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Vertical bone augmentation versus 7-mm-long implants in posterior atrophic mandibles. Results of a randomised controlled clinical trial of up to 4 months after loading

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

Purpose: To evaluate whether 7-mm-long implants could be a suitable alternative to longer implants placed in vertically augmented bone for the treatment of atrophic posterior mandibles.

Materials and methods: Sixty partially edentulous patients having 7 to 8 mm of residual crestal height and at least 5.5 mm thickness measured on a computed tomography scan above the mandibular canal were randomised to receive either two to three submerged 7-mm-long NanoTite External Hex implants (Biomet 3i) or 10-mm or longer implants (30 patients per group) placed in vertically augmented bone. Bone was augmented with anorganic bovine bone blocks (Bio-Oss) using a sandwich technique and resorbable barriers. The grafts were left healing for 5 months before placing the implants, which were submerged. Four months after implant placement, provisional acrylic prostheses were delivered. Definitive screw-retained metal-ceramic prostheses were delivered 4 months later. Outcome measures were: prosthesis and implant failures, any complications, and time needed to fully recover mental nerve sensitivity. All patients were followed up to the delivery of the final restorations (4 months after loading).

Results: No patient dropped out. In two patients of the augmented group, there was not enough space to place 10-mm or longer implants as planned and 7-mm-long implants were used instead. The most likely reason for this is that the Bio-Oss blocks fractured in many pieces at placement. One prosthesis could not be placed when planned in the 7-mm group versus three prostheses in the augmented group, because of failure of one implant in each patient. The difference was not statistically significant. All implants were successfully replaced and final prostheses delivered. Four complications (wound dehiscence) occurred during graft healing in the augmented group (one possibly associated with the failure of one implant) versus none in the 7-mm-long implant group. The difference was not statistically significant. No patient suffered from permanent paraesthesia of the alveolar inferior nerve; however, sensitivity was recovered significantly faster in the short implant group.

Conclusions: The early results of this study suggest that, when the residual bone height over the mandibular canal is between 7 and 8 mm, 7-mm short implants might be a preferable choice since the treatment is faster, cheaper and associated with less morbidity than vertical bone augmentation. These preliminary results must be confirmed by follow-ups of 5 years or more in order to monitor the performance of short implants over time.

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Introduction

The rehabilitation of the partially edentulous posterior mandible is a common clinical problem. The missing dentition can be replaced by partial removable dentures but theses prostheses are often little appreciated by the patients, because of their instability and discomfort. The ideal solution would be an implant-supported fixed prosthesis; however, the inadequate bone volume needed to place dental implants of 'sufficient' length due to the presence of the inferior alveolar nerve is a common problem. Ten to 12 mm in height of bone of adequate thickness can be considered the minimal amount of bone required to place implants of sufficient length (9 to 11 mm long) that are able to guarantee a good long-term prognosis of an implant-supported prosthesis and limit the risk of permanently damaging the alveolar inferior nerve. Unfortunately, very often the residual amount of bone above the mandibular canal is less than 10 mm, therefore implant rehabilitation is considered at a higher risk of failure.

There are three possible approaches to overcome this problem: 1) to vertically augment the bone, 2) to displace the alveolar inferior nerve in order to place an implant of 'adequate' length, and 3) to use short implants (7 mm or less).

Several techniques are currently used to vertically augment the posterior mandible, and a few have been tested in randomised clinical trials including: various vertical guided bone regeneration (GBR) procedures[1–3], alveolar distraction osteogenesis[1,2], onlay bone grafting[2] and the use of interpositional bone grafts[4,5]. Both autogenous bone and bone substitutes can be used, but a pilot study[5] suggested that Bio-Oss blocks might be preferable over autogenous bone harvested from the iliac crest as interpositional grafts since patient discomfort is reduced. While it has been shown that it is possible to vertically augment bone with different techniques, these procedures are quite technique sensitive, are associated with a significant post-operative morbidity and complications, can be expensive and require quite a long time to complete[6].

It has been suggested to transpose the alveolar inferior nerve to allow placement of longer implants[7]. This procedure is technically demanding and can be associated with permanent loss of nerve sensitivity, therefore it is currently not very popular. Unfortunately, the efficacy (advantages and disadvantages) of various nerve transposition techniques has never been tested in proper comparative trials.

Short implants could be the simpler, cheaper and faster alternative. The definition of 'short' implants is controversial since some authors consider implants with a length between 7 to 10 mm to be short[8]. Implants with lengths ranging from 5 to 7 mm are currently used, but the literature is lacking in comparative studies evaluating their efficacy in a reliable way. Nevertheless, it is commonly believed that implants 7 mm or shorter do not have a good long-term prognosis when compared with longer implants.

The aim of this randomised controlled clinical trial (RCT) was to compare the outcome of partial fixed prostheses supported by 7-mm-long implants (Nano-Tite™, External Hex, Biomet 3i, Palm Beach, FL, USA) with prostheses supported by longer implants (10 mm or longer) placed in posterior mandibular ridges vertically augmented with an interpositional block of anorganic bovine bone (Bio-Oss, Geistlich Pharma, Wolhusen, Switzerland). The present investigation is a preliminary report focusing on outcomes that occurred up to the insertion of the final prostheses. It was planned to follow-up the patients to the fifth year of function in order 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 (http://www.consort-statement.org/).

Materials and methods

Any patient with partial edentulism in the posterior mandible having a residual bone height between 7 to 8 mm and a thickness of at least 5.5 mm above the inferior alveolar canal measured on computed tomography (CT) scans requiring 2 to 3 adjacent implants, who was 18 or older and able to sign an informed consent form, was eligible for inclusion in this trial (Fig 1). A preoperative CT scan was used to quantify the amount of available bone above the alveolar inferior canal to decide whether patients could be included in the study (Fig 2). Patients were not admitted in the study if any of the following exclusion criteria were present:

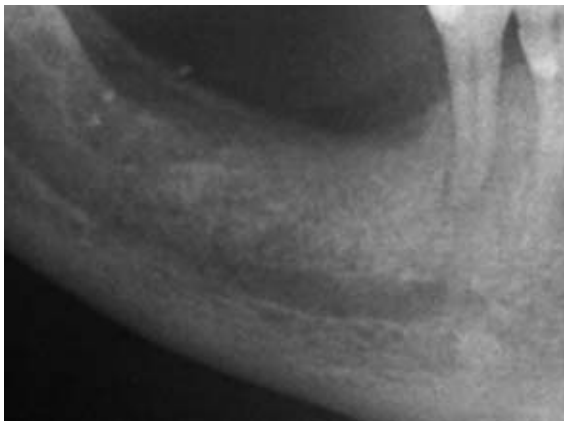


Fig 1 Preoperative radiograph of one of the patients included in the study.

