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Rehabilitation of posterior atrophic edentulous jaws: prostheses supported by 5 mm short implants or by longer implants in augmented bone? One-year results from a pilot randomised clinical trial

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

Purpose: To evaluate whether 5 mm short dental implants could be an alternative to augmentation with anorganic bovine bone and placement of at least 10 mm long implants in posterior atrophic jaws.

Materials and methods: Fifteen patients with bilateral atrophic mandibles (5–7 mm bone height above the mandibular canal), and 15 patients with bilateral atrophic maxillae (4–6 mm bone height below the maxillary sinus) and bone thickness of at least 8 mm, were randomised according to a split-mouth design to receive one to three 5 mm short implants or at least 10 mm long implants in augmented bone. Mandibles were vertically augmented with interpositional bone blocks and maxillary sinuses with particulated bone via a lateral window. Implants were placed after 4 months, submerged and loaded, after 4 months, with provisional prostheses. Four months later, definitive provisionally cemented prostheses were delivered. Outcome measures were: prosthesis and implant failures, any complication and peri-implant marginal bone level changes.

Results: In 5 augmented mandibles, the planned 10 mm long implants could not be placed and shorter implants (7 and 8.5 mm) had to be used instead. One year after loading no patient dropped out. Two long (8.5 mm in the mandible and 13 mm in the maxilla) implants and one 5 mm short maxillary implant failed. There were no statistically significant differences in failures or complications. Patients with short implants lost on average 1 mm of peri-implant bone and patients with longer implants lost 1.2 mm. This difference was statistically significant.

Conclusions: This pilot study suggests that 1 year after loading, 5 mm short implants achieve similar if not better results than longer implants placed in augmented bone. Short implants might be a preferable choice to bone augmentation since the treatment is faster, cheaper and associated with less morbidity, however their long-term prognosis is unknown.

Conflict of interest statement: MegaGen Implant Co., Gyeongbuk, South Korea partially supported this trial and donated the implants and prosthetic components, however the data belonged to the authors and by no means did MegaGen Implant Co. interfere with the conduct of the trial or the publication of the results.
Introduction

In many clinical situations it is not possible to place dental implants of ‘adequate length’ because there is less than 8 mm of residual vertical bone height. Clinicians are faced with the dilemma of whether to augment the bone or to place short implants having an intra-bony length of 8 mm or less1. Seven millimetres or shorter implants have been associated with decreased success rates when compared to longer implants2. This comparison is inappropriate because when adequate amounts of bone are available, dentists tend to place longer implants. In the absence of adequate bone height, the outcome of short implants should be compared with those of longer implants placed in augmented bone. Various techniques are currently used to augment the bone, though just a few of these techniques have been evaluated in randomised clinical trials (RCTs)3,4. Augmentation procedures are more technically demanding and therefore require skilful operators. They can be associated with significant postoperative morbidity and complications, can be more expensive, and may require longer times (up to 1 year) before patients are able to chew on their implant-supported prostheses3,4. If short implants could provide similar clinical outcomes, they could be a simpler, cheaper and faster alternative to longer implants placed in augmented bone. There are only a few short-term comparative studies evaluating their efficacy in a reliable way5-7. Preliminary results of these RCTs suggest that 7- to 8-mm-long implants can be a better alternative to augmentation procedures. There is no RCT evaluating even shorter implants such as those only 5 mm long.

The aim of this RCT was to compare the outcome of partial fixed prostheses supported by 5 mm-long implants (Rescue implant with internal connection, MegaGen Implant Co., Gyeongbuk, South Korea) with prostheses supported by implants at least 10 mm long placed in posterior jaws augmented either with mandibular interpositional blocks of anorganic bovine bone (Bio-Oss; Geistlich Pharma, Wolhusen, Switzerland) or with granular Bio-Oss placed through a lateral window below the lifted maxillary membrane.

The present study reports the clinical outcome up to 1 year after loading and is the follow-up of a previous publication8. 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 to the CONSORT statement for improving the quality of reports of parallel-group randomised trials (http://www.consort-statement.org/).

