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The influence of repeated abutment changes on peri-implant tissue stability: 3-year post-loading results from a multicentre randomised controlled trial

Key words *dental implant, immediate loading, keratinised mucosa, peri-implant marginal bone levels, repeated abutment disconnections*

Purpose: To evaluate the influence of at least three abutment disconnections in conventional loaded implants against placement of a definitive abutment in immediately non-occlusal loaded implants on hard and soft tissue changes. A secondary aim was to evaluate whether the presence of less than 2 mm of keratinised mucosa is associated with increased peri-implant marginal bone loss and soft tissue recessions.

Materials and methods: Eighty patients requiring one single crown or one fixed partial prosthesis supported by a maximum of three implants were randomised, after implants were placed with more than 35 Ncm, according to a parallel group design to receive definitive abutments that were loaded immediately (definitive abutment or immediate loading group) or transmucosal abutments, which were delayed loaded after 3 months and removed at least three times:

1. At impression taking (3 months after implant placement);
2. When checking the zirconium core on titanium abutments at single crowns or the fitting the metal structure at prostheses supported by multiple implants;
3. At delivery of the definitive prostheses (repeated disconnection or conventional loading group).

Patients were treated at four centres and each patient contributed to the study, with only one prosthesis followed for 3 years after initial loading. Outcome measures were: prosthesis failures, implant failures, complications, pink aesthetic score (PES), buccal recessions, patient satisfaction, peri-implant marginal bone level changes and height of the keratinised mucosa.

Results: Forty patients were randomly allocated to each group according to a parallel group design. Six patients from the definitive abutment group dropped out or died, and one left from the repeated disconnection group. One implant, from the repeated disconnection group, fractured (difference = 3%; CI 95%: -2%, 8%; $P = 1$). Four provisional crowns and one definitive single crown had to be remade because of poor fitting, and one definitive crown and one definitive prosthesis because of ceramic and implant fracture, respectively, in the repeated disconnection group vs one provisional prosthesis from the definitive abutment group due to frequent debondings (difference = 15%; CI 95%: 2%, 28%; $P = 0.060$). Five patients from the definitive abutment group and four patients from the repeated disconnection group were affected by complications (difference = 4%; CI 95%: -11%, 20%; $P = 0.725$). PES scores assessed at 3 years post-loading were 11.7 (standard deviation = 1.8) mm for the definitive abutment group and 11.3 (1.5) mm for the repeated abutment changes group (difference = 0.4; CI 95%: -0.4, 1.2; $P = 0.315$). However, there was a difference of

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0.26 out of a maximum score of 2 in favour of the definitive abutment group for soft tissue contour only. Buccal recessions at 3 years post-loading amounted to -0.1 (0.8) mm for the definitive abutment group and -0.1 (1.2) mm for the repeated abutment changes group (it was actually a soft tissue gain; difference = 0.01 mm CI 95%: -0.48, 0.50; *P* = 0.965). All patients declared being very satisfied or satisfied with the function and aesthetics of the prostheses and said they would undergo the same procedure again, with the exception of one patient from the repeated disconnection group who was uncertain regarding function. Mean peri-implant marginal bone loss 3 years after loading was 0.07 (0.18) mm for the definitive abutment group and 0.50 (0.93) mm for the repeated abutment changes group (difference = 0.43 mm; CI 95%: 0.13, 0.74; *P* = 0.007). The height of keratinised mucosa at 3 years post-loading was 2.8 (1.3) mm for the definitive abutment group and 2.8 (1.6) mm for the repeated abutment changes group (difference = 0.03; CI 95%: -0.67, 0.73; *P* = .926). Up to 3 years after initial loading there were no statistically significant differences between the two procedures, with the exception of 0.4 mm more marginal bone loss at implants subjected to three abutment disconnections. There were no significantly increased marginal bone loss (difference = 0.1 mm, CI 95%: -0.3, 0.5, *P* = 0.590) or buccal recessions (difference = 0.1 mm, CI 95%: -0.4, 0.7, *P* = 0.674) at implants with less than 2 mm of keratinised mucosa at loading.
Conclusions: Three-year post-loading data showed that repeated abutment disconnections significantly increased bone loss of 0.43 mm, but this difference may not be considered clinically relevant; therefore clinicians can use the procedure they find more convenient for each specific patient. Immediately non-occlusally loaded dental implants are a viable alternative to conventional loading and no increased bone loss or buccal recessions were noticed at implants with less than 2 mm of keratinised mucosa.

Conflict of interest statement: *This trial was partially funded by Dentsply Sirona Implants, the manufacturer of the implants and other products evaluated in this investigation. However, data belonged to the authors and by no means did the manufacturer interfere with the conduct of the trial or the publication of the results, with the exception of rejecting a proposal to change the protocol, after the trial was started, allowing the use of indexed abutments.*

■ Introduction

Implant-supported prostheses are an effective and reliable treatment for replacing missing teeth. Their success is mainly based on the ability of the bone to integrate and stabilise dental implants[1]. This process is known as "osseointegration" and implants can be submerged unloaded for the duration of the healing period. After several months, implants are exposed and healing or provisional abutments are connected on them for the period necessary to complete the restorative procedures. Depending on the procedures used, healing or temporary abutments may have to be disconnected and reconnected several times, and it was concluded, based on the results of an experimental study performed on five dogs[2], in which five abutment disconnection-reconnection were made, that 0.7 mm more marginal peri-apical bone loss occurred at implant subjected to repeated abutment disconnection. If this observation is correct then it would be better in clinical practice to minimise the number of abutment disconnections by placing a definitive abutment immediately, and which preferably should not be removed thereafter. On the other hand, there might be clinical situations where it could be a disadvantage to place immediately a definitive abutment since it is not always possible to predict the amount of soft tissue shrinkage. Therefore it would be good to retain the possibility of changing abutments, when necessary, without causing too much disruption to the peri-implant tissues.

One randomised controlled trial[3] reported 0.2 mm higher peri-implant marginal bone levels by not removing definitive abutments at immediate post-extractive implants, 3 years after loading,

which was statistically significant. Such procedure was therefore termed as "one abutment at one time concept". From a clinical point of view, a statistically significant mean difference of 0.2 mm may not be clinically noticeable and should not discourage clinicians to change abutments if needed or even to use healing and/or provisional abutments. Another controlled, but non-randomised study, tested the same hypothesis[4] in posterior edentulous mandibles and found no statistically significant difference in marginal bone loss three years after implant placement, at implants treated according to the 'one abutment at one time' concept compared to abutments disconnected four times. Two RCTs by the same group[5,6] reported 0.3 and 0.5 mm of more bone loss after 1 year for implants whose abutments were disconnected multiple times, both differences being statistically significant, while no significant differences were observed in another RCT[7].