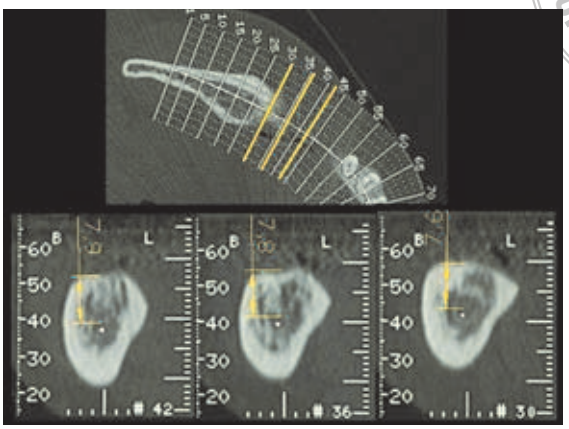


Fig 2 Preoperative dental computed tomography (CT) scans used to evaluate patient eligibility (6 to 8 mm of bone above the nerve canal) in the study.

- general contraindications to implant surgery
- subjected to irradiation in the head and neck area less than 1 year ago
- under chemotherapy for malignant tumour
- treated or under treatment with intravenous amino-bisphosphonates
- poor oral hygiene, lack of motivation or periodontal disease
- uncontrolled diabetes
- pregnant or lactating
- substance abuse
- psychiatric problems or unrealistic expectations
- lack of opposite occluding dentition in the area intended for implant placement
- acute infection in the area intended for implant placement
- participating in other trials in which the present protocol could not be properly followed
- referred only for implant placement
- extraction sites with less than 3 months of healing.

Patients were placed into 1 of 3 groups according to what they declared: not smokers, light smokers (up to 10 cigarettes per day) or heavy smokers (more than 10 cigarettes per day). Patients were recruited and treated in three different private practices but were treated by the same operators (PF performed all of the surgical procedures and PC performed all of the prosthetic procedures), using similar and standardised procedures.

The principles outlined in the Declaration of Helsinki on clinical research involving human subjects were adhered to. All patients received thorough explanations and signed a written informed consent form prior to being enrolled in the trial. After consent was given, eligible patients were randomised to receive either 7-mm-long implants (Fig 3) or an interpositional block of anorganic bovine bone (Bio-Oss, Geistlich Pharma) to allow placement of identical implants 10 mm long or longer (Fig 4).

Study models were used to plan the amount of vertical augmentation required by the patients. Within 10 days prior to bone augmentation and implant placement, all patients underwent at least one session of oral hygiene instructions and professionally delivered debridement when required.

All patients to be vertically augmented received prophylactic antibiotic therapy: 1 g of amoxicillin + clavulanic acid (or erythromycin 500 mg if allergic to penicillin) starting the night before the intervention, twice a day, for 7 days. All patients were treated under local anaesthesia using articaine with adrenaline 1:100.000. No intravenous sedation was used.

For the augmentation procedure, a surgical template was used to indicate the planned implant positions (Fig 5). A paracrestal incision was made through the buccal area respecting the emergence of the mental nerve, to expose the alveolar ridge (Fig 6). A mucoperiosteal flap was carefully retracted trying to avoid tension on the mental nerve. A horizontal osteotomy was made approximately 2 to 4 mm above the mandibular canal using piezosurgery (Mectron Piezosurgery Device™; Mectron, Carasco, Genoa, Italy). Two oblique cuts were then made in the

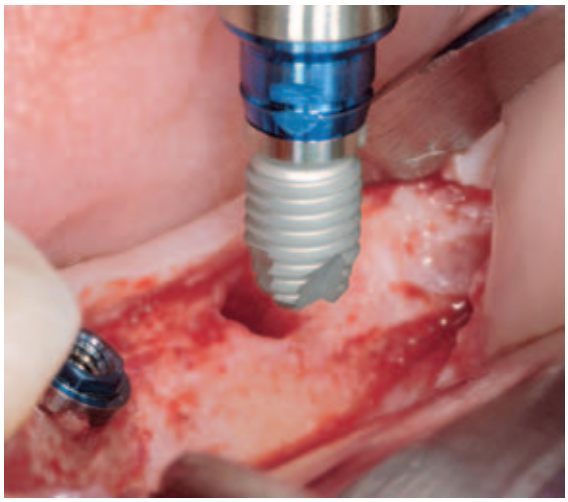


Fig 3 Two 7-mm-long implants placed in one of the patients randomised to the short implant group.

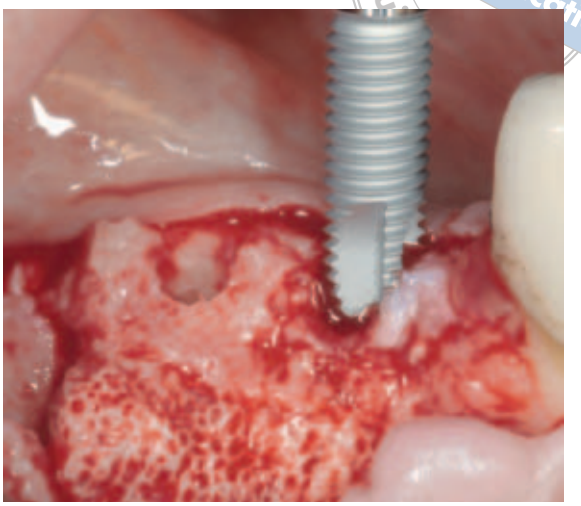


Fig 4 A 13-mm-long implant placed in one of the patients randomised to the augmented group. Part of the bone block (Bio-Oss) is visible in the bottom portion of the image.

