Journal of Cranio-Maxillo-Facial Surgery xxx (2013) 1–8

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Simultaneous implant placement and bone grafting with particulate mineralized allograft in sites with buccal wall defects, a three-year follow-up and review of literature

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ARTICLE INFO

Article history:
Paper received 27 January 2013
Accepted 31 July 2013

Keywords:
Ridge buccal vertical defect
Non-submerged implant placement
Particulate mineralized allograft
Resorbable collagen membrane

ABSTRACT

Objectives: To assess the relationship between the vertical buccal defect size and the outcome of single-stage (non-submerged) implant placement and simultaneously augmentation of sites with mineralized particulate allograft (Puros Cancellous) using collagen membranes (Ossix Plus).

Subjects and methods: Records of 108 partially edentulous patients with localized, buccal bone defects in the posterior maxilla and/or mandible [156 tissue-level Straumann implants, 38 male, 70 female, average age = 46.7 (6.4) years] were used for this study. Sectional CBCT scans were used to evaluate ridge forms before implant placement and after bone grafting (36 ± 2.2 months). The initial vertical buccal wall defect was recorded by measuring the amount of vertical Implant Platform's Rough Surface Exposure (IPRSE) when implants were placed [small (<3 mm), medium (3–5 mm), and large (>5 mm)]. The ridge contour at 36 (±2.2) months was classified into 3 categories [completely corrected (no IPRSE seen on CBCT), partially improved (some IPRSE seen on CBCT), no difference/worse].

Results: Complete defect correction occurred in 66 (61.1%) patients followed by improved ridge contours in 38 patients. Significant differences were observed in the outcome of simultaneous grafting of sites with different pre-treatment vertical defect sizes (chi-square = 69.394, $df = 4$, $P < 0.001$). Two graft failures (one needed regrafting) and 2 implant failures were also seen. Treatment was effective in complete correction of 100% and 79.3% of small and medium-sized vertical defects, respectively. Large-sized defects showed only partial improvement in 90% of cases, without any complete correction. Cumulative implant and graft survival was 98.1%.

Conclusions: Single-stage implant placement and simultaneous grafting with mineralized particulate allograft showed promising outcome in correcting small and medium sized vertical buccal wall bone defects (<5 mm).

1. Introduction

Advanced bone grafting techniques have helped to eliminate concerns about bone deficiencies and allow implant placement according to prosthodontic needs. Localized osseous defects can be treated with various techniques such as grafting with bone blocks or particulates in an onlay form, an inlay technique with or without Guided Bone Regeneration (GBR), distraction osteogenesis, or orthodontic therapy (Esposito et al., 2006; Borzabadi-Farahani, 2012; Borzabadi-Farahani and Zadeh, 2013). The GBR uses barrier membranes to exclude unwanted soft-tissue cells from occupying spaces around bone graft materials during the early stages of healing. GBR with the particulate augmentation material has been used to treat small, localized vertical/horizontal ridge defects for implant site development (Minichetti et al., 2004; Block and Degen, 2004; Le et al., 2008; Le and Burstein, 2008). While the use of GBR simultaneously with 2-stage implant placement has been widely reported (Park and Wang, 2006; Le and Burstein, 2008), insufficient information exists on the efficacy of performing GBR with a 1-stage implantation technique.

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http://dx.doi.org/10.1016/j.jcms.2013.07.026

Table 1
Examples of studies using GBR ± particulate bone grafting to augment horizontal and/or vertical alveolar ridge defects. Either implants placed at the time bone grafting/GBR or delayed approach was used.

