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Posterior atrophic jaws rehabilitated with prostheses supported by 6-mm-long 4-mm-wide implants or by longer implants in augmented bone. Five-year post-loading results from a within-person randomised controlled trial

KEY WORDS

bone substitutes, inlay graft, short dental implants, sinus elevation, vertical augmentation

ABSTRACT

Purpose: To evaluate whether 6-mm-long by 4-mm-wide dental implants could be an alternative to implants at least 10-mm long placed in bone augmented with bone substitutes in posterior atrophic jaws.

Materials and methods: A total of 20 patients with bilateral atrophic mandibles and 20 patients with bilateral atrophic maxillae, having 5 to 7 mm of bone height below the maxillary sinus or 6 to 8 mm above the mandibular canal, had their sides of the jaws randomly allocated according to a split-mouth design. They were allocated to receive one to three 6-mm-long and 4-mm-wide implants, or implants at least 10-mm long in augmented bone by two different surgeons in different centres. Mandibles were vertically augmented with interpositional equine bone blocks and resorbable barriers, and implants were placed 3 months later. Maxillary sinuses were augmented with particulated porcine bone via a lateral window and implants were placed simultaneously. All implants were submerged and loaded, after 4 months, with provisional prostheses. Four months later, definitive prostheses were delivered. Outcome measures were prosthesis and implant failures, any complication and radiographic peri-implant marginal bone level changes. The follow-up was 5 years after loading for all patients.

Results: Eight patients (five treated in mandibles and three in maxillae) dropped out before the 5-year post-loading follow-up. Four short implants (two maxillary and two mandibular) affected by peri-implantitis failed together with their prostheses versus three mandibular prostheses which could not be placed on implants at least 10-mm long due to graft failures; one was associated with the loss of three implants because of infection. There were no statistically significant differences in implant ($P = 1.0$) and prosthesis failures ($P = 1.0$). In total, 19 complications occurred in 14 patients at augmented sites versus five complications in four patients with 6-mm-long implants ($P = 0.118$). More complications occurred at grafted sites both in mandibles ($P = 0.727$), and maxillae ($P = 0.063$), although the differences were not statistically significant. In mandibles,

patients with 6-mm-long implants lost an average of 1.34 ± 0.35 mm of peri-implant bone at 5 years versus 2.11 ± 0.59 mm in patients with implants at least 10-mm long. The difference was statistically significant (mean difference = 0.77 ± 0.70 mm; 95% CI: 0.32 to 1.21 mm; $P = 0.003$). In maxillae, patients with 6-mm-long implants lost an average of 1.52 ± 0.47 mm of peri-implant bone at 5 years versus 1.85 ± 0.51 mm in patients with implants at least 10-mm

long. The difference was statistically significant (mean difference = 0.33 ± 0.36 mm; 95% CI: 0.14 to 0.53 mm; *P* = 0.002).

Conclusions: Results at 5 years after loading indicate that 6-mm-long implants with a conventional diameter of 4 mm achieved similar results to longer implants placed in augmented bone. Short implants might be a preferable choice to bone augmentation, especially in posterior mandibles since the treatment was faster, cheaper and associated with less morbidity. However, 10-year post-loading data are necessary before making reliable recommendations.

Conflict of interest statement: *Tecnoss and Southern Implants partially supported this trial and donated biomaterials, implants and prosthetic components used in this study. However, the data belonged to the authors and by no means did the manufacturers interfere with the conduct of the trial or the publication of its results.*

Introduction

One problem for rehabilitating patients with atrophic jaws is insufficient bone height for placing implants of 'adequate' length to support fixed dental prostheses. In these conditions, short dental implants with an intrabony length of 8 mm or less[1] are used as an alternative to bone augmentation for placing longer implants. While longer implants might have a better long-term prognosis in non-augmented bone[2], the long-term prognosis of short implants compared to longer implants placed in augmented bone is still unknown. There are several randomised controlled trials (RCTs) comparing the effectiveness of dental prostheses supported by short implants with those supported by longer implants placed in augmented bone[3-13]. Preliminary results of these ongoing trials having follow-ups up to 8 years post-loading, suggest that 4- to 8-mm-long implants can be a viable, if not a better alternative to augmentation procedures, especially in posterior mandibles. However only one RCT presented, at the time of writing this report, 8-year post-loading results[13], one 5-year data[4], and three trials presented data at 3 years post-loading[7,11,12].

In some previous studies, short implants with wider diameters were used[4,7]. This decision, at the time, was dictated by the scarcity of commercially available very short implants with a diameter less than 6 mm[7] due to the widespread belief that wider diameters were needed to compensate for short lengths[4,7]. When using very short implants (5-mm long) with a wide diameter (6 mm), 43% of the patients could not be rehabilitated since they did not have sufficient bone width in the posterior jaws to accommodate such a diameter[7]. It was concluded that, in order to treat larger groups of patients, the long-term prognosis of short implants with smaller diameters had to be investigated.

Different bone augmentation techniques are currently used; however, the effectiveness of only a few of these procedures has been evaluated in RCTs[14,15]. There is not yet clear evidence of which could be the more effective, vertical bone augmentation or sinus elevation procedures[14,15]. Augmentation procedures are technically demanding, can be associated with significant postoperative morbidity and complications, can be more expensive, and may require hospitalisation and longer times (up to 1 year) for rehabilitating the patients[14,15].

Short implants could be a simpler, cheaper and faster alternative if they could provide similar clinical outcomes to longer implants placed in augmented bone. The aim of this RCT was to compare the outcome of partial fixed prostheses supported by 6-mm-long and 4-mm-diameter implants with prostheses supported by implants at least 10-mm long placed in posterior jaws augmented either with mandibular interpositional blocks of collagenated equine bone or with granular porcine bone placed through a lateral window below the elevated maxillary membrane.