Another interesting aspect of the rehabilitation with implant-supported prostheses is the possibility to load implants immediately without waiting for bone healing around the implants. This procedure has important advantages, especially for the patients, who can have fixed prostheses on the same day of implant placement, if the risk of implant failure is not increased. There is substantial evidence that immediate loading can be as effective as delayed loading[8], if implants are inserted with a sufficient insertion torque[9,10], however the efficacy of immediate loading procedures still needs to be fully evaluated.

The aims of this pragmatic multicentre randomised controlled trial (RCT) of parallel group design were to compare hard and soft tissue changes between immediately non-occlusal loaded implants which had definitive abutments placed at implant placement and never removed vs conventionally loaded implants which had provisional abutments changed at least three times:

- At impression making, 3 months after implant placement;
- When checking the zirconium core on titanium abutments for single crowns or the fitting of the prostheses metal structure;
- At delivery of the definitive crowns/prostheses.

A secondary aim was to explore whether the presence of less than 2 mm of buccal keratinised peri-implant mucosa could be associated with increased buccal recessions and peri-implant marginal bone loss.

This is the third report in a series presenting the clinical outcome at 3 years post-loading. Data at 4 months[11] and 1 year[12] post-loading were published previously. Further reports on this study will be published after the completion of the, 5-, 7- and 10-year follow-ups. This present article is reported according to the CONSORT (Consolidated Standards of Reporting Trials) statement for improving the quality of reports of parallel-group randomised trials (http://www.consort-statement.org/).

Materials and methods

The trial was designed as a multicentre randomised controlled trial of parallel group design with two arms. One arm consisted of patients having implants that received abutments which were removed at least three times and were conventionally loaded after 3 months of unloaded healing (Figs 1a to j). Patients in the other arm received definitive abutments immediately after implant placement, which were immediately loaded with a provisional, acrylic fixed temporary prosthesis, without removing the abutments (Figs 2a to j).

Any partially edentulous patient requiring one fixed prosthesis, supported by a maximum of three implants, who was 18 years old or older, and able to understand and sign a written informed consent form, was eligible to be included in this trial. Only one prosthesis per patient was considered in the study, supported by implants inserted with an initial insertion torque of at least 35 Ncm, as assessed with a manual ratchet. Implants not achieving such torque were not included in the study.

Preoperative radiographs (periapical, panoramic, computerised tomography (CT) scans or other radiographic examinations at the discretion of the operators), together with clinical inspections, were used to determine bone volume and anatomic landmarks.

Patients were not included in the study if any of the following exclusion criteria were present:

- General contraindications to implant surgery;
- Subjected to irradiation in the head and neck area;

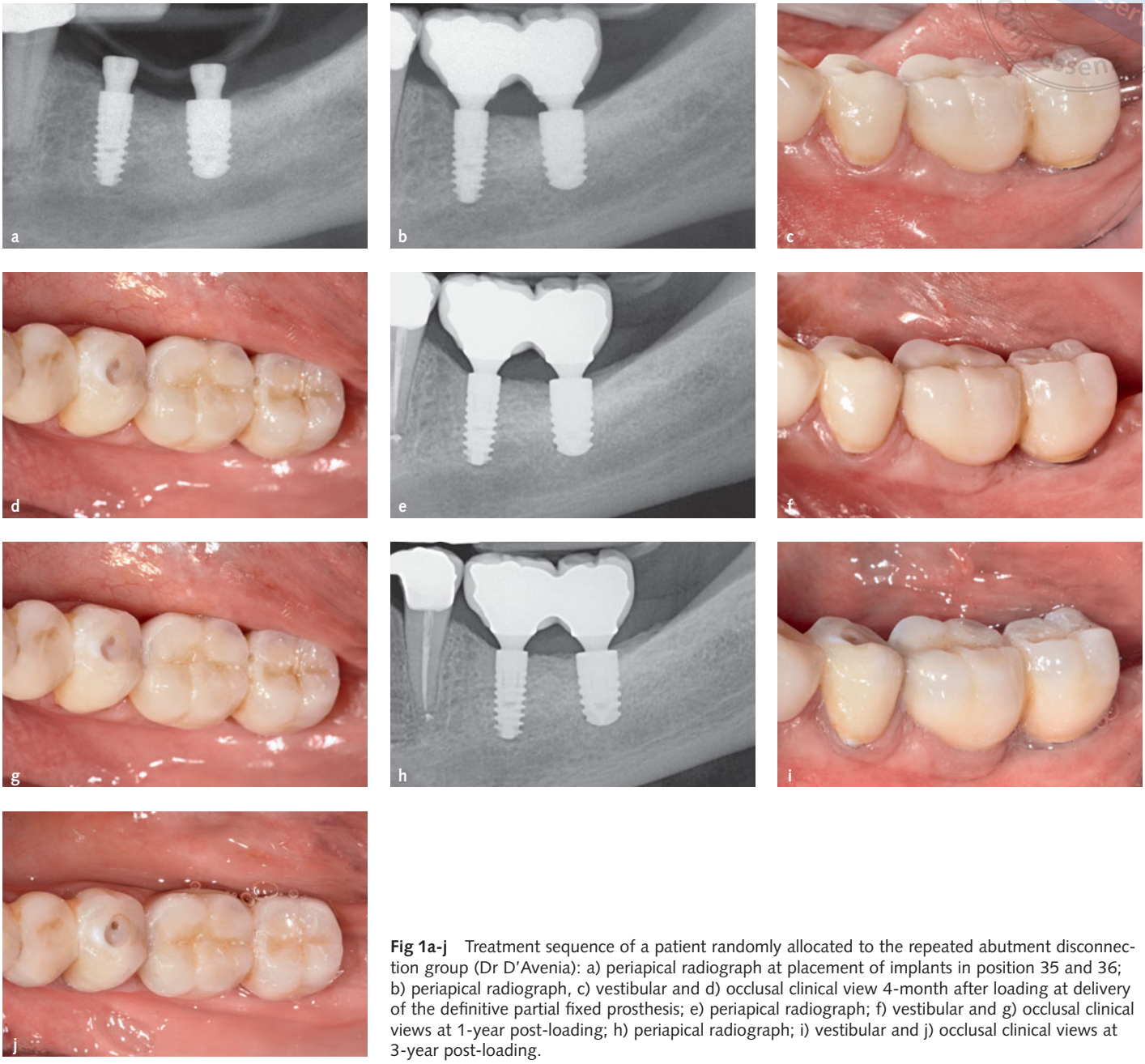

Fig 1a-j Treatment sequence of a patient randomly allocated to the repeated abutment disconnection group (Dr D'Avenia): a) periapical radiograph at placement of implants in position 35 and 36; b) periapical radiograph, c) vestibular and d) occlusal clinical view 4-month after loading at delivery of the definitive partial fixed prosthesis; e) periapical radiograph; f) vestibular and g) occlusal clinical views at 1-year post-loading; h) periapical radiograph; i) vestibular and j) occlusal clinical views at 3-year post-loading.

