Comparative Clinical Study of The Use of Coralline Calcium Carbonate as a Graft Material and Open Flap Debridement Alone for Treatment of Human Periodontal Infrabony Pockets

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Abstract

The purpose of this study was to evaluate the clinical response to coralline calcium carbonate (CalCarb) bone replacement graft material in human infrabony periodontal pocket, and compares to open flap debridement. Twenty two patients completed the study with clinical data collected at baseline and after 6 months post-treatment. (14 males, 8 females; average age 42.77 ± 10.27, range 27 to 58 years) (11) patients received CalCarb grafts and (11) patients received open flap debridement (OFD) alone in randomly selected patient as part of their planned infrabony pocket defect correction surgery. Parameters measured in this study (clinical probing depth, gingival recession, clinical attachment level). Statistical analysis for data with the use of a statistical software program at baseline and after 6 months, the mean value of postsurgical pocket depth parameter for patients treated with CalCarb was highly significant difference higher than presurgical mean value for the same parameter, these results consist with other many studies (19-24). For the mean values for the reduction of pocket depth (3.76 ± 1.68) and gaining of clinical attachment level (3.50 ± 0.71) were higher in patients treated with CalCarb, than those treated with OFD (3.30 ± 0.79) (2.97 ± 0.45) respectively. Natural coralline porous calcium carbonate appears to be a clinically useful graft material.

Key words: Grafts, bone; periodontal diseases/surgery; surgical flaps; calcium carbonate; debridement.

Introduction

The primary goal of periodontal treatment is the maintenance of the natural dentition in health and comfortable function (Zander HA 1976). When periodontal disease has caused a loss of the attachment apparatus, optimal care seeks to regenerate the periodontium to its pre-disease state. Regeneration has been defined as the reproduction or reconstitution of a lost or injured part to restore the architecture and function of the periodontium (American Academy of Periodontology, 1992). To be considered a regenerative modality, a material or technique must histologically demonstrate that bone, cementum and a functional periodontal ligament (a new attachment apparatus) can be formed on a previously diseased root surface. Bone grafts and their synthetic substitutes have been used in an attempt to gain this therapeutic endpoint (Bassam 2011, Daniel 2011 Andreas 2011). The use of bone grafts for reconstructing osseous defects produced by periodontal disease dates back to Hegedus in 1923 (Hegedus Z 1923) and was revived by (Nabers & O’Leary 1965). A number of synthetic or inorganic graft materials are available for use in the treatment of intrabony lesions. Number of reviews (: American Academy of Periodontology, 1993,

The synthetic materials can be classified by their ability to be bioabsorbed. The absorbable materials include the ceramics, beta tricalcium phosphate, hydroxyapatite, calcium sulfate and calcium carbonate. The nonabsorbable materials include porous hydroxyapatite, dense hydroxyapatite, bioglass and acalcium-coated polymer of hydroxyethylmethacrylate and polymethylmethacrylate. Controlled studies that have compared the synthetic materials to flap curettage in intrabony defects have shown a clinical advantage to their use (Galgot PN 1992, Shahmiri S 1992, Yukna RA 1989, Yukna RA, 1994, Yukna RA1998). Clinical results are encouraging for these materials based on their biocompatibility, enhancement of clinical attachment levels, reduction of probing depths and hard tissue fill of the intrabony defects. Nevertheless, these materials have not demonstrated the potential for initiating or enhancing new attachment apparatus formation. Calcium carbonate shows promise for bone repair in periodontal defect (Yukna RA1994, Yukna RA 1998, Mora F,1995, Kim C-K 1996, Yukna RA.1990)

Kim et al in 1996 provided a comparison of treatment of intrabony defects with calcium carbonate alone versus a combination of graft and guided tissue regeneration, this study provided clinical outcome with nonsignificant differences for combination graft-barrier membrane compared to a graft alone. A porous coralline calcium carbonate artificial bone replacement graft material that is not altered by processing and is entirely resorbable has become available. It is a natural coral in the form of aragonite (> 98% [CaCO3]). Elements such as fluoride, strontium, and magnesium are present in slightly greater than 1% total concentration. Other metals comprise < 0.005% of the structure, and there is no protein material present. The material possesses a porosity of > 45% with the good interconnections between them. This porosity provides a surface area of > 1 square meter per gram of material. Animal studies have shown progressive resorption by means of enzymatic processes with simultaneous replacement by new bone. (Guillemin G 1987, Souyris F 1985) For periodontal use, it is provided as granules 200 to 500 micrn in diameter. The purified material is sterilized by gamma radiation.

Aim of the study
The purpose of this study was to evaluate the clinical response to coralline calcium carbonate (CalCarb) bone replacement graft material in human infrabony periodontal pocket, and compared to open flap debridement alone.

