Pietro Felice, Claudio Marchetti, Adriano Piattelli, Gerardo Pellegrino, Vittorio Checchi, Helen Worthington, Marco Esposito

Vertical ridge augmentation of the atrophic posterior mandible with interpositional block grafts: bone from the iliac crest versus bovine anorganic bone. Results up to delivery of the final prostheses from a split-mouth, randomised controlled clinical trial

Key words *bone augmentation, bone grafting, bovine anorganic bone, dental implants, inlay graft, vertical augmentation*

Purpose: To compare the efficacy, complications and patient preference of two different techniques for vertical bone augmentation of the posterior mandible: bone blocks harvested from the iliac crest versus anorganic bovine bone blocks (Bio-Oss®) were used as inlays.

Materials and methods: Ten partially edentulous patients, requiring bilateral and vertical bone augmentation of the posterior mandible (having 5 to 7 mm of residual crestal height and at least 5 mm thickness above the mandibular canal to allow for implant placement) had their posterior mandibles randomly allocated to both interventions. Resorbable barriers were used to cover the grafts. After 4 months, implants were inserted, and after a further 4 months, provisional prostheses were inserted. Definitive prostheses were delivered 4 months later. Prosthesis and implant failures, the amount of vertically regenerated bone measured on computerised tomography (CT) scans, any complications, the time needed to fully recover mental nerve sensitivity and patient preference were all recorded. All patients were followed up for up to 1 month after the delivery of the final restorations.

Results: Up to 5 months post-loading no patients dropped out or were excluded. Both procedures obtained significant bone gain and achieved the desired results. Four months after grafting, autogenous bone loss was on average 1.1 mm (P=0.088) and Bio-Oss 0.6 mm (P=0.001). There were no statistically significant differences in bone gain and maintenance among the two procedures. The sides treated with Bio-Oss recovered their full mental nerve sensitivity significantly faster than those treated with autogenous bone (4 versus 6.3 days). Three complications occurred during graft healing; two in the autogenous bone group and one determining the complete failure of the augmentation procedure. No implants or prosthesis could be placed in the planed area. There was no statistically significant differences in the occurrence of complications between the procedures. After implant placement one complication occurred in the autogenous bone group (probably as a consequence of a previous complication). Patients significantly preferred the treatment with Bio-Oss: 3 weeks after augmentation seven patients preferred Bio-Oss and three patients found the treatments to be 'equally good' (odds ratio 0.045 [5% confidence interval (CI) 0.00 to 0.87], P=0.04). One month after delivery of the final prostheses, eight patients preferred Bio-Oss and two patients found the treatments to be 'equally good' (odds ratio 0.03 [95% CI 0.00 to 0.64], P=0.02).

Conclusions: This pilot study suggests that it might be sensible to use Bio-Oss blocks rather than bone harvested from the iliac crest as the interpositional graft in the treatment of resorbed posterior mandible, as patient discomfort is reduced.

Pietro Felice
Resident
Department of Periodontology and Implantology, University of Bologna, Bologna, Italy

Claudio Marchetti
Associate Professor
Department of Oral and Maxillofacial Surgery, University of Bologna, Bologna, Italy

Adriano Piattelli
Professor of Oral Medicine and Pathology, Dean and Director of Studies and Research, Dental School, University of Chieti-Pescara, Chieti, Italy

Gerardo Pellegrino
Oral Surgery & Implantology Fellow, Department of Oral and Dental Sciences, University of Bologna, Bologna, Italy

Vittorio Checchi
Resident
University of Naples, Second Polyclinic, Naples, Italy

Helen Worthington
Professor of Evidence Based Care

and
Co-ordinating Editor, Cochrane Oral Health Group, School of Dentistry, The University of Manchester, Manchester, UK

Marco Esposito
Senior Lecturer
Oral and Maxillofacial Surgery, School of Dentistry, The University of Manchester, UK

and
Associate Professor, Department of Biomaterials, The Sahlgrenska Academy, Göteborg University, Sweden

Correspondence to:
Marco Esposito, School of Dentistry, Oral and Maxillo-facial Surgery, The University of Manchester, Higher Cambride Street, Manchester, M15 6FH
Email: espositomarco@hotmail.com

■ Introduction

The lack of sufficient bone volume to place dental implants in the posterior atrophic mandible owing to the presence of the inferior alveolar nerve is a common problem in partially edentulous patients. Patients can be rehabilitated with partial removable dentures, which are not always appreciated. Short implants have been suggested as an alternative[1]. However, some authors consider 7 to 10mm to be long implants[1], but in several circumstances the available bone above the inferior alveolar nerve is only 5 to 7mm in height. Therefore, this may not be sufficient and it appears that failure rates for shorter implants (7mm) are higher. To overcome this problem it has been suggested the alveolar inferior nerve is transposed to allow for placement of longer implants[2]. However, this procedure is technically demanding and can be associated with a permanent loss of nerve sensitivity. The ideal approach would be to augment bone vertically in a predictably successful way. Several techniques are currently used, including various vertical guided bone regeneration (GBR) procedures[3-8], alveolar distraction osteogenesis[4,7] and onlay bone grafting[7]. Although it has been shown that it is possible to vertically augment bone with different techniques, the number of complications and failures of the augmentation procedures is still too high (well over 20%) to recommend widespread use of such procedures[9]. Another possible approach is the use of an interpositional bone graft[10-13].

The aim of this randomised controlled clinical trial was to evaluate efficacy, complications and patient preference by comparing two techniques to vertically augment atrophic posterior mandibles using an interpositional graft: autogenous bone blocks from the iliac crest versus anorganic bovine bone blocks.

The present investigation is a preliminary report focusing on patient preference, the amount of vertically regenerated bone and the complications that occurred up until the insertion of the final prostheses. In a separate report the histological data will be presented. It was planned to prolong the follow-up to the fifth year of function to evaluate the success of the procedures over time. The present article is reported according the CONSORT statement for improving the quality of reports of parallel-group randomised trials[14].

■ Materials and methods

The following patients were eligible for inclusion in the trial: those with bilateral partial edentulism in the posterior mandible, who had a residual bone height between 5 and 7mm and a thickness of at least 5mm above the inferior alveolar canal (measured on CT scans), required vertical bone augmentation to allow placement of two implants per side, who were 18 years or older and able to sign an informed consent (Figs 1 and 2).

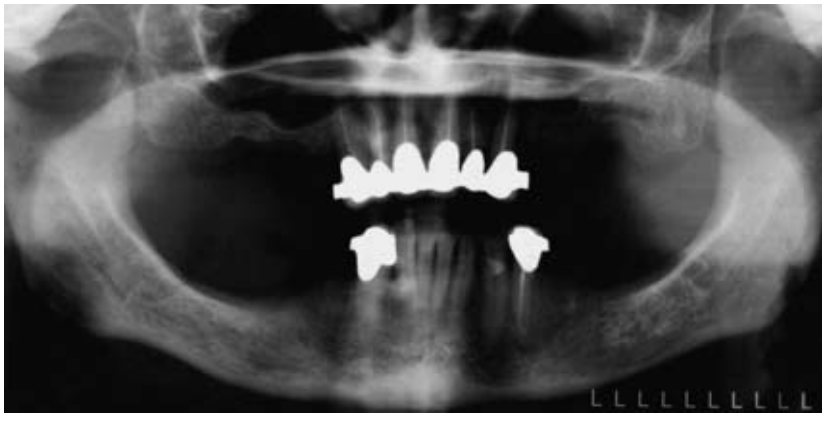


Fig 1 Preoperative panoramic radiograph.

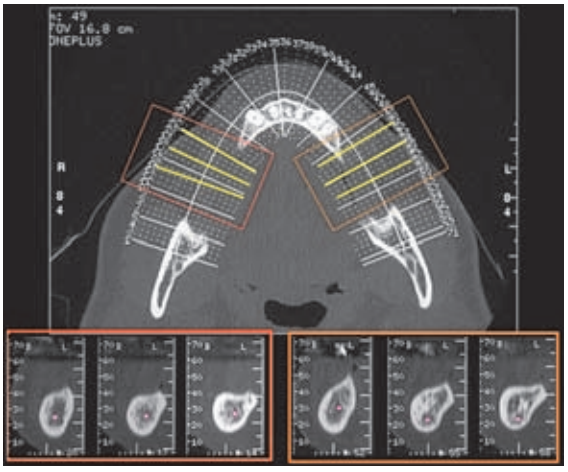


Fig 2 Dental computerised tomography scans before augmentation showing, at the bottom, the paraxial views of the retroforaminal regions.

Patients were not admitted to participate in the study if any of the following exclusion criteria were present:

- general contraindications to implant surgery
- patients subjected to irradiation, chemotherapy, or immunosuppressive therapy in the previous 5 years
- poor oral hygiene and motivation
- uncontrolled diabetes
- pregnant or lactating
- substance abusers
- smoke more than 15 cigarettes per day
- suffered from psychiatric problems or unrealistic expectations
- acute infection in the area intended for implant placement
- positive to HIV and hepatitis B and C
- affected by autoimmune diseases such as rheumatoid arthritis, systemic lupus erythematosus, sclerodermia, Sjögren syndrome and dermatomyositis/polymyositis
- treated or under treatment with intravenous amino-bisphosphonates
- previously subjected to reconstructive procedures of the posterior mandible
- under chronic treatment with steroids or non-steroidal anti-inflammatory drugs.

