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ORIGINAL ARTICLE

Clinical results of implant placement in resorbed ridges using simultaneous guided bone regeneration: a multicenter case series

Ioannis Konstantinidis · Tarun Kumar · Udatta Kher · Panagiotis D. Stanitsas · James E. Hinrichs · Georgios A. Kotsakis

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Abstract
Objectives The purpose of this case series was to evaluate the new bone formation following guided bone regeneration (GBR) with a calcium phosphosilicate (CPS), alloplastic bone putty at peri-implant dehiscence defects and to assess survival rate of implants placed in the augmented sites after 12 months of function.
Materials and methods Implants were placed in patients exhibiting Seibert class I ridge defects resulting in peri-implant dehiscence defects. The defects were treated following GBR principles with the use of a CPS alloplastic bone graft putty in combination either with a collagen membrane or a titanium mesh. The height of each bony dehiscence was clinically measured at the time of implant placement and again during second-stage surgery. The percentage of complete defect coverage, frequency of adverse events, and risk factors for residual defect were determined.
Results Thirty-six implants were placed in 26 patients. Twenty-seven of the 36 sites employed a collagen membrane in conjunction with the CPS while the remaining nine sites utilized a titanium membrane. Mean gain in bone height was 3.23±2.04 mm, with 75 % of the peri-implant defects achieving complete regeneration. A negative correlation was identified between patient age and complete coverage of the peri-implant defect ($p=0.026$). The implant survival rate at 12 months was 97.22 %.
Conclusion Use of CPS bone putty during delayed implant placement at peri-implant dehiscence sites either in combination with a collagen membrane or a titanium mesh results in predictable defect coverage.
Clinical relevance The handling characteristics of CPS putty may simplify GBR protocol. Implants placed in conjunction with GBR have a very good survival rate after 1 year of follow-up.

Keywords Calcium phosphosilicate (CPS) · Alloplastic bone putty · Guided bone regeneration (GBR) · Peri-implant dehiscence defects

I. Konstantinidis (✉)
Department of Prosthodontics, TU Dresden, Dresden, Germany
e-mail: ioannis.konstantinidis@uniklinikum-dresden.de

T. Kumar
Bapuji Implant Centre, Bapuji Dental College & Hospital, Davangere, India

U. Kher
Department of Implantology, SDM College of Dental Sciences, Dharwad, India

P. D. Stanitsas
Department of Computer Science and Engineering, University of Minnesota, Minneapolis, USA

J. E. Hinrichs · G. A. Kotsakis
Advanced Education Program in Periodontology, University of Minnesota, Minneapolis, USA

Introduction

Implant placement frequently has to be performed in deficient ridges. As alveolar ridge resorption physiologically occurs following each tooth extraction, ridge dimensions may be unfavorable for implant placement in the ideal restoratively dictated location [1, 2]. The use of guided bone regeneration (GBR) for the treatment of ridge deficiencies is considered a safe and predictable treatment modality [3, 4].

However, this therapeutic approach introduces a separate surgical procedure and an extended healing period that significantly delays the time of implant rehabilitation for the patient. The placement of implants in residual ridges in conjunction with simultaneous guided bone regeneration has been suggested in order to minimize total treatment time and allow for

implant placement in compromised sites [5–7]. Various types of bone grafts have been used for this indication with no biomaterial showing any significant advantage over another in terms of bone regeneration and implant survival [8].

A new generation of putty bone substitutes that display enhanced handling characteristics has recently received significant attention. Putty bone substitutes are usually composed of similar active ingredients as particulate ones, but are enriched with a binder/carrier that provides a unique viscous consistency to the graft. The use of demineralized bone matrix putty and putty xenograft bone substitutes have been successfully employed in oral surgical procedures such as ridge preservation and sinus augmentation [9–11].

The use of an alloplastic putty bone substitute has been also shown to yield promising results in vivo both in animals and humans [12–14]. This alloplastic putty bone substitute biomaterial is composed of calcium phosphosilicate (CPS) particles embedded in a synthetic absorbable binder composed of glycerol and polyethylene glycol with a 70/30 % ratio of active ingredient to binder, respectively. The active ingredient (CPS particles) has a bimodal particle distribution. The smaller particles resorb quicker to give the initial burst of calcium and phosphate ions and the larger particles continue to resorb over time, resulting in sustained stimulation in the area. In vitro studies have shown that CPS putty promotes the differentiation of osteoprogenitor cells into mature osteoblasts, resulting in bone regeneration in the grafted area [15, 16].