The present report presents clinical outcomes up to 5 years after loading. Previous publications

reported the preliminary results at 5 months[16] and 1[17] and 3 years[3] post-loading. 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 (http://www.consort-statement.org/) and it extension checklist for reporting within-person randomised trials (http://www.consort-statement.org/extensions/overview/withinperson) to improve the quality of reports of within-person randomised controlled trials.

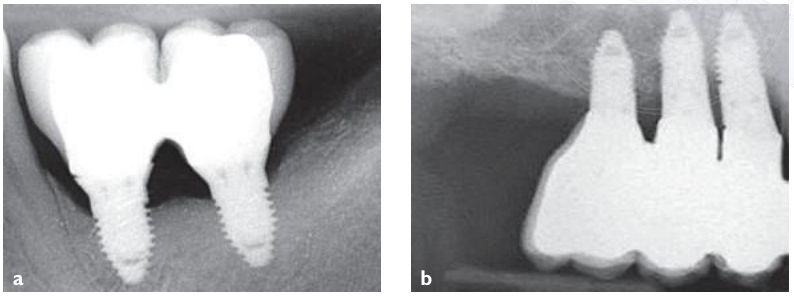

Fig 1a-b Periapical radiographs taken at 5 years after loading of representative sides randomised to 6-mm-long implants in **(a)** the mandibles and **(b)** the maxillae.

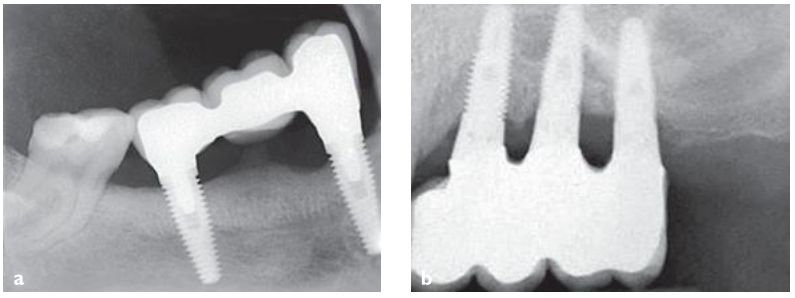

Fig 2a-b Periapical radiographs taken at 5 years after loading of representative sides randomised to **(a)** augmentation with an interpositional equine bone block and **(b)** one-stage lateral window maxillary sinus elevation with granules of porcine bone to allow placement of implants at least 10-mm long.

Materials and methods

Trial design

This was a two-centre RCT of within-person design evaluating two different interventions with blind assessment, when possible. Each patient had both sides of the posterior jaw randomised to receive one partial fixed prosthesis supported by one to three 6-mm-long and 4-mm-diameter implants (Fig 1) and by implants at least 10-mm long placed in jaws augmented either with a mandibular interpositional block of collagenated equine bone (Fig 2a) or with granular porcine bone placed through a lateral window into the maxillary sinus (Fig 2b).

Eligibility criteria for participants

Any partially edentulous patient having bilateral edentulism in posterior jaws (premolars and molars) with a similar degree of bone atrophy at both sides of the jaw requiring one to three dental implants, being 18 years or older, and able to understand and sign an informed consent form was eligible for this trial. Vertical bone heights at implant sites had to be 6 to 8 mm above the mandibular canals or 5 to 7 mm below the maxillary sinuses. Bone thickness at future implant sites had to be at least 5 mm as measured on computed 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 categorised into three groups according to what they declared: non-smokers, moderate smokers (up to 10 cigarettes per day) or heavy smokers (more than 10 cigarettes per day). Patients were recruited and treated in different centres: one

operator (Dr Pietro Felice) treated patients in three Italian private practices and two university hospitals, whereas the other operator (Dr Roberto Pistilli) treated patients in a public hospital, following similar and standardised procedures.

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. All sites numbered 1 were to be randomised according to a split-mouth design to be either augmented to allow placement of one to three implants 4-mm wide and at least 10-mm long or to receive one to three implants 6-mm long and 4-mm wide. The augmentation procedure consisted in the insertion of an interpositional block of collagenated cancellous equine bone (OsteoBiol Sp-Block, Tecnoss, Giaveno, Italy) in mandibles or a mix of cancellous and cortical porcine-derived collagenated bone having a granulometry of 250 to 1000 µm (OsteoBiol Gen-Os, Tecnoss) in maxillary sinuses. Both sides were to be treated during the same surgical session (one side to be augmented and the other to receive short implants).

Augmentation procedure

Within 10 days prior to bone augmentation and implant placement procedures, all patients underwent at least one session of oral hygiene instructions/debridement when required.

All patients received prophylactic antibiotic therapy: 2g of amoxicillin (or clindamycin 600 mg if allergic to penicillin) 1 hour prior to augmentation and a rinse for 1 minute with chlorhexidine 0.2%. Just before administering local anaesthesia, the sequentially numbered envelope corresponding to the patient recruitment number was opened to discover which side had to be augmented and which side had to receive short implants. Both sides were to be treated during the same surgical session. The surgeon had to operate first on the side selected by the random allocation. 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 amount of vertical augmentation required. 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 while trying to minimise mental nerve stretching. 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 made in the coronal third of the mandibular bone with the mesial cut at least 2 mm away from the adjacent teeth. The height of the osteotomised segment had to be at least 3 mm to minimise the risk of fracture when inserting the stabilising screws. The segment was then raised in a coronal direction, sparing the lingual periosteum. The collagenated cancellous equine bone blocks (OsteoBiol Sp-Block) were then modelled 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 OsteoBiol Gen-Os granules of porcine bone. The grafted areas were covered with a collagen resorbable barrier (OsteoBiol Evolution, Tecnoss, Fine 30 × 30 mm) derived from equine pericardium. Periosteal incisions were made to release the flaps as coronally as needed.