- Those who were immunosuppressed or immunocompromised;
- Being treated or under treatment with intravenous amino-bisphosphonates;
- Untreated periodontitis;
- Poor oral hygiene and poor motivation;
- Uncontrolled diabetes;
- Pregnant or nursing;
- Substance abuse;
- Psychiatric problems;
- Full edentulism;
- Post-extractive sites with a buccal bone loss more than 3 mm in relation to the palatal wall;
- Need of bone augmentation at implant placement, with the exception of use of a bone substitute in post-extractive sites;
- Lack of opposite occluding dentition/prosthesis in the area intended for implant placement;
- Acute infection in the area intended for implant placement;
- When immediate non-occlusal loading was not possible;

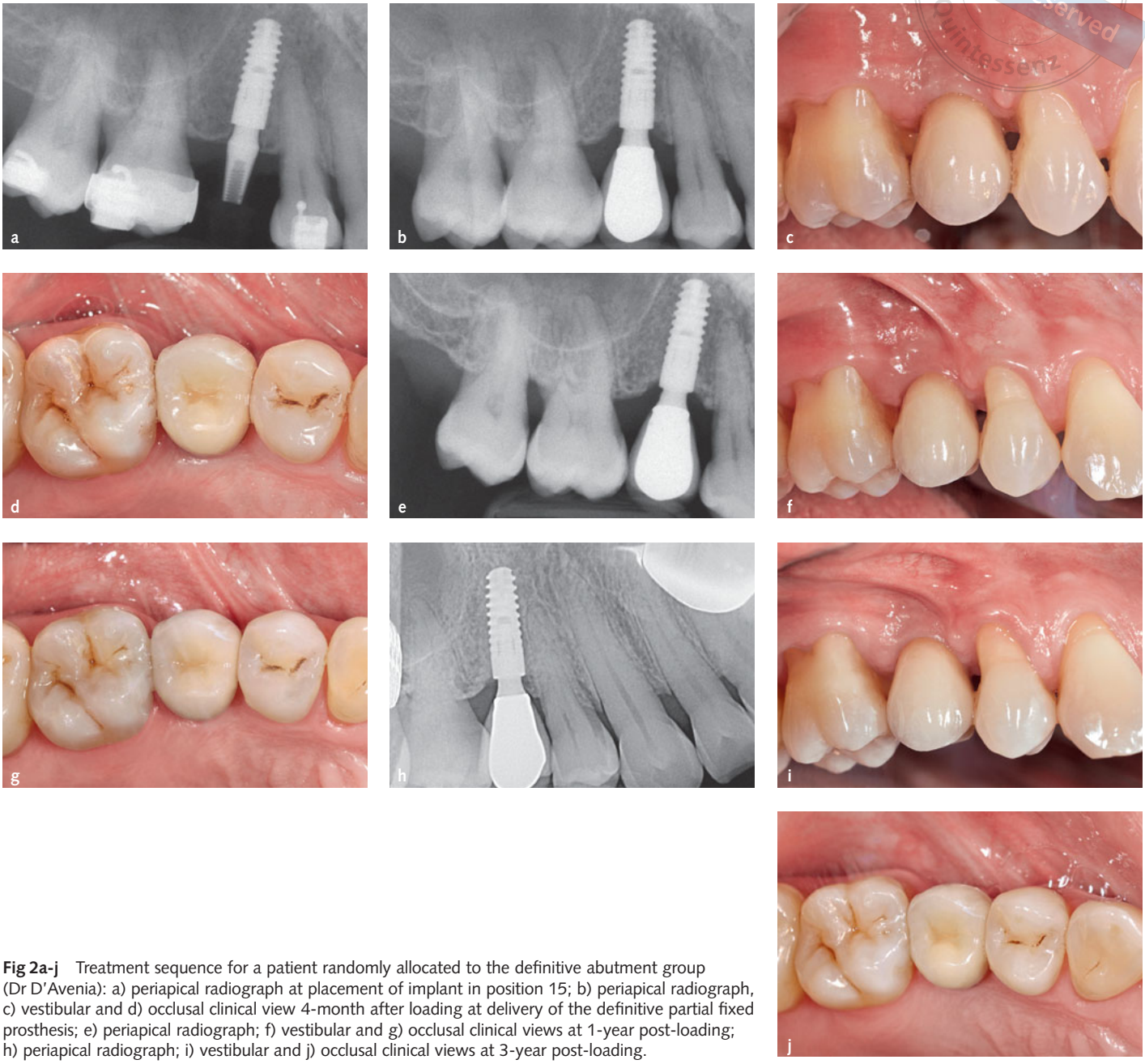

Fig 2a-j Treatment sequence for a patient randomly allocated to the definitive abutment group (Dr D'Avenia): a) periapical radiograph at placement of implant in position 15; b) periapical radiograph, c) vestibular and d) occlusal clinical view 4-month after loading at delivery of the definitive partial fixed prosthesis; e) periapical radiograph; f) vestibular and g) occlusal clinical views at 1-year post-loading; h) periapical radiograph; i) vestibular and j) occlusal clinical views at 3-year post-loading.

- Patients who could not be restored with a retrievable prosthesis to allow individual implant stability assessment (with exceptions of single implants);
- Implants that did not achieve an insertion torque of at least 35 Ncm;
- Implants that could not be restored with standard straight or angulated titanium Ankylos (Dentsply Sirona Implants, GmBH, Mannheim, Germany) abutments;
- Patients participating in other studies, if the present protocol could not be properly followed;
- Patients unable to commit to a 10-year follow-up.

The study was approved on 17 December 2009 by the ethical committee of the University of Naples, Federico II (protocol number 187/09). 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, in order to

document that they understood the scope of the study (including procedures, follow-up evaluations and any potential risks involved), were allowed an opportunity to ask questions pertaining to this study, and were apprised of treatment alternatives. The study was open to qualifying patients with no consideration given to sex or race. For patients who had more than one eligible implant site, the operator was free to choose the site to be included in the study at the screening visit.

Patients were recruited and treated in four Italian private practices by experienced operators (Drs Luongo, D'Avenia, Bressan and Grusovin); each clinician treated 20 patients. Originally six centres agreed to participate in the study, but two centres had to be excluded because one never recruited any patients and the other centre supplied incomplete data without any evidence in the case report forms that the planned abutment removal procedures were ever implemented.

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).

The investigational devices used were Ankylos C/X titanium dental implants with internal connection (Dentsply Sirona Implants). Operators were free to choose implant lengths (8, 9.5, 11 or 14 mm) and diameters (3.5, 4.5 or 5.5 mm) according to clinical indications and their preferences to be restored with standard straight or angulated Ankylos C non-indexed titanium abutments. It was soon apparent that the selection of non-indexed abutments for an indexed implant was not the ideal choice, given that while removing and reconnecting the abutment, it could be repositioned in a slightly different position, which would require adjustment or even the remaking of the prosthesis. As soon as the problem was brought to the attention of the study advisor it was proposed that the research protocol be modified by using indexed abutments, but the sponsor rejected the proposal.

