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# A prospective clinical study of nonsubmerged immediate implants: clinical outcomes and esthetic results

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Fax: +61 3 9341 1547 Fax: +61 3 9341 1596 e-mail: schen@mira.net **Key words:** bone grafts, bone regeneration, esthetics, immediate implants, non-sub-merged healing, radiographic bone levels, randomized-controlled trial, resorbable membranes

#### **Abstract**

**Objectives:** To evaluate healing of marginal defects in immediate transmucosal implants grafted with anorganic bovine bone, and to assess mucosal and radiographic outcomes 3–4 years following restoration.

Material and methods: Thirty immediate transmucosal implants in maxillary anterior extraction sites of 30 patients randomly received BioOss™ (N = 10; BG), BioOss™ and resorbable collagen membrane (N = 10; BG + M) or no graft (N = 10; control). **Results:** Vertical defect height (VDH) reductions of 81.2  $\pm$  5%, 70.5  $\pm$  17.4% and 68.2  $\pm$  16.6%, and horizontal defect depth (HDD) reductions of 71.7  $\pm$  34.3%, 81.7  $\pm$  33.7% and 55  $\pm$  28.4% were observed for BG, BG+M and control groups, respectively, with no significant inter-group differences. Horizontal resorption was significantly greater in control group (48.3  $\pm$  9.5%) when compared with BG  $(15.8 \pm 16.9\%)$  and BG+M  $(20 \pm 21.9\%)$  groups (P = 0.000). Ten sites (33.3%) exhibited recession of the mucosa after 6 months; eight (26.7%) had an unsatisfactory esthetic result post-restoration due to recession. Mucosal recession was significantly associated (P = 0.032) with buccally positioned implants (HDD 1.1  $\pm$  0.3 mm) when compared with lingually positioned implants (HDD 2.3  $\pm$  0.6 mm). In 19 patients followed for a mean of 4.0  $\pm$  0.7 years, marginal mucosa and bone levels remained stable following restoration. Conclusion: BioOss™ significantly reduced horizontal resorption of buccal bone. There is a risk of mucosal recession and adverse soft tissue esthetics with immediate implant placement. However, this risk may be reduced by avoiding a buccal position of the implant

#### Date:

Accepted 9 March 2006

#### To cite this article:

Chen ST, Darby IB, Reynolds EC.
A prospective clinical study of non-submerged immediate implants: clinical outcomes and esthetic results.

Clin Ceal Impl. Res. 18, 2007, 552–562.

Clin. Oral Impl. Res. 18, 2007; 552–562 doi: 10.1111/j.1600-0501.2007.01388.x Implants placed into extraction sockets have been shown to be a predictable alternative to conventional treatment approaches (Mayfield 1999; Chen et al. 2004). In clinical practice, two treatment protocols have emerged: the submerged protocol and the non-submerged protocol. In the submerged protocol, primary closure of the wound is achieved using a variety of flap and soft tissue grafting techniques

in the extraction socket.

(Becker et al. 1991; Landsberg 1997; Rosenquist 1997). A second surgical procedure is then required to expose the implant for connection of the abutment. In the nonsubmerged protocol, the surgical flaps are adapted to a healing abutment to allow the wound to heal with the abutment exposed to the oral cavity (Cochran & Douglas 1993; Lang et al. 1994). Recent reports have demonstrated clinically successful

fill of the marginal peri-implant defect fill when a non-submerged approach is used in conjunction with bone grafts and barrier membranes (Lang et al. 1994; Hämmerle & Lang 2001) and with a blood clot alone in the defect (Paolantonio et al. 2001; Botticelli et al. 2004).

We have recently shown that although vertical bone defect fill was similar using different combinations of autogenous bone grafts and/or barrier membranes, resorption of the buccal bone was significant in all groups expect for those treated with nonresorbable expanded polytetrafluoroethylene membranes (Chen et al. 2005). Resorption of the buccal bone may in turn have an adverse effect on the stability of the peri-implant mucosa and the soft tissue esthetic outcomes. Bone grafts with slow resorption rates such as deproteinized anorganic bone may alter the rate of buccal resorption (Hämmerle & Lang 2001), which may in turn be important for maintaining stability of the marginal peri-implant mucosa.

The aim of this prospective controlled clinical study was to (i) evaluate healing of marginal defects adjacent to implants in extraction sockets grafted with anorganic bovine bone using a non-submerged protocol and (ii) assess the soft tissue and radiographic outcomes of treatment over an observation period of 3 years following restoration of the implants.

#### Material and methods

#### Selection criteria

A total of 30 consecutive patients were selected between July 1999 and May 2000 from a private specialist periodontal practice to participate in the study. The study was approved by the University of Melbourne Human Research Ethics Committee. Patients were selected for inclusion if they required extraction and replacement of one or several non-adjacent teeth in the maxillary anterior and premolar regions with implant reconstructions. Those selected were required to provide written informed consent, and were excluded if there was acute infection associated with the tooth of interest and/or clinical attachment loss of 5 mm or more on the buccal aspect of the tooth to be extracted. General exclusion criteria also included poor plaque control, untreated chronic periodontitis and systemic and psychological contraindications to treatment. Smokers were not excluded.

## Clinical procedure

Treatment was performed in the dental office under local anaesthesia. Following the administration of local anaesthesia (0.2% xylocaine with 1:80,000 adrenaline, Astra Pharmaceuticals, North Ryde, NSW, Australia), full-thickness mucoperiosteal flaps were raised following buccal and palatal sulcular incisions and buccal vertical-releasing incisions. The teeth were carefully extracted using luxators and forceps. The extraction sockets were carefully debrided with hand instruments to remove apical granulation tissue. Sites were then prepared for implant placement according to standard techniques for extraction sockets (Becker & Becker 1990). Implants with a sand-blasted and acid-etched surface (ITI Implant System; Institut Straumann AG, Waldenberg, Switzerland) were placed completely within the confines of the socket. The implant shoulders were positioned at the level of the buccal crestal bone, and no less than 2-3 mm apical to the final anticipated mucosal margin level.