Materials And Methods
Patient selection
Twenty-two patients in the private clinic and/or patients screened at the Babylon University (Periodontal Department) who were accepted for treatment included reconstructive periodontal surgical procedures that would utilize bone replacement grafts to treat infrabony periodontal pocket. Male and female patients at least 25 years old were selected for the study as they presented with severe periodontal defects. Only those female patients with a negative pregnancy test were allowed to undergo the procedure. Patients selected for the study should be in good physical health, demonstrate an acceptable level of oral hygiene and be committed to a long-term maintenance program.
Ideally, the patient should be a nonsmoker, since the long-term results of regenerative therapy are diminished in smokers (Rosen PS 1996, Rosenberg ES 1994, Tonetti MS 1995). Eleven patients received CalCarb grafts material for the treatment of their periodontal defects, while the other eleven patients received open flap debridement (OFD) only.

**Defect selection**

Each tooth exhibited a probing depth of ≥4 mm on at least one aspect of the tooth, these findings supported by radiographical picture, furcations and dehiscences were excluded.

Gingival coverage of the graft is important in its containment post surgery. Though recession and soft tissue cratering and friability do not preclude a grafting procedure, they may reduce the chance of success if they are extensive.

**Preoperative preparation**

Patients should be required to perform plaque control to an acceptable level. Postoperative gains in clinical attachment levels have been the greatest following regenerative therapy when plaque control is optimal (Cortellini P 1994). Occlusal therapy consisting of adjustment or splinting of teeth should be accomplished prior to surgery to reduce or eliminate excessive mobility or fremitus patterns. The literature suggests that teeth with demonstrable mobility have a poorer long-term outlook after surgery (Wang HL 1994).

**Clinical Measurements**

The clinical measurements by using periodontal probe (Williams) after at least one week from scaling and polishing visit. At the baseline visit (second visit) and 6 months after treatment, the following clinical parameters were measured:

- Probing depth (PD)
- Gingival recession (GR)
- Clinical attachment level (CAL)

**Anesthesia**

The use of regional anesthesia, where appropriate, ensures patient comfort. The use of local infiltration with epinephrine can facilitate hemostasis. Good hemostasis is important for visualization of the osseous defect and root surface, debridement of the site, and limiting graft displacement (Paul S 2000).

**Flap design**

Preservation of flap tissue is important for regenerative techniques to ensure coverage and containment of the graft post surgically. A sulcular incision is performed on the facial and lingual, with the interproximal space being conserved by either papilla preservation (Cortellini P 1995, Murphy KG 1996 Takei H 1985) or extending the incision interdentally as far as possible. The objective should be preserving the papilla, when the interproximal space between the teeth is wide, the tissue pattern is thick or maintaining aesthetics is essential. The flap should be extended at least one tooth mesial and distal to the graft site.

The flap should be reflected to allow for complete visualization of the intrabony lesion while minimizing the trauma to the soft tissue. Additional care should be taken to avoid either flap perforation or loss of the papilla due to granulomatous tissue from the lesion that adheres to the inner aspect of the flap. The use of either an Periosteal elevator can minimize these undesirable situations. Any granulomatous tissue that may be adherent to the inner surface of the flap or papillae from the lesion should be judiciously removed, which maximizes the space available for graft material. Excessive thinning, however, can compromise blood supply and flap survival.
Defect or root debridement
The defect should be debrided of all soft tissue using hand, ultrasonic, and rotary instruments. Essential for success is the meticulous removal of all hard and soft accretions on the root surface and any clinically affected cemental surface and root anomalies. A saturated solution of either citric acid (pH 1) applied to the root surface to biologically enhance regeneration through removal of the smear layer and residual colonies of bacteria, including possible exposure of collagen fibrils. Excess solution should be removed from the cotton pellets to minimize cellular damage to the adjacent hard and soft tissues (such as bone or periodontal ligament).

Graft management
The CalCarb graft material was mixed with two drops of patient blood(I.V) in a sterile dappen dish. The contents can be hand-mixed with sterilized spatula. The graft is next delivered to the bony defect with a (dedicated) amalgam carrier or a spatula and added in incremental fashion. Light pressure should be used to maintain space between the graft particles to allow neovascularization of the site. The defect should be filled or slightly overfilled to maximize regeneration while not compromising flap closure or vascular supply.