Clinical procedures

Patients received prophylactic antibiotic therapy: 2 g of amoxicillin (or clindamycin 600 mg if allergic to penicillin) 1 h prior to surgery and rinsed for 1 min with chlorhexidine 0.2%. All patients were treated under local anaesthesia using 1% Alfacaina 40 mg/ml with Epinephrine 1:200.000 (Dentsply Sirona Implants). Tooth extractions, when needed, were performed as atraumatically as possible in order to preserve the buccal alveolar bone. Extraction sockets were carefully cleaned of any remains of granulation tissue. Flapless implant placement was also allowed and the decision to elevate the flap or not was left to the individual clinician. The standard implant site preparation procedure as recommended by the implant manufacturer was used. In brief, the round bur or lance drill was used to prepare the cortical entrance, followed by drills of increasing diameters. Bone quality was subjectively recorded as hard, medium or soft. Tapping was done only in presence of hard bone. Implants were placed 1 mm subcrestally to the palatal wall. The insertion torque was assessed manually using the Ankylos ratchet. Implants not achieving an insertion torque of at least 35 Ncm or placed at angles which did not allow the use of standard straight or angulated Ankylos titanium abutments were not included in the study. Implants that were not properly seated using a manual force of 35 Ncm were removed and the site was tapped. In the case of post-extractive implants having a buccal wall loss up to 3 mm when compared to the palatal wall and in the presence of an implant-bone gap, a bone substitute (Frios Algipore, Dentsply Sirona Implants) could be used to fill the gap. After implants were placed, a sealed envelope containing the group allocation code was opened, and the surgeon knew whether to place definitive abutment(s,) which were not removed, or to place transmucosal healing abutment(s) to be removed on at least three occasions. Flaps were repositioned and sutured around the abutments. Healing abutments should have their coronal portion at the level of the soft tissues, or 1 mm above the soft tissues. Fixed full acrylic non-occluding provisional prostheses were prepared and connected on the definitive abutments of the immediately loaded group within 24 h. The immediate provisional prostheses were not in contact, either in static occlusion or during movements with the opposite dentition (non-occluding loading). Just after implant placement, periapical radiographs (baseline) were made with the paralleling technique. The amount of keratinised mucosa was measured at

buccal sites of each implant. Patients were prescribed ibuprofen 400 mg two to four times a day with meals, for as long as required. They were instructed to use 0.2% chlorhexidine mouthwash for 1 min, twice a day for 2 weeks and to avoid brushing and trauma on the surgical sites. Postoperative amoxicillin 1 g, twice a day for 6 days, was prescribed to patients treated with a bone substitute or in the case of long and complicated surgery. Patients allergic to penicillin were prescribed Clindamycin 300 mg twice a day for 6 days. Within 1 week all patients were recalled and checked.

Implants in the repeated abutment disconnection group were left to heal unloaded for 3 months. During the healing period operators were allowed to use different types of provisional dentures or prostheses. Possible options were no use of provisional prosthesis; removable provisional prostheses not pressing on soft tissues, or provisional prostheses fixed to the adjacent dentition. At the end of the healing period, the healing abutments were removed, the copy transfer inserted, impressions (Aquasil Ultra, Dentsply Sirona Implants) taken at implant level, and the healing abutments were repositioned. Applying a 20 Ncm rotational force also tested the stability of individual implants.

Healing abutments were removed three times, as described below:

1. When taking the impression at implant level.
2. When testing the fit of the metal core for single crowns or the titanium framework for fixed prostheses. The healing abutments were placed back after checking the suitability of the prosthetic components.
3. During delivery of the definitive metal-ceramic prostheses. Here the stability of individual implants was checked again by applying a 20 Ncm rotational force.

After 3 months with provisional prostheses, the stability of individual implants from the definitive abutment group was tested by applying a 20 Ncm rotational force. An impression at abutment level was taken using Aquasil Ultra without removing the definitive abutments. Within 1 month after the definitive impression, implants from both groups were tested for stability by applying a 20 Ncm rotational force, retrievable metal-ceramic prostheses were delivered (with the exception of crowns) and intraoral radiographs of the study implants were taken. Patients were enrolled on an oral hygiene programme, with recall visits planned at least every 6 months for the entire duration of the study.

Outcome measures

This study tested the null hypothesis that there were no differences in the clinical outcomes between immediately placing definitive abutments supporting non-occluding provisional restorations vs connecting healing abutments, which were disconnected three times before prosthesis delivery and loaded after 3 months, against the alternative hypothesis of a difference. Primary outcome measures were:

- Prosthesis failure: whether it was not possible to place the prosthesis due to implant failures or secondary to implant losses, or replacement of prosthesis for any reasons.
- Implant failure: implant failure was defined as implant mobility and/or any infection dictating implant removal or any mechanical failure rendering the implant unusable, such as implant fracture or deformation of the implant-abutment connection. The stability of each implant was measured manually by tightening the abutment screw at delivery of the definitive prostheses. Partial prostheses were removed 1 and 3 years after loading to assess implant stability, whereas single crowns were rocked with the metallic handles of two dental instruments.
- Any complication and adverse event was recorded and reported, with the exception of the provisional crown misfits determined by the use of non-indexed abutments, which were counted as prosthetic failures, when the crown had to be remade.

Secondary outcome measures were:

- Buccal peri-implant tissue recessions were assessed by a blinded outcome assessor (Dr Sbricoli) on plaster models created from alginate impressions taken at delivery of the definitive prostheses (baseline) and 1 and 3 years after initial loading. Measurements were done vestibularly from an occlusal reference point perpendicular to the marginal gingiva. For incisors, the reference point was the middle of the incisal margin; for canines and premolars it was the tip

of the cuspid; and for molars the deepest occlusal vestibular margin between the two cusps. Values were averaged at patient level and then at group level.