After installation of the implants, the following landmarks were identified adjacent to the marginal peri-implant defect (Fig. 1): S, rim of the implant shoulder, BC, top of the bone crest, IB, internal border of the buccal bone crest, EB, external border of the socket at the buccal bone crest, and D = base of the defect on the buccal aspect of the implant. The periimplant defect was then characterized by the following parameters measured with a calibrated Williams periodontal probe to the nearest millimetre: (i) the distance from the rim of the implant shoulder (S) to the base of the defect (D), or vertical defect height (VDH), (ii) the horizontal distance between the implant shoulder (S) and the internal border of the socket (IB) at the mid-point of the implant, or horizontal defect depth (HDD), (iii) the horizontal distance between the implant shoulder (S) and external buccal border of the socket (EB), or buccal bone distance (BBD) and (iv) the vertical distance between the implant shoulder (S) and bone crest (BC), or shoulder to bone crest (SBC). At sites with dehiscence defects of the buccal

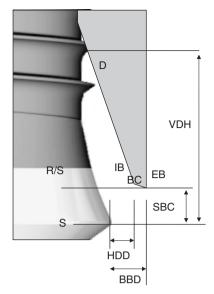


Fig. 1. Diagrammatic representation of surgical landmarks. BC. bone crest; D, base of defect; EB, external border of buccal bone; IB, internal border of buccal bone; R/S, junction between the rough and smooth portions of the implant; S, rim of implant shoulder on the buccal aspect. Parameters measured: BBD, external horizontal buccal bone distance; HDD, horizontal defect depth; SBC, vertical distance between implant shoulder and bone crest; VDH, vertical defect height.

bone, the HDD was measured as the distance from S to a straight line formed by placing a periodontal probe horizontally at the intact crestal bone on the mesial and distal margins of the dehiscence. Protective healing caps of appropriate lengths were attached to the implants.

The patients were then randomly assigned to one of the following groups: (i) bone graft (BG) group, (ii) bone graft and resorbable membrane group (BG+M) and (iii) non-grafted control. In the BG and BG+M groups, anorganic bovine bone mineral (BioOss; Geistlich Pharma AG, Wolhusen, Switzerland) was lightly packed into the marginal defect adjacent to the coronal extent of the crestal bone. Following placement of the graft, resorbable collagen barrier membranes (BioGide; Geistlich Pharma AG) were trimmed and adapted around the protective healing caps of the implants in the BG + M group. The membranes extended over the buccal crest and onto the buccal surface of the bone by approximately 10 mm. In the control group, bone graft and barrier membranes were not used; rather, a blood clot was allowed to form in the marginal defect. The buccal flaps were then coronally advanced following periosteal releasing incisions at the base of the flap to facilitate a semi-submerged mode of healing. The wound edges were secured with interrupted sutures. In four cases, dehiscence defects of the buccal plate were discovered following extraction of the teeth. For ethical reasons, these cases were randomly allocated to the BG or  $\mathrm{BG} + \mathrm{M}$  groups only.

Systemic antibiotics (amoxycillin 1.5 gm daily in three divided doses) were prescribed for 5 days. Patients were asked to rinse twice daily with a solution of chlorhexidine digluconate (Periogard 0.2%, Colgate, Sydney, Australia) and to refrain from using mechanical plaque removal methods at the surgical sites for 2 weeks. Sutures were removed 2 weeks post-operatively, and patients instructed to commence brushing the exposed healing caps with a soft-bristled toothbrush.

Surgical re-entry was scheduled 6 months after initial surgery.

At the time of re-entry, the condition of the peri-implant mucosal margin was visually inspected, and the presence or absence of tissue recession in relation to the adjacent natural teeth was recorded as being absent or present. The position of the implant healing cap was assessed as being buccal or lingual to a reference line drawn between the cervical margins of the adjacent teeth. A buccal position was recorded if the outer border of the healing cap was at or buccal to this reference line. Upon reflection of buccal flaps, the landmarks described previously were identified and the appropriate clinical measurements were taken.

Following a further healing period of 2 months, patients were referred to their respective restorative dentists for completion of the implant restorations.

## Follow-up

Patients were recalled following completion of the implant crowns, and were scheduled for recalls 1, 2 and 3 years following restoration.

#### Clinical indices

The following clinical indices were obtained before commencement of treatment, and at the subsequent recalls following restoration of the implants at 0, 1, 2 and 3 years: (i) full-mouth plaque index (PI), consisting of dichotomous recordings of the absence or presence of plaque at the gingival margin expressed as a percentage of the total sites examined (O'Leary et al. 1972), and (ii) full-mouth bleeding index (BI), consisting of dichotomous recordings of the absence or presence of bleeding after gentle probing of the gingival sulcus expressed as a percentage of the total sites examined (Ainamo & Bay 1975).

In addition, the following dichotomous indices were recorded for the implant sites: (i) implant plaque index (imPI) consisting of recordings of the absence or presence of plaque at the implant healing caps or final crowns at the buccal, mesial, distal and palatal surfaces, and (ii) implant bleeding index (imBI) consisting of recordings of the absence or presence of bleeding following gentle probing of the peri-implant sulcus at the healing caps or final crowns at the buccal, mesial, distal and palatal surfaces. The impPI and impBI were expressed as a percentage of the total sites examined.

## Radiographic examination

Standardized periapical radiographs were obtained with a parallelling device (Rinn XCP Holder, Dentsply, Elgin, IL, USA) attached to an acrylic jig at the time of surgical re-entry, and at 0, 1, 2 and 3 years after prosthetic loading.

#### Complications

Technical and biological complications were recorded at each recall appointment over the 3-year post-restoration observation period. A complication was defined as any event that required clinical chairside time after delivery of the prosthesis (Lang et al. 2004).

## Statistical analysis

For continuous data, differences within treatment groups were analysed with the paired Student's t-test. Differences between treatment groups were assessed with analysis of variance (ANOVA). Residuals for individual parameters were plotted to confirm normality of the distributions. The Pearson  $\chi^2$  test was used to analyse categorical data and where meaningful, tables were collapsed to increase the number in cells when frequencies were small. Differences in radiographic measurements at baseline, 12 and 36 months were tested using repeated measures ANOVA with appropriate adjustments for multiple comparisons. All analyses were carried out using the statistical package Minitab (Minitab Release 14, Minitab Inc., PHILADELPHIA, PA, USA).