Author	#Pts./Imps.	Defect	Graft	Membrane	Study design
Von Arx et al., 1998	15/20	Dehiscence and Fenestration	Autogenous	Ti Mesh	Prospective
Lorenzoni et al., 1999	59/85	Vertical	No bone graft	Non-resorbable	Prospective
Brunel et al., 2001	14/14	Non-specific	HA	Resorbable	Prospective
Buser et al., 2002	40/61	Horizontal	Autogenous	Non-resorbable	Prospective
Block and Degen, 2004	11/35	Horizontal	Allograft	None	Prospective
Chiapasco et al., 2004	11/25	Vertical	Autogenous	Non-resorbable	Prospective
Blanco et al., 2005	19/26	Dehiscence and Fenestration	Autogenous	Non-resorbable	Prospective
Simion et al., 2007	7/27	Vertical	Bovine + Autogenous	Ti Mesh	Prospective
Juodzbalys et al., 2007	17/20	Dehiscence	Bovine	Resorbable	Prospective
Llambés et al., 2007	11/32	Vertical	Autogenous	Resorbable	Prospective
Louis et al., 2008	44/45 (site)	Horizontal + Vertical	Autogenous + HA	Ti Mesh	Retrospective
Hämmerle et al., 2008	12/12 (site)	Horizontal	Bovine	Resorbable	Prospective
Pieri et al., 2008	16/44	Horizontal + Vertical	Bovine + Autogenous	Ti Mesh	Prospective
Canullo and Malagnino, 2008	10/24	Vertical	Bovine	Non-resorbable	Retrospective
Le et al., 2010	15/32	Vertical	Allograft	Resorbable	Prospective
De Angelis et al., 2011	80/80	Non-specific	A-Bovine (40); B-No graft (40)	Resorbable	Prospective
Block et al., 2012	12/?	Horizontal	Bovine	Resorbable	Retrospective
Miyamoto et al., 2012	41/87	Horizontal + Vertical	Autogenous	Ti Mesh	Retrospective

The ideal bone graft material should be biocompatible, osteoconductive (i.e., provide a framework or scaffold for new bone to grow into), and osteoinductive (i.e., a material that stimulates bone to grow such as growth factors) (Kolk et al., 2012). Autogenous bone (from the same individual) is widely viewed as the gold standard material because of its osteogenic, osteoinductive and osteoconductive capacities (Kolk et al., 2012). However, it has been associated with increased surgical time/cost, and limitations in the quality and quantity of obtainable bone (Leonetti and Koup, 2003). Donor site morbidity may include alterations in appearance, temporary loss of function, impaired wound healing, iatrogenic injury, and pain (Leonetti and Koup, 2003). Various allografts (from the same species), xenografts (from a different species), and synthetic (alloplastic) materials have been used as substitutes for autografts, although some have been reported not to heal as predictably as autogenous bone (Leonetti and Koup, 2003; Kolk et al., 2012).

Allograft materials do not appear to challenge the immune system significantly (Spin-Neto et al., 2012). Allografts exist as demineralized, mineralized, as well as particulate or block (onlay) forms. The Demineralized Freeze-Dried Bone Allograft (DFDBA) works mostly by osteoconduction; the bone morphogenetic protein, naturally present in the DFDBA, is exposed during the demineralization and can induce osteogenesis (Urist and Strates, 1971). This osteoinductive capacity varies according to donor age, tissue retrieval time after death, storage temperature and sterilization method (Noumbissi et al., 2005). Koutouzis and Lundgren (2010) reported that implants placed in post-extraction sockets augmented with DFDBA exhibited minimal marginal bone loss similar to implants placed in native bone. Despite early histomorphometric findings that mineralized bone powder resorbed without any new bone formation (Glowacki et al., 1981); more recently, mineralized allografts have been successfully reintroduced (Leonetti and Koup, 2003; Minichetti et al., 2004; Block and Degen, 2004; Noumbissi et al., 2005; Park and Wang, 2006; Le et al., 2008; Le and Burstein, 2008; Le and Woo, 2009; Acocella et al., 2012). The mineralized allografts have both osteoinductive and osteoconductive properties. In comparison to autogenous bone grafts, and despite the lack of osteogenic properties (Kolk et al., 2012), the mineralized allografts produced comparable results when used to restore the deficient alveolar ridges (Beitlitum et al., 2010).