Patients were recruited and treated in the Department of Oral and Maxillofacial Surgery of the S. Orsola-Malpighi University Hospital of Bologna, Italy. Ethical approval for the study was obtained from the ethical committee of the S. Orsola-Malpighi Hospital (number 110/2007/U).

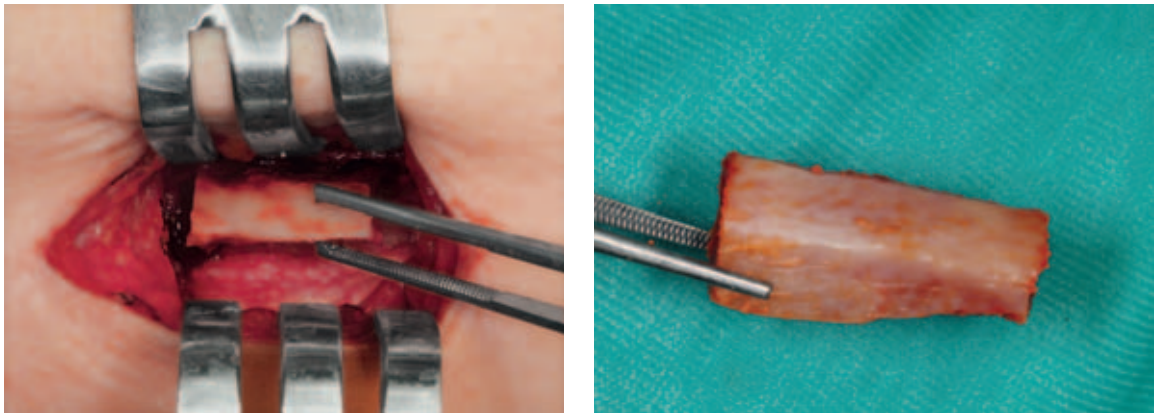
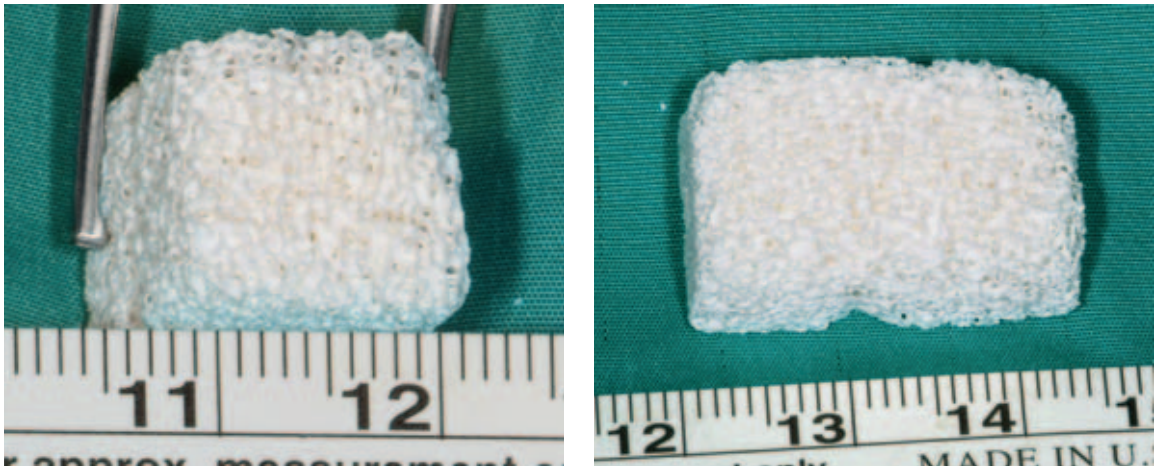


Fig 3a and b Bone block being prepared from medial surface of anterior iliac crest (a), and after harvesting (b).



Figs 4a and b Block of anorganic bovine bone (Bio-Oss).

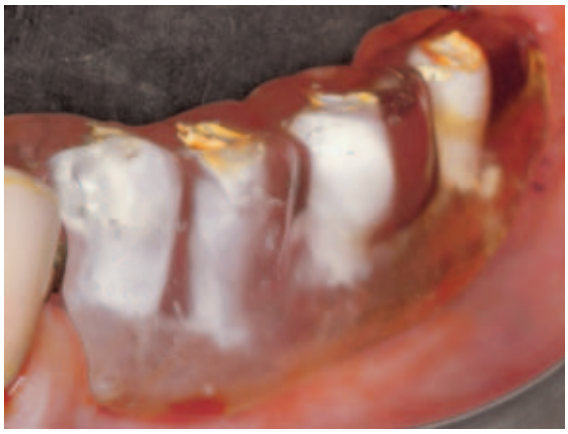
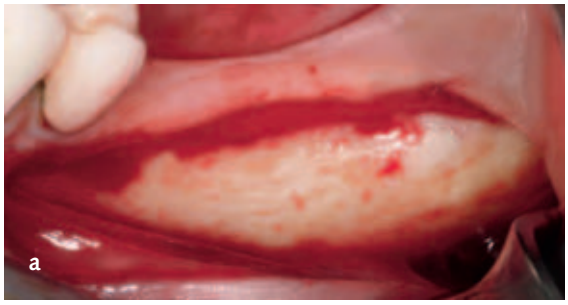
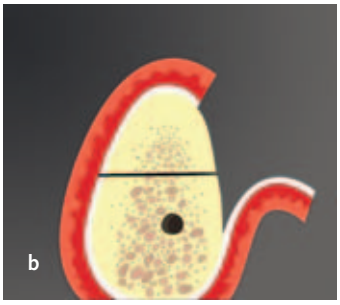


Fig 5 A surgical template indicated the planned position of the implants.





Figs 6a and 6b A paracrestal incision was made on the buccal side.

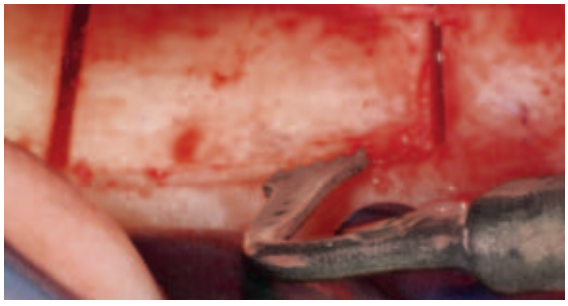
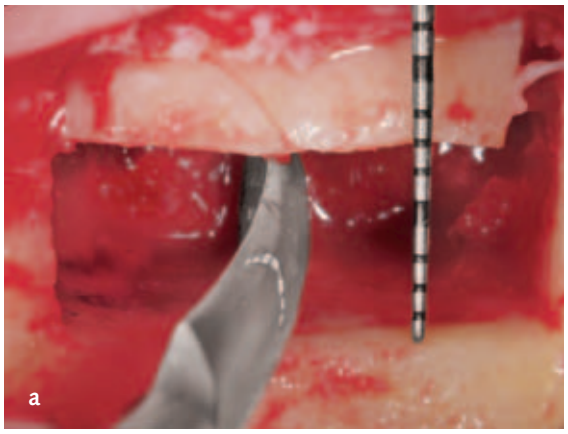


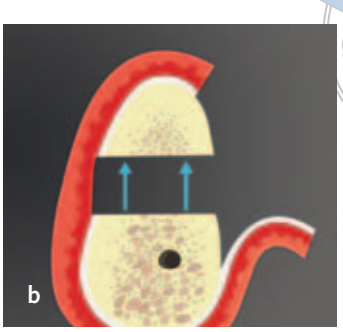
Fig 7 Horizontal and vertical osteotomies were made.

Posterior edentulous ridges requiring vertical augmentation were randomised to receive an interpositional block graft either harvested from the iliac crest (Fig 3a to b) or a block of anorganic bovine bone (Bio-Oss®, Geistlich, Pharma, Wolhusen, Switzerland, Fig 4).

A preoperative computerised tomography (CT) scan was used to quantify the amount of available bone above the alveolar inferior canal, to decide whether or not patients could be included in the study. Study models were used to plan the amount of vertical augmentation required by the patients.

The day before the augmentation procedure, the envelopes containing the randomised codes were opened and the surgeon knew which side to treat with each procedure. All patients received prophylactic antibiotic therapy – ceftriaxone (Ceftriaxon, Tyrol Pharma, Bordon, UK) was administered intravenously on induction at a loading dose of 2 g, and then 1 g twice daily, from the day after surgery for 10 days. All patients were treated under general anaesthetic and both augmentation procedures were implemented in a single session. First the two mandibular sites were prepared. The grafts were then harvested from the iliac crest and placed into the corresponding randomised site. Finally the Bio-Oss was placed in the contralateral site. Local anaesthesia was induced with articain 4% and adrenaline 1:100.000. A surgical tempate was used to indicate the position of the planned implants (Fig 5). A paracrestal incision was made through the buccal area avoiding the emergence of the mental nerve, to expose the alveolar ridge (Fig 6). A mucoperiosteal flap was carefully retracted, trying to avoid tension





Figs 8a and b The cranial osteotomised segment was moved upward (a). Illustration of the same procedure (b).