Materials and methods

Any partially edentulous patient having bilateral edentulism in posterior jaws (premolars and molars) with a similar degree of bone atrophy on both jaw sides requiring one to three dental implants, being 18 years or older, and able to sign an informed consent form was eligible for this trial. Vertical bone heights at implant sites had to be 5 to 7 mm above the mandibular canals (Fig 1) and 4 to 6 mm below the maxillary sinuses (Fig 2). Bone thickness had to be at least 8 mm. Bone dimensions were measured on preoperative computer tomography (CT) scans. Exclusion criteria were:

- general contraindications to implant surgery
- subjected to irradiation in the head and neck area
- immunosuppressed or immunocompromised
- treated or under treatment with intravenous amino-bisphosphonates
- untreated periodontitis
- poor oral hygiene and motivation
- uncontrolled diabetes
- pregnant or nursing
- substance abuse
- psychiatric problems or unrealistic expectations
- lack of opposite occluding dentition in the area intended for implant placement
- acute or chronic infection/inflammation in the area intended for implant placement
- patients participating in other trials, if 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 3 groups according to what they declared: non-smoker, light smoker (up to 10 cigarettes per day) or heavy smoker (more than 10 cigarettes per day). Patients were recruited and treated in different private practices and two
hospitals, but were treated by the same operator (PF performed all of the surgical procedures) following 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, the surgeon recorded one site of his choice as site number 1 and the contralateral as site number 2. Site number 1 of eligible patients was randomised according to a split-mouth design to be either augmented to allow placement of at least 10 mm-long implants or to receive 5 mm-long implants (test procedure). The augmentation procedure consisted of an interpositional block of anorganic bovine bone (Bio-Oss) in mandibles or 100% granular Bio-Oss in the maxillary sinus. The side randomised to the augmentation procedure was treated first and implants were placed 4 months after the augmentation procedure during the same surgical session in both sites.

**Augmentation procedure**

Study models were used to plan the amount of vertical augmentation required by the patients at both mandibular sites. Within 10 days prior to bone augmentation and implant placement, all patients underwent at least one session of oral hygiene instructions/debridement when required, and 1 minute rinsing with 0.2% chlorhexidine mouthwash was prescribed twice a day.

All patients received prophylactic antibiotic therapy: 2 g of amoxicillin (or clindamycin 600 mg if allergic to penicillin) 1 hour prior to augmentation and a 1-minute rinse with 0.2% chlorhexidine mouthwash. All patients were treated under local anaesthesia (articaine with adrenaline 1:100,000). No intravenous sedation was used.

For the mandible, a surgical template was used to indicate the planned implant positions. A paracrestal incision was made through the buccal area respecting the emergence of the mental nerve, to expose the alveolar ridge. 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 coronal third of the mandibular bone with the mesial cut at least 2 mm distal to the last tooth in the arch. The height of the osteotomised segment had 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 and Bio-Oss blocks were modelled to completely fill the sites to the desired height and shape, interposed between the raised fragment and the mandibular basal bone, and fixed with titanium miniplates and miniscrews (Gebrüder Martin, Tuttlingen, Germany) to both the basal bone and the osteotomised crestal bone. Gaps in the vertical osteotomies were filled with particulated bone from the blocks. The grafted areas were covered with a resorbable barrier (Bio-Gide®, Geistlich Pharma). Periosteal incisions were made to release the flaps as coronally as needed.

For maxillas, a crestal incision was made, and after flap elevation a lateral window was prepared with piezosurgery (Mectron) and carefully displaced internally after elevation of the maxillary membrane. The sinus was loosely packed with granular Bio-Oss and the lateral window was covered with a resorbable Bio-Gide barrier. Flaps were sutured with Vicryl 4.0 sutures (Ethicon FS-2, St-Stevens-Woluwe, Belgium), until the incisions were perfectly sealed. Ice packs were provided and 1 g amoxicillin (or 300 mg clindamycin) was prescribed to be taken twice a day for 7 days. Ibuprofen 400 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%) twice a day for 2 weeks, to have a soft diet for 1 week, and to avoid brushing and trauma on the surgical sites. No removable prosthesis was allowed for 1 month. Patients were seen after 3 days and sutures were removed after 10 days. All patients were recalled for additional postoperative check-ups 1, 2 and 3 months after the augmentation procedure.

**Implant placement**

Four months after augmentation, CT scans were taken to assess bone volumes for planning implant surgery. Implants were placed at both sites, during the same surgical session. A total of 2 g of amoxicillin (or 600 mg clindamycin) was administered 1 hour prior to implant placement and patients rinsed for 1 minute with 0.2% chlorhexidine mouthwash. Infiltration anaesthesia (articaine with adrenaline 1:100,000) was used in both mandible and maxilla. After a crestal incision and flap elevation, miniplates were removed, and knife edge ridges were flattened to reach a thickness of at least 8 mm. One to three 5 mm-long and 6 mm in diameter (short implant group) or 10 mm-long and 6 mm in diameter implants (augmented group) were to be inserted under prosthetic guidance using a surgical template (Fig 3). Only 5 to 10 mm-long Rescue (MegaGen) dental implants, with a diameter of 6 mm, with internal connection, made of commercially pure titanium with a surface blasted with hydroxyapatite particles and cleaned with acid were to be used according to the original protocol.