Reports of particulate grafting for implant placement are mainly limited to the use of autogenous, allograft, or xenograft (Table 1) materials. The mineralized allografts have been studied for repairing localized, peri-implant bone defects, mostly reporting the outcome of a two-staged (delayed implant placement) surgical approach in a relatively small number of cases (Simion et al., 2001; Minichetti et al., 2004, 2005; Beitlitum et al., 2010; Le et al., 2010; Jacotti et al., 2012). Factors that determine the clinical outcome of simultaneous particulate grafting and single-stage implant placement in sites with buccal wall defects have not yet been investigated. To our knowledge there is no report on the long-term follow-up of grafting with allografts and simultaneous implant placement in a non-submerged protocol. This follow-up study assessed the

Table 2
Patient selection criteria for study.

Inclusion	Good general and oral health (ASA 1 or 2)
	Lack of oral or systemic conditions that could adversely affect treatment outcomes such as uncontrolled diabetes (HgbA1c > 6.5), medical conditions that affect healing or circulation, active periodontitis adjacent to the graft site, etc.
	In need of a dental implant to replace missing teeth in sites with a buccal wall defect
	Partially edentulous patients
Exclusion	Severe ridge resorption with large vertical labial defects that would expose a significant number of implant threads and affect the initial stability of the implant

Table 3
Buccal wall bone defect classifications used in the study.

	Classification	Description of defect
Pre-treatment vertical defect size[a]	Large	Greater than 5 mm in depth
	Medium	3–5 mm in depth
	Small	Less than 3 mm in depth
Post-treatment CBCT defect assessment	Complete correction	No Implant Platform's Rough Surface Exposure (IPRSE) can be seen on CBCT at the site of the original buccal wall defect
	Partial improvement	Some IPRSE can be seen on CBCT
	No difference or worse	No change in visible defect size or further bone recession and implant platform exposure at the original defect site

[a] The vertical buccal wall defect measurement expresses the amount of vertical implant platform's rough surface exposure when implants were first placed.

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Table 4
Distribution of buccal wall defects in maxilla and mandible.

	Large ($N = 30$)		Medium ($N = 58$)		Small ($N = 20$)	
	Mandible	Maxilla	Mandible	Maxilla	Mandible	Maxilla
Bone defects by size & jaw	24	6	41	17	9	11

relationship between the vertical buccal defect size and the outcome of single-stage (non-submerged tissue-level) implant placement and simultaneously augmenting the site with mineralized particulate allograft using a collagen membrane.

2. Material and methods

Subjects were consecutive partially edentulous patients with buccal bone defects in the posterior maxilla and/or mandible from the first author's practice [108 patients, 38 males and 70 females, average age = 46.7 (6.4) years]. The records were anonymised so that ethical approval was not needed. Some patients had extensive defects of a second adjacent missing tooth location, or a second single tooth site in a non-adjacent anatomical location. The selection criteria are shown in Table 2. None of the patients was a smoker. Study casts were fabricated and a surgical template to guide placement of implants relative to the planned restoration was created from prosthetic wax-ups. Pre- and post-operative digital photography was also available for the maxillary and mandibular ridges, and treatment results at all sites.

Patients received 156 implants and simultaneous grafting of buccal ridge defects. A tissue-level transmucosal implant design (ITI, Straumann USA LLC, Andover, MA) was selected so that its fixed restorative platform could be positioned at the soft-tissue margin at the time of graft placement. Implants ranged from 4.1 to 4.8 mm in diameter, and from 8 to 12 mm in length. Patients were prescribed oral rinsing with 0.12% chlorhexidine gluconate (Peridex, Zila Pharmaceuticals, Phoenix, AZ) immediately before surgery, and twice daily for 7 days after surgery. Post-operative medications included penicillin 500 mg (clindamycin 300 mg for patients allergic to penicillin) 4 times a day for 7 days, and analgesics.