Fig 9 The Bio-Oss block was trimmed and shaped to fit between basal bone and cranial segment.

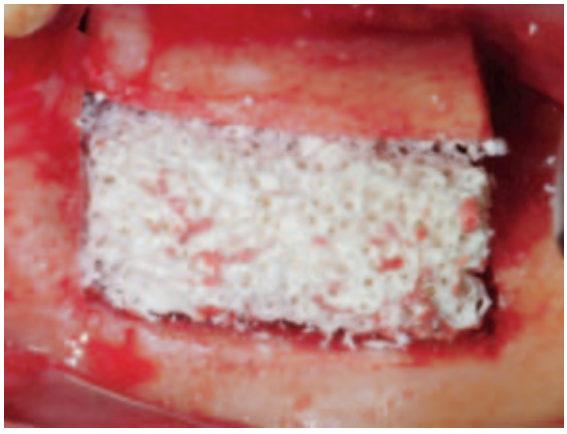


Fig 10 The Bio-Oss block was placed as an interpositional graft.

on the mental nerve. A horizontal osteotomy was made approximately 2 to 4 mm above the mandibular canal using piezosurgery (Mectron Piezosurgery Device™; Mectrons s.p.a., Carasco Genoa, Italy). Two oblique cuts were then made into the coronal third of the mandibular bone with the mesial cut made at least 2 mm distal to the last tooth in the arch (Fig 7). The height of the osteotomised segment had to be of at least 3 mm to allow for the insertion of the stabilising screws without fracturing. The osteotomised segment was then raised in a coronal direction sparing the lingual periosteum (Fig 8a and b). At this point the autogenous bone block was harvested from the medial surface of the anterior iliac crest[15]. The iliac crest donor site was infiltrated with local anaesthetic (lidocaine 1%) and the non-scalpel-bearing hand was used to displace the skin medially before the incision was made. A 3 cm long incision was started 1 cm behind the anterior superior iliac spine and made through the displaced skin directly over the crest. Dissection was continued following the axis of the iliac crest through subcutaneous tissues, Scarpa's fascia and periosteum, directly over the crest. The periosteum and the overlying muscles on the top of the crest and on the medial aspect of ilium were then dissected. The corticotomy of the medial portion of anterior iliac crest was performed with a fissure bur or a reciprocating saw: two vertical cuts defined a bone portion of 2 cm length; these two vertical cuts (about 1 cm long) were connected by a horizontal cut along the medial portion of the top of iliac crest, cut above, and with a second horizontal cut, below, in the medial surface of the iliac bone. The osteotomy of the cancellous portion was completed with chisels, obtaining a monocortical-cancellous rectangular block. The wounds were routinely drained for 2 days and the overlying soft tissues were closed with three layers of sutures. According to the outcome of the randomisation, the autogenous bone and Bio-Oss blocks were modelled to completely fill the sites to the desired height and shape (Fig 9), interposed

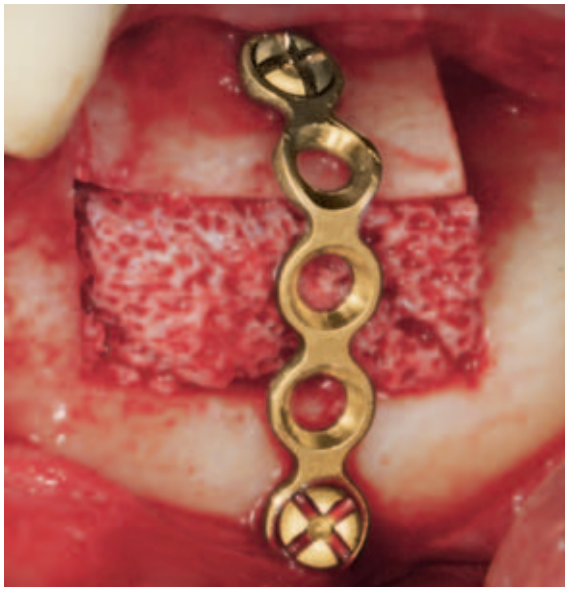


Fig 11 The graft was fixed with miniplates and screws.

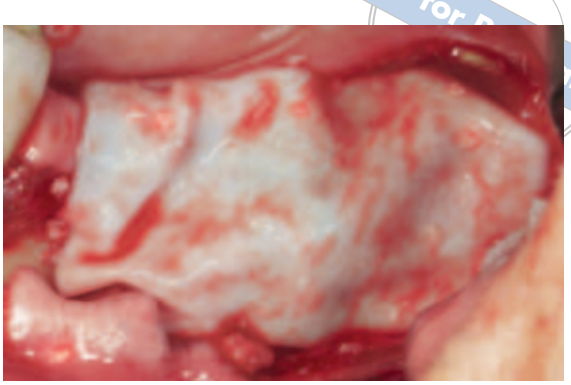
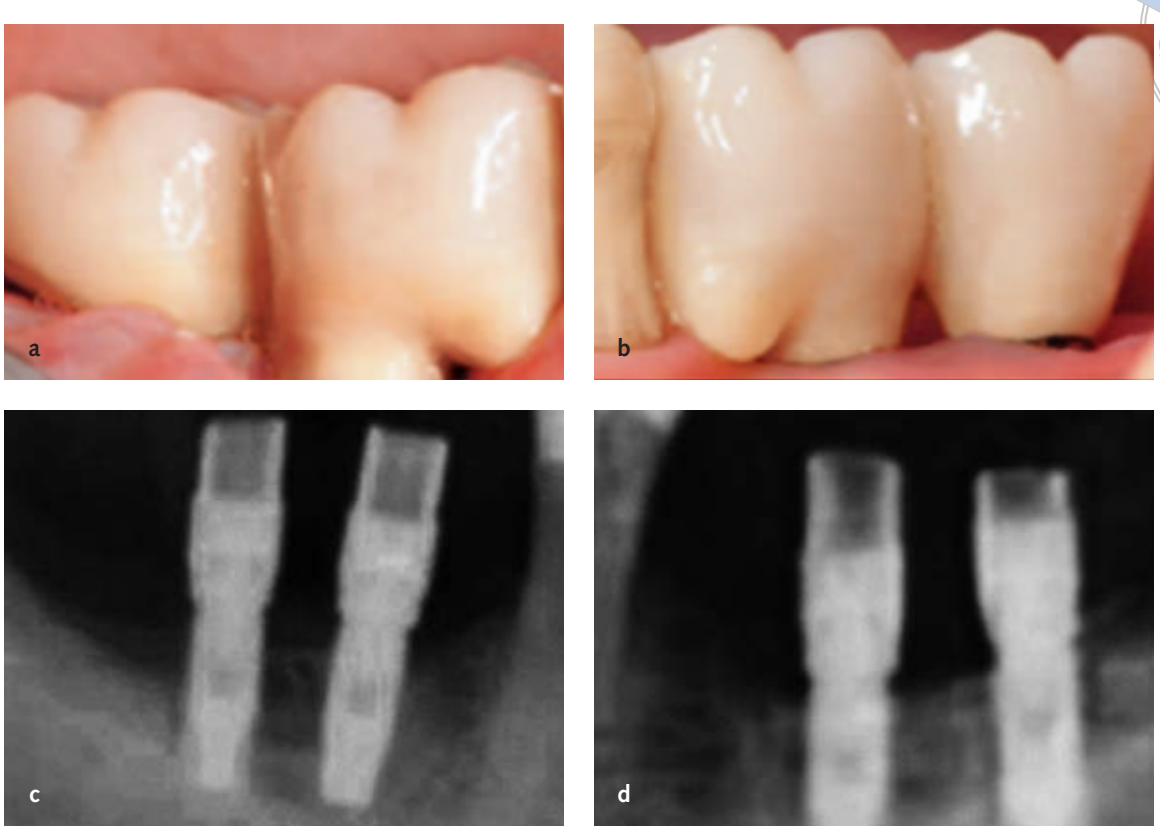


Fig 12 A resorbable collagen membrane was used to cover the graft material.