- Aesthetic evaluation of the vestibular and occlusal clinical pictures, including the two adjacent teeth at 4 months, 1 and 3 years after loading (Figs 1g and h, 2g and h), and performed on a computer screen. The aesthetic evaluation was carried out by a blinded outcome assessor (Dr Sbricoli) using the pink aesthetic score (PES)[13]. In brief, seven variables were evaluated: mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiencies, soft tissue colour, and texture. A 0-1-2 scoring system was used; 0 being the lowest and 2 being the highest value, with a maximum achievable score of 14 per implant.
- Patient satisfaction was assessed at definitive prostheses delivery, 1 and 3 years after initial loading by the independent outcome assessors at each centre who asked patients the following questions:
  - Are you satisfied with the function of your implant-supported prosthesis? Possible answers: "Yes absolutely", "Yes partly", "Not sure", "Not really" and "Absolutely not".
  - Are you satisfied with the aesthetic outcome of your implant- supported prosthesis? Possible answers: "Yes absolutely", "Yes partly", "Not sure", "Not really" and "Absolutely not".
  - Would you undergo the same therapy again? Possible answers: "Yes" or "No". Patients' comments were also recorded.
- Peri-implant marginal bone level changes assessed on periapical radiographs taken with the paralleling technique at implant placement (Figs 1b and 2b), 4 months after loading, at delivery of definitive prostheses (Figs 1c and 2c) at 1 year after loading (Figs 1f and 2f) and 3 years after initial loading (Figs 1 h and 2 h). In the case of unreadable radiographs, new radiographs were made. A blind outcome assessor (Dr Sbricoli) scanned the non-digital radiographs in TIFF format with a 600 dpi resolution, and stored the radiograph files on a personal computer. The blind assessor measured the peri-implant marginal bone levels using the Scion Image (Scion Corporation, Frederick, MD, USA) software. The software was calibrated for every single image using the known distance of two consecutive threads. Measurements of the mesial and distal bone crest levels adjacent to each implant was made to the nearest 0.01 mm. Reference points for the linear measurements were: the coronal margin of the implant collar and the most coronal point of bone-to-implant contact. Implants with bone up to the coronal margin of the implant collar were given a value of zero. Mesial and distal measurements of each implant were averaged and a mean calculated at patient level and then at group level.
- Height of the keratinised mucosa was measured with a periodontal probe rounded off to 0.5 mm in the middle of the buccal side of each study implant at loading of definitive prosthesis and 1 year and 3 years after initial loading by the local blind outcome assessors.

At each centre there was a local blind outcome assessor who recorded implant stability, recessions, height of the keratinised mucosa and patient satisfaction.

Methodological aspects

The sample size was calculated for the radiographic peri-implant marginal bone level changes. A sample size of 55 in each group had 90% power to detect a difference by means of peri-implant marginal bone level changes of 0.300 mm, assuming that the common standard deviation is 0.480, using a two group *t*-test with a 0.050 two-sided significance level. For n = 40 patients in each group the power is still at 78%. We planned to recruit 60 patients per arm, but unfortunately data for only 40 patients became available since two centres did not contribute any data.

Six computer generated restricted random lists were created. Only one investigator (Dr Esposito), who was not involved in the selection and treatment of the patients, knew the random sequence and had access to the random list stored on a password- protected portable computer. The random codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Only after the implants were placed, the envelope corresponding

to the patient recruitment number was to be opened and the clinician knew whether to place a definitive or a healing abutment. 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 (Dr Neumann) with expertise in dentistry analysed the data. Differences in the proportion of patients with prosthesis failure, implant failures, and complications (dichotomous outcomes), as well as patient satisfaction were compared using Chi-square test or Fisher's exact test, if expected counts were up to 5. The differences between the two study groups for mean PES scores, peri-implant radiographic marginal bone level changes, buccal recessions and amount of keratinised mucosa were compared using the *t*-test.

The differences between the different study centres were compared using ANOVA for metrical variables and chi-square test for count data. Changes in bone levels in both groups were tested by *t*-tests for paired samples. Mean buccal recession and peri-implant bone loss at 3 years post-loading for implants with a buccal keratinised mucosa height of less than and more than 2 mm were compared using *t*-tests. The level of significance was $\alpha = 0.05$. The statistical analyses were carried out using IBM SPSS Statistics 23.0.

Results

Two of the six centres had to be excluded from the study. One because it never treated any patients and the other centre because it supplied incomplete data without any evidence in the case report forms that the planned abutment removal procedures were ever implemented. The four included centres treated 20 patients each (80 patients in total), with 128 implants supporting 41 single crowns and 39 fixed partial prostheses.

Originally 142 patients were screened for eligibility, but 62 patients were not included in the trial for the following reasons: insufficient bone to place 8.0 × 3.5 mm implants (18 patients); not available for a 10-year follow-up (15 patients); specifically requested an immediate loading procedure (12 patients); in need of bone augmentation procedure at implant placement with the exception of using a bone substitute in post-extractive sites (eight patients); need to use other implants in addition to implants already placed (four patients); implants placed with a torque inferior to 35 Ncm (two patients); throat cancer prior to study initiation (one patient); insufficient oral hygiene (one patient); not possible to perform immediate non-occlusal loading (one patient).

All patients had their sites treated according to the allocated interventions. Seven patients dropped out at the 3-year follow-up.

Six patients from the definitive abutment group:

- One patient moved to another town after the 4-month follow-up;
- One patient died of a heart attack just before the 1-year after loading follow-up;
- One patient stopped attending follow-up because of a severe stroke after the first year of follow-up;
- One patient moved to another town after the first year of follow-up;
- One patient died of cancer 2 years after loading.
- One patient refused to attend the 3-year follow-up because she was affected by malaria contracted in Africa.

One patient from the repeated disconnection group:

- One patient moved away and was seen for the last time at the 2-years after loading follow-up.

The following data were lost or not recorded:

The recession data could be extrapolated by measuring the clinical pictures using the ImageJ software (image processing software – Bethesda, MD, USA). The known length of the mesiodistal distance of the implant crown was used to calibrate the software. Then the measure of the recession was obtained. These procedures were not possible in all cases therefore at the end we missed data of recession of four patients at 4-month post-loading (Dr Luongo); four patients at 1-year post-loading (Dr Luongo); three patients at 4-month post-loading (Dr D'Avenia);

- Recessions: 20 patients both at 4-month and 1-year post-loading (Dr Luongo).
- 3 patients at 4-month post-loading (Dr D'Avenia)
- Clinical pictures: eight patients at 4-month post-loading (Dr Bressan); one patient both at

4-months and 1-year post-loading (Dr Grusovin); occlusal pictures only at 3 years of four patients (two of Dr Luongo's and one each from Dr D'Avenia and Dr Bressan).

The data of all remaining patients were included in the statistical analyses.

The main protocol deviation was due to the use of non-indexed abutments on indexed implants. This was actually a mistake made at the protocol formulation stage. This problem was only limited to the repeated abutment disconnection group. Another protocol violation, noted by the study monitor at Dr Luongo's centre, was the opening of random codes before implant insertion in two patients, thus invalidating the allocation concealment procedure. It is not possible to quantify for how many other patients this protocol deviation occurred. Subject numbers and randomisation numbers were different at Dr D'Avenia's centre after patient number 8; therefore the randomisation number was not in accordance with subject numbers, but according to the chronology of the surgeries.