2.1. Clinical records and outcome measurements

Sectional Cone Beam CT (CBCT) scans (Picasso Duo; VATech, South Korea) were used to rule out additional pathologies, identify anatomical landmarks, and determine the ridge form and bone volume before implant placement. The initial vertical buccal wall defect was evaluated clinically and recorded (Table 3) by measuring the amount of vertical Implant Platform's Rough Surface Exposure (IPRSE) when implants were initially placed (<3 mm, 3–5 mm, and >5 mm depth). No assessment of the horizontal or bucco-lingual bone defects was made. Table 4 shows the distribution of buccal wall defects.

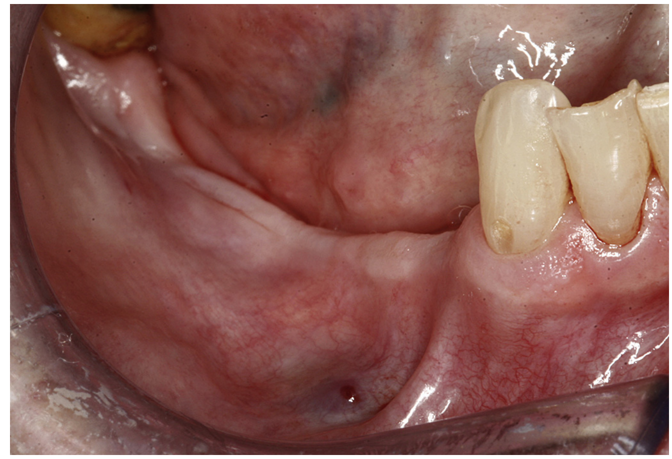

Fig. 2. The implant site with knife edge ridge shape.

2.2. Allograft

The mineralized, allogenic cancellous bone particulates of 250–1000 microns (Puros Cancellous, Zimmer Dental Inc., Carlsbad, CA) were used for augmentation. According to the manufacturer, this graft material undergoes solvent preservation to preserve the trabecular pattern and osteoconductive properties of the bone (Noumbissi et al., 2005). Particulate material was selected for localized defects as it could form the appropriate ridge contour and support the overlying soft tissue for a natural anatomical appearance. The allograft was hydrated according to the manufacturer's instructions and mixed with the patient's blood.

2.3. Graft site preparation

Two different conservative surgical incisions were used to minimize disruption of the soft tissue's vascular network and preserve adjacent soft-tissue papillae. In small ridge defects, a sulcus flap without vertical releasing incisions was used. In other cases with more extensive defects, an open-book flap design (Fig. 1) was used to enhance visualization and access (Le and Burstein, 2008). The open book flap consisted of a crestal

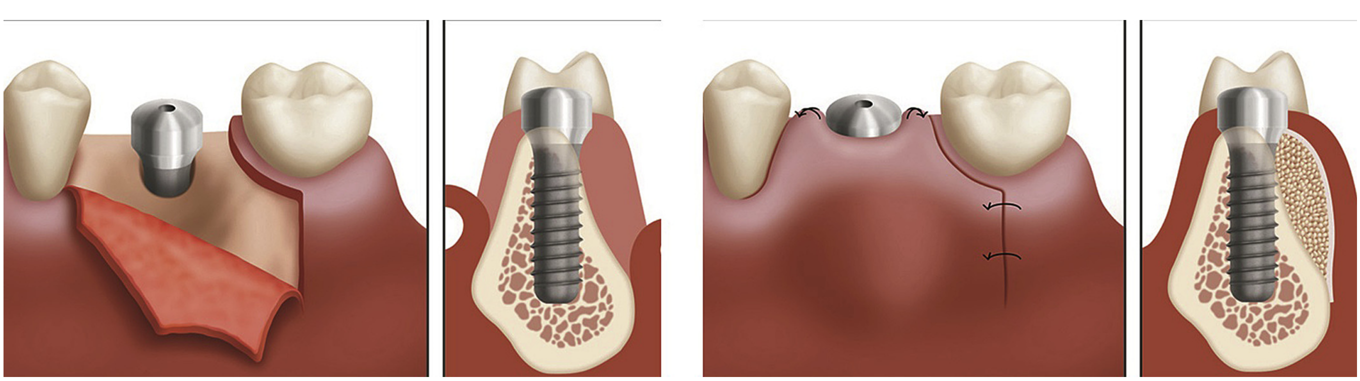

Fig. 1. The open book flap.