Up to date, no evaluation of the clinical efficacy of the CPS putty in guided bone regeneration has been reported in the literature.

The purpose of this case series was to clinically evaluate the new bone formation at peri-implant dehiscence defects by utilizing of a calcium phosphosilicate (CPS), alloplastic bone putty for guided bone regeneration (GBR). The gain in bone height following GBR was set as the primary outcome. Adverse events and survival rate of implants placed in augmented sites after 12 months of function were recorded as secondary outcomes.

Materials and methods

In this case series study, patients that presented in three different centers for implant placement were screened according to standard clinical protocols of each center. If the treatment plan included delayed implant placement with simultaneous guided bone regeneration, verbal and written consent was obtained and the patients were enrolled in the study. All patients were treated according to the Declaration of Helsinki (1975), as revised in 2000. Treatment planning and the surgical protocol did not deviate from routine protocols of each center for study purposes. Inclusion criteria for this study were as follows:

- Seibert class I ridge deficiencies [17]
- Bone dehiscence resulting in implant thread exposure during implant placement in healed ridges
- 18–65 years of age
- Noncontributory medical history
- Tooth extraction at least 6 months prior to the screening appointment.

Exclusion criteria were as follows:

- Unwillingness to sign the informed consent
- History of long-term therapy with medication that may affect bone healing (oral or IV bisphosphonates, corticosteroids, NSAIDS, etc.)
- Medical history that contraindicated oral surgical treatment
- Use of tobacco
- Pregnancy for female participants
- Sites where GBR was deemed unnecessary following implant placement
- Circumferential (horizontal) bone defects around the placed implants

The defects were treated following GBR principles with the use of a CPS alloplastic bone graft putty in combination either with a collagen membrane, or a titanium mesh. Prior to initiation of the study, a consensus was reached among the three implant surgeons in regards to the type of measurements. Based on study protocol all surgeons were asked to use the same type of probe (15 UNC Color-Coded Probe, Hu-Friedy, Chicago, IL) for intraoperative measurements in order to minimize interclinician variability. Each implant surgeon was given freedom to choose the type of barrier used in conjunction with the CPS putty according to standard clinical protocols of each clinic.

Surgical procedure

Prior to initiation of the surgical procedure patients were instructed to rinse with 0.12 % chlorhexidine for 30 s. Following local anesthesia, full-thickness mucoperiosteal flaps were reflected in the surgical area and the bony defects were visualized (Fig. 1). Tapered implants were placed in each edentulous site in the desired 3-dimensional location as determined during preoperative treatment planning. Implant placement in each case was performed according to the implant manufacturer's recommendations and implants were placed in the desired prosthetic position as planned on the diagnostic casts. Following implant placement the defect height in each site was evaluated using a periodontal probe (Fig. 2). Intraoperative measurements included placement of a graded probe (15 UNC Color-Coded Probe, Hu-Friedy, Chicago, IL) parallel to the long axis of the implant with its terminal end placed

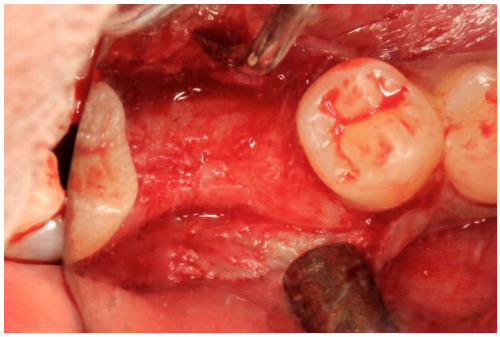

Fig. 1 Intraoperative clinical image from a representative case. Note the buccal concavity that is consistent with the preoperative assessment of Seibert class I defect