Flap closure
The goal of flap management is to obtain tension-free primary closure over the entire graft or defect complex. This may involve either osteoplasty of ledges or exostoses of bone or scalloping of the flap on the facial and/or lingual aspect to allow abutting of the papillae activity (Yukna RA 1982) and inhibit bacterial growth within the wound. A black silk suture (3-0) using vertical mattress or an interrupted technique. After suturing, slight pressure on the facial and lingual flaps is applied to minimize the clot beneath the flap. It is optional to place a surgical dressing to protect the wound. Placement of a dressing must be accomplished, however, without displacement of the graft or compromise of the blood supply to the gingival flaps for a period of 7 to 10 days, at which time the dressing and sutures were removed. No further dressings were placed unless special conditions dictated otherwise.

Postoperative management/periodontal maintenance
The administration of antibiotics beginning immediately post-surgery is thought to aid in plaque control (Sanders JJ 1983) Amoxicillin 500 mg t.i.d was prescribed for the 10-day immediate postsurgical period. NSAIDs were begun one hour prior to surgery and continued t.i.d for 3 days postsurgically.

Patients should also be placed on a chlorhexidine mouthwash to further aid in this process (Carlos 2011). For the first 4–6 weeks, patients should refrain from brushing the surgical area to prevent disturbance of the blood clot (Garrett S 1993). Postoperative visits are scheduled bimonthly for the second month, and every 3 months thereafter. Sutures are retained as long as they maintain closure and do not contribute to plaque accumulation and inflammation. Postoperative visits include plaque removal (both mechanically and with topical chlorhexidine), selective stain removal and reinforcement of oral hygiene. Patients may receive gingivoplasty of the area if soft tissue cratering is present 6 months post-surgery. Periodontal probing or recording of clinical attachment levels should not be done prior to 6–12 months, since probing force may damage the healing site, thereby diminishing the regenerative outcome.
Statistical Analyses
The changes of pretreatment and post-treatment PD, CAL, and GR measurements were the basis for data analysis with the use of a statistical software program. The paired-samples t-test was used to compare the mean values of presurgical and postsurgical treatment for periodontal pocket depth for each treatment group. While the independent-samples t-test was used to compare the mean scores of all other investigated clinical parameters (reduction of pocket depth, gingival recession and gaining of clinical attachment loss) between the two treatment groups.

Results
Twenty two patients completed the study with clinical data collected at baseline and after 6 months post-treatment. (14 males, 8 females; average age 42.77 ± 10.27, range 27 to 58 years) (11) patients received CalCarb grafts and (11) patients received open flap debridement (OFD) alone in randomly selected patient as part of their planned infrabony pocket defect correction surgery.
Table 1 & 2. showed clinical evaluation of tissue response to the two treatments showed no untoward reactions to either the CalCarb grafting material or to the surgical debridement. In all cases, healing was essentially uneventful. There was no evidence of any unusual adverse responses to the CalCarb graft material.
Table 1 showed a clinical evaluation of presurgical and after surgical treatment of periodontal pocket depth for each treatment group. For the first group (fifty-five defects treated with CalCarb graft) the mean value was lower post surgically treatment than that presurgical treatment and there's high significant difference between them, in the other group (fifty seven defects treated with OFD) the mean value of periodontal pocket depth was also lower in postsurgical treatment than that in presurgical treatment value but there's no significant differences between them.
In table 2. Fifty-five defects which received CalCarb grafts demonstrated non significantly better mean pocket depth reduction (3.76 mm) versus a mean of pocket depth reduction (3.30 mm) for fifty seven defects treated with OFD. While the mean values of pocket depth for both presurgical and after surgical treatment were higher in sites received CalCarb material than sites treated with OFD.
Other findings showed similar clinically superior results for gaining in clinical attachment with the use of CalCarb but there's no significant differences between it and the results of treated with OFD.
At the same time gingival recession findings demonstrate a non significant higher in defects which received CalCarb (1.740 mm) than OFD (1.53mm).
Table 1. Mean values and Standered deviations (±SD) For Presurgical and Postsurgical treatment of Periodontal pocket depth following treatment with Coraline Calcium Carbonate (CalCarb)Graft or Open Flap Debridement alone (OFD) and Significant Differences between them.

<table>
<thead>
<tr>
<th></th>
<th>Presurgical Pocket depth Mean ± SD</th>
<th>Postsurgical Pocket depth Mean± SD</th>
<th>P value</th>
<th>Sign.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cal Carb (55 sites)</td>
<td>5.44 ± 1.61</td>
<td>1.67 ± 0.73</td>
<td>0.007</td>
<td>H.S</td>
</tr>
<tr>
<td>OFD (57 sites)</td>
<td>5.03 ± 1.33</td>
<td>1.4 ± 0.46</td>
<td>0.06</td>
<td>N.S.</td>
</tr>
</tbody>
</table>

Table 2. Clinical results following treatment with Coraline Calcium Carbonate (CalCarb)Graft or Open Flap Debridement alone (OFD) in Human Infrabony Periodontal Pockets.

