Comparison of Guided Bone Regeneration using a Bovine Collagen Membrane vs a Calcium Sulfate Barrier

Ibtisam Al-Hashimi, Jeffrey A Rossmann

ABSTRACT
Resorbable membranes have eliminated the need for re-entry for removal and reduce the incidence of adverse soft tissue reactions that accompany membrane exposure. However, the lack of rigidity often makes these more prone to collapse. Calcium sulfate has shown promise as a regenerative material alternative in a socket preservation application. The purpose of this study was to compare calcium sulfate and bovine collagen as a barrier in guided bone regeneration.

Materials and methods: Eighteen sites were treated in this randomized, blinded clinical study. Patients were divided into 2 groups, 9 sites each. Group 1, had bovine collagen membrane (Ossix™) and group 2 had calcium sulfate barrier (CalciGen Oral™) to cover the graft. All sites were augmented with autogenously bone and demineralized freeze-dried bone composite graft at 1:1 ratio. Implants were placed in the grafted area 4 to 6 months post grafting. Vertical and horizontal ridge measurements were made before and after grafting by two blinded examiners.

Results: The collagen membrane group had a mean bone gain of 1.06 ± 1.01 mm in width and 0.19 ± 1.11 mm in height. In comparison, the calcium sulfate group had a mean bone loss of −0.14 ± 0.74 mm in width and −0.19 ± 0.74 mm in height. Student t-test revealed a significant difference in width dimension between the two groups, p = 0.01.

Conclusion: Overall results of this study suggest that calcium sulfate might have limited use as barrier for ridge augmentation.

Keywords: Guided bone regeneration, Collagen membrane, Calcium sulfate, Membranes, Ridge augmentation.


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Conflict of interest: None declared

INTRODUCTION
Guided bone regeneration (GBR) is based on the concept of creating a space that allows cells producing a desired type of tissue to grow while excluding undesired cell types. Often, clinical decisions made regarding what type of materials to use for GBR include: the type of bone or bone mixture, the type of membrane, and the use of growth factors. The critical criteria regarding membranes for GBR that have been established include: biocompatibility, cell occlusiveness, integration by the host tissues, clinical manageability and the space making function. In addition, the tissue reactions resulting from the resorption of bioresorbable membranes should be minimal, reversible and they should not adversely influence the regeneration of the desired tissues.

Collagen membranes usually tolerate exposure and do not require a second stage surgery for their removal. They are hemostatic, chemotactic for fibroblasts, and are effective at inhibiting epithelial migration and promoting new connective tissue formation. Numerous authors have reported on the successful use of collagen membranes in GTR and GBR procedures. One disadvantage of these membranes is a lack of rigidity.

Calcium sulfate (CS) consists of medical grade plaster of Paris (calcium sulfate alpha-hemihydrate) that hardens when set. Dreesman first reported the use of calcium sulfate as a bone graft material in 1892. Animal studies have shown CS to be osteoconductive. CS does not inhibit normal bone formation and has an average resorption rate of 4.7 weeks. CS has also been shown to support fibroblast migration, be occlusive to soft tissue, and is angiogenic. Many authors have reported on the successful use of calcium sulfate in human periodontal defects, extraction sockets, around implants and in sinus lift procedures. They reported that it was an effective barrier membrane, had angiogenic properties, served a hemostatic function, was an effective pharmaceutical/growth factor delivery vehicle and could be used in combination with other bone graft materials. Despite the widespread success of CS in several clinical applications, reports as to its use in guided bone regeneration for ridge augmentation are limited. The purpose of this study was to clinically compare CS vs bovine collagen as a membrane in GBR procedures in humans.

MATERIALS AND METHODS
Eighteen sites in 15 patients (7 men and 8 women) were evaluated in this randomized, blinded clinical trial. There were nine sites in the collagen membrane group and 9 sites in the CS group (Table 1). All sites were located in the maxilla and the posterior mandible (Table 2). None of the sites were located in the anterior mandible. All patients signed an informed consent to clinical research approved by The Baylor College of Dentistry Institutional Review Board for the Protection of Human Subjects. To enroll in the study patient must require a single implant in either maxilla or mandible. Patients with poor oral hygiene, smokers, history of head and neck radiation therapy, or serious systemic illness were excluded from the study.