## Results

## Demographic profile and baseline measurements

Demographic and baseline defect data are presented in Table 1. The mean initial VDH, HDD, BBD and SBC were  $9.6 \pm 2.2$ ,  $1.8 \pm 0.7$ ,  $2.3 \pm 0.7$  and  $1.6 \pm 2.8$  mm, respectively. There were no significant differences between the treatment groups with respect to age and gender distribution, and initial VDH, HDD, BBD and VCH of the marginal defects. Teeth were removed predominantly for reasons of vertical root fractures

Table 1. Patient demographics (age and gender) and initial vertical defect height (VDH), initial horizontal defect depth (HDD), initial buccal bone distance (BBD) and initial vertical distance from implant shoulder to bone crest (SBC)

Group	N	Age* (years)	No. female (%)	Initial VDH* (mm)	Initial HDD* (mm)	Initial BBD* (mm)	Initial SBC* (mm)
Bone graft only (B) Bone graft + membrane (BM) Control (C) All	10 10 10 30	$50.4 \pm 10.1$ $43.2 \pm 10.8$ $42.1 \pm 11.0$ $45.2 \pm 10.1$ $P = 0.135$ (NS)	6 (60) 7 (70) 7 (70) 20 (66.7) P= 0.861 (NS)	$\begin{array}{c} 10.1\pm1.7\\ 10.0\pm2.6\\ 8.7\pm2.2\\ 9.6\pm2.2\\ P\!=\!0.302~(\text{NS}) \end{array}$	$1.9 \pm 0.9$ $1.8 \pm 0.9$ $1.9 \pm 0.5$ $1.8 \pm 0.7$ $P = 0.904$ (NS)	$\begin{array}{c} 2.4 \ \pm \ 0.3 \\ 2.2 \ \pm \ 0.2 \\ 2.3 \ \pm \ 0.5 \\ 2.3 \ \pm \ 0.7 \\ P = 0.837 \ (\text{NS}) \end{array}$	$1.3 \pm 1.0$ $2.9 \pm 3.3$ $0.6 \pm 0.8$ $1.6 \pm 2.8$ $P = 0.166 \text{ (NS)}$
*Moon   CD							

\*Mean  $\pm$  SD.

NS, not statistically significant (P > 0.05).

Table 2. Changes in vertical defect height (VDH), horizontal defect depth (HDD), buccal bone distance (BBD) and vertical distance from implant shoulder to bone crest (SBC), by treatment group

Group	Ν	VDH*		HDD*		BBD*		gain SBC*	
		mm	%	mm	%	mm	%	mm	
Bone graft only (BG) Bone graft + membrane (BG + M)		8.2 ± 1.5 7.2 ± 2.9	81.2 ± 5.0 70.5 ± 17.4	1.5 ± 1.0 1.5 ± 0.9	71.7 ± 34.3 81.7 ± 33.7	$\begin{array}{c} 0.4 \; \pm \; 0.5 \\ 0.6 \; \pm \; 0.7 \end{array}$	15.8 ± 16.9 20 ± 21.9	$0.1 \pm 3.4 \\ (-0.5) \pm 3.7$	
Control All	10 30	$6.0\ \pm\ 2.4$	68.2 ± 16.6	1.1 ± 0.6	55.0 ± 28.4	1.1 ± 0.3†	$48.3~\pm~9.5\dagger$	1.3 ± 0.9	
All	50	P = 0.130  (NS)	P=0.111 (NS)	P=0.491 (NS)	P=0.194 (NS)	P = 0.020 (S)	P = 0.000 (S)	P = 0.409 (NS)	

\*Mean  $\pm$  SD.

†B and BG + M groups significantly different from the control group.

NS, not statistically significant (P > 0.05); S, statistically significant (P < 0.05): ANOVA.

(11/30) and persistent endodontic pathology (11/30). Other reasons for tooth extraction included trauma (3/30), caries (2/30), external root resorption (2/30) and chronic periodontitis (1/30). Implants were placed in 18 central incisors sites, two lateral incisors sites, three canine sites and four premolar sites. Two patients presented with two non-adjacent implants sites for implant-supported fixed partial dentures. In these patients, one site was chosen randomly for inclusion in the study. Twenty-eight sites represented single tooth implant replacements. Two patients were cigarette smokers.

## Post-operative healing

Healing in one patient (BM group) was complicated by abscess formation 4 months following implant placement. A flap was raised, revealing incomplete bone regeneration within the original peri-implant defect. The dimensions of the residual defect were recorded and included in the final analysis. The exposed implant surface was disinfected with alternating swabs of hydrogen peroxide (3% w/v) and 2% chlorhexidine gel (Periogard 2%; Colgate). The defect was grafted with anorganic bovine bone mineral (Bio-Oss; Geistlich Pharma AG) and collagen membrane (BioGide; Geistlich Pharma AG). No complications during the healing period were noted for implants in the remaining 29 patients.

The patients maintained a consistent level of oral hygiene and periodontal health throughout the healing period, with no significant differences between groups for PI and BI scores at the time of surgical reentry (mean PI =  $24.0 \pm 10.1\%$ ; P = 0.943 ANOVA; and BI =  $6.8 \pm 3.7\%$ ; P = 0.635

ANOVA). Furthermore, the implant sites showed low levels of plaque accumulation and excellent mucosal health. All implants had successfully integrated at the end of the 6-month healing period.

## Defect and external dimensional change

Healing of the original marginal defect was characterized by a combination of varying degrees of bone fill and resorption of the buccal bone. Exclusion of the case in the BG+M group complicated by infection during the healing period had no material effect on the results. Thus, the results observed in all 30 cases are presented.

VDH reductions amounting to  $81.2 \pm 5.0\%$ ,  $70.5 \pm 17.4\%$  and  $68.2 \pm 16.6\%$ , and HDD reductions of  $71.7 \pm 34.3\%$ ,  $81.7 \pm 33.7\%$  and  $55 \pm 28.4\%$  were observed for BG, BG+M and control groups, respectively (Table 2). Within each of the treatment and control groups, the reductions of VDH and HDD were found to be significant (P < 0.001). Between groups, VDH and HDD reductions were somewhat less in the control group than in the two treatment groups; however, the differences between groups did not approach statistical significance.