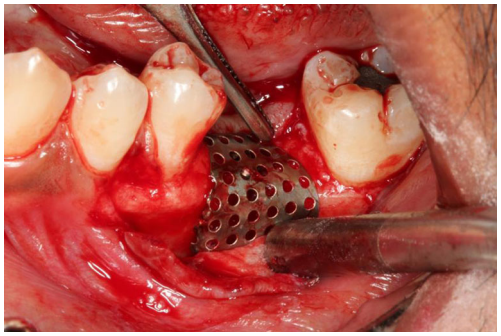

Fig. 3 Either a titanium mesh or a collagen membrane was used as a barrier for bone regeneration. The clinical photograph shows the titanium mesh try-in following trimming for adequate adaptation

on the most apical point of the bony dehiscence. The distance from the end of the probe to the implant platform was recorded in each implant site. All measurements were rounded down to the nearest millimeter. The cortical plate of the ridge around the exposed implant threads was perforated multiple times prior to grafting to enhance vascularity in the region. Either a resorbable collagen membrane or a titanium mesh, based on the clinician's preference, were contoured to the appropriate dimensions and were tried in (Fig. 3). Subsequently the CPS putty (Novabone putty, Novabone LLC, Alachua, FL) was directly delivered to the site using a preloaded cartridge delivery system (Fig. 4). The CPS putty was contoured over the implant using dry gauze under finger pressure and the barrier of choice was positioned over the CPS putty (Fig. 5). A periosteal releasing incision was placed at the base of the buccal flap to aid in coronal advancement, and the flaps were sutured to their original position with primary closure. All implants were left to heal in a submerged manner. An appropriate postoperative antibiotic and analgesic regimen was prescribed in accordance with the participant's medical history. All patients were instructed to rinse with 0.12 % chlorhexidine for 2 weeks postsurgery. The incidence of membrane exposure and other adverse events (infection, dysesthesia, osteomyelitis) were assessed and recorded during surgical follow-up visits using an individualized recall routine for each patient.

Patients were scheduled for second-stage surgery at least 4 months following implant placement. At the time of implant uncovering, the intraoperative measurement was repeated as previously described (Fig. 6).

Implant survival was assessed during implant uncovering and at 6 months and 1 year postloading. Implant survival assessment was based on implant mobility, diagnosis of peri-implantitis, radiographic bone levels, and evaluation of subjective symptoms such as pain and/or altered sensation [18, 19]. Proximal bone levels were assessed on periapical radiographs at 12 months postloading using the long-cone paralleling technique with Eggen film holders. The known implant length was utilized for calibration in each case as previously described by Kotsakis et al. [14]. The bone level was measured as the distance between the implant platform and the coronal edge of the first bone-to-implant contact.

Statistical analysis

Gain in defect height as measured clinically was set as the primary outcome. A nonparametric test (Wilcoxon signed-rank test) was utilized due to its robustness to test the null hypothesis that GBR with CPS putty does not result in significant gain in bone height around peri-implant dehiscence defects. Fisher's exact test was used to evaluate the difference between the exposure rates for collagen membranes versus

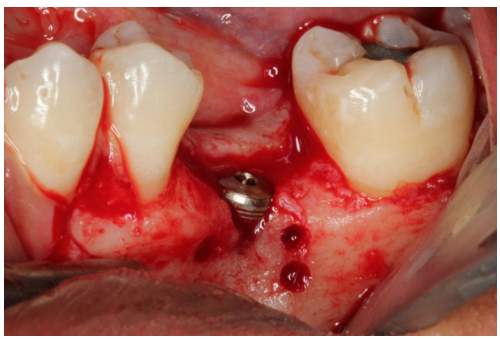

Fig. 2 Cortical perforations can also be observed at the buccal aspect of the ridge to increase blood supply in the area

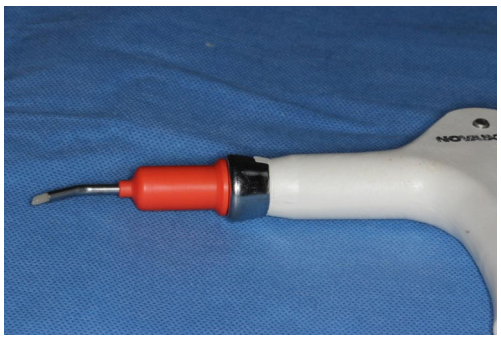

Fig. 4 The narrow-ended cartridge delivery system simplified graft delivery in the site