The following additional deviations from the protocol were noticed: Repeated abutment disconnection group:

Some of the centres changed the prosthetic abutment procedure to minimise the risk of having ill-fitting prostheses:

- Dr Luongo unscrewed the healing abutments twice. Three months after implant placement the healing abutment was unscrewed for the third time and a final impression was taken. The healing abutment was repositioned. After 1 week the definitive abutments and the temporary prostheses were placed (fourth abutment removal). After 2 weeks the temporary crowns were unscrewed and the position impressions were taken. After a further 2 weeks the definitive prostheses were placed.
- Dr D'Avenia unscrewed the healing abutments, selected the correct abutments directly inside the mouth (with the same difficulties encountered in the immediate loading group), and gently tightened the abutments by hand with a light force, approximately 7 to 10 Ncm. Then the impressions at abutment level were taken with the corresponding snap-on cap. The dental technician worked on an abutment analogue, which was based on a plaster model, and delivered the baked porcelain of the definitive crown in posterior regions and the metal cast in aesthetic areas for try-in. The healing abutment was then unscrewed (second abutment removal), the definitive abutment was tightened by hand as previously described, and the prosthetic restoration tried-in. Usually only small occlusal and interproximal adjustments were necessary for porcelain fused to metal crowns in the posterior region. For the cast try-in cases he took a Pattern resin index. The porcelain fused to metal crown was finished and glazed. For anterior implants a rescue provisional crown was prepared. The standard abutment was definitively screwed and never removed (third abutment removal). In the case of a major abutment rotational mismatch occurring (four patients), the rescue provisional restorations were used. A re-positioning impression was made for the definitive prostheses.
- Dr Bressan removed the healing abutments (first abutment removal) and took the impression directly on the implants; then he removed the healing abutments (second abutment removal), placed the definitive abutments – which were gently tightened by hand – and tried the metal core. Then he removed the healing abutments (third abutment removal), placed the definitive abutments, gently tightened them by hand, and tried the ceramic before cooking it. Finally he delivered the definitive prostheses (fourth abutment removal), placed the definitive abutments, tightened the screws using a torque controller and cemented the prostheses. A new definitive crown had to be prepared in one patient due to a major problem of abutment rotational mismatch.
- Dr Grusovin unscrewed the healing abutments three times and during the third disconnection she connected the definitive abutments and made the definitive impressions.
- Dr D'Avenia used an indexed abutment instead of a non-indexed standard abutment because of aesthetic reasons in a young patient with high aesthetic expectations and a slightly gummy smile. In addition the same patient was treated with a connective tissue graft from the palate.

Table 1 Patient and intervention characteristics.

	Abutment disconnection n = 40	Definitive abutments n = 40
Females	24 (60%)	23 (58%)
Mean age at implant insertion (sd; range)	57.6 (12.9; 33-85)	55.6 (13.6; 30-81)
Smoking up to 10 cigarettes/day	9 (23%)	6 (15%)
Smoking more than 10 cigarettes/day	3 (8%)	2 (5%)
Implants in upper jaws	30/70 (43%)	21/58 (36.2%)
Implants in lower jaws	40/70 (57%)	37/58 (64%)
Implants in incisor position	7/70 (10%)	10/58 (17%)
Implants in canine position	4/70 (6%)	1/58 (2%)
Implants in premolar position	25/70 (36%)	23/58 (40%)
Implants in molar position	34/70 (49%)	24/58 (41%)
Implants in hard bone	17/70 (24%)	13/58 (22%)
Implants in medium bone	38/70 (53%)	31/58 (53%)
Implants in soft bone	15/70 (21%)	14/58 (24%)
Site previously augmented with bone substitute	4 (10%)	2 (5%)
Implants with 3.5 mm diameter	47/70(67%)	36/58 (62%)
Implants with 4.5 mm diameter	21/70 (30%)	19/58 (33%)
Implants with 5.5 mm diameter	2/70 (3%)	3/58 (5%)
Implants 8 mm long	29/70 (41%)	17/58 (29%)
Implants 9.5 mm long	24/70 (34%)	23/58 (40%)
Implants 11 mm long	14/70 (20%)	14/58 (24%)
Implants 14 mm long	3/70 (4%)	4/58 (7%)
Implants inserted flapless	3 (8%)	9 (23%)
Post-extractive implants	1/70 (1%)	7/58 (12%)
Implants in simultaneously augmented sites	1/70 (1%)	6/58 (10%)
Single crowns	16 (40%)	25 (63%)
Prostheses supported by 2 to 3 implants	24 (60%)	15 (38%)

- Dr Grusovin restored two patients with metal-resin rather than metal ceramic crowns and in one case could not place the implant 1 mm under the crest.

Definitive abutment group

- Dr D'Avenia had to delay the placement of definitive crown in one patient because she was pregnant and could not have the periapical radiograph taken at 4 months post-loading.
- Dr Grusovin restored two patients with metal-resin crowns instead of metal-ceramic ones and one patient had his provisional crown replaced by the definitive one with a 4-month delay.
- Dr Bressan restored one patient directly with a definitive prosthesis, instead of using a provisional one.

Main results

Patients were recruited and implants inserted between April 2010 and September 2012. The follow-up for all patients was 3 years post-loading.

The main baseline patient and intervention characteristics, divided by study group, are presented in Table 1. There were no apparent significant baseline imbalances between the two groups.

- Prosthesis failures: three definitive and four provisional restorations from the repeated disconnection group and one provisional prosthesis from the definitive abutment group had to be remade. However, all but one remake in the repeated disconnection group were caused by poor fitting of the crowns, but this was due to using non-indexed abutments on indexed implants. One definitive crown had to be remade because it

fractured 6 months after delivery, and another definitive prosthesis had to be remade because one of its three supporting implants fractured after almost 3 years in function. Finally, a provisional prosthesis in the definitive abutment group had to be remade because repeated debondings (see complications). Considering all the crowns that had to be remade as failures, there were no statistically significant differences between the two groups. Seven in 39 (17.9%; CI 95%: 7.5, 33.5%) crowns had to be remade in the repeated disconnection group and 1 in 34 (2.9%; CI 95%: 0.1%, 15.3%) crowns in the definitive abutment group (difference = 15.0%; CI 95%: 1.7%, 28.3%; $P = 0.060$).