Resorption of the buccal bone resulted in a significantly greater reduction in BBD of the control group ( $48.3 \pm 9.5\%$ ) when compared with BG ( $15.8 \pm 16.9\%$ ) and BG+M ( $20\% \pm 21.9\%$ ) groups. Changes in SBC were observed as a loss of crestal height in the control ( $1.3 \pm 0.9$  mm) and BG ( $0.1 \pm 3.4$  mm) groups. Conversely, a gain in crestal bone height amounting to  $0.5 \pm 3.7$  mm was seen in the BG+M group. The differences between the groups were not statistically significant.

Interpretation of modeling and crestal changes of the buccal bone was confounded by the presence of pre-treatment dehiscence defects in four sites ranging in height from 6 to 10 mm (one in the BG group and three in the BG + M group). A separate analysis on the data set without the four dehiscence cases showed that vertical crestal bone resorption was similar for the treatment and control groups, with SBC changes ranging from 1 to 1.3 mm (Table 3). However, significantly greater horizontal resorption was observed in the control group (48.3  $\pm$  9.5%) when compared with BG (13.9  $\pm$  16.7%) and BG + M (19.4  $\pm$  22.1%) groups. The characteristics of sites that presented with initial dehiscence defects of the buccal bone are shown in Table 4. Both treatments were successful in achieving a gain in crestal bone height and limiting the extent of buccal bone resorption.

## Residual defect morphology

Three healing patterns of the marginal defect were observed at the time of surgical re-entry: (i) no defect (ND), i.e. complete fill of the original defect, (ii) a residual infrabony defect in the presence of an intact buccal crest, or moat defect (MD), and (iii) a dehiscence defect (DD), resulting from horizontal and vertical resorption of the buccal bone with exposure of the implant surface (Table 5).

Of the 26 sites with initially intact buccal bone, six healed with complete defect fill (ND). Nine sites healed with MD and 11 with DD. There were no differences in the distribution of residual defect types between groups (P = 0.464;  $\chi^2$ -test). Sites that healed with ND showed complete defect fill resulting in obliteration

Table 3. Initial vertical defect height (VDH), initial horizontal defect depth (HDD), initial buccal bone dimension (BBD) and initial vertical distance from implant shoulder to bone crest (SBC), and changes in SBC and BBD for 26 sites with initially undamaged buccal bone, by treatment groups

Groups	N	Sites with intact buccal bone walls							
		Initial defect di	mensions		Re-entry defect dimensions				
		Initial VDH (mm)*	Initial HDD (mm)	Initial BBD (mm)	Initial SBC (mm)	Vertical shoulder to bone crest (SBC) loss (mm)	Buccal bone dimension (BBD) reduction (%)		
Bone graft only (BG)	9	9.9 ± 1.6	1.8 ± 0.8	2.3 ± 1.0	0.3 ± 0.9	1.1 ± 1.2	13.9 ± 16.7		
Bone graft + membrane (BG + M)	7	9.7 ± 2.6	1.6 ± 0.9	2.1 ± 0.7	1.0 ± 1.3	1.0 ± 0.6	23.8 ± 23.4		
Control	10	$8.7 \pm 2.2$	1.9 ± 0.5	$2.3 \pm 0.5$	$0.6~\pm~0.8$	1.3 ± 0.9	$48.3 \pm 9.5$		
Total	26								
		P=0.485 (NS)	P = 0.779 (NS)	P = 0.914  (NS)	P=0.875 (NS)	P=0.888 (NS)	P=0.015 (S)		

<sup>\*</sup>Mean  $\pm$  SD.

Table 4. Change in vertical distance from implant shoulder to bone crest (SBC) and residual defect type for sites with initial dehiscence defects of the buccal plate

Patient	Group	Initial SBC (height of dehiscence) (mm)	Initial width of dehiscence (mm)	Initial HDD (mm)	SBC change (mm)	SBC change (%)	Residual height of rough implant surface exposed (mm)	Residual defect type
#3	BG + M	9	5	2	8	88.9	<b>– 1</b>	No defect
#13	BG + M	7	5	1	3	42.9	2	Dehiscence
#20	BG + M	6	3	3	4	66.7	0	Dehiscence
#29	BG	10	3	3	9	90	0	Moat
	Mean	8	4	2.3	6	72.1	0.3	

Table 5. Characteristics of sites with complete defect fill (no defect ND sites), moat defect (MD) and dehiscence defect (DD), and frequency distribution of defects by treatment group

	Pre-treatm (mm)	Pre-treatment (mm)			Re-entry (mm)			Crestal bone changes (mm)		Frequency of residual defect-type by treatment group	
	Buccal crestal width*	Implant shoulder to bone crest (SBC)	Initial horizontal defect depth (HDD)	SBC	Infrabony defect height	HDD	Vertical crestal resorption	Horizontal resorption	Bone graft group (BG)	Bone graft + membrane group (BG + M)	Control group
Healed (ND) 6	0.7 ± 0.4	0.8 ± 0.9	1.8 ± 0.9	1.2 ± 0.4	0.2 ± 0.4	0.0+	0.3 ± 1.2	0.7 ± 0.5	2	3	1
Moat (MD)	0.9 ± 0.2 <sup>^</sup>	$0.0~\pm~0.5$	1.6 ± 0.5	$0.9~\pm~0.3$	1.2 ± 0.4^^^	$0.9 \pm 0.2^{+}$	$0.9~\pm~0.6$	$0.6 \pm 0.9$	4	1	4
Dehiscence 11 (DD)	0.5 ± 0.2	1.0 ± 1.1	1.9 ± 0.7	3.0 ± 1^^	0.3 ± 1.1	$0.5~\pm~0.5$	2.1 ± 1.2++	0.9 ± 0.7	3	3	5
All 26	P = 0.020 (S)	P = 0.057 (NS)	P = 0.460  (NS)	P = 0.000 (S	S) $P = 0.031$ (S)	P = 0.000 (S	S) $P = 0.008$ (S)	P = 0.427 (NS)			

<sup>\*</sup>Mean  $\pm$  SD.

of the HDD and a shallow residual VDH of 0.2  $\pm$  1.4 mm. These sites were also characterized by minimal vertical crestal bone resorption (0.3  $\pm$  1.2 mm) and residual SBC of 1.2  $\pm$  0.4 mm.