For maxillae, after crestal incision and 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 OsteoBiol Gen-Os granules of porcine bone and 10-mm or longer commercially pure titanium implants (Southern Implants, Irene, South Africa) with external hexagon and a roughened grit-blasted surface were inserted. The sinus was overfilled with OsteoBiol Gen-Os granules and the lateral window was covered with an OsteoBiol Evolution resorbable collagen 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, 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 two to four times a day during meals, as long as required. Patients were instructed to use chlorhexidine gel 1% (Corsodyl, GlaxoSmithKline Consumer Healthcare, Baranzate (MI), Italy) 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

At mandibular grafted sides, implants were placed 3 months after augmentation, whereas implants were inserted in maxillae simultaneously to sinus elevation procedures. Sometimes CT scans were taken to assess bone volumes for planning implant surgery. A total of 2 g of amoxicillin (or 600 mg clindamycin) were administered 1 hour prior to implant placement and patients rinsed for 1 minute with 0.2% chlorhexidine. Infiltration anaesthesia (articaine with adrenaline 1:100,000) was used. After crestal incision and flap elevation, miniplates were removed, and when present knife-edge ridges were flattened to reach a thickness of at least 5 mm. Operators placed one to three implants 6-mm long at sides randomly allocated to short implants, and, if possible, one to three implants at least 10-mm long (11.5, 13 or 15 mm) at augmented sides guided by surgical templates. All implants had a 4-mm diameter. The standard placement procedure as recommended by the manufacturer was used. Drills with increasing diameters were used to prepare the implant sites, which were slightly under-prepared. When inserting the implants, the surgical motor unit was set to a torque of 25 Ncm and resistance at implant insertion was recorded as ≤ 25 Ncm or > 25 Ncm. Implant heads were placed slightly supracrestally. Cover screws were placed and flaps were closed over the implants with Vicryl 4.0 sutures. Periapical radiographs (baseline) were obtained with the paralleling technique. If bone levels around the study implants were hidden or difficult to be estimated, a second radiograph was obtained. Ibuprofen 400 mg was prescribed to be taken two to four times a day during meals, as long as required. Patients were instructed to rinse with 0.2% chlorhexidine for 1 minute twice a day for 2 weeks and to avoid brushing and trauma on the surgical sites. No removable prosthesis was allowed. Sutures were removed after 10 days.

Prosthetic and follow-up procedures

After 3 months of submerged healing, implants were exposed, and impressions with pick-up impression copings were acquired 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 or cemented crowns or reinforced acrylic restorations rigidly joining the implants were delivered on temporary abutments. The occlusal surfaces were in slight contact with the opposite dentition. Periapical radiographs of the study implants were taken. Four months after delivery of provisional prostheses, implants were manually tested for stability, and definitive metal-ceramic or metal resin restorations rigidly joining the implants, with occlusal surfaces in ceramic or resin, were cemented with provisional cement (Implacem, Dentalica, Milan, Italy by Dr Felice; or TempBond, Kerr Italia, Scafati (SA), Italy by Dr Pistilli) on titanium abutments, and oral hygiene instructions were reinforced, if necessary.

One month after delivery of the definitive prostheses, patients were asked by the independent outcome assessors about their preference between the two therapies.

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 independent outcome assessors (Dr Gerardo Pellegrino and Dr Valeria Corvino at Dr Felice's centres up to 1 year after loading, replaced by Dr Stefano Chersoni and Dr Mauro Andrisani, and from year 3 after loading also by Dr Cesare

Berti; and by Dr Gerardo Pellegrino at Dr Pistilli's centre up to 1 year after loading, replaced by Dr Roberto Cassoni).

Outcome measures

This study tested the null hypothesis that there were no differences in the clinical outcomes 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), loss of the prosthesis secondary to implant failure(s), and replacement of the prosthesis for any reasons.
- Implant failure: implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, and any mechanical complications rendering the implant not usable (e.g. implant facture). 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), 1, 3 and 5 years after initial loading by tightening the abutment screws with the prostheses removed using a manual wrench with a 15 Ncm force. At the 1-, 3- and 5-year follow-ups, two metallic handles of dental instruments were used to evaluate the stability of single crowns, which were not removed.
- Any complications.
- Peri-implant marginal bone level changes evaluated on periapical radiographs taken with the paralleling technique at implant placement, at delivery of the provisional prostheses, and at 1, 3 and 5 years after loading. Radiographs were scanned, digitised in JPG, 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, TX, USA) and the OsiriX (Pixmeo Sarl, Bernex, Switzerland) software. The software was calibrated for every single image using the known implant diameter. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.01 mm and averaged at implant level, then at patient level and finally at 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.
- Patient preference was assessed 1 month after delivery of the provisional prostheses by an independent assessor asking the patients which treatment they preferred. The answers could have been: 1) the augmented site; 2) short implants; 3) none, both treatments were equally good; 4) none, both treatments were equally bad. The patients could also express their comments.
- Other outcome measures (i.e. days needed to fully recover mental nerve sensitivity after augmentation and implant placement) were reported in a previous publication[16].

Methodological aspects

Six dentists (Dr Gerardo Pellegrino, Dr Valeria Corvino, Dr Stefano Chersoni, Dr Mauro Andrisani, Dr Cesare Berti and Dr Roberto Cassoni) not involved in the treatment of the patients performed all clinical measurements without knowing group allocation; however, mandibular augmented sites could be easily identified because of the different anatomy of the two sides after the augmentation procedure. One dental practitioner (Dr Carlo Barausse) not involved in the treatment of the patients performed all radiographic assessments without knowing group allocation; however, augmented sites could be easily identified on radiographs due to the different implant lengths.