between the raised fragment (Fig 10) and the mandibular basal bone and fixed with titanium miniplates and miniscrews (Gebrüder Martin & Co., Tuttlingen, Germany) (Fig 11) to both the basal bone and the osteotomised crestal bone. Gaps in the vertical osteotomies were filled with particulated Bio-Oss from the blocks or autogenous particulated bone from the iliac crest, according to the randomisation schedule. The grafted areas were covered with a resorbable barrier (Bio-Gide®, Geistlich Pharma) (Fig 12). Periosteal incisions were made to release the flaps coronally as required and the flaps were sutured with Vicryl 4.0 sutures (Ethicon FS-2, St-Stevens-Woluwe, Belgium), until the incisions were perfectly sealed. Patients were given a non-steroidal analgesic drug (ketoprofen, Orudis, Aventis Pharma, Bridgewater, UK) at a dose of 200 mg twice daily for 3 days and thereafter only if required. Cortisone (betametazon) 4 mg was administered twice daily for 2 days and once a day on day 3. Patients were instructed to use 1% Corsodyl gel (GlaxoSmithKline, Middlesex, UK) 2 to 3 times a day for 2 weeks and then 0.2% chlorhexidine mouthwash twice a day for an additional 10 days, to consume a soft diet for the following 2 weeks, and to avoid brushing and trauma on the surgical sites. No removable prostheses were allowed for 1 month. All patients remained hospitalised for 3 days. Sutures at the iliac crest were removed after 7 days and in the oral cavity after 10 days. All patients were recalled for additional post-operative check-ups 3 and 6 weeks and 3 months after the augmentation procedure. Four months after augmentation, miniplates were removed, knife edge ridges were flattened to reach a thickness of at least 5 mm, and two study implants were inserted in each side using surgical templates under local anaesthetic. The choice of the implant type, diameter and length was decided by the surgeon according to the anatomical limitations and the treatment plan. Implants were placed with the neck flush with the surrounding bone and were submerged for a healing period of 4 months. Two grams of amoxicillin were administered preoperatively and then 1 g twice a day for 5 days. Ibuprofen 600 mg was prescribed to be taken as required. Four months later, the implants were exposed, abutments were placed, and screw-retained implant-supported acrylic resin temporary fixed partial dentures were delivered. Definitive screw-retained prostheses (Figs 13a and b) were inserted 4 to 5 months after delivery of the provisional fixed partial dentures. Patients were enrolled in an oral hygiene programme with recall visits every 3 to 4 months for the entire duration of the study. Intraoral radiographs were made with the paralleling technique at abutment connection and at insertion of the provisional prosthesis. In case the bone levels around the study implants were hidden or difficult to read, a second radiograph was taken.



Figs 13a to d Placement of final metal-ceramic prosthesis: (a) right side (iliac bone) (courtesy of Dr Primo Galletti); (b) left side (Bio-Oss) (courtesy of Dr Primo Galletti); (c and d) radiographs showing placement.

All surgical interventions were performed by a single experienced operator (Dr Pietro Felice). Identical bilateral prostheses were fabricated by three different dentists. Follow-ups were conducted at the referring centres by an independent outcome assessor (Dr Fabio Rossi) together with the surgical operator (Dr Pietro Felice).

This study tested the null hypothesis that there was no difference between the two procedures against the alternative hypothesis that a difference between the procedures was present.

The outcome measures were:

- Prosthesis failure: planned prosthesis, which could not be placed due to implant failure(s) and loss of the prosthesis secondary to implant failure(s).
- Implant failure: implant mobility and removal of stable implants dictated by progressive marginal bone loss or infection. Stability of individual implants was measured with the removed prosthesis at abutment connection (4 months after implant placement) at delivery of the provisional and definitive prostheses by applying a reverse torque of 15 Ncm.
- Any biological or prosthetic complications were grouped in two categories: those related to the bone grafting procedures up to implant placement and those occurring after implant placement.
- The amount of bone gained in vertical direction measured on CT scans in mm (rounded to 0.5 mm) at implant surgery (baseline), immediately post-operatively, and after 4 months. The mean vertical bone height was determined on paraxial 1.5 mm thin slices at 6, 12 and 18 mm posterior to the mental foramina (Fig 14), measuring the distance between the upper border of the inferior alveolar canal to the upper border of the crestal bone (Fig 15) using the Autocad-Autodesk® Software (San Rafael, CA, USA). The amount of vertical bone resorbed after 4 months was calculated in the same way.
- The time (in days) needed to fully recover mental sensitivity after the augmentation procedure.

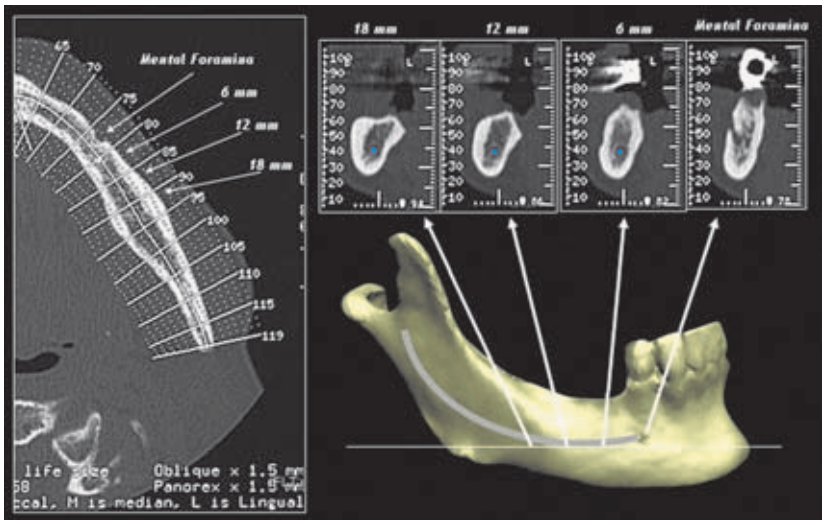


Fig 14 Dental computerised tomography (CT) before augmentation. Paraxial CT views of 1.5 mm thin slice scans in the left retroforaminal region. The measurements were made 6, 12, and 18 mm posterior to the mental foramina.

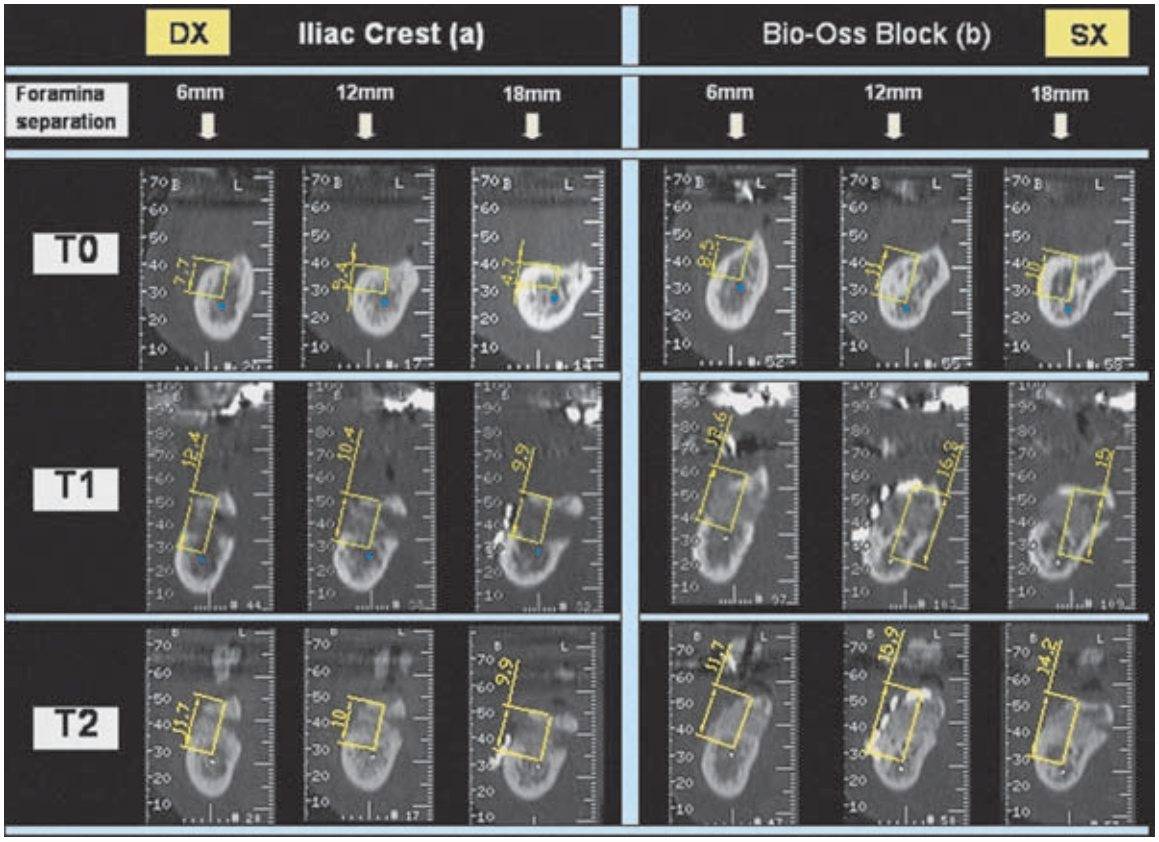


Fig 15 Measurements of CT scans before surgery (T0), immediately after surgery (T1) and at 4 month assessment, just before implant placement (T2).