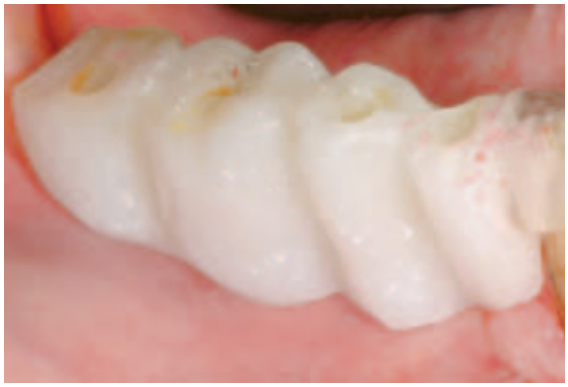


Fig 5 A surgical template indicated the planned position of the implants.

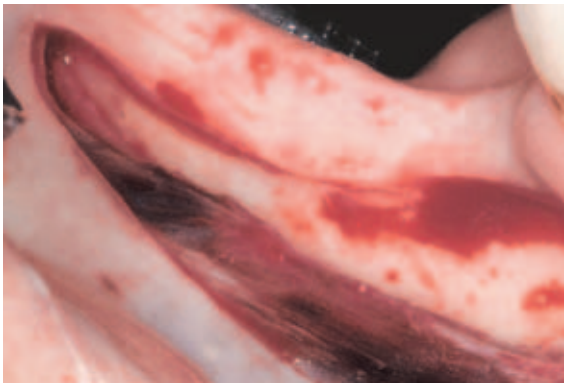


Fig 6 A paracrestal incision was made on the buccal side.

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 has to be at least 3 mm to allow the insertion of the stabilising screws without fracturing. The segment was then raised in a coronal direction sparing the lingual periosteum (Fig 8), and Bio-Oss blocks were modelled to completely fill the sites to the desired height and shape (Fig 9), interposed between the raised fragment and the mandibular basal bone (Fig 10), 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. The grafted areas were covered with a resorbable barrier (Bio-Gide®, Geistlich Pharma) (Fig 12). Periosteal incisions were made to release the flaps as coronally as needed and the flaps were sutured with Vicryl® 4.0 sutures (Ethicon FS-2, St-Stevens-Woluwe, Belgium), until the incisions were perfectly sealed.

Ibuprofen 600 mg was prescribed to be taken 2 to 4 times a day during meals, as long as required. Patients were instructed to use Corsodyl gel (1% chlorhexidine gluconate) twice a day for 2 weeks and then 0.2% chlorhexidine mouthwash twice a day for up to the second month, to have a soft diet for one week, and to avoid brushing and trauma on the sur-

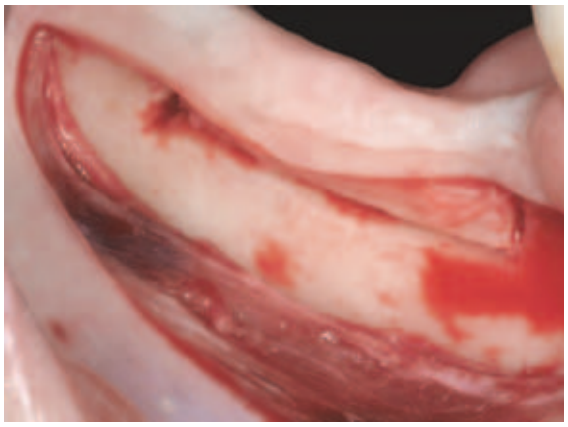


Fig 7 Horizontal and vertical osteotomies were made.

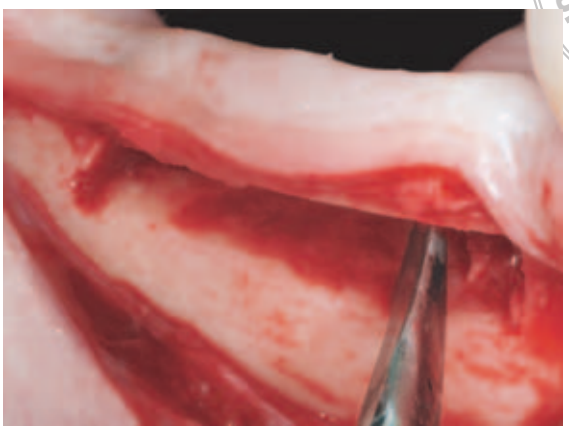


Fig 8 The cranial osteotomised segment was moved upward.

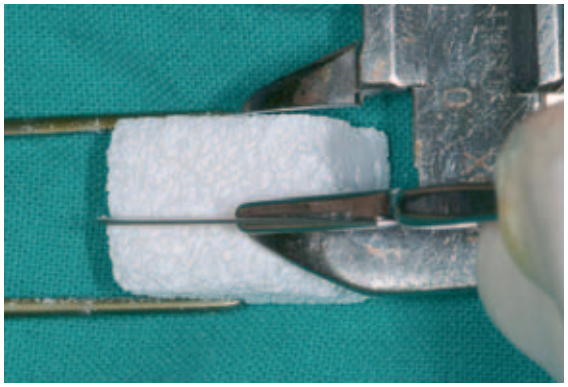


Fig 9 The block of anorganic bovine bone (Bio-Oss) was trimmed and shaped to be completely fitted between basal bone and cranial segment.

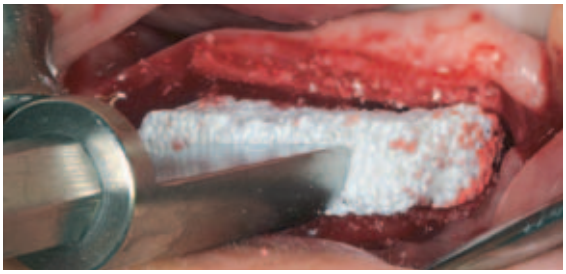


Fig 10 The Bio-Oss block was placed as an interpositional graft.

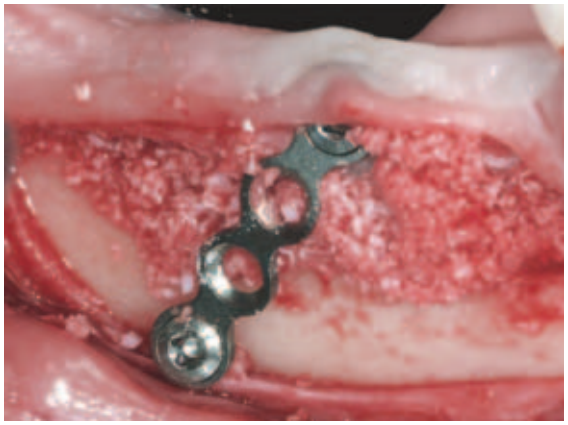


Fig 11 The graft was fixed with miniplates and screws.