The sample size was calculated for patient preference, which was based on a previous trial[18], to detect a preference of one group over another against the alternative hypothesis that the treatments are 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 the 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 doubled since the two groups (maxillae and mandibles) were kept separate because patients could have a different preference according to the location of the intervention. In total, 40 partially edentulous patients with similar bilateral posterior jaw atrophies were included: 20 patients were partially edentulous in the maxilla and 20 in the mandible.

A computer-generated restricted random list was created. Only one of the investigators (Dr Marco Esposito), not involved in the selection and treatment of the patients, was aware of the random sequence and could have access to the random 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 before giving anaesthesia and surgeons were to treat both sites in the same surgical session, starting from the intervention allocated to site number 1. 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 dental practitioner with expertise in statistics (Dr Jacopo Buti) analysed the data, without knowing the group codes. The prosthesis was the statistical unit of the analyses. Differences in the proportion of patients with prosthetic failures, implant failures and complications were compared between the two groups using the exact McNemar test and between the two surgeons using the Fisher exact test. Differences of means for radiographic bone levels between groups were compared by paired *t* tests. Comparisons between each time point and the baseline measurements were made by paired *t* tests to detect any changes in marginal peri-implant bone levels. Comparisons between surgeons for marginal peri-implant bone changes were made by independent *t* tests, while Fisher exact test was used to calculate differences in drop-outs and patients with mandibular graft failures between the two centres All statistical comparisons were conducted at the 0.05 level of significance and the data for maxillae and mandibles were analysed separately.

Results

A total of 49 patients were screened for eligibility, but nine patients were not included in the trial for the following reasons: three patients did not want to undergo the bone augmentation procedure, two patients had been treated with intravenous amino-bisphosphonates, two patients were unable to attend the various follow-ups for at least 5 years, one patient was affected by uncontrolled diabetes and one patient was immunodepressed. In total, 40 patients were considered eligible and were consecutively enrolled in the trial, 20 at each centre (10 with bilateral edentulous mandibles and 10 with bilateral edentulous maxillae).

All patients were treated according to the allocated interventions. Eight patients dropped-out up the 5 years after loading:

- One patient (mandible) before the 1-year post-loading follow-up for breast carcinoma.
- Two patients (mandible) after the 1 year follow-up could not be contacted any longer.
- One patient (maxilla) after the follow-up at 1 year and 4 months: she moved away but referred she has no problems at the prostheses.
- One patient (maxilla) after the 2 years follow-up: he moved away, and he lost the prosthesis on the short implants and did not seek for a new prosthesis.
- One patient (mandible) did not attend the maintenance appointments after the 3-year post-loading recall visit; initially he answered he had no time and would have contacted us, but when we tried to contact him again he became unreachable.
- One patient (mandible) moved abroad after the 3-year post-loading; by phone he referred not to have any problem with both prostheses.
- One patient (maxilla) became unreachable after the 3-year post-loading visit.

Table 1 Patient characteristics for mandibles and maxillae

Characteristic	Mandibles (n = 20)	Maxillae (n = 20)
Females (n)	10	9
Mean age at implant insertion, y (range)	54.1 (42-70)	57.6 (45-80)
Smokers (n)	2 moderate	3 heavy

Table 2 Intervention characteristics for mandibles and maxillae (n = 40 patients)

Characteristic	Long implants	Short implants
Mandibular implants	47	41
Maxillary implants	44	39
Mandibular implants placed with ≤ 25 Ncm torque*	4 (in 3 patients)	5 (in 4 patients)
Maxillary implants placed with ≤ 25 Ncm torque†	12 (in 7 patients)	10 (in 10 patients)
Length of mandibular implants, mm (mean ± SD)	10.8 ± 1.7	6
Length of maxillary implants, mm (mean ± SD)	11.8 ± 1.0	6

*At bilateral sites in three patients.

†At bilateral sites in four patients.

The periapical radiographs of three patients (all mandibles) and of another three patients (two mandibles and one maxilla) were not taken at the 3 and 5 years follow-up, respectively. The data of all remaining patients were evaluated in the statistical analyses. The following deviations from the protocol occurred: 14 patients (seven from Dr Felice's centre and seven from Dr Pistilli's centre) with bilateral edentulous mandibles did not want to have both sites treated at the same surgical session, therefore they had to be treated in two separate occasions. For one patient, it was not possible to place the implants in the mandibular grafted area 6 months after augmentation because the graft was completely resorbed; he was re-grafted with an onlay equine bone block instead. In three patients treated by Dr Felice, the osteosynthesis plates (to be used to stabilise mandibular blocks) were not placed because they were not available at the treatment centre, though the augmentation procedures were successful and without complications. One patient treated by Dr Pistilli was rehabilitated at the augmented mandible with two 10-mm- and one 6-mm-long implants, rather than the three 10-mm-long implants. Two patients had mandibular implants placed in augmented bone 4 months instead of 3 months after augmentation.

Patients were recruited and treated from November 2009 to July 2010. The follow-up of all patients was 5 years 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. Initially, 91 implants were placed in the augmented group and 80 in the short-implant group. There were no apparent significant baseline imbalances between the two groups. The main results are summarised in Table 3.

Prosthesis failures

Three mandibular prostheses could not be placed when planned at augmented sites as a consequence of three mandibular graft failures versus one maxillary and one mandibular prostheses on short implants lost 2 years and 3 years and 9 months after loading, respectively. The differences were not statistically significant considering both mandibles and maxillae together ($P = 1.0$; Table 3) or separately (mandibles: $P = 0.625$; maxillae: $P = 1.0$). One of the mandibular graft failures also determined the early failures of the three implants inserted in the graft (for details please see the previous publication[16]). One patient received short implants at the augmented side instead, whereas the other patient was re-grafted and received three long implants. All mandibular patients were rehabilitated with partial fixed prostheses whereas the maxillary patient decided not to undergo retreatment.