- Patient preference assessed 3 weeks after the augmentation procedure and 1 month after delivery of the definitive prostheses by an independent assessor asking the patients which was the preferred treatment, the answer was one of the following: 1) bone from the iliac crest, 2) bone substitute, 3) none, both treatments were equally good, 4) none, both treatments were equally bad.
- Peri-implant marginal bone levels evaluated on intraoral radiographs taken with the paralleling technique at implant placement, 1 and 5 years after loading. Data on this outcome will be reported in future publications.
- Histological and histomorphometric evaluation of the augmented bone retrieved with a trephine bur at implant placement. Data on this outcome will be reported in future publications.

Two dentists (Dr Fabio Rossi and Dr Gerardo Pellegrino) not involved in the treatment of the patients made all the clinical and radiographic assessments without knowledge of group allocation, therefore, outcome assessors were blind to these assessments. However, Bio-Oss-treated sites could be identified on radiographs because they appeared more radiopaque.

Sample size was calculated to detect a preference of one group over another against the alternative hypothesis that the treatments are equally preferred. This reduces to a simple one-sample proportion scenario. A one-group chi-square test with a 0.050 two-sided significance level will have 80% power to detect the difference between the null hypothesis proportion of 0.500 and the alternative proportion of 0.900, when the sample size is 10. Therefore, ten subjects were included in this study. A computer-generated restricted randomisation list was created by an office of the S. Orsola-Malpighi hospital. None of the investigators were aware of the randomisation sequence.

The randomised codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially one day before surgery. Therefore, treatment allocation was only partially concealed to the investigators in charge of enrolling and treating the patients included in the trial.

All data analysis was carried out according to a pre-established analysis plan. A biostatistician with expertise in dentistry analysed the data, without knowing the group codes. Differences in means at patient level for continuous outcomes (bone levels and days needed to fully recover mental sensitivity) between groups were compared using paired *t* tests.

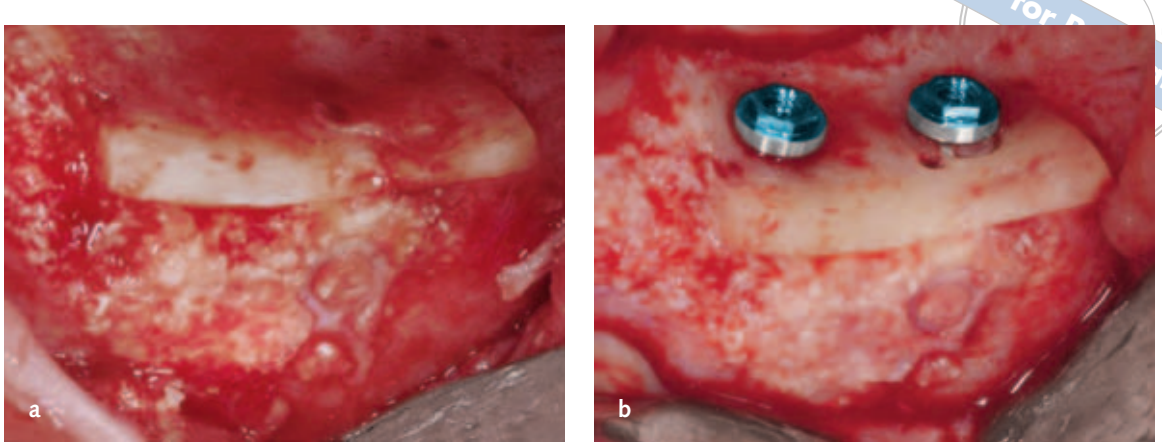
The differences in the proportion of patients with prosthesis failures, implant failures and complications (dichotomous outcomes) were compared between the groups using the McNemar chi-square test. The preference data were analysed like binary data from a cross-over trial. The methods of Curtin[16] were then used to calculate the odds ratio, 95% confidence interval and *P* value for the preference of one intervention over the other. All statistical comparisons were conducted at the 0.05 level of significance.

Results

Sixteen patients were screened for eligibility. However, six patients could not be included in the trial for the following reasons: three patients had less than 5 mm of bone height above the mandibular canal (about 3 mm of residual bone height), two patients assumed intravenous bisphosphonates for previous breast cancer treatment and one patient was affected by uncontrolled diabetes. Ten patients were considered eligible and were consecutively enrolled in the trial. All patients were treated according to the allocated interventions, no drop-out, exclusion or deviation from the protocol occurred up to the insertion of the final prosthesis, and the data of all patients were evaluated in the statistical analyses.

Patients were recruited and subjected to vertical bone augmentation from January to March 2007. The last definitive prosthesis was inserted in March 2008. The follow-up focused on the time between bone augmentation to 1 month after the delivery of the final prosthesis, about 14 months after the augmentation procedure.

The mean patient age at the time of augmentation procedure was 54 years (range 32 to 73) and there were six females and four males. Three patients declared themselves to be smokers. In total 38 study implants were placed: 24 were 4 mm diameter 3i Nanotite cylindrical implants with external connection (Biomet 3i, Palm Beach, FL, USA) (Figs 16a and b); ten were 3.5 mm diameter Ankylos implants (Friadent-Dentsply, Mannheim, Germany) and four were 3.8 or 4.5 mm diameter XiVE implants (Friadent-Dentsply). All patients received the same brand of implants at both sides with one exception: a patient who received two implants of one brand (Biomet 3i) on one side and two implants of another brand (Ankylos) on the contralateral side. Implants were inserted according to the manufacturers' instructions. The mean length of the study implants inserted in autogenous bone was 9.0±3.31 mm and 9.2±1.35 mm in Bio-Oss. There did not appear to be baseline imbalances among groups. No prosthesis or study implant failed up to the placement of the final prostheses. However, two implants and one prosthesis in one side treated with autogenous bone could not be



Figs 16a and b Clinical situation after 4 months at the Bio-Oss treated site after having (a) removed the miniplate and (b) inserted the implants.

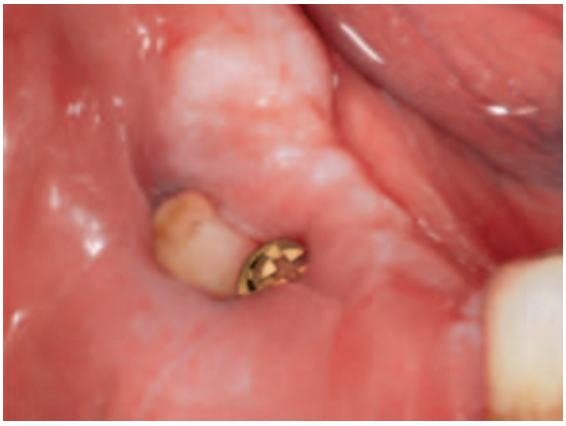
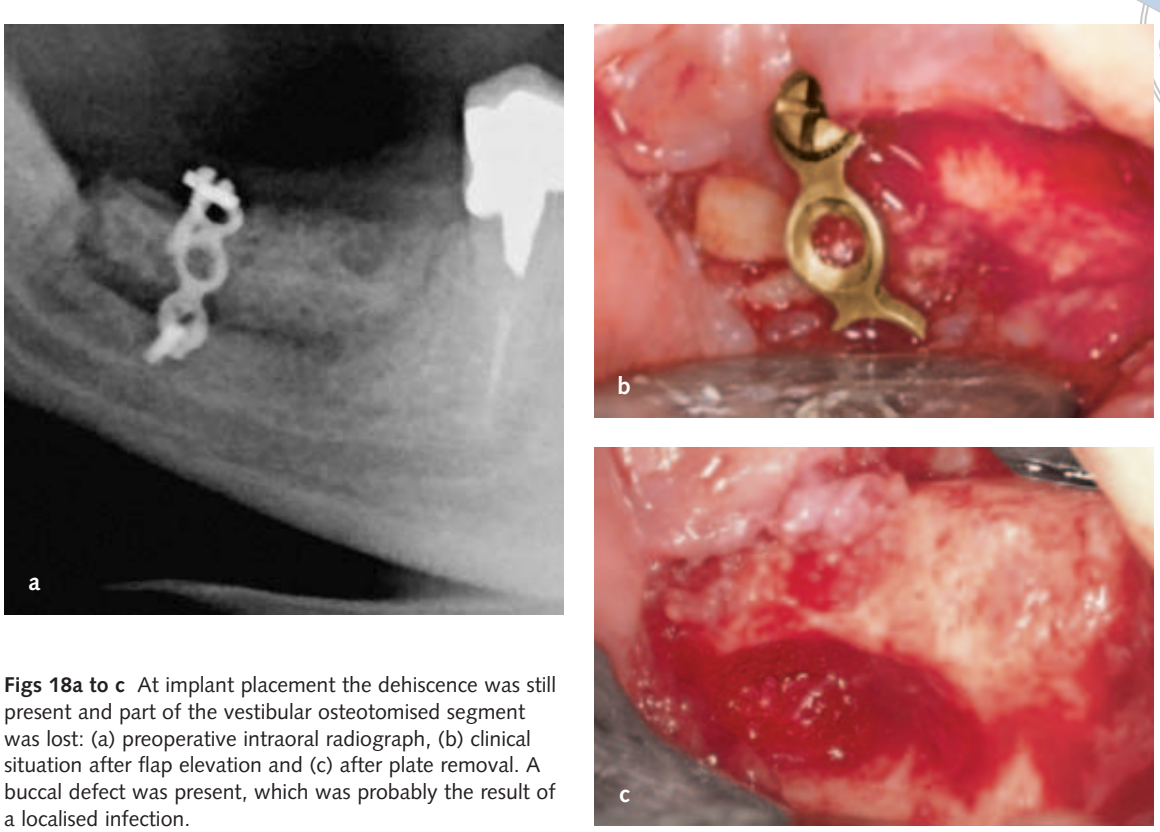


Fig 17 Two weeks after augmentation, one site augmented with autogenous bone presented a buccal dehiscence of about 1 cm in diameter, exposing part of the titanium miniplate.