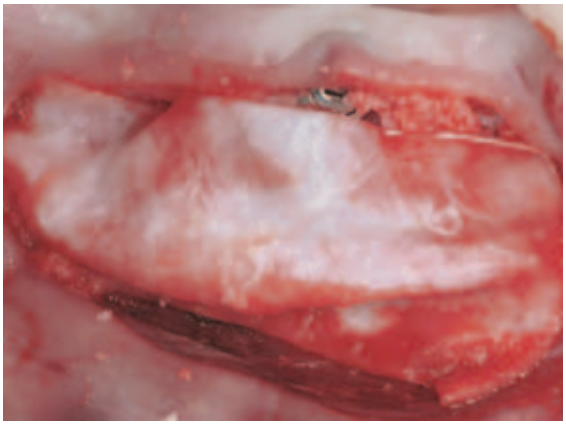


Fig 12 A resorbable collagen membrane was used to cover the graft material.

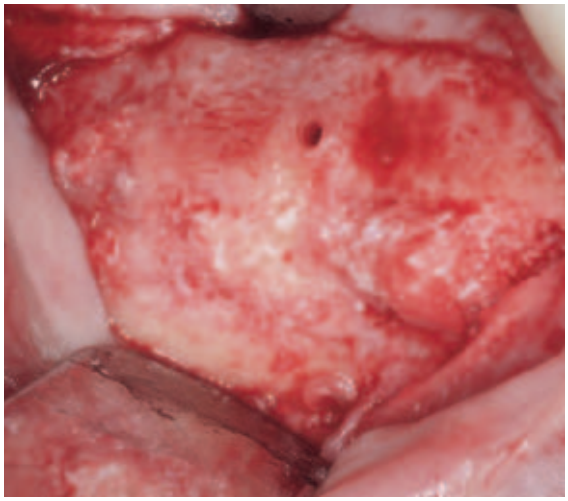


Fig 13 After 5 months of healing the site was reopened and the miniplate was removed.

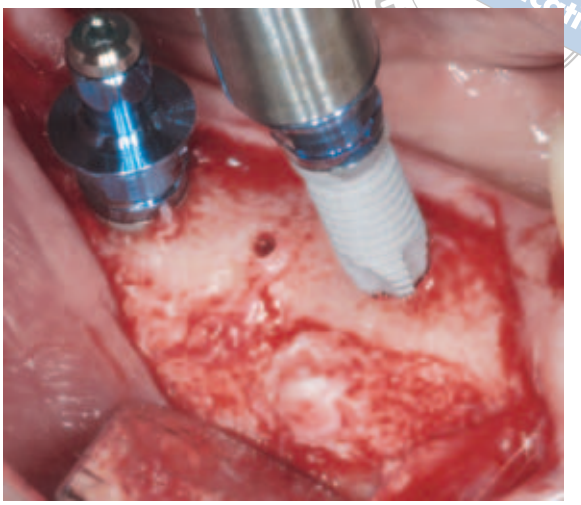


Fig 14 NanoTite parallel-walled External Hex implants were inserted.

gical sites. No removable prosthesis was allowed for one month. Patients were seen after 3 days and sutures were removed after 10 days. All patients subjected to vertical augmentation were recalled for additional post-operative check-ups 1, 2, 3 and 4 months after the augmentation procedure. Five months after augmentation, miniplates were removed (Fig 13), knife edge ridges were flattened to reach a thickness of at least 5.5 mm when needed, and implants were inserted under local anaesthesia (Fig 14). A total of 2 g of amoxicillin (or erythromycin 500 mg) were administered 1 hour prior to implant placement. Two to three 7-mm-long (short implant group) or 10-mm-long implants or longer (augmented group) were inserted under prosthetic guidance using a surgical template after crestal incision and flap elevation. NanoTite parallel-walled Biomet 3i dental implants, of 4 mm diameter, with external connection and made of titanium alloy (Ti_6Al_4V) were used. The NanoTite implants were dual etched and then partially covered (about 50% of the surface) with nanoscale calcium phosphate crystals, a surface modification procedure termed DCD (discrete crystalline deposition). The operator used 7-mm-long implants for the test group, but was free to choose the length (10 mm, 11.5 mm, 13 mm and 15 mm) for the control group. The standard placement procedure recommended by the manufacturer was used. Drills with increasing diameters (2, 2.8, 3.5 and 4.3 mm, when needed) were used to prepare the implant sites. Implant sites were slightly underprepared and the surgical unit was settled with a torque of 25 Ncm. In all cases, the head of the implants was placed supracrestally so that the neck of the implant (0.6 mm in height) was not embedded into bone. Resistance at implant insertion was recorded (<25 Ncm, <35 Ncm, <45 Ncm and >50 Ncm; in the latter case the manual wrench was used to seat the implant). A submerged technique was used and cover screws were placed. Flap closure was obtained with Vicryl 4.0. Intraoral radiographs (baseline) were made with the paralleling technique. In the case that the bone levels around the study implants were hidden or difficult to estimate, a second radiograph was made. Ibuprofen 600 mg was prescribed to be taken 2 to 4 times a day during meals, as long as required. Patients were instructed to use 0.2% chlorhexidine mouthwash for one minute twice a day for 2 weeks, to have a soft diet for one week, and to avoid brushing and trauma on the surgical sites. No removable prosthesis was allowed. Sutures were removed after 10 days.