Implant failures

Three implants failed early in an infected graft of one patient versus four short implants lost in two patients (two mandibular and two maxillary implants) for peri-implantitis 2 years and 3 years and 9 months after loading. The differences in proportions for implant failures were not statistically significant considering both mandibular and maxillary grafting procedures together ($P = 1.0$;

Table 3 Summary of the main results for mandibles and maxillae at 5 years after loading

Result	Long implants	Short implants	*P* value
Failure to place implants at least 10-mm long in mandibles (n = 20)	4/20	NA	NA
Failure to place implants at least 10-mm long in maxillae (n = 20)	0/20	NA	NA
Failed prostheses (n = 35)	3*	2	1.000
Failed mandibular prostheses (n = 18)	3*	1	0.625
Failed maxillary prostheses (n = 17)	0	1	1.000
Patients with failed implants (n = 35)	1 (3 implants)	2 (4 implants)	1.000
Patients with failed mandibular implants (n = 16)	1 (3 implants)	1 (2 implants)	1.000
Patients with failed maxillary implants (n = 18)	0	1 (2 implants)	1.000
Patients with complications (n = 35)	14 (19 complications)	4 (5 complications)	0.118
Patients with mandibular complications (n = 17)	9 (14 complications)	3 (3 complications)	0.727
Patients with maxillary complications (n = 17)	5 (5 complications)	1 (2 complications)	0.063
Mandibular side preferred by patients (5 mo post-loading)	0/20	20/20	< 0.0001†
Maxillary side preferred by patients (5 mo post-loading)	0/20‡	15/20	< 0.0001†

NA, not applicable.

*One patient had a complete graft failure and was re-grafted; another patient lost all three implants and the graft; the other lost the graft. All patients were retreated and could be rehabilitated with fixed prostheses supported by short implants.

†Statistically significant differences.

‡Five patients had no preference, and declared that both procedures were equally acceptable.

Table 3) or separately (mandibles: $P = 1.0$; maxillae: $P = 1.0$).

Complications

Fourteen grafted patients were affected by 19 complications versus four patients treated with short implants (five complications). The difference was not statistically significant ($P = 0.118$; Table 3). More specifically, in mandibles nine grafted patients had 14 complications versus three patients with three complications with short implants. The difference was not statistically significant ($P = 0.727$; Table 3). In maxillae five grafted patients had five complications versus one patient with two complications with short implants. The difference was not statistically significant ($P = 0.063$; Table 3). In three (15%) patients, the mandibular graft became infected and had to be removed. Another seven minor postoperative complications (temporary lower lip paraesthesia lasting 1 to 4 days) occurred at mandibular augmented sites. One of these patients, who did not attend to consecutive maintenance visits, presented 2 years and 4 months after loading peri-implant mucositis around three implants which was successfully treated with supragingival scaling and chlorhexidine gel twice a day for 14 days. Finally one patient developed peri-implantitis 4 years and 1 month after loading around both implants. He had pain, swelling and purulent exudate. A major bone loss was present (Fig 3a). Both implants were treated with open flap debridement with ultrasound plus

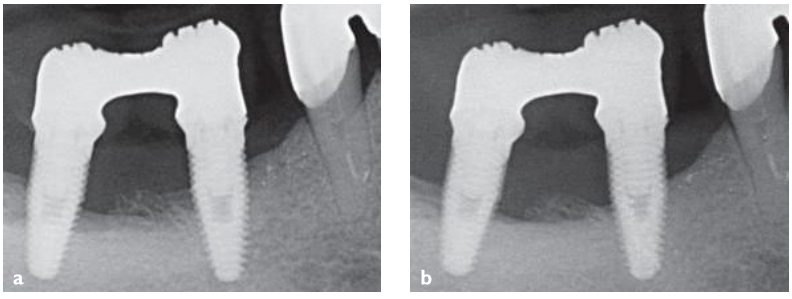

Fig 3a-b Periapical radiographs of one patient with both 10-mm-long mandibular implants in augmented bone affected by peri-implantitis: **(a)** at the detection of the disease process (4 years and 1 month after loading); **(b)** 1 year after treatment when the disease was under control.