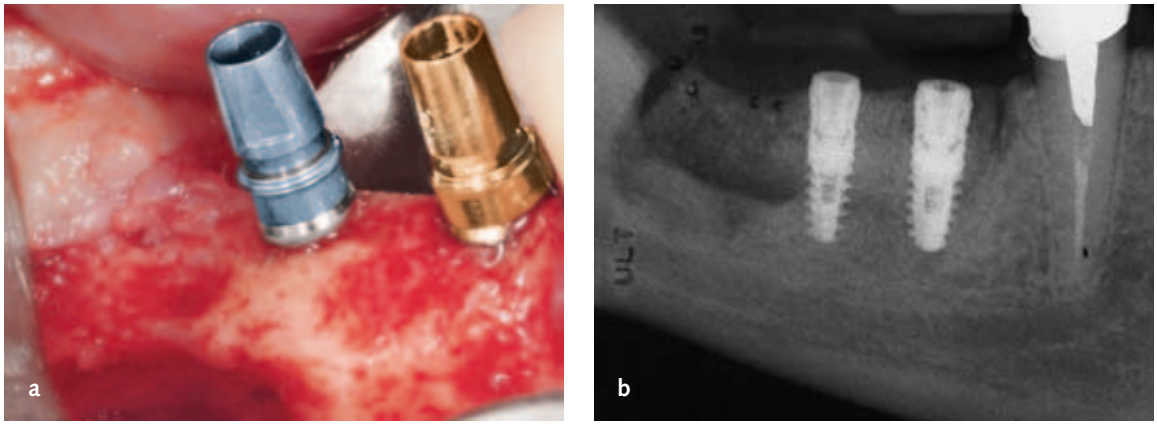
placed because of the complete failure of the graft. The differences in prosthesis and implant failures were not statistically significant ($P=1.95\%$, CI = not estimable).

After the augmentation procedures, two complications occurred in two patients of the autogenous bone group versus one complication in the Bio-Oss group. Two weeks after augmentation with autogenous bone one patient presented a buccal dehiscence of about 1 cm in diameter, exposing part of the titanium miniplate and the screw holding the vertically displaced bone segment (Fig 17). The patient was prescribed an increased use of chlorhexidine for the entire duration of the healing process and the dehiscence decreased in diameter. At implant placement the dehiscence was still present and part of the vestibular osteotomised segment was lost (Figs 18a to c), but the two implants could be placed (Figs 19a and b). In another patient the osteotomised bony fragment, which was too thin, fractured when the surgeon attempted to stabilise it with the miniscrew (Figs 20a to c) and a large wound dehiscence appeared after 1 week (Fig 21). After 2 weeks the patient was re-operated on and the entire autogenous graft was removed (Figs 22a and b). This procedure was a complete failure because the amount of residual bone was insufficient to allow implant placement (Fig 22b). The last complication occurred in a site treated with Bio-Oss (Figs 23a to c). At surgery the lingual soft tissues were perforated with the tip of the piezo-electric instrument (Fig 23a). After 1 week a lingual dehiscence was found over the vertically displaced bone segment (Fig 23b). After topical anaesthesia, the exposed bone was ground with a round diamond bur and the site healed completely after 10 days (Fig 23c). The difference in complications during graft healing was not statistically significant ($P=0.57$, odds ratio=0.44, 95% CI=0.03 to 7.17). Only one complication occurred in the autogenous bone group after implant placement, in the same patient who experienced a wound dehiscence for the entire healing period of the graft. One implant displayed two exposed threads with no visible inflammation of the surrounding tissues. The difference was not statistically significant ($P=1$, 95% CI=not estimable).

The augmentation in vertical height was 5.1 mm in the autogenous bone group and 6.2 mm in the Bio-Oss group (Table 1). Both techniques resulted in a statistically significant vertical bone gain from baseline (Table 1). There were no statistically significant differences between groups for the amount of post-operative vertically augmented bone ($P=0.098$; Table 1).



Figs 18a to c At implant placement the dehiscence was still present and part of the vestibular osteotomised segment was lost: (a) preoperative intraoral radiograph, (b) clinical situation after flap elevation and (c) after plate removal. A buccal defect was present, which was probably the result of a localised infection.

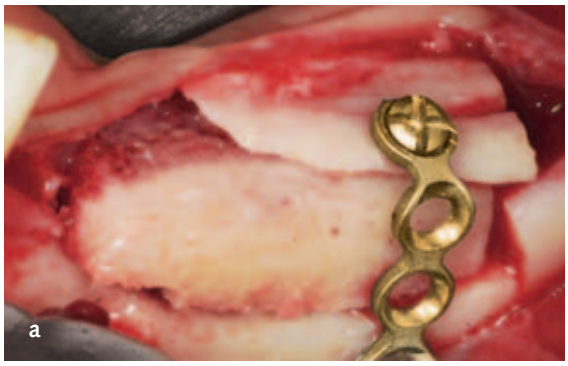


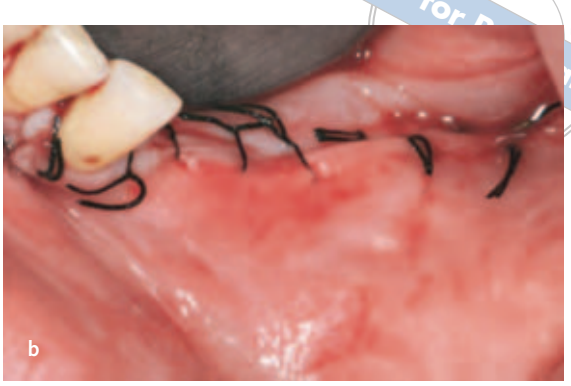
Figs 19a and b (a) Both the planned implants were successfully placed; (b) intraoral radiograph.

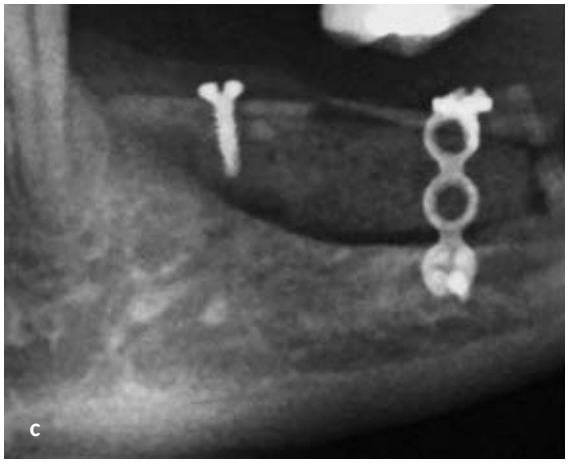
Over a 4-month period the autogenous bone group lost 1.1 mm of bone (not statistically significant: P=0.088, Table 2) and the Bio-Oss group 0.6 mm (statistically significant: P=0.001). There were no statistically significant differences between groups for bone loss (P = 0.073; Table 2) after 4 months.

The sides treated with Bio-Oss recovered their full mental nerve sensitivity significantly faster than those treated with autogenous bone (4.0±2.7 vs 6.3±4.2 days; P=0.03, 95% CI of the difference 0.28 to 4.33).

Three weeks after augmentation, seven patients preferred Bio-Oss to autogenous bone and three patients found the treatments 'equally good' (odds ratio 0.045 [95% CI 0.00 to 0.87], P = 0.04). One month after delivery of the final prostheses, eight patients preferred Bio-Oss to autogenous bone and two patients found the treatments 'equally good' (odds ratio 0.03 [95% CI 0.00 to 0.64] P = 0.02). At both assessments, patients significantly preferred the treatment with Bio-Oss compared with a graft harvested from the iliac crest.







Figs 20a to c A fracture of the cranial segment occurred when fixating the autogenous bone graft with (a) mini-screws, (b) after sutures and (c) intraoral radiograph.