Sites that healed with MD demonstrated incomplete bone fill and a residual infrab-

ony defect 1.2  $\pm$  0.2 mm in height (significantly greater than ND and DD groups) and 0.9  $\pm$  0.17 mm in depth. Vertical resorption of 0.9  $\pm$  0.2 mm occurred during the healing phase, resulting in a residual SBC of 0.9  $\pm$  0.3 mm. Initial buccal crestal bone width was the greatest for MD

sites  $(0.9 \pm 0.22 \,\text{mm})$  and significantly greater than DD sites  $(0.5 \pm 0.2 \,\text{mm})$ .

Sites that healed with DD had significantly greater vertical resorption of the buccal bone crest than ND and MD sites (3.0  $\pm$  1.0 mm, P=0.000) and a residual defect depth of 0.5  $\pm$  0.5 mm. No statistical

<sup>^</sup>Significantly different from the control group; Tukey's test (BG group -P = 0.000 BG + M group -P = 0.005).

NS, not statistically significant (P > 0.05); S, statistically significant (P < 0.05): ANOVA.

<sup>^</sup>Significantly different from the DD group; (Tukey's test P = 0.023).

<sup>^^</sup>Significantly different from ND and MD groups; (Tukey's test P = 0.000).

<sup>^^^</sup> Differences from the ND group (Tukey's test P = 0.057) and DD group (Tukey's test P = 0.056).

<sup>\*</sup>Significantly different from the MD group (Tukey's test P=0) and DD group (Tukey's test P=0.015).

<sup>\*\*</sup>Significantly different from ND group (Tukey's test P = 0.011); difference with MD group (Tukey's test; P = 0.056).

NS – not statistically significant (P > 0.05); S – statistically significant (P < 0.05): ANOVA.

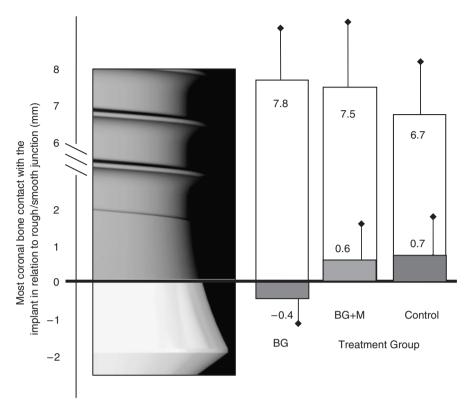


Fig. 2. Most coronal bone contact with the implant in relation to the implant rough/smooth (R/S) junction at surgical re-entry, by treatment group (all sites included). Implants used had a smooth collar height of 1.8 and 2.8 mm. Clear boxes represent pre-treatment defect height in relation to the implant R/S junction.

differences were found between the residual defect types and pre-treatment VDH, HDD and BBD, and for horizontal resorption of the buccal bone (*P*>0.05; ANOVA).

## Clinical success

The implants used in this study had a roughened titanium surface and a polished collar section either 1.8 or 2.8 mm in height and were designed to be placed in healed sites with the rough–smooth (R/S) junction at the level of the crestal bone. In this study, the implants were placed with the collar at the level of the crestal bone, resulting in a sub-crestal position of the R/ S junction. An analysis of the height of regenerated bone in relation to the R/S junction is shown in Fig. 2. The mean of regenerated bone height  $0.4 \pm 0.8$  mm coronal to the R/S junction in the BG group, and  $0.6 \pm 1.8$  and 0.7  $\pm$  1.4 mm apical to the R/S junction in the BG+M and control groups, respectively. The extent of vertical bone regeneration was clinically acceptable in all treatment and control groups.

## Marginal mucosal changes

After the initial healing period of 6 months, 10 out of 30 (33.3%) sites exhibited recession of the marginal mucosa of 1-3 mm on the buccal aspect of the implant healing caps (three each in BG and control groups, and four in the BG+M group). This included the case that was complicated by an infection during the healing phase. Seven were located at central incisor sites, one at a lateral incisor site and two at canine sites. Five of the 10 patients with receded sites agreed to have connective tissue grafts to repair the recession for esthetic reasons. In the remaining 20 sites that did not present with recession, two sites were judged to be at risk of marginal tissue recession due to thin marginal mucosa. Connective tissue grafting was recommended to and accepted by these two patients.

The final soft tissue esthetic outcome was determined following connection of the definitive implant crowns (Table 6). Eight sites (26.7%) were assessed by the operator as having an unsatisfactory postrestoration esthetic result due to marginal tissue recession when compared with contralateral teeth. Six were at central incisor

sites and one each at a lateral incisor and canine site. Three of these sites had previously received connective tissue grafts in an unsuccessful bid to prevent recession. However, only two patients (one each in the BG and BG+M groups) expressed dissatisfaction with the esthetical outcome due to marginal tissue recession; however, both declined further treatment to treat the recession. The patient in the BG+M group was the case in which a peri-implant infection occurred during the initial healing phase.

Further analysis showed no effect of initial VDH, HDD, BBD, SBC and biotype on the presence or absence of marginal tissue recession after 6 months of healing at the implant healing caps. However, the bucco-lingual position of the implant healing cap had a significant effect on recession. Sites with the healing caps positioned buccally were significantly associated with marginal tissue recession when compared with sites with lingually positioned healing caps (P = 0.045; Fisher's exact test; Table 7).

Six out of the eight cases with an operator-assessed unsatisfactory post-restoration esthetic outcome were buccally positioned. At sites with healing caps placed buccally, the initial HDD was 1.1  $\pm$  0.3 mm compared with 2.3  $\pm$  0.5 mm for sites with lingually placed healing caps. This difference was statistically highly significant |P=0.000|.

## Follow-up

All 30 patients presented for follow-up examination following insertion of the implant crowns. At the subsequent recall periods, a high attrition rate was observed. Three patients were lost to follow-up after at the 1-year post-restoration recall, and six did not return for the 2-year examination. A further two patients could not be recalled for the 3-year post-restoration follow-up. Thus, a total of 19 out of the original 30 patients (eight in the control group, six in the BG group and five in the BG+M group) were available for examination at the 3-year post-restoration follow-up (mean period of  $4 \pm 0.7$  years from initial surgery).