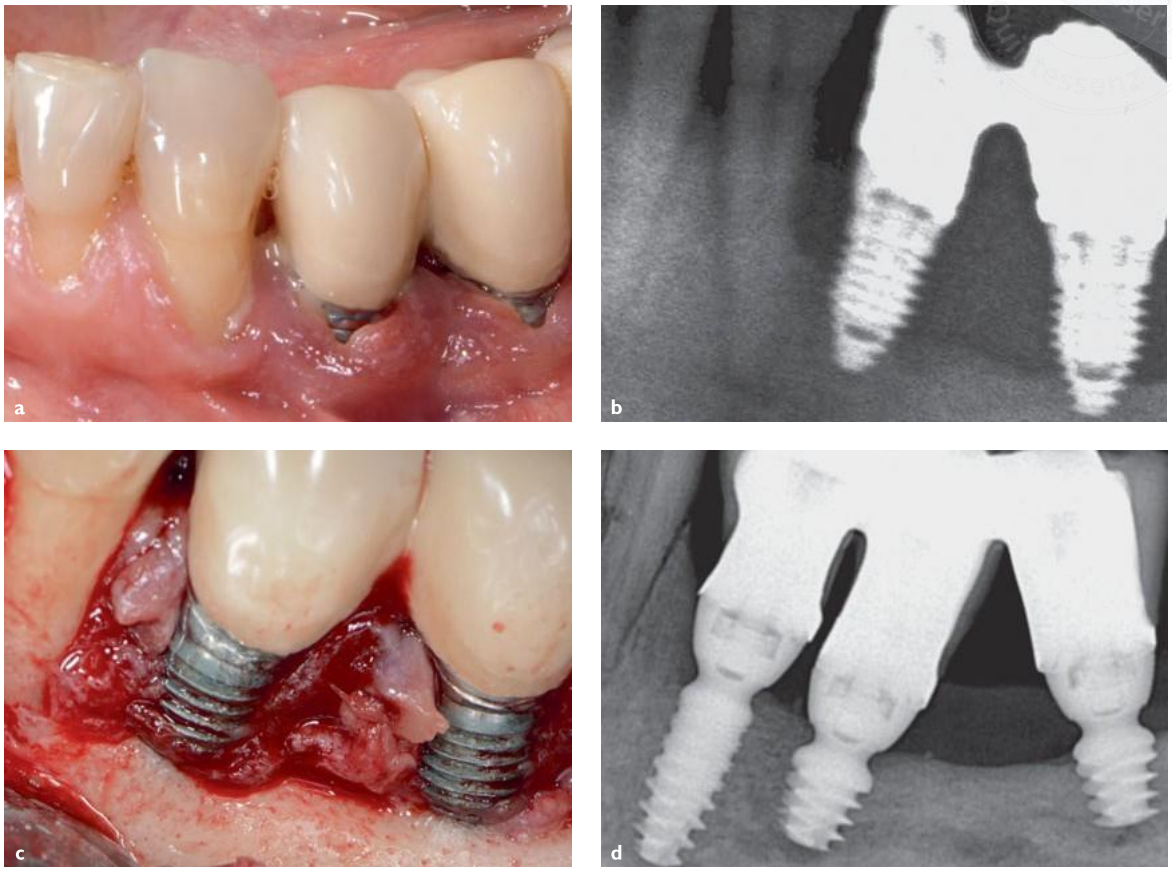

Fig 4a-c Clinical views and periapical radiographs of one patient with both 6-mm-long mandibular implants affected by peri-implantitis: **(a and b)** at the detection of the disease process (3 years and 9 months after loading); **(c)** both implants and the canine were removed and replaced with three implants **(d)**, two of which were 4-mm long due to the severe atrophy of the residual bone.

application of orthophosphoric acid 37%. Amoxicillin plus clavulanic acid (1g) was prescribed twice a day for 1 week together with chlorhexidine gel twice a day for 21 days and the situation stabilised (Fig 3b). In augmented maxillae, the sinus membrane was perforated in four patients during the sinus elevation procedure. A resorbable barrier (OsteoBiol Evolution) was placed internally to contain the granules of grafted bone and all grafts healed uneventfully. One crown had a chipping and was fixed chairside with some polishing. Patients with short implants were affected by the following complications: loosening of a mandibular abutment screw 2 years after loading; one mandibular prosthesis on two implants debonded 2 years and 4 months after loading; two maxillary implants, in the same patient, were affected by peri-implantitis and failed 2 years after loading; and two mandibular implants, in the same patient, were affected by peri-implantitis and failed 3 years and 9 months after loading (Fig 4).

Patient preference

One month after delivery of the definitive prostheses, all 20 patients treated with mandibular implants and 15 patients treated with maxillary implants preferred short implants, whereas five patients treated with maxillary implants described both procedures as equally acceptable. These differences were statistically significant ($P < 0.0001$; Table 3).

Peri-implant marginal bone level changes

For mandibular implants, marginal bone levels are described in Table 4. Both groups gradually lost statistically significant marginal peri-implant bone ($P < 0.001$) at loading and 1, 3 and 5 years after loading (Table 5). While there were no statistically significant differences between the two groups for peri-implant bone level changes at loading ($P = 0.511$) and at 1 year after loading ($P = 0.738$), at 3 years after loading patients with implants at least 10-mm long lost significantly more peri-implant

Table 4 Mean radiographic peri-implant marginal bone levels at mandibular implants between groups and time periods

	Implant placement		Loading			1 y after loading			3 y after loading			5 y after loading		
	N	Mean (SD)	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]
Short implants	20	0.28 (0.15)	20	0.87 (0.25)		19	1.33 (0.22)		15	1.49 (0.31)		12	1.56 (0.33)	
Aug-mented	19	0.37 (0.19)	19	0.92 (0.22)		18	1.44 (0.21)		14	1.86 (0.17)		12	2.41 (0.75)	
Difference	19	0.09 (0.05)	19	0.04 (0.09)	[−0.15; 0.23]	18	0.10 (0.07)	[−0.04; 0.24]	14	0.37 (0.36)	[0.16; 0.58]	12	0.85 (0.86)	[0.30; 1.39]
P value	NA		0.6758			0.14			0.002*			0.006*		

NA, not applicable.

*Statistically significant differences.

Table 5 Comparison of mean changes in peri-implant marginal bone levels at mandibular implants at loading and 5 years

	Placement – loading			Placement – 1-y post-loading			Placement – 3-y post-loading			Placement – 5-y post-loading		
	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]
Short implants	20	0.59* (0.05)	[0.49; 0.69]	19	1.05* (0.06)	[0.93; 1.17]	15	1.25* (0.35)	[1.05; 1.45]	12	1.34* (0.35)	[1.11; 1.56]
Aug-mented	19	0.55* (0.05)	[0.45; 0.65]	18	1.07* (0.06)	[0.95; 1.19]	14	1.54* (0.14)	[1.46; 1.63]	12	2.11* (0.59)	[1.73; 2.48]
Difference	19−0	05 (0.07)	[−0.19; 0.10]	18	0.02 (0.07)	[−0.12; 0.16]	14	0.29 (0.37)	[0.08; 0.51]	12	0.77 (0.70)	[0.32; 1.21]
P value	0.5108			0.7384			0.010**			0.003**		

*All changes from baseline statistically significantly different ($P < 0.001$).