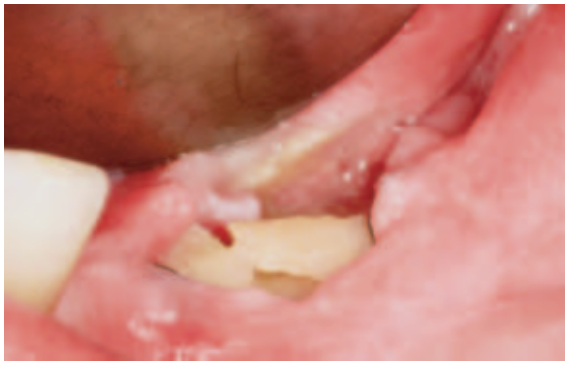
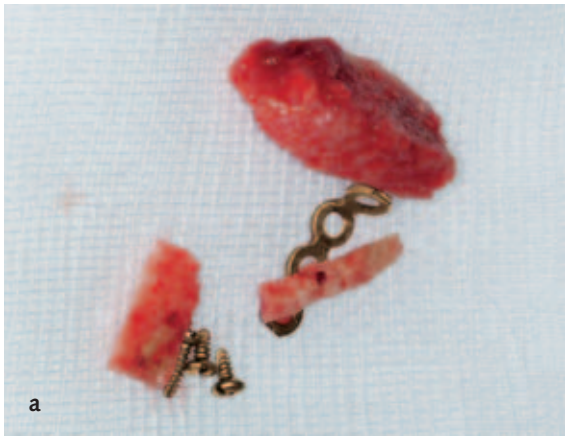


Fig 21 The wound broke down 1 week after augmentation.



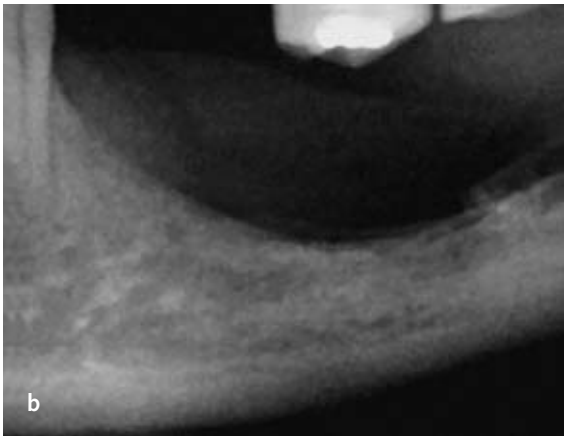
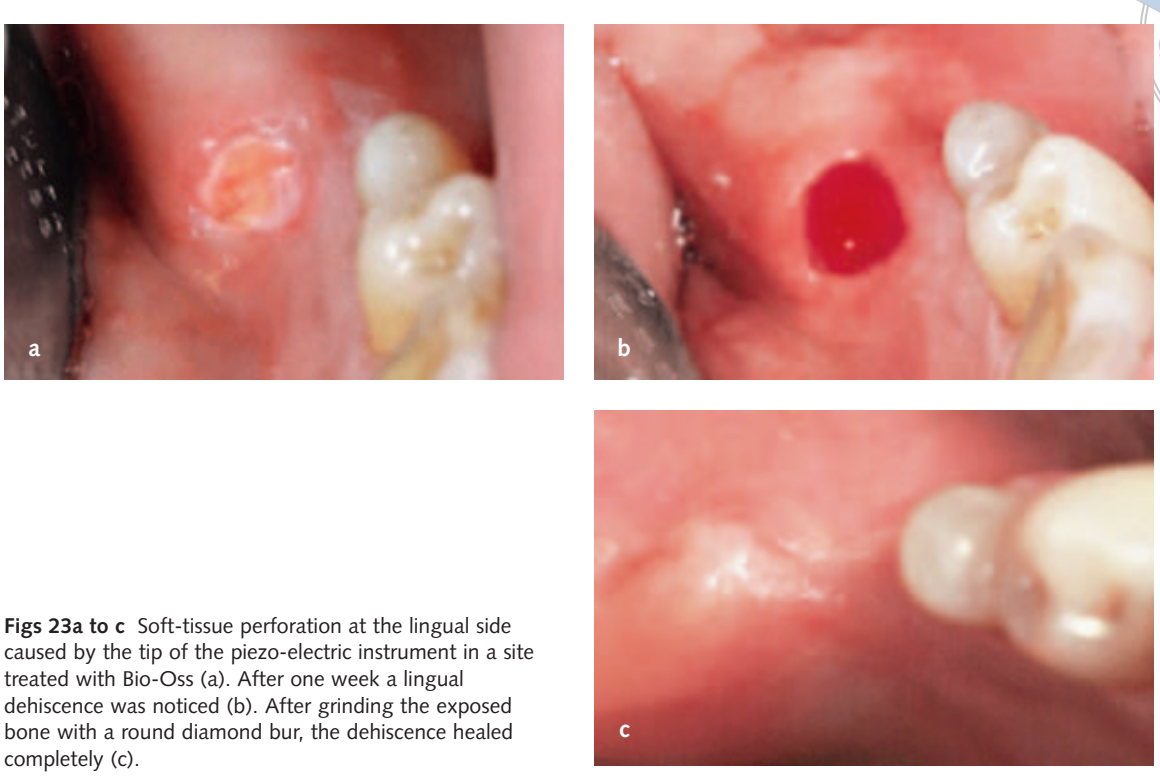


Fig 22a and b Two weeks after augmentation, (a) the entire autogenous graft was removed; (b) intraoral radiograph.



Figs 23a to c Soft-tissue perforation at the lingual side caused by the tip of the piezo-electric instrument in a site treated with Bio-Oss (a). After one week a lingual dehiscence was noticed (b). After grinding the exposed bone with a round diamond bur, the dehiscence healed completely (c).

	Autogenous bone (n=10)	Bio-Oss (n=10)			
	Mean (SD)	Mean (SD)	Mean difference (SD)	*P* value from paired *t* test	95% CI
Baseline (pre-operative)	7.4 (1.9)	7.7 (1.7)			
Post-operative	12.5 (2.1)	13.9 (2.4)	-1.5 (2.5)	0.098	-3.23 to 0.33
Vertical bone gain	5.1 (1.1)	6.2 (2.2)			
P value from paired *t* test	<0.001*	<0.001*			
95% CI	4.30 to 5.88	4.60 to 7.76			

* Significant differences

Table 1 Comparisons of mean vertical bone gain (in mm) between baseline and just after the vertical augmentation procedure for each of the two study groups, and comparisons between the groups.

	Autogenous bone (n=10)	Bio-Oss (n=10)			
	Mean (SD)	Mean (SD)	Mean difference (SD)	*P* value from paired *t* test	95% CI
Post-operative	12.5 (2.1)	13.9 (2.4)	-1.5 (2.5)	0.098	-3.23 to 0.33
After 4 months	11.4 (3.1)	13.3 (2.4)	-1.9 (3.0)	0.073	-4.03 to 0.21
Vertical bone loss	-1.1 (1.8)	-0.6 (0.4)			
P value from paired *t* test	0.088	0.001*			
95% CI	-2.31 to 0.19	-0.86 to 0.34			

* Significant differences

Table 2 Comparisons of mean bone loss (in mm) between just after augmentation and after 4 months for each of the two study groups, and comparisons between the groups.

Discussion

This trial was designed to assess the most effective approach (interpositional Bio-Oss blocks or bone blocks from the iliac crest) for vertical bone augmentation and, in the presence of similar results, to identify the technique that was preferred by the patient, associated with fewer complications and discomfort, simpler to use and the least expensive. In particular the study was designed to evaluate whether or not a novel technique for localised vertical bone augmentation using an interpositional block of Bio-Oss as a bone substitute could offer some advantages over autogenous bone grafts from the iliac crest. The authors were particularly interested in evaluating patient preference, as harvesting bone from the iliac crest requires general anaesthesic and hospitalisation, is technically demanding and time-consuming, and can be anticipated to be painful and expensive; on the other hand little is known about the clinical efficacy of bone substitutes[9].

Both techniques were able to achieve the planned goal, unless a major complication occurred. In one case the augmentation procedure with autogenous bone was a complete failure. This was probably caused by the fracture of the thin osteotomised segment, which occurred when attempting to stabilise it with a surgical plate. The instability of the fractured bone that followed may have determined the failure of the entire procedure. The osteotomised segment was probably too thin and this could be one of the limitations of this technique, as it cannot be applied when the bone above the inferior canal is less than 5 mm in height. The remaining complications that occurred, which were two cases of dehiscence, could be handled without significantly compromising the outcome of the therapy.

It is difficult to draw conclusions from direct comparisons with other randomised controlled trials evaluating alternative techniques (i.e. osteodistraction, guided bone regeneration, onlays bone blocks) for vertical bone augmentation, because these are still too scarce and underpowered[7,8,15]. However, it could be said that the use of an interpositional bone substitute could be a valid alternative when localised vertical augmentation is needed. On the contrary the use of bone blocks harvested from the iliac crest offered no advantages, but required hospitalisation and created more discomfort to the patients, which was reflected by the definite patient preference toward the less invasive procedure. So, despite the small sample size, this trial was able to provide some useful clinical indications.