## Complications

Two patients experienced complications during the observation period. One patient

Table 6. Frequency table of buccal marginal mucosal recession observed after 6 months of healing and supplementary connective tissue grafting, by post-restoration operator-assessed esthetic outcome

		No additional sof grafting performe		Additional soft tissue grafting performed (CT+)		
Final esthetic N (%) outcome		No recession	Recession	No recession	Recession	
Satisfactory	22 (72.3)	18	0	2	2	
Unsatisfactory	8 (26.7) 30 (100)	0	5	0	3	

Table 7. Frequency table of recession and initial horizontal defect depth (HDD) by healing cap position

Healing cap position	Recession after 6 months of healing		Initial HDD*	Post-restoration esthetic result		
	No	Yes	(mm)	Satisfactory	Unsatisfactory Frequency (%)	
	Frequency (%)	Frequency (%)	_	Frequency (%)		
Buccal	5 (45.5)	7 (58.3)	1.1 ± 0.3	6 (54.6)	6 (75)	
Lingual	15 (78.9)	3 (16.7)	$2.3 \pm 0.5$	16 (84.2)	2 (25)	
Total	20 (66.7)	10 (33.3)		22 (73.3)	8 (26.7)	
	$P = 0.018$ ; $\chi^2$ test		P = 0.000	$P = 0.018$ ; $\chi^2$ test		
	P = 0.045;			P = 0.034;		
	Fisher's exact test			Fisher's exact test		

Table 8. Plaque index (PI), gingival bleeding index (BI), implant plaque index (imPI) and implant sulcus bleeding index (imBI), clinical probing pockets and clinical crown lengths at 1 and 3 years after restoration

_					Clinical probing pockets (mm)			Clinical crown length (mm)		
	P  (%)*	BI (%)	imPl (%)	imBl (%)	Proximal	Buccal	Lingual	Proximal	Buccal	Lingual
3 years 2	$26.6 \pm 12.6$ $20.9 \pm 9.7$ P = 0.041 (S)	$9.6 \pm 5.9$ $7.2 \pm 6.3$ P = 0.208 (NS)	$5.6 \pm 10.7$ $6.9 \pm 16.7$ P = 0.772 (NS)	$8.3 \pm 24.3$ $9.7 \pm 17.5$ P = 0.826 (NS)	$2.6 \pm 0.4$ $2.5 \pm 0.4$ P = 0.205 (NS)	$2.6 \pm 0.7$ $2.7 \pm 0.5$ P = 0.772 (NS)	$2.4 \pm 0.5$ $2.3 \pm 0.6$ P = 0.331 (NS)	6.8 ± 1.4 6.8 ± 1.2 P=1.000 (NS)	$10.1 \pm 1.5$ $10.1 \pm 1.5$ P = 0.749 (NS)	9.8 ± 2.0 9.8 ± 2.1 P=0.805 (Ns)

developed mild inflammation of the marginal mucosa on the buccal aspect of the implant during the first year of observation. This persisted throughout the 3-year follow-up period despite local debridement and instruction in home care. A second patient developed an acute abscess in the third year of follow-up. The infection was confined to the marginal mucosa and was effectively treated with local debridement and systemic antibiotics. There were no technical complications during the observation period.

## Oral hygiene and tissue health

Exploratory data analysis revealed no differences between groups for the parameters of interest and the data were therefore pooled. No differences were noted between the 1- and 3-year post-restoration examinations with respect to BI, imPI and impBI. The PI showed a significant reduction between the 1- and 3-year recalls (Table 8). This indicated that all patients maintained a high level of plaque control and gingival tissue health throughout the observation period.

## Clinical probing pockets

No significant changes were observed in clinical probing pockets at the buccal, proximal and palatal surfaces of the implants. The marginal mucosa was stable, with no change in clinical crown length between I and 3 years for all surfaces (Table 8).

## **Radiographic parameters**

Repeat measures ANOVA showed a significant increase in DIB from the time of implant placement (0.2  $\pm$  0.8 mm for all groups) to surgical re-entry 6 months later (2.1  $\pm$  0.7 mm for all groups; Fig. 3). No differences were observed between groups from surgical re-entry to final follow-up (4.0  $\pm$  0.7 mm for all groups).

## Discussion

This study demonstrated that with a non-submerged healing protocol, marginal

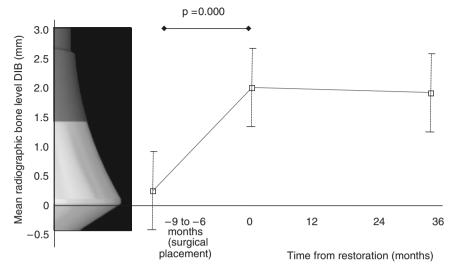


Fig. 3. Mean radiographic crestal bone level (DIB) at initial surgery, at the time of restoration and at 3-years post-restoration (vertical bars indicate standard deviation).

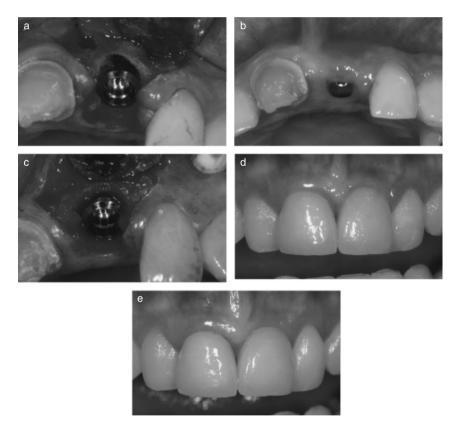


Fig. 4. (a) Occlusal view of an implant in the 21 extraction socket of a control case. No bone graft or membrane was used. (b) Occlusal view of the implant after 6 months of transmucosal healing. Note the partial submergence of the healing cap. For this case, a 'lingual' position of the healing cap was recorded, as the outer border of the healing cap was lingual to a line drawn between the cervical margins of the adjacent teeth. (c) Occlusal view of the implant at surgical re-entry. The buccal marginal defect had completely filled with osseous tissue. Buccal resorption of the labial bone was evident. (d) Buccal view of the 21 implant 1 year following initial surgery. (e) Buccal view of the 21 implant 4 years and 5 months following initial surgery. Note the stable marginal mucosa.

defects adjacent to implants placed into fresh extraction sockets heal predictably with bone fill and clinically acceptable defect resolution. Defect resolution occurred to a similar extent at sites treated with bone grafts and at non-grafted control sites. This provides further evidence that marginal defects of this type heal spontaneously without bone fillers and spacemaintaining barrier membranes, as reported previously using submerged (Paolantonio et al. 2001; Covani et al. 2003; Chen et al. 2005) and non-submerged healing (Botticelli et al. 2004) protocols. Therefore, the choice of healing protocol does not appear to influence healing of these marginal bony defects. However, maintenance of good plaque control and mucosal health during the healing phase is an important criterion for successful bone regeneration with the non-submerged protocol (Lang et al. 1994). Experimental studies have demonstrated that lack of maintenance during the healing phase may have a detrimental effect on regeneration of bone within the marginal defect of transmucosal immediate implants (Brunel et al. 1998; Alliot et al. 1999).

