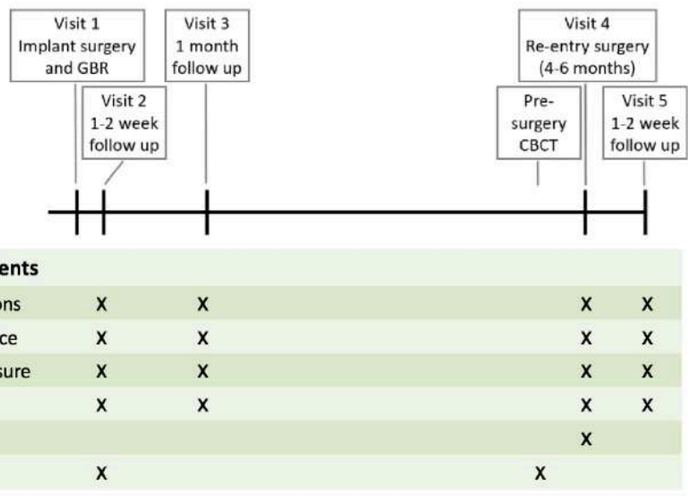


Figure 2. Study time point and assessments.

Results

A total of 27 implants were placed in 20 participants (16 two stage, 11 single stage). CelGroTM demonstrated excellent handling characteristics during surgery. Mucosal healing was successful at all sites, with no adverse tissue reactions, adverse events, or membrane exposures observed (Fig. 3). At the completion of the healing period, CBCT scan demonstrated that sufficient bone was regenerated around each implant to proceed to completion of implant therapy. The regenerated bone was of a density comparable to mature cortical bone. QT scale assessment was consistent with CBCT scan. The median QT score = 5 (maximum score for bone regeneration), indicating that void filling material was fully integrated into mature bone (Fig. 4, 5). CBCT measurement of bone dimensions demonstrated that defect height was significantly reduced and facial bone wall thickness increased compared to baseline.

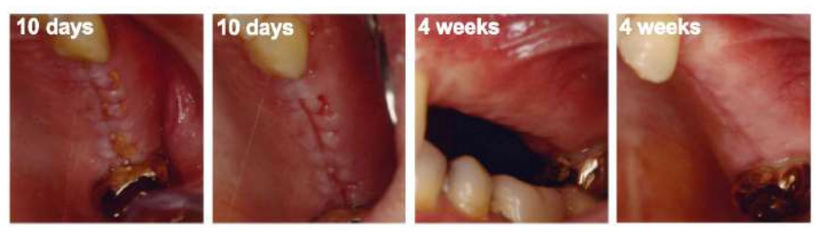


Figure 3. Mucosal healing after GBR with CelGro

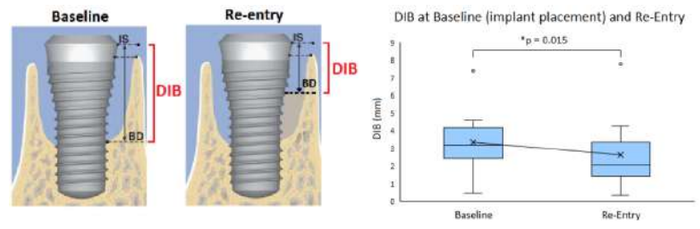


Figure 4. DIB after healing with CelGro

Figure 5. CBCT scan of bone regeneration

Conclusion

CelGroTM is a native porcine collagen membrane with excellent biocompatibility and handling characteristics. High quality, mature bone was regenerated at all implant sites, resulting in bone regeneration in both vertical and horizontal dimensions. The results of this study indicate that CelGroTM 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.

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