After four months of submerged healing, implants were exposed, manually tested for stability and an impression with the pick-up impression copings was taken using a polyether material (Impregum™, 3M/ESPE, Neuss, Germany) and a customised resin impression tray. The vertical dimension was registered and models were made with class 4 precision plaster and mounted in a standard articulator. A provisional screw-retained acrylic restoration rigidly joining the implants was delivered on prefabricated abutments (Biomet 3i) (Fig

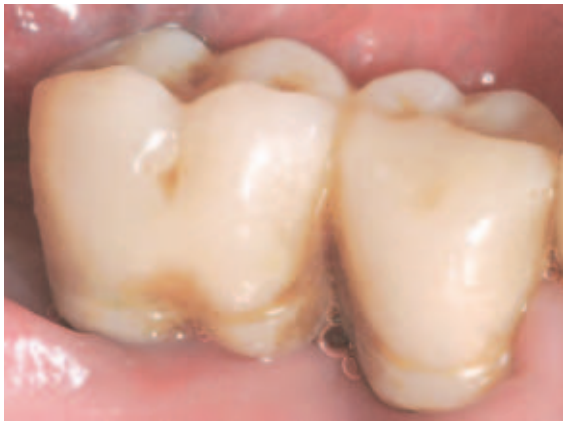


Fig 15 About 4 months after implant placement, a provisional full acrylic bridge was delivered.

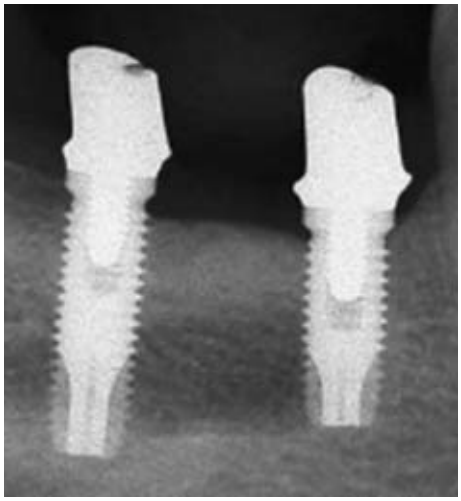


Fig 16 Intraoral radiograph taken at delivery of the provisional prosthesis.

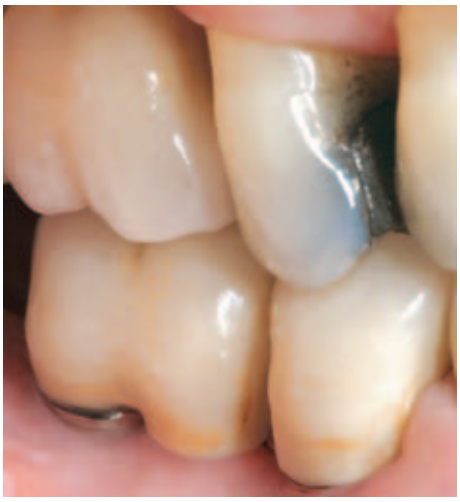


Fig 17 Four months after delivery of the provisional prosthesis a final metal-ceramic prosthesis was inserted.

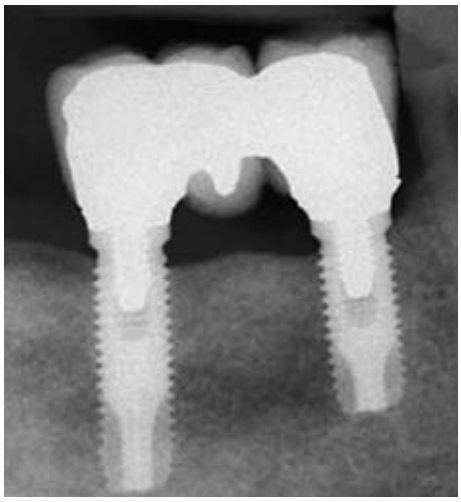


Fig 18 Intraoral radiograph taken at delivery of the definitive prosthesis.

15). The occlusal surface was in slight contact with the opposite dentition. Intraoral radiographs of the study implants were taken (Fig 16). Four months after delivery of the provisional prostheses, implants were manually tested for stability and a definitive screw-retained metal-ceramic restoration rigidly joining the implants with occlusal surfaces in ceramic was delivered on titanium-based UCLA abutments (Biomet 3i) (Fig 17). Intraoral radiographs of the study implants were taken (Fig 18). Patients were enrolled in an oral hygiene programme with recall visits every 4 months for the entire duration of the study.

Follow-ups were conducted by an independent outcome assessor (GP) together with the surgical operator (PF). This study tested the null hypothesis that there were no differences between the two procedures against the alternative hypothesis of a difference.

Outcome measures were:

- Prosthesis failure: planned prosthesis that 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. The stability of an individual implant was measured after removing the restorations at delivery of the provisional prosthesis (4 months after implant placement), and at delivery of the definitive prosthesis (4 months after delivery of the provisional prosthesis) by applying a reverse torque of 15 Ncm.
- Any biological or prosthetic complications.
- Time (days) needed to fully recover mental sensitivity after the augmentation procedure (augmented group) and implant placement (short implant group).
- Peri-implant marginal bone levels evaluated on intraoral radiographs taken with the paralleling technique at implant placement, at delivery of the provisional prosthesis and at 1 and 5 years after loading. Data on this outcome will be reported in future publications.

One clinician (GP) not involved in the treatment of the patients performed all clinical and radiographic assessments without knowing group allocation, therefore the outcome assessor was blind. However, the Bio-Oss augmented sites could be identified on radiographs because they appeared more radiopaque and implants were longer.

The sample size was calculated for the primary outcome measures (implant failure): a two-group continuity-corrected chi-square test with a 0.050 two-sided significance level has 80% power to detect the difference between a proportion of 0.100 and a proportion of 0.300 for patients experiencing at least one implant failure (odds ratio of 3.857) when the sample size in each group is 72. However, it was decided to recruit only 30 patients in each group. A computer-generated restricted randomisation list was created. Only one of the investigators (ME), not involved in the selection and treatment of the patients, was aware of the randomisation sequence and could have access to the randomisation list stored in his password-protected portable computer. The randomised codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially after eligible patients signed the informed consent form to be enrolled in the trial. Therefore, treatment allocation was concealed to the investigators in charge of enrolling and treating the patients.

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. The patient was the statistical unit of the analyses. Differences in the proportion of patients with prosthesis failures, implant failures, complications (dichotomous outcomes) and days needed to fully recover mental sensitivity (data was dichotomised: day zero or not) were compared between the groups using the Fisher exact probability test. All statistical comparisons were conducted at the 0.05 level of significance.