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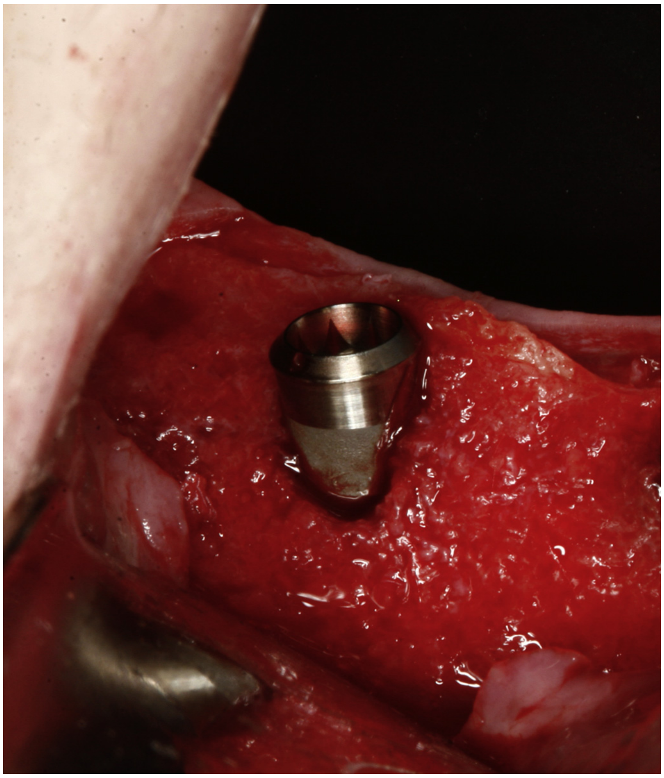

Fig. 3. A vertical defect with exposure of 3 mm of the implant platform's rough surface.

incision made lingual to the ridge midline to ensure there was an adequate amount of keratinized tissue present in the flap. This was followed by a distal, curvilinear, vertical incision that followed the gingival margin of the distal tooth. A wide subperiosteal reflection was made to expose 2- to 3-times the treatment area, and the papilla was then reflected on the mesial side of the edentulous site.

Osteotomies were prepared via sequential cutting under copious irrigation using the custom surgical guide, and implants were placed according to the manufacturer's protocol. During placement, the implant's restorative platform was positioned approximately 1 mm below the level of the soft-tissue margin, and a wide-diameter healing cap was attached to implant. The peri-implant soft tissue was released and advanced by scoring the periosteum so that tension-free closure could be obtained around the neck of the transmucosal implant. This was done as moderate graft resorption could occur if there was not an adequate tissue seal at the implant neck or if tension-free closure could not be achieved.

Periosteum release was performed as the last step, to induce bleeding, just before graft placement. The allograft was packed into the defect and over-contoured by approximately 20–30% to compensate for anticipated apical migration and resorption of the graft material (Simon et al., 2000). After grafting, allografts were covered with resorbable cross-linked collagen membranes (Ossix Plus, OraPharma Inc., Warminster, PA, USA). A wide healing abutment was attached to the implant. The soft tissues were re-approximated and sutured around the healing abutment with a sling suture to achieve a good seal, creating a tenting effect over the allograft. The healing abutment helped to hold the particulate material in place. Patients were asked to consume soft foods and to refrain from wearing removable prostheses, during the early healing period of two weeks.