**Statistically significant differences.

bone (0.29 mm) than patients with 6-mm-long implants ($P = 0.010$; Table 5). Also at 5 years after loading, patients with implants at least 10-mm long lost significantly more peri-implant bone (0.77 mm) than patients with 6-mm-long implants ($P = 0.003$; Table 5). For maxillary implants, marginal bone levels are described in Table 6. Both groups gradually lost statistically significant marginal peri-implant bone ($P < 0.001$) at loading and 1, 3 and 5 years after loading (Table 7). There were no statistically significant differences between the two groups for peri-implant bone level changes at loading ($P = 0.159$) and at 1 year after loading ($P = 0.255$). Conversely at 3 years after loading patients with implants at least 10-mm long lost significantly more peri-implant bone than patients with 6-mm-long implants (0.22 mm; $P = 0.003$; Table 7). Also at 5 years after loading, patients with implants at least 10-mm long lost significantly more peri-implant bone (0.33 mm) than patients with 6-mm-long implants ($P = 0.002$; Table 7). Combining both maxillary and mandibular implants, marginal bone levels are described in Table 8. Both groups gradually lost statistically significant marginal peri-implant bone ($P < 0.001$) at loading and 1, 3 and 5 years after loading (Table 9). There were no statistically significant differences between the two groups for peri-implant bone level changes at loading ($P = 0.585$) and at 1 year after loading ($P = 0.295$). At 3 years after loading patients with implants at least 10-mm long lost significantly more peri-implant bone than patients with 6-mm-long implants (0.25 mm; $P < 0.001$; Table 9). Also at 5 years after loading, patients with implants at least 10-mm long lost significantly more peri-implant bone (0.52 mm) than patients with 6-mm-long implants ($P < 0.001$; Table 9).

Table 6 Mean radiographic peri-implant marginal bone levels at maxillary implants between groups and time periods

	Implant placement		Loading			1 y after loading			3 y after loading			5 y after loading		
	N	Mean (SD)	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]
Short implants	20	0.39 (0.19)	20	0.86 (0.31)		20	1.41 (0.31)		18	1.68 (0.40)		16	1.93 (0.54)	
Augmented	20	0.44 (0.21)	20	1.02 (0.33)		20	1.53 (0.29)		18	1.95 (0.38)		16	2.28 (0.46)	
Difference	20	0.06 (0.06)	20	0.16 (0.09)	[−0.05; 0.37]	20	0.13 (0.08)	[−0.04; 0.29]	18	0.27 (0.30)	[0.12; 0.42]	16	0.35 (0.36)	[0.16; 0.54]
P value	NA		0.1253			0.1250			0.002*			0.013*		

NA, not applicable.

*Statistically significant differences.

Table 7 Comparison of mean changes in peri-implant marginal bone levels at maxillary implants at loading, and 1, 3 and 5 years

	Placement – loading			Placement – 1-y post-loading			Placement – 3-y post-loading			Placement – 5-y post-loading		
	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]
Short implants	20	0.47* (0.05)	[0.38; 0.57]	20	1.02* (0.06)	[0.90; 1.14]	18	1.28* (0.37)	[1.10; 1.47]	16	1.52* (0.47)	[1.26; 1.77]
Augmented	20	0.57* (0.04)	[0.48; 0.67]	20	1.09* (0.05)	[0.99; 1.18]	18	1.50* (0.37)	[1.32; 1.68]	16	1.85* (0.51)	[1.58; 2.12]
Difference	20	0.10 (0.07)	[-0.04; 0.24]	20	0.07 (0.07)	[−0.05; 0.18]	18	0.22 (0.26)	[0.08; 0.35]	16	0.33 (0.36)	[0.14; 0.53]
P value	0.1585			0.2547			0.003†			0.002†		

*All changes from baseline statistically significantly different ($P < 0.001$).

†Statistically significant differences.

Table 8 Mean radiographic peri-implant marginal bone levels at both mandibular and maxillary implants together between groups and time periods

	Implant placement		Loading			1 y after loading			3 y after loading			5 y after loading		
	N	Mean (SD)	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]
Short implants	40	0.33 (0.18)	40	0.86 (0.27)	[0.78; 0.95]	40	1.38 (0.27)	[1.23; 1.45]	33	1.60 (0.37)	[1.47; 1.73]	28	1.77 (0.49)	
Augmented	40	0.41 (0.20)	39	0.97 (0.28)	[0.88; 1.06]	38	1.49 (0.26)	[1.40; 1.57]	32	1.91 (0.31)	[1.80; 2.02]	28	2.33 (0.59)	
Difference	40	0.07 (0.24)	39	0.10 (0.42)	[−0.04; 0.24]	38	0.11 (0.31)	[0.01; 0.22]	32	0.31 (0.33)	[0.19; 0.43]	28	0.56 (0.66)	[0.31; 0.82]
P value	0.060		0.144			0.031*			< 0.001*			< 0.001*		

*Statistically significant differences.

Table 9 Comparison of mean changes in peri-implant marginal bone levels at both mandibular and maxillary implants together at loading, and 1, 3, and 5 years

	Placement – loading			Placement – 1-y post-loading			Placement – 3-y post-loading			Placement – 5-y post-loading		
	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]	N	Mean (SD)	[95% CI]
Short implants	40	0.53* (0.21)	[0.46; 0.60]	39	1.03* (0.25)	[0.95; 1.12]	33	1.27* (0.35)	[1.15; 1.40]	28	1.44* (0.43)	[1.27; 1.61]
Augmented	39	0.56* (0.20)	[0.50; 0.63]	38	1.08* (0.22)	[1.01; 1.15]	32	1.52* (0.29)	[1.41; 1.62]	28	1.96* (0.55)	[1.75; 2.17]
Difference	39	0.03 (0.31)	[−0.07; 0.13]	38	0.04 (0.26)	[−0.04; 0.13]	32	0.25 (0.31)	[0.14; 0.36]	28	0.52 (0.57)	[0.30; 0.74]
P value	0.585			0.295			< 0.001†			< 0.001†		

*All changes from baseline statistically significantly different ($P < 0.001$).