Although it was not possible in this study to determine whether the regenerated bone achieved direct contact with the previously exposed implant surface, the successful outcomes observed in the patients who were followed up for a mean period of 4 years suggest that the regenerated bone was functional and stable over this period of time.

An additional finding of this study was that bone fill and defect resolution occurred in conjunction with horizontal and vertical changes to the buccal bone. In the nongrafted control sites, approximately half the original horizontal dimension was lost following resorption of the buccal bone. These results were similar to previous clinical reports at non-grafted immediate implant sites (Schropp et al. 2003; Botticelli et al. 2004; Chen et al. 2005). In contrast, anorganic bovine bone grafted to the marginal defects of the BG and BG + M groups limited the resorption to about 25% of the original horizontal dimension.

At the 26 sites with intact buccal bone, vertical resorption of the buccal crest was similar in grafted and control sites and amounted to approximately 1 mm. Thus, it was observed that anorganic bovine bone, while successful in limiting horizontal resorption, had no effect in preventing vertical resorption of the buccal socket margin. Previous clinical reports have reported similar crestal bone changes in extraction sockets alone (Lekovic et al. 1997, 1998; Simon et al. 2000; Iasella et al. 2003) or adjacent to implants (Gher et al. 1994).

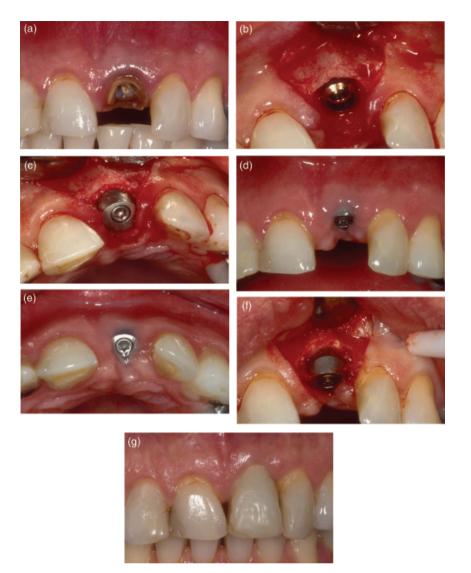


Fig. 5. (a) Pre-treatment view of the retained root of tooth 21 in a bone graft-only (BG) case. (b) Buccal view of the implant after placement in the extraction socket. The implant shoulder was positioned at the level of the buccal crestal bone. (c) Occlusal view of the implant and bevelled healing cap attached. The buccal marginal defect measured 1 mm horizontally. The defect was grafted with anorganic bovine bone (BioOss™). (d) Buccal view of the 21 implant site after 6 months of transmucosal healing. The marginal mucosa was thin and had receded slightly. (e) Occlusal view of the 21 implant after 6 months of healing. Note the position of the implant healing cap in relation to the adjacent teeth. For this case, a 'buccal' position of the healing cap was recorded, as the outer border of the healing cap was slightly buccal to a line drawn between the cervical margins of the adjacent teeth. (f) Buccal view of the 21 implant at surgical re-entry. The buccal marginal defect was completely filled with osseous tissue. Slight loss of vertical crestal height in relation to the implant shoulder was noted. However, minimal horizontal resorption of the buccal plate was observed. (g) Buccal view of the 21 implant 1 year following surgical re-entry. The implant was restored with a provisional crown. Note the marginal tissue recession that had occurred compared with the pre-treatment situation (a).

The grafts in the present study were placed within the confines of the defect and did not extend coronal or external to the buccal socket walls. Other studies investigating preservation of socket dimensions after tooth extraction have reported gains in vertical bone of about 1 mm by 'overbuilding' the marginal defects (Iasella et al. 2003) or by overlaying the buccal bone externally with the graft (Simon et al. 2000).

The initial thickness of the buccal crestal bone may be a factor in determining the extent of crestal bone resorption during the healing phase. Compared with ND and MD sites, DD sites with half the initial buccal crestal bone thickness (0.5 mm) of ND and MD sites, exhibited significantly greater (2.1 mm, or up to three times) vertical resorption. It was interesting to note that all defect types exhibited similar

horizontal resorption, suggesting that the initial buccal bone thickness influences vertical resorption, but not horizontal resorption. Further evidence for this phenomenon may be derived from a recent experimental study in dogs. Significantly greater crestal bone resorption was observed at the thin buccal socket margins when compared with the thicker lingual margins (Araujo et al. 2005). The authors concluded that this thin buccal bone, composed entirely of bundle bone, was susceptible to interruption of the vascular supply as a consequence of flap reflection. Elevation of a flap separates the periosteum from the underlying bone causing vascular interruption, inflammatory reactions and subsequent bone resorption (Wilderman 1963; Wood et al. 1972; Bragger et al. 1988).

Although the initial defect characteristics of the ND and MD sites were similar, the outcomes in relation to defect fill were different. The reasons for the difference between these two groups remain unclear, although grafted sites did have a greater proportion of complete fill (5/10 for BG and BG+M sites compared with 1/5 for control sites). Further research with larger sample sizes would be required to identify the factors influencing the degree of defect fill.

In the four sites with initial dehiscence defects of the buccal bone (dehiscence height ranging from 6 to 10 mm from the implant shoulder), grafting procedures were successful in restoring the buccal plate, and achieving clinically successful vertical bone regeneration. Although the vertical regeneration only amounted to 72.1% of the original defect height, the newly constituted crestal bone was located at a mean of distance of 0.3 mm apical to the R/S interface.