2.4. Post-operative evaluation of graft sites

Patients were evaluated clinically at 2, 6, 12, 24, and 36 months after augmentation to determine osseointegration and assess the peri-implant hard and soft-tissues. The sectional CBCT scans were used after graft healing at 36 (SD = 2.2) months, and the site of the original vertical bone defect was evaluated for the presence of any vertical bone defect. The sectional CBCT findings were used to evaluate the defect site improvement. The restored ridge contours were evaluated and classified into 3 categories (completely corrected, partially improved, no difference/worse) (Table 3 and Figs. 2–9).

2.5. Statistical analysis

Statistical analysis was performed with SPSS software, Version 17.0 (Statistical Package for Social Sciences; SPSS Inc., Chicago, Illinois, USA). Prior to assessing the cohort of graft cases, the reliability of the post-treatment defect assessment criteria was assessed. The agreement between the 2 assessments of 20 cases was substantial (Kappa statistics > 0.9). The chi-square test was used to evaluate differences in the outcome of grafting among implants with various vertical defect sizes. The level of significance was set at 0.05 ($P < 0.05$).

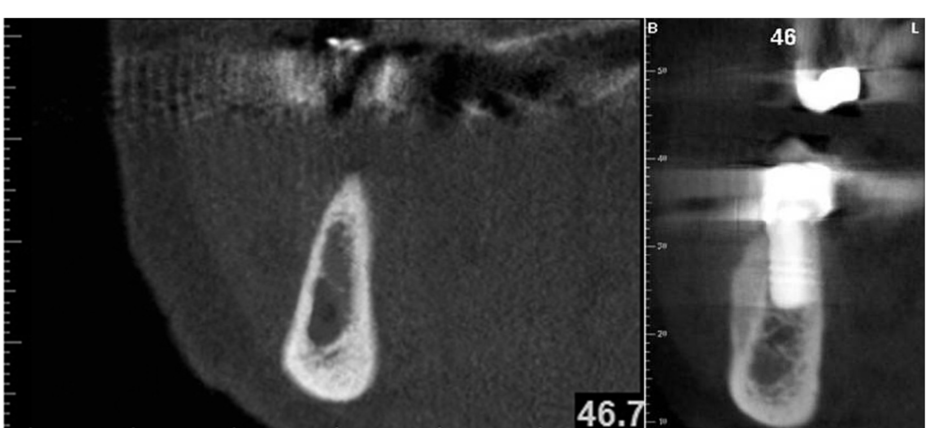

Fig. 4. The inverted post-operative CBCT taken before placing a 4.1 mm tissue-level Straumann implant and at 34 months follow-up after implant placement and simultaneous bone grafting with particulate allograft, note the complete coverage of the rough surface of the implant platform and correction of the defect.

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Fig. 5. Post-operative intraoral photo at 34 months follow-up.

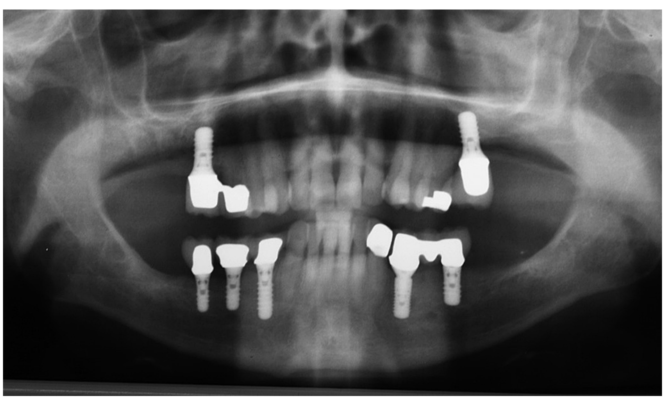

Fig. 6. Post-operative panoramic view at 34 months follow-up.

3. Results

2 patients had wound dehiscence with graft exposure; only one required secondary graft placement (graft failure). The other patient had a minor soft-tissue dehiscence, resulting in a minor graft exposure. There was no infection, the patient was instructed to keep the area clean, and the site was closely monitored. Granulation tissue quickly covered the graft site and formed new keratinized tissue to cover the wound. Two patients experienced infection and loss of integration around an implant. In both cases, the implant was removed and recorded as implant failures; both were successfully retreated using the same protocol.