A computer generated randomization determined whether sites would be augmented with collagen membrane...
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JCD (DFDBA + autogenous + collagen membrane), group 1, or with calcium sulfate barrier (DFDBA + autogenous + CS), group 2. Three blinded examiners not performing any of the surgeries made all clinical measurements during the course of the study (DGK, WWH, TWS). At least two examiners made measurements for each surgery. Measurements from the buccal-lingual and occlusoapical parts of the vacuum-formed retainer were taken to the nearest half-millimeter with a University of North Carolina periodontal probe (Figs 1A and B). The measurements were repeated if they differed by more than 1 mm until the difference between the examiners was less than or equal to 1 mm; then they were averaged, except for 51 of the 252 paired measurements (20%) there was >1 mm difference between the two examiners. The horizontal ridge augmentation procedure was performed according to the methods outlined by Buser et al.39,40 A full thickness flap was reflected and measurements to the exposed bony ridge were taken for height and width (buccal-lingual and occlusoapical). The cortical plate was perforated with a ½ round bur in the area receiving the bone graft. DFDBA (250-710 µm cortical particles; LifeNet, Virginia Beach, Va) was hydrated in sterile saline and mixed 50:50 volume ratio with autogenously bone obtained with a Safescraper® (Biomet 3i, Palm Beach Gardens, FL). For group 1, 1 to 2 mm thick CS putty was placed over the grafted site and allowed to set. While group 2, the grafted was covered with collagen membrane. The flap was sutured with 5-0 polyglactin 910 sutures (Vicryl Rapide™, Ethicon, Cincinnati, OH).

Postoperatively, patients were prescribed amoxicillin 500 mg three times daily for 7 days (clindamycin 150 mg four times daily for 7 days was used in case of allergies to penicillin), ibuprofen 400 mg every 4 to 6 hours for 2 days (then as needed) chlorhexidine 0.2% rinse ½ oz. twice daily for 3 weeks. The patients were seen on a weekly basis until soft tissue healing had occurred. Supragingival plaque was removed and oral hygiene was reinforced at these visits. The sutures were removed at 1 to 3 weeks.

After 4 to 6 months of healing, all the sites were re-entered and the implant was placed (Certain® Prevail®, Biomet 3i, Palm Beach Gardens, FL). The same blinded examiners repeated the buccolingual and occlusoapical measurements (Figs 2 and 3).

The primary variables evaluated were the increase in ridge dimensions found in this study are less than those reported by Kirkland et al. When using a

<table>
<thead>
<tr>
<th>Table 1: Patient distribution</th>
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<tbody>
<tr>
<td>Collagen (n = 9)</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Age (mean ± SD) (range) years</td>
</tr>
</tbody>
</table>

*CS: Calcium sulfate

<table>
<thead>
<tr>
<th>Table 2: Site distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collagen (n = 9)</td>
</tr>
<tr>
<td>Posterior maxilla (1st molar to 1st premolar)</td>
</tr>
<tr>
<td>Anterior maxilla (canine to canine)</td>
</tr>
<tr>
<td>Posterior mandible (1st molar to 1st premolar)</td>
</tr>
</tbody>
</table>

*CS: Calcium sulfate

Figs 1A and B: Measurements taken with the UNC periodontal probe and the vacuum formed retainer: (A) buccal-lingual, (B) occlusoapical

RESULTS
There was a significant correlation between the 2 evaluators for all measurements (p = 0.05 and p = 0.01), which allowed averaging the measurements obtained by the 2 examiners. Table 3, shows changes in height and width for groups 1 and 2. There was a net gain in width and height for the collagen group; whereas there was a net loss in width and height for the CS group. Overall there was a significant in the width dimension between the two groups, p = 0.01.

DISCUSSION
The gains in ridge dimensions found in this study are less than those reported by Kirkland et al. When using a
polylactide membrane over a composite bone graft consisting of DFDBA, bioactive glass and doxycycline hyclate granules to augment isolated alveolar ridge defects bordered by teeth. At 12 months, Kirkland et al determined there was an increase in ridge width of 3.3 mm, and increase in ridge height of 1.9 mm. They reported a decrease in soft
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Table 3: Comparison of mean difference in ridge height and width with collagen membrane vs calcium sulfate

<table>
<thead>
<tr>
<th>(Mean ± SD) mm</th>
<th>Collagen (n = 9)</th>
<th>Calcium sulfate (n = 9)</th>
<th>p†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>1.06 ± 1.01</td>
<td>−0.14 ± 0.74</td>
<td>0.01</td>
</tr>
<tr>
<td>Width</td>
<td>0.19 ± 1.11</td>
<td>−0.19 ± 0.74</td>
<td>0.66</td>
</tr>
</tbody>
</table>

†Student's t-test

Although, some authors have reported on the successful use of calcium sulfate as a barrier over noncomposite bone as well as a sole graft material/barrier, the clinical outcome may have been different had the calcium sulfate been mixed in with the bone graft. This may have made the composite graft more solid and reduced the risk of cracking of the barrier. It is also important to consider that the calcium sulfate barrier may have been too thin and may simply resorb too rapidly for effective GBR regardless of the added stability that mixing it with the bone graft may provide. A slowly resorbing calcium sulfate-based bone graft material may provide a better outcome.

CONCLUSION

Calcium sulfate has been shown to be useful for the treatment of periodontal defects, ridge preservation procedures and sinus lift procedures. However, the results of this study appear to support limited use of calcium sulfate as a membrane in guided bone regeneration procedures.

REFERENCES


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