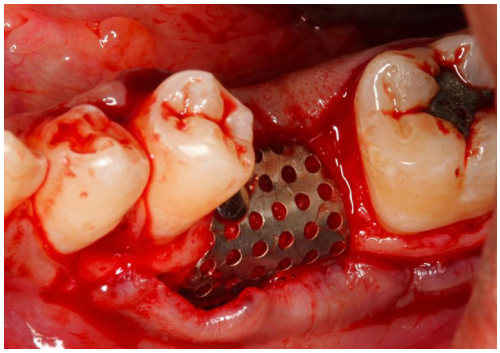

Fig. 5 For sites treated with titanium mesh, titanium screws were utilized to stabilize the mesh around the grafted area

titanium meshes. Exposure rate was defined as the rate of membrane exposures per sites treated for each subgroup, while implant failure rate was recorded as the number of implants that did not osseointegrated in each subgroup. Correlations among patients' age, preoperative defect height, type of membrane, or membrane exposure and the presence or absence of peri-implant defect at uncovering were investigated using Spearman's rank correlation coefficient in pairs. Statistical analysis was performed on a site-level. $p<0.05$ was set as the level of statistical significance for all tests.

Results

Implant placement with simultaneous GBR was performed in 36 singular edentulous sites in 26 patients (14 ♂, 12 ♀; mean patient age 42.17±14.39 years). Four different implant systems were used depending on each clinician's preference, or restorative dentist's request. In 24 cases "Tapered Internal implants" were placed (Biohorizons, Birmingham, AL, USA), in seven cases "Seven" implants were utilized (MIS Implants Technologies Inc., Fair Lawn, NJ, USA), in four cases "CMI IS" implants (NeoBiotech, Seoul, South Korea), and in one case a "Tapered Screw-Vent" implant (Zimmer Dental, Carlsbad, CA, USA).

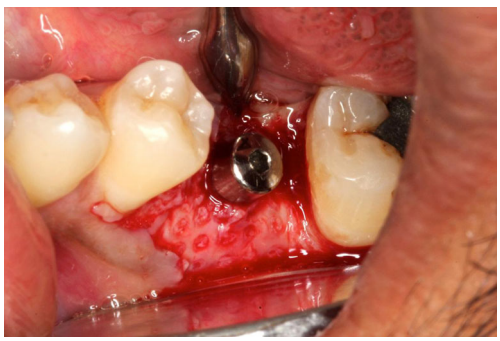

Fig. 6 During the second stage, a comparative intraoperative linear measurement of the defect was taken. In this case, complete coverage of the defect had occurred, with bone lying above the cover screw. A round surgical bur under saline irrigation was used to allow for the placement of the healing abutment

The median time between implant placement and second-stage surgery was 5 months (range 4–7 months). A collagen membrane was utilized in 27 of the sites while a titanium mesh was employed in the remaining nine sites. Membrane/titanium mesh exposure was noted in 5/36 sites (13.89 %). Titanium mesh and collagen membranes had a 33.33 % (3 out of 9 cases) and 7.41 % (2 out of 27 cases) exposure rate, respectively ($p=0.158$) (Table 1). In two cases when a collagen membrane was exposed, the exposed portion was trimmed off and the patient was instructed to rinse with 0.12 % chlorexhidine until the area was completely epithelized. In both cases, spontaneous soft tissue closure was achieved after 2 and 4 weeks, respectively. Titanium mesh exposure was treated by hygiene instructions aiming in gentle cleaning of the area with an extra soft toothbrush and rinsing with 0.12 % chlorhexidine once daily. In one case, spontaneous coverage of the titanium mesh was noted following this regimen. In the remaining cases, the titanium mesh was maintained in place until at least 4 months had elapsed using the above regimen. The soft-tissue defects around the mesh were contained and did not expand after initiation of the proposed hygiene regimen. Other than membrane exposure, mild to moderate postoperative edema was the most frequent adverse event noted following treatment with either a collagen membrane, or a titanium mesh in this case series. In a few cases, edema co-existed with extra-oral contusion in the region. All patients reported mild discomfort for the first days following surgery that was well tolerated with non-steroid anti-inflammatory medication.