A technical difficulty in the application of inlay bone grafting in the posterior mandible is the management of the soft tissues to maintain sufficient blood supply to the cranial segment. In particular, we believe that is important to spare the lingual periosteum, which cannot be put under undue strain, limiting the vertical bone gain that can be obtained with this procedure. However, with vertical GBR and onlay bone grafting techniques there are also difficulties in managing the soft tissues. A piezo-electric device was used, as the belief that the risk of complications such as the damage to the lingual flap could be minimised compared with the use of rotating instruments. Although this assumption is generally accepted there is not yet any solid evidence to support it.

All patients had paraesthesia of the chin and the lower lip post-operatively, and the longest sensitivity impairment lasted for 13 days. This was due to the stretching of the nerve bundles of the inferior alveolar nerve exiting from the mental foramen. The sides subjected to vertical augmentation with a bone substitute recovered their sensitivity faster than the sides treated with autogenous bone. It is difficult to explain this difference, but it might be hypothesised that the handling of Bio-Oss was simpler than autogenous bone blocks.

A case series evaluating interpositional grafts from the ramus in the posterior mandible also reported that all eight treated patients had some impaired sensitivity post-operatively, the longest lasting for 6 weeks[10]. In contrast, two other small studies that included six patients respectively[11,12], reported that no patient presented signs of post-operative impaired sensitivity after interpositional iliac crest grafting to the posterior mandible. These contradictory findings are difficult to explain. However, it could be that different surgeons obtain different results or that post-operative sensitivity was not properly assessed.

Among the main limitations of the present investigation was that patient allocation was only partially concealed. In fact, the envelopes contain-

ing the randomisation codes were opened the day before the mandibles were vertically augmented. It might be possible that the prior knowledge of the interventions influenced the attention of the surgeon to the procedures. Ideally the envelopes containing the randomisation codes should have been opened after both osteotomies were completed. Three different types of implants were used and this might be a confounding factor, particularly for future peri-implant bone level assessments, if different implant designs are associated with different bone resorption patterns.

The sample was small, but just sufficient to provide significant results regarding patient preference and recovery of mental sensitivity. A larger trial in view of these preliminary results may not be justified both from an ethical and a scientific point of view.

All treated patients were accounted for with no exclusions and all assessments were carried out by independent and blind assessors. However, the assessor could understand whether or not he was measuring vertical increments of autogenous bone or Bio-Oss on CT-scan because Bio-Oss tended to appear more radiopaque than autogenous bone. As periapical radiographs were taken at implant placement, it will be possible to monitor marginal bone level changes over time, using a masked assessor. Also, the histomorphometrical assessment of the retrieved bone sample will be conducted by a masked assessor.

When successful, both techniques were equally effective in augmenting bone vertically. A postoperative mean bone gain of 5.1 mm in the iliac crest group and 6.3 mm in the Bio-Oss group is comparable with what is reported in a pilot RCT for interpositional iliac crest grafting in posterior mandible, where the inlay technique obtained 5.8 mm of mean bone gain in six patients[12]. Some apparently contradictory results could be observed in the present study while evaluating the bone loss that occurred between augmentation and implant placement (4 months).

There were no significant differences in bone loss for sites treated with autogenous bone despite the fact that 1.1 mm of bone were lost, whereas the bone loss at the sites treated with Bio-Oss was statistically significant despite the fact that only 0.6 mm were lost. This apparent contradiction can be explained in the following way: in the autogenous bone group there was a larger variation in the results (i.e. greater standard deviations) because one graft failed. A larger sample size would probably provide a significant loss also for the autogenous bone.

The variation in the Bio-Oss treated sites was much smaller and this resulted in a statistically significant difference, even if the actual amount of bone lost was almost half of that lost in the autogenous bone group.

Regarding vertical graft resorption prior to implant placement in the posterior mandible, the only comparison can be made with another pilot RCT that reported a mean resorption of 0.9 mm for the group treated with interpositional grafts[12], which appears to be in line with our results.

An interesting clinical question that should be addressed in future research is if, for patients with similar bone height (5 to 7 mm) above the mandibular canal, it would be preferable to apply this vertical augmentation procedure or to use short implants (4 to 7 mm long). The other relevant clinical question is what to offer to patients that have <5 mm of remaining bone above the mandibular canal.

With respect to the external validity of the present findings, it should be recognised that both techniques were tested in real clinical conditions and that patient inclusion criteria were rather broad. Therefore, the results can be easily generalised to a wider population with similar characteristics. However, the surgeon was experienced with both techniques and this factor might limit the extrapolations of the present results.

■ Conclusions

Both techniques achieved good results. However, the sides subjected to vertical augmentation with a bone substitute block recovered their sensitivity faster compared with the sides treated with autogenous bone block from the iliac crest. Moreover patients clearly preferred the bone substitute. Therefore, despite the small number of patients included in this study it might be possible to conclude that the use of a block of Bio-Oss is preferable to harvesting bone from the iliac crest.

Acknowledgements

The authors wish to thank Dr Fabio Rossi for acting as independent outcome assessor and Dr Primo Galletti for some of the prosthetic rehabilitations. Geistlich (Italy) is acknowledged for generously donating the 10 Bio-Oss blocks and 20 resorbable barriers used in the investigation.

References

1. das Neves FD, Fones D, Bernardes SR, do Prado CJ, Neto AJ. Short implants – an analysis of longitudinal studies. Int J Oral Maxillofac Implants 2006;21:86-93.
2. Rosenquist B. Implant placement in combination with nerve transpositioning: Experiences with the first 100 cases. Int J Oral Maxillofac Implants 1994;9:522-531.
3. Simion M, Jovanovic SA, Tinti C, Benfenati SP. Long-term evaluation of osseointegrated implants inserted at the time or after vertical ridge augmentation. A retrospective study on 123 implants with 1–5 year follow-up. Clin Oral Implants Res 2001;12:35-45.
4. Chiapasco M, Romeo E, Casentini P, Rimondini L. Alveolar distraction osteogenesis vs. vertical guided bone regeneration for the correction of vertically deficient edentulous ridges: a 1–3-year prospective study on humans. Clin Oral Implants Res 2004;15:82-95.
5. Roccuzzo M, Ramieri G, Spada MC, Bianchi SD, Berrone S. Vertical alveolar ridge augmentation by means of a titanium mesh and autogenous bone grafts. Clin Oral Implants Res 2004;15:73-81.
6. Merli M, Migani M, Bernardelli F, Esposito M. Vertical bone augmentation with dental implant placement: efficacy and complications associated with two different techniques. A retrospective cohort study. Int J Oral Maxillofac Implants 2006;21:600-606.
7. Chiapasco M, Zaniboni M, Rimondini L. Autogenous onlay bone grafts vs. alveolar distraction osteogenesis for the correction of vertically deficient edentulous ridges: a 2–4-year prospective study on humans. Clin Oral Implants Res 2007;18:432-440.
8. Merli M, Migani M, Esposito M. Vertical ridge augmentation with autogenous bone grafts: resorbable barriers supported by ostheosynthesis plates versus titanium-reinforced barriers. A preliminary report of a blinded, randomised controlled clinical trial. Int J Oral Maxillofac Implants 2007;22:373-382.
9. Esposito M, Grusovin MG, Kwan S, Worthington HV, Coulthard P. Interventions for replacing missing teeth: bone augmentation techniques for dental implant treatment. Cochrane Database of Systematic Reviews 2008: Chichester, UK: John Wiley & Sons, Ltd.
10. Jensen OT, Kuhlke L, Bedard JF, White D. Alveolar segmental sandwich osteotomy for anterior maxillary vertical augmentation prior to implant placement. J Oral Maxillofac Surg 2006;64:290-296.
11. Jensen OT. Alveolar segmental 'sandwich' osteotomies for posterior edentulous mandibular sites for dental implants. J Oral Maxillofac Surg 2006;64:471-475.
12. Marchetti C, Trasarti S, Corinaldesi G, Felice P. Interpositional bone grafts in the posterior mandibular region: a report on six patients. Int J Periodontics Restorative Dent 2007;27:547-555.
13. Bianchi A, Felice P, Lizio G, Marchetti C. Alveolar distraction osteogenesis versus inlay bone grafting in posterior mandibular atrophy: a prospective study. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2008;105:282-292.
14. CONSORT statement, 2007; http://www.consort-statement.org/
15. Converse JM, Campbell RM. Bone grafts in surgery of the face. Surgical Clinics of North America 1954:375-401.
16. Curtin F, Elbourne D, Altman DG. Meta-analysis combining parallel and cross-over clinical trials. II: Binary outcomes. Statistics in Medicine 2002;21:2145-2159.
17. Chiapasco M, Consolo U, Bianchi A, Ronchi P. Alveolar distraction osteogenesis for the correction of vertically deficient edentulous ridges: a multicenter prospective study on humans. Int J Oral Maxillofac Implants 2004;19:399-347.