Results

Sixty-nine patients were screened for eligibility, but nine patients could not be included in the trial for the following reasons: four patients were hesitant to receive short implants (three of these patients were referred and the referring dentists might have advised the patients on the potential risk of receiving short implants), two patients received intravenous bisphosphonates, two patients refused for economic reasons and received a partial removable denture, and one patient had insufficient bone height above the mandibular canal. Sixty patients were considered eligible and were consecutively enrolled in the trial. All patients were treated according to the allocated interventions, and no drop-outs or exclusions occurred up to the insertion of the final prosthesis. The data of all patients were evaluated in the statistical analyses. The following deviations from the protocol occurred:

- Augmented group: in three patients the Bio-Oss blocks fractured into many pieces at placement (Fig 19). In two of these patients no clinical useful bone gain was obtained and only 7-mm-long implants could be placed instead of the 10 mm or longer implants as planned.
- Short implant group: in one patient two upper implant threads remained exposed at implant placement. A titanium mesh was placed to regenerate bone and was stabilised with the cover screw (Fig 20). One patient decided to have the prostheses made in Croatia for financial reasons, however she is still attending the follow-up visits.

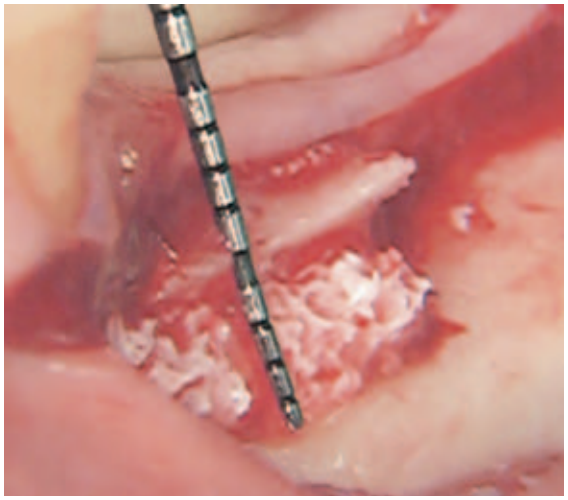


Fig 19 In three patients the Bio-Oss block fractured at placement, unfortunately they were not replaced. In two cases the expected augmentation procedure was not successful and 7-mm short implants had to be used, instead of the planned longer implants.

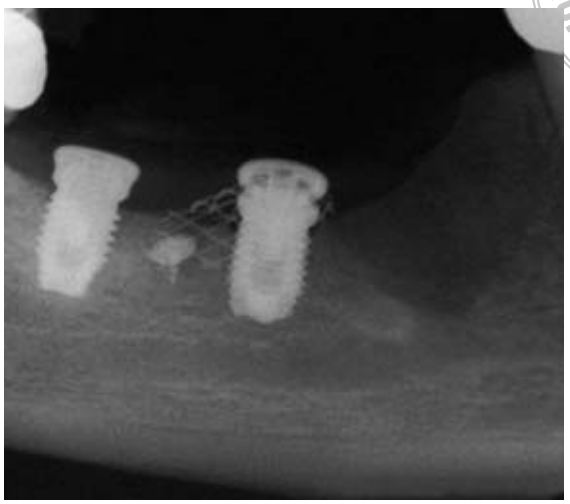


Fig 20 In one patient of the short implant group, two upper threads of the distal implant remained exposed at implant placement. A titanium mesh, stabilised by the implant cover screw, was placed to regenerate the missing bone.

The great majority of the implants belonging to the short implant group and some belonging to the vertically augmented group became exposed during healing because of their supracrestal position. So, in only four patients (including the one where the mesh was used) of the short implant group versus 24 patients of the augmented group, was a surgical exposure of the implant necessary.

Patients were recruited and subjected to vertical bone augmentation from June 2007 to April 2008. The last final prosthesis was inserted in December 2008. The follow-up of all patients was up to the delivery of the final prostheses, 4 months after implant loading.

The main baseline patient characteristics are presented in Table 1. Sixty-one implants were placed in the augmented group and 60 in the short implant group. There were no apparent significant baseline imbalances between the two groups.

The main results are summarised in Table 2. Three implants in three patients failed in the augmented group versus one implant in the short implant group up to the placement of the final prostheses. Consequently, three versus one prostheses could not be placed at the planned time, though all implants were successfully replaced and loaded. The differences in proportions of prosthesis and implant failures were not statistically significant (-0.07; P = 0.62; 95% CI = –0.23 to 0.08). In the augmented group, one 7-mm-long implant in position 46 was found to be mobile at the abutment connection. It was immediately replaced by an implant 10-mm long of 4-mm diameter.

Table 1 Patient and intervention characteristics.

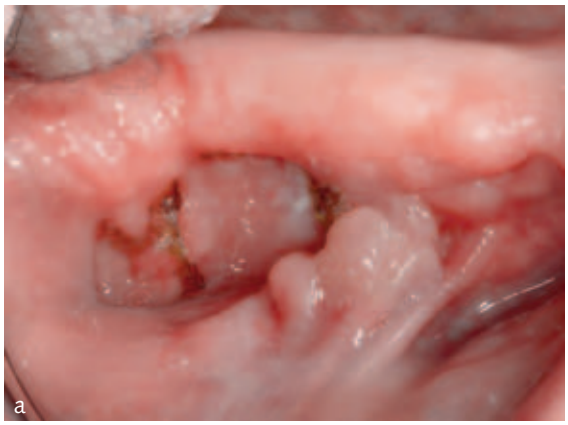
	Augmented (n=30)	Short implants (n=30)
Females	15	23
Mean age at implant insertion (range)	55 (43–67)	56 (40–83)
Smokers	11 light	11 light and 1 heavy
Total number of inserted implants	61	60
Number of implants placed with less than 25 Ncm torque (number of patients)	12 (6)	4 (2)
Mean length of placed implants (mm)	11.2	7

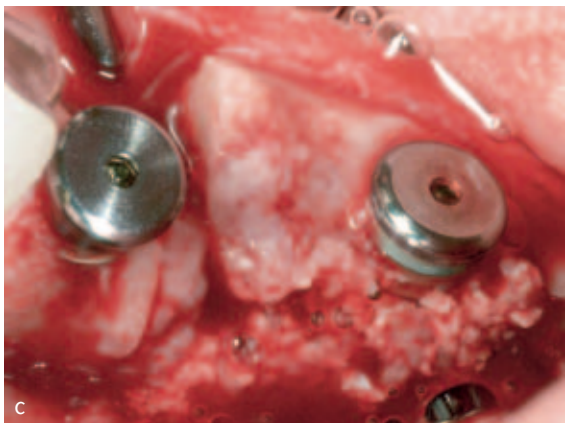
Table 2 Summary of the main results.