Clinical evaluation during second-stage surgery revealed osseointegration of 35/36 implants. All implants were followed up for at least 12 months postloading. No more implants lost osseointegration at the 6- and 12-month follow-up visits for a cumulative survival rate of 97.22 % after 12 months of loading. The implant that failed to osseointegrate was placed in a 45-year-old female with noncontributory medical history. After 5 months of uneventful healing, the implant was categorized as a failure due to clinical mobility at second-stage surgery.

Table 1 Record of adverse events

	No. of sites	Membrane exposure	Exposure rate (%)	Implant failure rate (%)
Titanium mesh	9	3	33.33	0
Collagen membrane	27	2	7.41	3.70
Total	36	5	13.89	2.78

The table presents the record of adverse events associated with treatment in each subgroup. Fisher's exact test was used to evaluate the difference between the exposure rates and implant failures between the collagen membranes versus titanium meshes subgroups. No statistical difference was identified between subgroups either for exposure rate, or implant failure

Table 2 Defect fill post-GBR

	Collagen membrane	Titanium mesh	Total
Defect height (implant placement)	3.11±1.91	4.78±1.79	3.53±2.06
Defect height (second stage)	0.35±0.69	0.22±0.44	0.31±0.63
Difference	2.77±1.97*	4.56±1.74	3.23±2.04*
Percentage of sites with 100 % defect coverage	74.07 %	77.78 %	75.00 %

The table provides information on the fate of the buccal defects following healing. Both types of barrier were equally successful in reducing the buccal defect, or achieving 100 % coverage. In the column labeled "Total," the weighted average of results from the "collagen membrane" and the "titanium mesh" subgroups is reported

*$p<0.001$, highly statistically significant

The average gain in buccal ridge height was 3.23± 2.04 mm, with no remaining buccal defect in 75 % of the sites (27/36). The difference between initial and postoperative defect height was highly statistically significant in favor of the posttreatment evaluation (Table 2). In the remaining sites, the residual defect was reduced in comparison to baseline and ranged between 1–2 mm. Clinically, in three cases where a titanium mesh had been utilized, the implants were completely submerged under the newly formed hard tissue. Complete coverage of the implant platform was only seen in one case treated with GBR utilizing a collagen membrane. A negative correlation was identified between patient age and complete coverage of the peri-implant defect, but no correlation was identified among preoperative defect height, type of membrane, or membrane exposure and the presence or absence of peri-implant defect at uncovery (Table 3).

The mean distance between the margin of the implant platform and the coronal edge of bone-to-implant contact was 0.44±0.28 mm on the mesial and 0.46±0.21 mm on the distal as seen radiographically at the 12-month evaluation.

Discussion

This study aimed at assessing the clinical outcomes of GBR around peri-implant dehiscence defects of implants placed in residual ridges. Gain in vertical bone height was set as the primary outcome. Complete defect coverage was achieved in 75 % of the total cases treated, while in the remaining sites, no buccal defect was found to be more than 2 mm in height. It is important to note that when estimating the defect height intraoperatively, only positive values were recorded. When the regenerated tissue was found to be either at the level or coronal to the implant platform, a "zero" value was assigned to the defect height. During the second-stage surgery in several cases where titanium mesh was utilized the regenerated tissue was found to cover the implant platform and in some cases the implant was completely submerged under the newly formed hard tissue.

Secondary outcomes assessed were implant survival and adverse events associated with the procedure. Implant survival was 97.2 % with only one implant failing at the time of uncovery. Data from an animal study comparing a simultaneous and a staged approach for GBR concurrently with or prior to implant placement, respectively, revealed no significant clinical difference between the two treatment modalities. The authors concluded that both approaches yielded similar and maintainable osseointegration [20].

A systematic review dealing with clinical outcomes of GBR procedures to correct peri-implant defects reported a survival rate of 95.7 % with a range of 84.7–100 % among the included studies. The lower end of this range was attributed to GBR with nonresorbable e-PTFE membranes. If only collagen membranes were evaluated, the survival rate ranged from 95.4 to 100 % [21]. The above data along with our results point out that when the appropriate biomaterials are used GBR is a reliable and predictable treatment modality for the regeneration of peri-implant defects simultaneously with implant placement.