In the remaining 104 patients, defects were completely corrected in 66 (61.1% of all cases) patients (all had small or medium sized labial bone defects), and improved in 38 patients (Table 5). The chi-square test revealed significant differences in the outcome of simultaneous grafting among implants with different pre-treatment vertical defect sizes (chi-square $= 69.394$, d$f = 4$, $P < 0.001$). Treatment was effective in complete correction of all small-sized (less than 3 mm depth). Overall, 79.3% complete correction was seen in medium-sized (3–5 mm depth) vertical buccal wall bone defects. Large-sized defects (greater than 5 mm depth) only showed partial improvement in 90% of cases, without any complete correction. Cumulative implant and graft survival was 98.1%.

4. Discussion

Similar to the present study, a recent systemic review concluded that survival rates of implants placed into augmented areas were comparable with that of implants placed into pristine bone (Klein and Al-Nawas, 2011). However, identifying best grafting technique for alveolar ridge augmentation remains challenging (Klein and Al-Nawas, 2011; Clementini et al., 2013). Most studies of lateral or vertical ridge augmentation have reported on the findings of two-stage approaches, exposure of a second surgical site to harvest autogenous graft material, ridge splitting/expansion techniques, or alveolar distraction osteogenesis that were associated with higher morbidity and increased treatment time (Table 1) (Chiapasco et al., 2009; Hansen et al., 2011; Urban et al., 2011; Aloy-Prósper et al., 2011). Implants for this study were placed in a single-stage technique with simultaneous grafting to support the soft-tissue margin approximately 1 mm above the implant margin.

The GBR can be achieved with materials such as the acellular dermal matrix, polytetrafluoroethylene (PTFE), and resorbable collagen membranes (Fotek et al., 2009). While good clinical results have been reported for GBR, potential complications and relatively high costs have been reported as disadvantages (Gielkens et al., 2007). In the present study, combining a resorbable collagen membrane, with haemostatic, chemostatic and cell adhesive characteristics (Mardas et al., 2011; Vignoletti et al., 2012), and mineralized particulate allograft satisfactorily performed their desired function. Resorption of the graft material over time would have resulted in buccal ridge deformity and exposure of the implant platform's rough surface as well as the metallic implant in the soft-tissue margin area; something that may have occurred in 39 graft sites. Grafting at the time of implant placement decreased

Fig. 7. Another case with lateral and vertical ridge defect showing the open book flap.

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Fig. 8. Single-stage implant placement and simultaneous augmentation with mineralized particulate allograft (Puros Cancellous) using collagen barrier membranes (Ossix Plus).

treatment time and number of invasive procedures for patients without adverse effects, mostly.

Both mineralized and demineralized allografts retain their natural bone collagen, the organic component that provides resilience, strength, and stability to the tissue (Keith, 2004). During the wound healing process, collagen initially serves as a haemostatic agent and facilitates natural cleansing through inflammatory infiltration (Leonetti and Koup, 2003). As healing progresses, collagen first acts as a template for new tissue growth by attracting and serving as a scaffold for attaching fibroblasts (Gross, 1997), and then continues to strengthen the new tissue overtime (Tadic and Epple, 2004). The inorganic component of bone is a crystalline matrix composed primarily of hydroxylapatite, providing bone with its firmness and rigidity (Gross, 1997). Demineralization removes calcium from the bone, which exposes the native BMP, but provides no structural stability (Kolk et al., 2012). In the present study, the mineralized allograft maintained adequate strength and shape in 61% of cases. All adverse events were caused by soft-tissue dehiscence or implant failure. Although some studies have evaluated the graft volume changes over time (Sbordone et al., 2013; Dasmah et al., 2012), this was not possible due to ethical issues, and instead available sectional CBCTs at approximately 36 months were used. Sectional CBCT scans offer some advantages such as comparable level radiation to conventional radiographs, relatively reasonable cost, and the ability to investigate the 3-dimensional image, which are lacking in conventional 2-dimensional radiographs (Benavides et al., 2012). Future clinical trials can examine the graft survival over a longer period or compare the performance of mineralized allograft with other graft materials. Although the horizontal buccal bone width was not assessed in the present study, the accuracy of CBCT in assessing the buccal bone width has been disputed recently. An animal CBCT study confirmed that when the horizontal bone width was less than 0.5 mm there was a significantly greater difference between the radiological and the histological evaluation of the buccal bone depth (Fienitz et al., 2012). Another animal study also concluded that considering the 0.5 mm accuracy in assessing the peri-implant bone thickness, evaluating whether the implant was covered completely by the hard tissue could be challenging and inaccurate (Wang et al., 2013). Therefore, limitations of the CBCT in interpreting the finding of the present study should be recognized, particularly when the bone thickness is less than 0.5 mm.