†Statistically significant differences.

Table 10 Comparison of outcomes between the two operators at 5 years after loading

Outcome	Dr Felice	Dr Pistilli	*P* value
Drop-out patients	6/20	2/20	0.235
Patients with mandibular graft failures	3/20	0/20	0.231
Patients with failed implants	2/17	1/18	0.603
Patients with failed prosthesis	4/17	1/18	0.177
Patients with complications	10/17	8/18	0.505
Peri-implant marginal bone loss [n; mean (SD)]	12; 2.18 (0.31)	16; 1.96 (0.49)	0.158

There were no statistically significant differences for implant failures, complications and marginal bone level changes between the two operators (Table 10).

Discussion

This study tested whether implants 6-mm long having a conventional diameter of 4 mm could be a possible alternative to augmentation procedures for placing longer implants for the rehabilitation of posterior atrophic jaws with implant-supported partial fixed prostheses. The main finding of this trial is that short implants can be a valid alternative to augmentation procedures, especially in atrophic mandibles, since vertical augmentation procedures may be associated with more severe postoperative complications. The present findings are in agreement with the findings of several other similar trials[4-12,17,19]. Bone augmentation procedures are technically more demanding than placing short implants; they are associated with higher postoperative morbidity, complications, longer treatment periods and an increased number of surgeries, at least up to 5 years after

loading. However the long-term prognosis of short implants is still unknown and the sample sizes of the present and other RCTs[4-12,17,19] are still too small to draw definitive conclusions.

The need to evaluate the outcome of short implants with a conventional diameter of 4 mm was emphasised by another trial in which 5-mm-long implants with a diameter of 6 mm were evaluated[13]. About half of patients who had sufficient bone height to accommodate a 5-mm-long implant did not have sufficient bone width in posterior jaws to accommodate 6-mm-diameter implants. Therefore the present study, together with other trials[5,6,8-12,17], does not support the hypothesis that in order to improve success rates of short implants, diameters of 6 mm or more are needed[4,13].

In this trial, it was decided to use blocks of collagenated equine bone instead of the blocks of sintered bovine bone used previously[6,7,18] because blocks of sintered bone are brittle and easily fragment during the shaping and insertion procedures. Therefore a more solid block of equine origin was used. Three of these blocks (15%) become infected and determined the failures of the augmentation procedures. Also, in other studies the most serious complications were found in vertically augmented mandibles[10,11]. It appears that infection of the block graft is the major problem to be solved. In the maxilla, a one-stage procedure (implants placed simultaneously with the sinus elevation procedure) was chosen in order to decrease the time patients had to wait to receive a fixed prosthesis, and the results were excellent since not a single implant failed.

Three implants were lost in one patient, but they were placed in an infected mandibular graft. In cases of suspected graft infection, it may be wiser to remove the graft completely and use short implants instead, if possible, or to attempt a second augmentation procedure. Other two short maxillary implants were lost because of peri-implantitis 2 years after loading. The patient did not come to the regular maintenance sessions for 1 year and once he came back the implants were already mobile and had to be removed. It is obvious that short implants, once affected by peri-implantitis, may be lost much faster than longer ones. This was confirmed by a second similar case at 3 years and 9 months after loading. Two other short mandibular implants were found painful and mobile in positions 34 and 35, so they were removed together with the adjacent compromised canine, but the patient could be rehabilitated by placing two extra-short 4-mm-long implants with a diameter of 4 mm and a conventional implant in position 33. In order to understand the choice between short implants or longer implants in augmented bone as the preferred therapy, it is mandatory to prolong the follow-up of the present trial up to 10 years after loading and at the same time to promote new long-term similar trials.

Patient preference was only assessed 1 month after delivery of the definitive prosthesis, 5 months after loading. The results were clear: all patients treated in the mandible and three out of four patients treated in the maxilla preferred short implants. The remaining patients augmented in the maxilla did not have a definite preference. This corresponds to the level of invasiveness of the augmentation procedure.

In the present trial 0.52 mm less bone loss occurred at short implants when compared to long implants in augmented bone. The observation that short implants lose less peri-implant marginal bone than long implants is not new and is in agreement with similar trials[4,7,10,11,13], and to one trial in which short implants were compared to long implants in non-augmented bone[20]. No convincing hypotheses can explain this observation, however. While a difference of 0.52 mm, observed in the present trial, may not have clinical impact, it is still preferable that short implants lose less peri-implant marginal bone than longer ones.

The main limitation of the present trial is the small sample size. Trials with larger sample sizes and yet longer follow-ups are needed to confirm or reject the present results.

Regarding the generalisation of the current results to wider populations, it should be stressed that, on one hand, both surgeons were very experienced, but on the other hand all procedures were tested in real clinical conditions and the patient inclusion criteria were not very strict. Therefore, similar results should be obtained by other experienced operators treating patients with similar characteristics.

Conclusions

Five-year post-loading data indicate that 6-mm-long implants achieved similar results to longer implants placed in augmented bone. Short implants might be a preferable choice to bone augmentation, especially in posterior mandibles where vertical augmentation procedures may be associated with more severe postoperative complications, since the treatment is faster, cheaper and associated with less morbidity. However, 10 years post-loading data from larger trials are necessary before being able to produce reliable recommendations.

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