In regard to adverse events, membrane exposure was noted in 13.9 % of all cases treated in this study. The incidence of exposure was greater in sites treated with a titanium mesh in

Table 3 Spearman's rank correlation coefficient between remaining defect and each of the independent variables

Independent variable	Dependent variables			
Residual defect	Age	Preoperative defect height	Type of barrier	Membrane exposure
p coefficient	0.382	0.234	−0.035	−0.051
p value	0.026	0.162	0.794	0.766

The influence of a variety of factors on complete defect coverage was evaluated. Only patient's age was found to have a moderate association with achieving 100 % defect coverage. The baseline length of the defect had a weak linear relationship with the outcome

comparison to a collagen membrane, albeit this difference did not reach statistical significance. Even though 33.3 % of the sites in the titanium mesh subgroup had premature exposure of the mesh, the GBR results were not compromised since complete coverage of the exposed implant surface was achieved in all cases of premature exposure.

This can be attributed to the follow-up care and close monitoring of these patients. Our findings on the exposure rate of collagen membranes are very similar to the ones reported in the abovementioned systematic review on the outcomes of GBR simultaneously with implant placement [21].

No adverse events were recorded following second-stage surgery. In a study with a test group similar to ours, Zitzmann et al. (2001) reported suppuration, pain, and swelling as adverse events [5]. Only postoperative edema was noted in patients in our study. The variation in the reported rate and magnitude of adverse events associated with this treatment modality point out that implant placement with simultaneous GBR is a technique sensitive procedure. This approach significantly decreases treatment time, but deprives the clinician of the chance to correct any remaining bony defect during a second surgical procedure when a stage approach is preferred. Therefore, any development that allows for the simplification of the GBR procedure can be highly beneficial [22].

The handling characteristics of the CPS putty in this study provided adequate viscosity and consistency to support a resorbable GBR membrane, thereby minimizing the time required to perform the GBR procedure. The delivery system allowed for direct application of the bone substitute on the residual bony crest without need for pre-mixing, and the physical characteristics of the putty prevented displacement of the biomaterial during barrier placement and loss of contour as often seen in particulate bone substitutes.

When the CPS putty gets in contact with the patient's blood, the binder that accounts for 30 % of its volume starts to rapidly resorb allowing space for neovascularization and ostoprogenitor cells are attracted on the CPS surface [15]. The modulation of the osteoblast cycle is achieved by induced release of ionic dissolution products: biologically active silicon and calcium released from the articles. The ionic dissolution products stimulate genes that control osteoblast proliferation and differentiation as confirmed by gene array analysis [16].

Owing to the above properties the term "osteostimulation" has been introduced to describe the bioactive properties of this biomaterial that extend beyond osteoconduction. Comparative assessment of the present study and the work of Le and Borzabadi-Farahani showed very similar results achieved with particulate mineralized allograft and with the CPS putty utilized in this study. Le and Borzabadi-Farahani found 79.3 % complete correction of small to medium-sized dehiscence type peri-implant defects treated with allograft compared to 75 % complete defect coverage with CPS putty in our study [23].

Results of two recent clinical studies showed that the application of CPS putty in extraction defects leads to an increased rate of bone healing and better bone quality at 5 to 6 months postextraction in comparison to an osteoconductive xenograft [14, 24]. In addition, the handling characteristics of the putty offer a clinical advantage in comparison to conventional particulate biomaterials. Further controlled studies are required to verify the clinical advantage of this biomaterial. Comparing the intraoperative time required for GBR using either CPS putty or conventional particulate bone substitutes may be beneficial in verifying our observations of ease of handling and simplification of the GBR procedure.

Conclusion

Use of CPS bone putty during delayed implant placement at peri-implant dehiscence sites either in combination with a collagen membrane, or a titanium mesh results in predictable defect coverage, even though complete coverage cannot be attained in all cases. When titanium mesh exposure is managed adequately the results of GBR are optimal. Implants placed in conjunction with GBR have a very good survival rate after 1 year of follow-up. The handling characteristics of CPS putty may simplify GBR protocol. Further randomized, controlled clinical trials are needed to validate these results.

Conflict of interest The authors declare that they have no conflict of interest.

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