After graft placement, the pattern, rate, and quality of new bone formation depend on complex reactions between the structure of a graft material and the healing processes of the biological host (Keith, 2004). Successful graft incorporation requires simultaneous revascularization and resorption as it is replaced with new bone that maintains the strength and volume of the graft (Keith, 2004). Antigens present in some allografts can occlude local blood vessels and preclude vascularization of the graft by triggering host tissue sensitivity and lymphoplasmacytic infiltration (Keith, 2004). Secondary graft necrosis and proliferation of inflammatory granulation tissue can also weaken the cortical component of the allograft and interfere with its incorporation and new bone formation (Keith, 2004). While various tissue processing techniques, such as freezing and freeze-drying (lyophilization), have been reported to attenuate these responses, they may also decrease the mechanical strength of the allograft (Keith, 2004).

In those cases judged to have improved ridge contours (39 sites), there may have been more noticeable resorption of the graft, but such occurrences are also common with autogenous bone grafts.

Fig. 9. Post-operative view; note the improved buccal keratinized tissue at the implant site.

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Table 5
Outcome of single-stage implant placement and simultaneous grafting according to the pre-operative buccal wall vertical defect size.

		Post-treatment defect assessment (CBCT)			Total
		Complete correction	Partial improvement	No difference or worse	
Pre-treatment vertical defect size	Large	0	27 (90%)[a]	3[b]	30
	Medium	46 (79.3%)	12	0	58
	Small	20 (100%)	0	0	20
Total		66	39	3	108

[a] Include a case with graft exposure, which fully recovered.
[b] Include 2 cases with implant failure and one case with graft failure.

The inflammatory response of the hard/soft host tissues was not observed, but it was not known if the commercial processing of the allograft in some way reduced the antigenic response potential of the host tissue. Since resorption and remodelling is a natural process in graft healing and often results in graft shrinkage, the authors routinely overcorrect the graft site to account for resorption and incorporating a vertical incision in the flap design so that the flap can be coronally advanced and supported by the graft. To conclude, a limitation of the study was the lack of a control group, i.e., a group of patients who were treated with conventional grafting and delayed implant placement. Prospective trials can compare the outcome of the present protocol used and conventional methods employing delayed implant placement. It would be also interesting to investigate the outcome of the present protocol by using other graft materials, bone-level implants, as well as assess the outcome in the anterior maxilla (Le and Borzabadi-Farahani, 2012) using immediate or delayed loading protocols.

5. Conclusion

Single-stage implant placement and simultaneous grafting with mineralized particulate allograft showed promising outcome in correcting small and medium sized vertical labial wall defects.

Conflict of interest

Authors have no conflict of interest to declare.

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Please cite this article in press as: Le BT, Borzabadi-Farahani A, Simultaneous implant placement and bone grafting with particulate mineralized allograft in sites with buccal wall defects, a three-year follow-up and review of literature, Journal of Cranio-Maxillo-Facial Surgery (2013), http://dx.doi.org/10.1016/j.jcms.2013.07.026