However, the operator correctly used the 5 mm-long Rescue implants in the test group, and EZ Plus MegaGen implants with internal connection of varying lengths (10, 11.5 and 13 mm), all with a diameter of 4 mm, at the augmented sites. The operator was allowed to place shorter implants (7 and 8.5 mm) at augmented sites if the augmentation procedure was not completely successful. The standard placement procedure as recommended by the manufacturer was used. For the Rescue implants, a 5 mm external diameter trephine was used first. Trephines were initially rotated in a counter-clockwise direction until the saw part of the trephine engaged the crest of the bone. The drilling was performed in a clockwise direction. The osteotomy site was extended with a 5.4 mm diameter pilot drill.

**Prosthetic and follow-up procedures**

After 3 months of submerged healing, implants were exposed and impressions with the pick-up impression copings were taken using a polyether material (Impregum, 3M/ESPE, Neuss, Germany) and customised resin impression trays. Four months after placement, implants were manually tested for stability and provisional screw-retained crowns or reinforced acrylic restorations rigidly joining the implants were delivered on temporary abutments (MegaGen).
The occlusal surfaces were in slight contact with the opposite dentition. Intraoral radiographs of the study implants were taken. Four months after delivery of provisional prostheses, implants were manually tested for stability and definitive metal-ceramic restorations rigidly joining the implants with occlusal surfaces in ceramic were cemented with provisional cement (TempBond, Kerr Italia, Scafati [SA], Italy) on Ez Post abutments (MegaGen), which were prepared in the laboratory or, in case of tilted implants, on UCLA gold abutments (MegaGen).

Patients were enrolled in an oral hygiene program 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 report presents data up to 1 year after prosthetic loading (Fig 4).

**Outcome measures**

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 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. The stability of each individual implant was measured after removing the restorations at delivery of the provisional prostheses (4 months after implant placement), at delivery of the definitive prostheses (4 months after delivery of the provisional prostheses) and 1 year after initial loading by tightening the abutment screws of the removed prostheses using a manual wrench with a 15 Ncm force. In cases of single implants, the metallic handles of two instruments were used to assess implant stability.
- Any biological or prosthetic complications.
- Peri-implant marginal bone level changes evaluated on intraoral radiographs taken with the paralleling technique at implant placement, at delivery of the provisional prostheses, and 1 year after loading. Radiographs were scanned, digitised in JPG format, converted to TIFF format with a 600 dpi resolution and stored in a personal computer. Peri-implant marginal bone levels were measured using the UTHSCSA Image Tool 3.0 (The University of Texas Health Science Center, San Antonio, USA) software. The software was calibrated for every single image using the known implant length. Measurements of the mesial and distal bone crest levels adjacent to each implant.
were made to the nearest 0.01 mm and averaged at patient level and group level. The measurements were taken parallel to the implant axis. Reference points for the linear measurements were the most coronal margin of the implant collar and the most coronal point of bone-to-implant contact.

Other outcome measures (days needed to fully recover mental nerve sensitivity after the augmentation and implant placement, and patient preference) were reported in a previous publication.

Methodological aspects

One dentist (GP) not involved in the treatment of the patients performed all clinical and radiographic assessments without knowing group allocation, however augmented sites could be easily identified both clinically when testing implant stability because of the different implant diameters and on radiographs because they appeared more radiopaque and the implants were different.

The sample size was calculated for patient preference, which was based on a previous trial to detect a preference of one group over another against the alternative hypothesis that the treatments were equally preferred. This reduced 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 a difference between the null hypothesis proportion of 0.500 and the alternative proportion of 0.900 when the sample size is 10. The sample was increased by one-third since it was hypothesised that patient preference would not be so definite, and the two groups (maxilla and mandible) were kept separate since patients could have a different preference according to the location of the intervention.

Thirty partially edentulous patients with similar bilateral posterior jaw atrophy were included: 15 patients were partially edentulous in the maxilla and 15 in the mandible.