	Augmented (n=30)	Short implants (n=30)
Failure of the augmentation procedure	2	Not applicable
Failure to place the prosthesis when planned	3	1
Failure of the implants	3	1
Complications	4	0
Transient postoperative paraesthesia of the lip/chin	16	2

Another implant 10-mm long in position 45 was found mobile at the abutment connection and was immediately replaced by an 11.5-mm-long implant of 5-mm diameter. An implant 11.5-mm long placed in position 36, where a vestibular dehiscence and resorption of the buccal bone possibly caused by infection occurred during the healing of the graft (Fig 21a-c), was found mobile 10 days after placement. It was replaced after 4 months by a 10-mm long, 4-mm diameter implant. The only failed implant belonging to the short implant group was placed in position 34 and was painful and mobile at placement of the healing abutment. Radiographically, a thin radiolucent line could be observed around this implant (Fig 22). It was placed 3 months after the removal of a previously fractured implant (Fig 23). During this procedure the root of the canine was accidentally damaged by the trephine bur. The implant was replaced with a longer implant (8.5 mm) of larger diameter (5 mm) and the canine was endodontically retreated (Fig 24).

Four complications (dehiscence) occurred in four patients of the augmented group versus none in the short implant group. The difference in proportions was not statistically significant (-0.13; P = 0.11; 95%





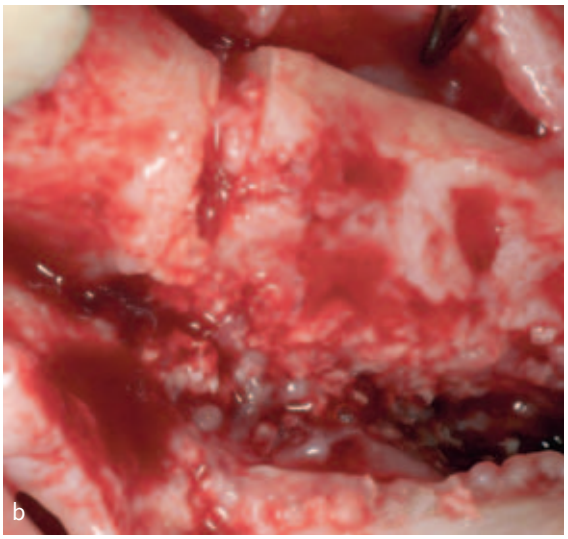


Fig 21a to c In four patients of the augmented group, vestibular dehiscences occurred during the healing of the graft. In two of these, partial resorption of the buccal bone occurred. The case illustrated shows a) the dehiscence before flap elevation, b) the situation after flap elevation and c) just after implant placement. One implant was lost 10 days after its placement, possibly due to infection.

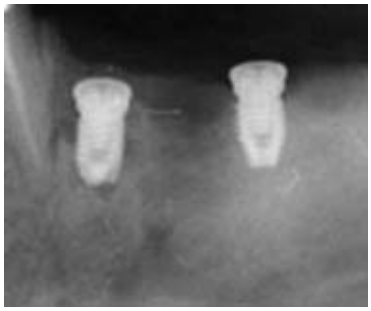


Fig 22 Periapical radiograph showing a thin radiolucent line around the implant placed in position 34. This was the only implant that failed in the short implant group. It was painful and mobile when tightening the healing abutment.

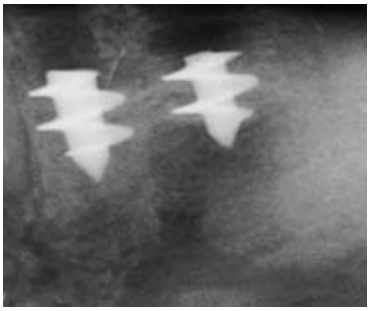


Fig 23 The failed implant of the short implant group was placed 3 months after the removal of previously fractured implants. During the removal procedure of one of the fractured implants, the root of the canine was accidentally damaged by the trephine bur.

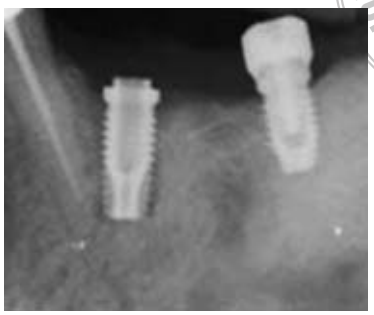


Fig 24 The failed short implant was replaced with a longer implant (8.5 mm) of larger diameter (5 mm) and the canine was endodontically retreated.

CI = -0.30 to 0.01). These dehiscences were observed after 10 (3 cases) to 30 days, and in one occasion it completely healed after resuturing. In the other three cases, they were still present at implant placement. In two cases, a partial loss of the graft occurred. The exposed bone was treated with the piezo-electric equipment to facilitate revascularisation. In one case, as previously described, the implant placed in the area failed 10 days after placement (Fig 21a to c).

No permanent paraesthesia of the alveolar inferior nerve occurred. Patients subjected to vertical augmentation recovered their full mental nerve sensitivity significantly later than those treated with short implants. In fact, 28/30 patients in the short implant group (93%) had no impaired alveolar inferior nerve sensitivity versus 14/30 in the augmented group (43%) (difference in proportions = 0.47; $P < 0.001$; 95% CI of the difference 0.24 to 0.64).

Discussion

This trial was designed to assess which could be the most effective approach to treat posterior mandibles with 7 to 8 mm of residual bone height over the mandibular canal with implant-supported partial fixed prostheses. A vertical bone augmentation procedure (interpositional blocks of anorganic bovine bone), thought to be one of the most predictable and efficient[5] treatment concepts, was compared with a conservative, but potentially risky approach of using 7-mm-long implants. In the presence of similar results, this trial could still indicate which procedure was associated with fewer complications and discomfort, was simpler and faster to use, and consequentially was less expensive.