<table>
<thead>
<tr>
<th></th>
<th>Cal Carb (55 sites) Mean ± SD</th>
<th>OFD (57 sites) Mean± SD</th>
<th>P value</th>
<th>Sign.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease in probing depth</td>
<td>3.76 ± 1.68</td>
<td>3.30 ± 0.79</td>
<td>0.68</td>
<td>Non sig.</td>
</tr>
<tr>
<td>Gingival recession</td>
<td>1.74 ± 0.47</td>
<td>1.53 ± 0.51</td>
<td>0.58</td>
<td>Non sig.</td>
</tr>
<tr>
<td>Gain in clinical attachment</td>
<td>3.50 ± 0.71</td>
<td>2.97 ± 0.45</td>
<td>0.27</td>
<td>Non sig.</td>
</tr>
</tbody>
</table>

Discussion

Twenty two patients participate in this study, to evaluate the clinical outcome (PD, GR and CAL) and re-evaluate these clinical parameters after 6 months of treatment without surgical re-entry. In our society, it is not easy to do surgical re-entry procedure, from ethical point of view. The use of reentry surgery for evaluation may be questioned, but such secondary revision surgery is often necessary in non-research bone graft therapy as the average response in osseous defects is defect fill. Often, this leaves a residual defect that requires further therapy (either additional grafting, debridement, or conservative osseous resection). (Yukna RA 1994)

The physical attributes of the CalCarb material make it appear to be similar to other synthetic bone replacement graft materials such as B-tricalcium phosphate, porous hydroxyapatite, and so-called "resorbable" hydroxyapatite. (White RA 1972, Weber 1973, Roy DM 1974, Chiroff RT 1975, Holmes RE 1979, Ripamonti 1991, Corsair A 1990, Orly I 1989, Shimoda S 1990, Kasperk C 1988) The CalCarb material is chemically different from all of these. Also, although it originates from coral as does porous

The natural calcium carbonate form of this material may provide biologic advantages in that a carbonate phase is required for the initiation of bone formation. Other allogeneic and alloplastic types of bone replacement graft materials need to undergo a surface transformation to carbonate from hydroxyapatite in order to start the bone formation cascade. CalCarb seemingly eliminates this backward conversion step and may allow more rapid progress toward formation of new bone in the site (Guillemin G 1987, Neuman WF 1967, Shimoda S 1990, Rey C 1989). CalCarb provided high benefit compared to surgical debridement (OFD) in the treatment of infrabony pocket associated with chronic periodontitis. These results consist with other many studies (Yukna RA 1994, Mora F 1995, Kim C-K 1996, Yukna RA 1990, Guillemin G 1987).

For mean value of postsurgical pocket depth parameter for patients treated with CalCarb was highly significant difference higher than presurgical mean value for the same parameter. For the mean values for the reduction of pocket depth and gaining of clinical attachment level were higher in patients treated with CalCarb than those treated with OFD only these results agreed with other studies using CalCarb as graft material (19-24) and other studies used other graft materials (Galgut PN 1992, Shahmiri S 1992, Yukna RA 1989). The reduction of probing depth and gain of clinical attachment level were improved in both treatment groups. These improvement might simply reflect a change in tissue composition of periodontal tissues, Armitage GC 1977 and Spray DH 1978 have found that inflammation of gingival tissue has a significant influence on the degree of probe penetration.

CalCarb is of an appropriate size for use in periodontal osseous defects (Zaner DJ 1984). The particle size and shape were also very easy to handle and manipulate during the surgical treatment. It appeared to have good hemostatic properties and was not readily displaced from the treatment sites once a CalCarb/blood coagulum had formed.

Most of this study was conducted in a private periodontal clinic and this environment may have provided some advantages, such as better patient compliance with appointments and plaque control, more routine sequence of therapy, and more realistic application of results to clinical periodontal practice. Since CalCarb appears to provide similar positive clinical results compared to OFD as do other available periodontal grafting materials, it is interesting to speculate on results that might be provided by a comparative study. While such research might provide some specific results, historically there have been few significant or substantial differences from such comparisons. (Strub JR 1979, Krejci CB 1987, Barnett JD 1989, Evans GH 1989)

**Conclusion**

Natural coralline porous calcium carbonate appears to be a clinically useful graft material and achieves essentially similar or slightly better responses in periodontal osseous defects as other bone replacement graft materials.
References
Carols Solís, Antonio Santos, José Nart, and Deborah Violant. 0.2% Chlorhexidine Mouthwash With an Antidiscoloration System Versus 0.2% Chlorhexidine Mouthwash: A Prospective Clinical Comparative Study. J Periodontol 2011, 82, 462-470.