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 information on how to treat site number 1 was enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially the same day of the augmentation procedure and the surgeon treated on that occasion only the site allocated to the augmentation procedure. 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 and complications (dichotomous outcomes) were compared using the exact McNemar test. Differences of means at patient level for continuous outcomes (radiographic bone levels) between groups were compared by paired t tests. Comparisons between each time point and the baseline measurements were made by paired tests, to detect any changes in marginal peri-implant bone levels. All statistical comparisons were conducted at the 0.05 level of significance.

Results

Sixty-seven patients were screened for eligibility, but 37 patients were not included in the trial for the following reasons: 23 patients did not have enough bone width, 4 patients did not have enough bone height, 7 patients were hesitant to receive short implants, 2 patients had radiotherapy for breast cancer and one was affected by osteoporosis. Thirty patients were considered eligible and were consecutively enrolled in the trial. All patients were treated according to the allocated interventions, no dropout occurred up to 1 year after loading (one patient actually moved away and did not attend the 1 year evaluation visit, but kindly provided the periapical radiographs taken by the new dentist) and the data of all patients were evaluated in the statistical analyses. The following deviations from the protocol occurred:

- EZ Plus 10 to 13 mm-long implants with a diameter of 4 mm were used at the augmented sites instead of the 10 mm-long (or shorter if necessary) Rescue implants of 6 mm diameter.
Three patients were not recruited despite not having any of the established exclusion criteria. Two patients were excluded for having received irradiation for breast cancer and one patient because of osteoporosis.

Patients were recruited and subjected to bone augmentation procedures from July 2008 to January 2009. The last definitive prosthesis was inserted in September 2009. The follow-up of all patients was up to 1 year after initial loading.

The main baseline patient and intervention characteristics, divided by study group and location, are presented in Table 1 and Table 2, respectively. Sixty-eight 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. In five patients, after vertical bone augmentation of the mandible there was not sufficient bone to place the planned 10 mm-long implants and 7 to 8.5 mm-long implants had to be used instead.

The main results are summarised in Table 3. Three implants failed in three different patients up to 1 year after loading: one short and two long implants. The difference in proportions for implant failures was not statistically significant ($P = 1.00$, difference 0.03, 95% CI from -0.11 to 0.18). The failed 5 mm short implant was found to be mobile at abutment connection. It was placed with an insertion torque below 25 Ncm. At implant placement the patient had a bilateral perforation of the maxillary sinus membranes. The implant was successfully replaced by one placed more distally and loaded. In one patient of the augmented group, one implant out of two 8.5 mm-long implants inserted was found to be mobile at abutment connection. It was placed to replace a tooth in position 46. A dehiscence was noticed 10 days after implant placement that persisted until abutment connection. Implant threads became exposed possibly because of infection. The implant has not been replaced. The other failed 13 mm-long maxillary implant was in position 27. Six months after loading, the patient started to...
feel some pain/discomfort when chewing. The prosthesis was removed to check implant stability; the implant was found to be mobile and was removed. The patient did not want to have it replaced since the prosthesis was supported by the two remaining implants.

As a consequence of the two implant failures (one long and one short implant) at abutment connection the respective prostheses could not be delivered as planned and shortened prostheses were used instead. The late implant failure did not determine the failure of its prosthesis, which was supported by three implants. The difference in proportions for prosthesis failures was not statistically significant (P value not calculable).

Six complications occurred in five patients up to 1 year after loading: two in the augmented group and four in the short implant group. The difference in proportions was not statistically significant (P = 0.62, difference = -0.07, 95% CI from -0.23 to 0.10). The two complications of the augmented group were one perforation of the sinus membrane which was treated by positioning a resorbable synthetic barrier (Inion, Tampere, Finland), and one dehiscence of about 4 mm diameter of the mandibular graft observed at suture removal and still present at implant placement. The dehiscence was treated with 0.2% chlorhexidine gel and mouthwash but the implant was then found to be mobile at abutment connection. The four complications in the short implant group were three perforations of the sinus lining at implant placement (two perforations were treated by placing a collagen barrier [Gingistat, OPOCRIN, Corlo, Italy] whereas the membrane perforation appeared to close spontaneously after lifting the membrane, though the implant was found to be mobile at abutment connection) and one case of symptomatic peri-implant bone loss around a mandibular implant in position 45. Eight months after loading, the patient experienced some discomfort/pain when chewing. After repeated maintenance recalls, at 11 months post-loading it was decided to explore the site surgically. Soft tissue was present below the first thread. The exposed implant surface was thoroughly cleaned, granules of anorganic bovine bone (Bio-Oss) were used to fill the gap, and a resorbable barrier (Bio-Gide) was placed to cover the area.