Both techniques were able to achieve the planned goals, unless a major complication occurred. In two cases, and in the absence of visible complications, the augmentation procedure was a failure in the sense that it failed to gain enough bone to allow the placement of longer implants. This was probably caused by the fracture of the Bio-Oss block. In fact, in both cases, the block went into pieces (Fig 19) when being placed in between the two bone segments. The following instability of the particulated xenograft material may have determined the failure of the augmentation procedure. It is therefore recommended to use a new block if the one being used breaks down into pieces, since it may no longer offer a stable platform for the osteotomised bone segment. Four implants in two patients of the short implant group were inserted with a torque <25 Ncm versus 12 implants in 6 patients of the augmented group. The difference was not statistically significant (data not reported), however, there is a trend suggesting that it might be easier to obtain primary stability with short implants in pristine bone, than with longer implants in augmented bone. This hypothesis needs to be tested in other trials. All complications (four dehiscences) occurred in the augmented group, during the healing phase of the grafts. In at least two patients, it can be speculated that an infection was present which determined a partial loss of the augmented bone and in one case probably determined the failure of one implant.

The augmentation procedure not only required an additional healing time of 5 months, but was also associated, in a highly statistically significant way, to more patients experiencing some post-operative paraesthesia of the alveolar inferior nerve. In fact, 16 patients (57%) had some post-operative paraesthesia versus only two patients (7%) of the short implant group. The paraesthesiae of the augmented group were probably associated with stretching of the nerve exiting from the mental foramen. All paraesthesiae were solved within 6 days. In a previous study[5], using the same augmentation technique, all 10 patients suffered from paraesthesia that disappeared after an average of 4 days. The reasons why the augmented patients in the present investigation had less problems with paraesthesia than those reported in the previous study[5], despite the fact that the surgeon and the procedures were identical, can only be speculated upon. It is possible that improved manual dexterity of the operator and the fact that in the present study the augmentations were performed under local anaesthesia, whereas in the other study were done under general anaesthesia, are reasons for the difference.

The augmentation procedure is also more technically demanding than placing short implants. One of the main difficulties is the management of the soft tissues to maintain sufficient blood supply to the cranially displaced bone segment, and to close the wound without too much tension to minimise the risk of wound dehiscence. A piezo-electric device was preferred over conventional rotating instruments in the belief that the risk of complications such as damage to the lingual flap could be minimised. While this assumption is generally accepted there is not yet any solid evidence supporting it[9].

There is another RCT[10–12] comparing fully atrophic edentulous mandibles with a symphyseal bone height of 6 to 12 mm augmented with an interpositional graft from the iliac crest and 4 'longer' implants, with a protocol using 4 'short' implants, 8 to 11 mm long, supporting overdentures and followed-up for 2 years post-loading. There were statistically more implant failures (in 5 patients out of 20 versus none), post-operative pain and complications in the augmented group (apart from obvious substantial differences in hospital stays, costs and time necessary to complete the treatment). Among the complications worth mentioning: a life-threatening haemorrhage, causing a massive sublingual oedema which left the patient in intensive care for 3 days; a necrosis of the graft determining the failures of all four inserted implants and two permanent unilateral dysaesthesia. All these complications with the exception of one of the permanent dysaesthesiae, occurred in the augmented group. The authors concluded that short implants were the best treatment solution for those patients. Another recent RCT[13] compared 8-mm-long hydroxyapatite-coated implants placed in crestally augmented maxillary sinuses with longer implants placed in sinuses augmented with the lateral approach technique with 50% particulated autogenous bone and 50% Bio-Oss, early loaded at 45 days post-placement. One year after loading, there were no statistically significant differences, but more implants failed and serious complications occurred in the group augmented with the lateral approach for receiving longer implants.

While there are some obvious differences between the present trial and the one mentioned above (i.e. use of different types of graft in different locations and the definition of 'short' implants), the results of both studies suggest that short implants are a preferable solution over vertical augmentation to allow placement of longer implants.

Among the main limitations of the present investigation was that the sample was small, but just sufficient to provide significant results regarding the recovery of mental sensitivity. Only 30 patients per group were included instead of the 72 patients suggested by the sample size calculation. The main justification for our decision was that we were unsure of the outcome of the study and we did not want to subject a higher number of patients to unnecessary risks. A secondary motivation was dictated by a pragmatic approach to the problem. In order to reach the estimated sample size, the recruitment time would have been prolonged for at least 18 months and we did not have sufficient resources and patience to achieve this. Larger trials are needed to explore the matter in more detail. On the other hand, all treated patients were accounted for with no exclusions and all assessments were done by an independent and blinded assessor. However, the assessor could detect whether he was measuring bone levels at augmented sites since the implants were generally longer and Bio-Oss tended to appear more radiopaque on radiographs than normal bone.

It is difficult to draw conclusions from direct comparisons with other RCTs evaluating alternative techniques for vertical bone augmentation (i.e. osteodistraction, guided bone regeneration, inlays or onlays of autogenous block), because the number of studies is still insufficient[2–5,14]. While it could be hypothesised that an interpositional bone substitute could be a valid alternative to other techniques for vertical ridge augmentation, vertical augmentation offered no advantages, but created more discomfort for the patients and longer treatment times than using 7-mm-long implants. So, despite its small sample size, the present trial provided some useful preliminary clinical indications. Interestingly, a recent RCT[15] also suggested that it is possible to successfully load immediately and early flapless-placed 7-mm short implants of identical type to those used in the present investigation even if placed in post-extractive sites, when these implants are inserted with a torque superior to 40 Ncm. These preliminary data, however, need to be substantiated by a larger number of studies and moreover by longer follow-up periods (5 years or more), since it is still possible that the advantages of using short implants are reversed after a few years of function by increasing failure rates.

How can such a good performance of 7-mm-long implants be explained while a few years ago results appeared to be less positive (about 10% failures reported at implant level)[8]? It can be speculated that the new implant surface used in the present investigation and in another investigation[15], with discrete calcium phosphate deposition (NanoTite), might have played an important role in the success. This, however, is a hypothesis which needs to be addressed by appropriately designed clinical trials.

Both techniques were tested in real clinical conditions and patient inclusion criteria were rather broad, therefore the results of the present trial 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 and similar results; however, when the residual bone height over the mandibular canal is between 7 and 8 mm, 7-mm short implants might be a preferable choice since the treatment is faster, cheaper and associated with less morbidity than vertical bone augmentation. These preliminary results must be confirmed by longer follow-ups of 5 years or more in order to monitor the performance of short implants over time.

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