- Implant failures: only one implant belonging to the repeated disconnection group, in position 25 supporting a fixed partial prosthesis, together with other two implants fractured after almost 3 years in function. It was replaced by an implant in position 24 and a new prosthesis was made. The same implant was previously affected by prosthesis debonding and peri-implantitis before fracturing, which may be indicative of overload aetiology. There were no differences for patients experiencing implant failures between the two groups (difference = 3%; CI 95%: -2%, 8%; $P = 1$).
- Complications: Nine patients had complications, four patients (10.3%; CI 95%: 2.9%, 24.2%) had nine complications in the repeated abutment disconnection group and five patients (14.7%; CI 95%: 4.9%, 31.1%) had eight complications in the definitive abutment group. All complications were successfully treated. There was no statistically significant difference for patients experiencing complications between the two groups (difference = 4.4%; CI 95%: -10.8%, 19.7%; $P = 0.725$). Complications at the repeated abutment disconnection group included one alveolar infection (Dr D'Avenia) at implant in position 47, which was noticed 1 week after implant placement where an immediate post-extraction implant was placed together with Algipore bone graft. There was local oedema, mucosal swelling and redness, together with spontaneous expulsion of part of the grafting material. The infection was treated with local irrigation of an antimicrobial solution (rifamycin) associated with the removal of the infected graft still present, which resulted in the almost complete removal of the graft. The infection was completely resolved within 1 week. A palatal wound dehiscence on implant 23 healed spontaneously (Dr Bressan). The same patient had his provisionally cemented definitive prosthesis debonded 1 week after its delivery. It was bonded again with Harvard definitive cement (Harvard Dental International, Hoppegarten, Germany) and developed peri-implantitis at implant 25, 22 months after loading, which was surgically treated the following month with open flap debridement and anorganic bovine bone with added collagen. Finally the implant fractured at the 3-year follow-up. One definitive crown fractured 6 months after its delivery (Dr Bressan) and was replaced by a new crown. A fistula, which was present at the definitive crown placement (Dr Grusovin), disappeared within 1 week after disconnecting and cleaning the definitive abutment. In the same patient, the definitive abutment unscrewed 1 week after delivery and was re-screwed into place. Again the crown debonded 35 months after loading and was cemented with temporary cement. Complications within the definitive abutment group included: One patient (D'Avenia) had three debondings of the provisional restorations on teeth 35 and 36 at 2, 5 and 10 weeks. A new provisional restoration was provided after the third debondings. Another patient (D'Avenia) had two debondings of a single crown at tooth 46 at 4 and 7 weeks, after immediate loading. After re-cementation no more debondings occurred. Another patient had a peri-implant mucositis with local swelling and bleeding around implant 37, 9 months after the delivery of the definitive restoration (Dr D'Avenia). She was treated with local instrumentation and disinfection with chlorhexidine mouthwash, chlorhexidine gel and rinses, together with oral hygiene instruction reinforcement. Improvements were observed at 1-year radiographic control. A definitive partial fixed prosthesis supported by implants in positions 24 and 25 bonded with a provisional cement (TempBond, Kerr, Orange, CA, USA), de-bonded after 6 months (Dr Bressan). It was bonded again with permanent cement (Harvard) In another patient (Dr Bressan) the definitive prosthesis

Table 2a PES scores at 4-months after loading by groups and by different aesthetic domains; standard deviation is in parenthesis.

	Mesial papilla	Distal papilla	Soft tissue level	Soft tissue contour	Alveolar process deficiencies	Soft tissue colour	Soft tissue texture	Total PES score
Abutment disconnection (N = 36)	1.51 (0.55)	1.23 (0.55)	1.94 (0.20)	1.68 (0.43)	1.75 (0.44)	1.74 (0.41)	1.69 (0.40)	11.6 (1.6)
Definitive abutment (N = 34)	1.57 (0.50)	1.15 (0.68)	1.93 (0.17)	1.72 (0.43)	1.81 (0.37)	1.70 (0.43)	1.77 (0.47)	11.7 (1.6)
Difference	0.06	-0.08	-0.01	0.04	0.06	-0.04	0.08	0.1
P-value	0.637	0.591	0.769	0.734	0.513	0.689	0.469	0.791

Table 2b PES scores at 1-year after loading by groups and by different aesthetic domains; standard deviation is in parenthesis.

	Mesial papilla	Distal papilla	Soft tissue level	Soft tissue contour	Alveolar process deficiencies	Soft tissue colour	Soft tissue texture	Total PES score
Abutment disconnection (N = 40)	1.42 (0.65)	1.09 (0.60)	1.81 (0.52)	1.50 (0.48)	1.68 (0.51)	1.80 (0.40)	1.69 (0.40)	11.0 (2.0)
Definitive abutment (N = 37)	1.45 (0.58)	1.15 (0.65)	1.92 (0.24)	1.75 (0.42)	1.64 (0.53)	1.69 (0.45)	1.81 (0.38)	11.4 (1.5)
Difference	0.03	0.06	0.12	0.25	0.04	0.11	0.12	0.43
P-value	0.811	0.691	0.212	0.017*	0.740	0.257	0.183	0.289

*Statistically significant difference

Table 2c PES scores at 3 years after loading by groups and by different aesthetic domains; standard deviation is in parenthesis.

	Mesial papilla	Distal papilla	Soft tissue level	Soft tissue contour	Alveolar process deficiencies	Soft tissue colour	Soft tissue texture	Total PES score
Abutment disconnection (N = 39)	1.51 (0.56)	1.31 (0.52)	1.79 (0.47)	1.56 (0.50)	1.67 (0.48)	1.77 (0.43)	1.72 (0.46)	11.33 (1.55)
Definitive abutment (N = 34)	1.53 (0.51)	1.18 (0.58)	1.88 (0.33)	1.82 (0.39)	1.74 (0.51)	1.79 (0.41)	1.79 (0.41)	11.74 (1.85)
Difference	0.02	0.13	0.09	0.26	0.07	0.03	0.08	0.40
P-value	0.895	0.310	0.365	0.015*	0.555	0.801	0.458	0.315

*Statistically significant difference

debonded 1 year and 10 months after delivery and was rebonded with Harvard.

- Pink aesthetic score: Four months after loading, the average PES score was 11.6 for the repeated abutment disconnection group and 11.7 for the definitive abutment group; the difference being not statistically significantly different (difference = -0.1, 95% CI: -0.9, 0.7; $P = 0.791$. See Table 2a). One year after loading, the average PES score was 11.4 for the immediate group and 11.0 for the delayed group, the difference being not statistically significantly different (difference = 0.4, 95% CI: -0.4, 1.2; $P = 0.289$, Table 2b). Three years after loading, the average PES score was 11.7 (1.8) for the immediate group and 11.3 (1.5) for the delayed group, the difference being not statistically significantly different (difference = 0.4, 95% CI: -0.4, 1.2; $P = 0.315$, Table 2c). When evaluating the single aesthetic domain, at 3 years post-loading, in only one domain was a statistically significant difference observed. This was recorded for soft tissue contour at implants from the definitive abutment group scoring 0.26 out of a maximum point score of 2 significantly better than implants from the abutment disconnection group ($P = 0.015$ in Table 2c).
- Buccal recession: Buccal recessions at 1-year post-loading, having the delivery of the definitive prostheses as baseline, amounted to 0.07 (0.35) mm for the definitive abutment group and to 0.12 (0.65) mm for the repeated

Table 3 Mean recessions between groups and time periods.

	1 year after loading			3 years after loading		
	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI
Abutment disconnection	39	0.12 (0.65)	-0.09 – 0.33	37	-0.12 (1.15)	-0.50 – 0.27
Definitive abutments	33	0.07 (0.35)	-0.05 – 0.20	30	-0.13 (0.76)	-0.41 – 0.16
Difference	0.05	-0.19 to 0.29		0.01	-0.48 – 0.50	
P-value	0.659			0.965		

abutment changes group. These figures correspond to a slight growth of buccal soft tissues in both groups. There were no statistically significant differences between the two groups (difference = 0.05 CI 95% -0.19 to 0.29; $P = 0.659$; Table 3). Buccal recessions at 3 years post-loading amounted to -0.1 (0.8) mm for the definitive abutment group and -0.1 (1.2) mm for the repeated abutment changes group. These figures correspond to a slight loss of buccal soft tissues in both groups. There were no statistically significant differences between the two groups (difference = 0.01 CI 95% -0.48 to 0.50, $P = 0.965$ – see Table 3).