There was no statistically significant difference at loading (P = 0.83) but there was a statistically significant difference of 0.18 mm between the 2 groups for peri-implant bone levels, at 1 year after loading (P = 0.014), with more bone loss for the long implants (Table 4). Both groups gradually lost statistically significant amounts of marginal peri-implant bone (P < 0.001) at loading and 1 year after loading (Table 5).

**Discussion**

This pilot trial was designed to evaluate whether 5 mm-long implants of 6 mm diameter could be a possible alternative for the rehabilitation of posterior atrophic jaws with implant-supported partial fixed prostheses. The control procedures were...
augmentation procedures tested in other trials: vertical bone augmentation with interpositional blocks of anorganic bovine bone\textsuperscript{6,9} for atrophic mandibles and 2-stage sinus lift with lateral window approach using 100\% bone substitute\textsuperscript{10}. All tested interventions were successful, though in one-third of the patients subjected to vertical augmentation of the mandible, the procedure did not obtain the planned height sufficient to place 10 mm implants and shorter implants (7 and 8.5 mm) had to be used instead. Only three implants were lost, two of them being of the long type (one in the mandible and one in the maxilla). Bone augmentation procedures are technically more demanding than placing short implants, they are usually associated with higher postoperative morbidity, complications, longer treatment periods and an increased number of surgeries. Taking all of these findings together, which are in agreement with the results of previous RCTs\textsuperscript{5,7,11} and systematic reviews\textsuperscript{3,4}, it is possible to suggest that short implants may be as effective or even more effective than augmentation of posterior jaws at least up to 1 year after loading, keeping in mind that the long-term prognosis is yet unknown and the sample size of the present and other published RCTs\textsuperscript{5,7,11} is still too small to draw definitive conclusions. More RCTs with larger sample sizes and longer follow-up are needed, and in particular, the potential role of the implant diameter for short implants should be investigated, since clinicians tend to compensate for the lack of height by using implants with a wider diameter\textsuperscript{5}. The problem is that it may be only half of patients that have bone widths of at least 8 mm as confirmed by the present recruitment data: 27 patients had to be excluded due to insufficient bone width. Future trials should also test the efficacy of 5 mm short implants but with smaller diameters (4–5 mm), to evaluate if patients with bone width of 5 to 7 mm could also be successfully treated without the need for more invasive bone augmentation interventions. It would also be interesting to test short implants against alternative less invasive bone augmentation techniques such one-stage mini-sinus lift procedures with a crestal approach\textsuperscript{5,12-14}.

Regarding peri-implant marginal bone levels, 1 year after loading and using the bone levels at implant placement as baseline data, short implants lost on average 1 mm and long implants about 1.2 mm. This difference between groups was statistically significant. The present data are very similar to those observed around another implant system used in similar conditions\textsuperscript{7}. Another interesting observation is that implants may need as little as 4 mm of bone support to be able to hold a functioning prosthesis, though the follow-up is too short to allow for generalisation.

The main limitation of the present investigation is the small sample size. Larger trials are needed to explore the matter in more detail. The use of a 2-stage lateral window approach to lift the maxillary sinus could be another limitation. Ideally, a more conservative approach such as a 1-stage lateral window procedure or even a crestal approach could have been used, since in a recent RCT 8 mm-long implants placed in a crestally elevated sinus with a residual bone height of 3 to 6 mm yielded slightly better success rates, even when loaded only 45 days after placement, than longer implants placed in a sinus augmented with a lateral window technique\textsuperscript{5}. On the other hand, all treated patients were accounted for with no exclusions and all assessments were performed by an independent assessor. The surgeon was very experienced with all tested techniques and this factor might limit the extrapolation of the present results, however all procedures were tested in real clinical conditions, therefore the results of the present trial can be generalised with confidence to a wider population with similar characteristics.

\section*{Conclusions}

All techniques provided good and similar results up to 1 year after loading, however, 5 mm short implants might be a preferable choice to augmentation procedures that allow for the placement of longer implants since the treatment was faster, cheaper and associated with less morbidity. Unfortunately, only a few patients have the sufficient bone width (at least 8 mm) to accommodate implants with a 6 mm diameter. These preliminary results must be confirmed by larger and longer follow-ups of 5 years or more. Short implants with diameters of 4 to 5 mm ought to be evaluated as well.
References