The sites selected for inclusion in this study were within the esthetic zone (Fig. 4). The observation that the buccal mucosa receded at 10 out of 30 (33.3%) of sites and the final post-restoration soft tissue esthetic result was unsatisfactory in eight out of 30 (26.7%) sites was therefore a disappointing outcome. Five out of 10 patients with recession agreed to have connective tissue grafts to correct the mucosal recession, while the remaining five patients declined due to their low esthetic demands. The connective tissue grafts were placed at the shoulder region of the implants and secured in place with sling sutures. The buccal flaps were coronally

advanced to cover the grafts and partially submerge the implants, and to gain mucosal height. In three out of the five grafted cases, these attempts were unsuccessful in preventing recession of the mucosa at the final implant crowns.

An analysis of the factors related to the frequency of recession did not show a relationship with initial VDH, HDD, BBD, SBC and biotype. In this context, it should be noted that the number of sites with recession was small and thus definitive conclusions regarding the influence of these factors cannot be drawn.

There was, however, a significant relationship between the bucco-lingual position of the implant and recession (Fig. 5). Thus, implants placed with the buccal edge of the healing caps at or buccal to a line drawn between the buccal surfaces of the adjacent teeth had a greater incidence of recession and unsatisfactory post-restoration esthetic outcomes. These implants were also found to have a significantly smaller initial HDD (1 mm) than implants placed lingually (2 mm), indicating that the implants were positioned more buccally in the extraction socket after placement. This suggests that despite careful preparation of the implant sites, the final implant shoulder position may have altered during installation of some of the implants. This may be explained by the geometry of the implants used in this study in which the shoulder was larger in diameter than the implant body (4.8 vs. 3.5 mm). Under-preparation at the crestal region of the palatal socket wall could have caused the implant to deflect buccally at the time of insertion.

Using a reference line drawn between the point of emergence of adjacent teeth, Buser et al. described the position of the implant shoulder as being in the 'comfort' zone for achieving optimum soft tissue esthetics when positioned I mm lingually, and in the 'danger' zone when positioned within I mm or buccally to this line (Buser et al. 2004). The results from the present study suggest that at implants in extraction sockets, a larger safety margin should be adopted with the implant shoulder positioned at least 2 mm from the internal buccal socket wall.

When considering the cases with initial dehiscence defects of the buccal bone, three of the four sites (75%) demonstrated marginal tissue recession after the 6-month healing period despite clinically successful regenera-

tion of bone and gain in crestal bone height at the dehiscence defects. The presence of initial defects in the buccal bone of extraction sockets should therefore be regarded as a risk factor for marginal tissue recession with immediate implant placement.

Although we observed significantly greater vertical resorption at sites with thin buccal crestal bone, it was not possible to draw inferences on the effect of resorption on marginal mucosal recession due to the low numbers in the study. The interaction between the bone modeling changes and soft tissue stability at implants remains unclear (Belser et al. 2004).

In the 19 patients available for postrestoration follow-up of 3 years, clinical and radiographic parameters remained stable over the observation period. No changes were observed in the level of the mucosa on the buccal, proximal and palatal surfaces once the implants were restored. This confirmed previous reports of stable peri-implant bone and mucosal conditions during follow-up periods of 1-5 years after completion of single tooth implant restorations (Scheller et al. 1998; Grunder 2000). Stable bone and mucosal conditions are regarded as important for maintaining long-term soft tissue esthetics with implant reconstructions (Hermann et al. 2001).

## Conclusions

From the present study, it may be concluded that marginal bone defects adjacent to implants placed into fresh extraction sockets with a non-submerged protocol heal predictably whether bone grafts and/or barrier membranes are used or not. Healing occurs with a combination of fill within the marginal defect and external modeling changes to the buccal bone.

The extent of the horizontal resorption may be reduced to 25% of the original buccal dimension with the use of anorganic bone grafts and/or barrier membranes. With respect to vertical resorption, thin buccal crestal bone represents a significant risk factor. The relationship between modeling changes in the buccal crestal bone region and soft tissue esthetic outcomes is unknown.

A high incidence of marginal tissue recession occurs in the 6-month healing period after placement of the implants. This recession may have a negative impact on the final esthetic result and may not readily be corrected with adjunctive soft tissue grafts. The position of the implant shoulder within the socket is a critical determinant for success. The implant shoulder of the type used in this study should be placed in a position to maintain an HDD of 2 mm. In doing so, careful preparation of the osteotomy and preparation of the palatal socket wall in maxillary anterior sites should be undertaken to achieve this objective. Oversized implants that fill the socket or reduce the HDD to <2 mm should be avoided. The risk of adverse esthetic outcomes for implants placed into extractions sockets under the conditions of the present study must therefore be carefully evaluated by the clinician.

Once restored, single tooth implants in extraction sockets may be expected to function with stable radiographic and mucosal conditions in the presence of good plaque control.

## 要旨

目的:無機牛骨を移植し即時埋入した粘膜 貫通型インプラントにおける辺縁骨欠損の 治癒を評価し、修復治療後3~4年後の粘 膜とX線上の結果を評価すること。

材料と方法:患者30名の上顎前歯部に合計30本の粘膜貫通型インプラントを即時埋入し、Bio Oss™使用(N=10;BG)、BioOss™と吸収性コラーゲン・メンブレン使用(N=10;対照)の3群に無作為に振り分けた。

結果: BG 群、BG+M 群、対照群の垂直的欠損高径(VDH)の減少は、8々81.2±5.0%、70.5±17.4%、68.2±16.6%であったが、群間に有意差は認められなかった。水平的吸収率は、BG 群 (15.8±16.9%) と BG+M 群 (20.0±21.9%) に比べ、対照群が有意に高かかった(48.3±9.48%、p=0.000)。

10箇所の部位(33.3%)は6ヶ月後に粘膜の退縮を示し、8部位(26.7%)は退縮のために修復治療後の審美性に問題が生じた。粘膜の退縮は、舌側寄りのインプラント位置(HDD2.3±0.6mm)に比べ、頬側寄りのインプラント位置に有意に相関していた(HDD1.1±0.3mm)。平均4.0±0.7年の経過観察を行った患者19名において、辺縁部粘膜と骨レベルは修復治療後に安定していた。

結論:BioOss™は頬側骨の水平的吸収を有意に減少した。インプラントの即時埋入には粘膜の退縮と軟組織の審美性に対する悪影響というリスクが伴うが、抜歯窩に埋入するインプラントの位置を頬側寄りにしないことによって、このリスクを減じることができる。

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