- Patient satisfaction: all patients declared themselves to be very satisfied or satisfied at the delivery of the definitive prostheses and all patients said they would undergo the same procedure again both at 4 months and 1 year after loading. More specifically, at 4-months post-loading there were no statistically significant differences in patient satisfaction for both function and aesthetics between the two groups. A total of 39 out of 40 (98%; CI 95%: 87%, 100%) in the definitive abutment and 37 out of 40 (93%; CI 95%: 80%, 98%) patients in the abutment disconnection group were very satisfied with functional outcome ($P = 0.62$). In the definitive abutment group 36 (90%; CI 95%: 76%, 97%) were very satisfied with the aesthetic outcome, while 38 (95%, CI 95%: 83%, 99%) patients in the abutment disconnection group ($P = 0.68$) were very satisfied. All other patients were satisfied with both the functional and aesthetic outcomes. One year after loading there were no statistically significant differences in patient satisfaction regarding function and aesthetics between the two groups. Thirty-seven out of 38 patients (97%; CI 95%: 86%, 100%) in the definitive abutment and 36 out of 40 (90%; CI 95%: 76%, 97%) in the abutment disconnection group were very satisfied with functional outcome ($P = 0.359$). Very satisfied with the aesthetic outcome were 36 (95%; CI 95%: 82%, 99%) in the definitive abutment and 37 (93%, CI 95%: 80%, 98%) of patients in the abutment disconnection group ($P = 0.68$). All other patients said they were satisfied with both the functional and aesthetic outcomes. Three years after loading there were no statistically significant differences in patient satisfaction for both function and aesthetics between the two groups – 34 out of 34 patients (100%; CI 95%: 89.7%, 100%) in the definitive abutment and 36 out of 39 (92.3%; CI 95%: 79.1%, 98.4%) patients from the abutment disconnection group were very satisfied with the functional outcome ($P = 0.495$). Very satisfied with the aesthetic outcome were 34 (100%; CI 95%: 89.7%, 100%) in the definitive abutment group and 36 (92.3%, CI 95%: 79.1%, 98.4%) patients from the abutment disconnection group ($P = 0.243$). All other patients were satisfied with both functional and aesthetic outcomes, with the exception of one patient from the repeated disconnection group who was uncertain regarding function.
- Marginal bone level changes (Tables 4 and 5; Figs 1b, c, f and Figs 2b, c, f): At implant placement there was a statistically significant difference (although not clinically relevant) between the two groups of 0.08 mm; in fact bone levels were 0.11 mm for the repeated abutment changes group and 0.03 mm for the definitive abutment group. There was no statistically significant difference at 4-month post-loading between the two groups for peri-implant bone levels (mean difference = 0.09 mm; CI 95%: -0.03 to 0.20, $P = 0.167$), but at 1 year and

Table 4 Mean radiographic peri-implant marginal bone levels between groups and time periods.

	Implant placement			4 months after loading			1 year after loading			3 years after loading		
	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI
Abutment disconnection	40	0.11 (0.19)	0.05, 0.16	40	0.20 (0.30)	0.10, 0.29	40	0.33 (0.53)	0.16, 0.50	39	0.61 (1.0)	0.28, 0.94
Definitive abutments	40	0.03 (0.11)	0.00, 0.06	40	0.11 (0.20)	0.05, 0.17	38	0.09 (0.20)	0.03, 0.16	34	0.11 (0.2)	0.04, 0.17
Difference	0.08 (SE = 0.03)		0.01, 0.14	0.09 (SE = 0.06)		-0.03, 0.20	0.24 (SE = 0.09)		0.06, 0.42	0.50 (SE = 0.17)		0.17, 0.84
P-value	0.015*			0.167			0.011*			0.004*		

*Statistically significant difference

Table 5 Mean radiographic peri-implant marginal bone level changes between groups and time periods.

	Difference placement – 4 months			Difference placement – 1 year			Difference placement – 3 years		
	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI
Abutment disconnection	40	-0.09 (0.20)	-0.16, -0.03	40	0.23 (0.49)	0.07, 0.38	39	0.50 (0.93)	0.20, 0.80
Definitive abutments	40	-0.08 (0.16)	-0.13, -0.03	38	0.06 (0.12)	0.02, 0.10	34	0.07 (0.18)	0.01, 0.13
Difference	-0.01 (SE = 0.04)		-0.09, 0.07	0.16 (SE = 0.08)		0.00, 0.33	0.43 (SE = 0.16)		0.13, 0.74
P-value	0.97			0.046*			0.007*		

*Statistically significant difference

3 years the difference was statistically significant (mean difference = 0.24 mm; CI 95%: 0.06, 0.42, $P = 0.011$, and mean difference = 0.50 mm; CI 95%: 0.17, 0.84, $P = 0.004$, respectively – see Table 4). There was no difference for bone loss at 4-month post-loading (mean difference = -0.01 mm; CI 95%: -0.09 to 0.07, $P = 0.97$) but at 1 year and 3 years the repeated abutment changes group lost significantly more bone (mean difference = 0.16; CI 95%: 0.00, 0.33; $P = 0.046$, and mean difference = 0.43 mm; CI 95%: 0.13, 0.74; $P = 0.007$, respectively, Table 5). Both groups gradually lost statistically significant marginal peri-implant bone at 4 months post-loading: 0.08 mm ($P = 0.003$) for definitive abutments and 0.09 mm ($P = 0.006$) for repeated abutment changes group, at 1-year post-loading: 0.06 mm ($P = 0.003$) for definitive abutments and 0.23 mm ($P = 0.006$) for repeated abutment changes group; and at 3-year post-loading: 0.07 mm ($P = 0.026$) for definitive abutment and 0.50 mm ($P = 0.002$) for the repeated abutment changes group (Table 5).

- Keratinised mucosa: The mean buccal keratinised mucosa at delivery of definitive prostheses (4 months after loading) was 2.8 (1.8) mm at the abutment disconnection group and 2.9 (1.4) mm at the definitive abutment group. One year after loading it was 2.8 (1.7) mm at the abutment disconnection group and 2.8 (1.5) mm at the definitive abutment group. Three years after loading it was 2.8 (1.6) mm at the abutment disconnection group and 2.8 (1.3) mm at the definitive abutment group. There were no statistically significant differences in mean buccal keratinised mucosa heights at 4 months (difference = 0.1 mm; CI 95%: -0.7, 0.8; $P = 0.865$), 1-year post-loading (difference = -0.0 mm; CI 95%: -0.8, 0.7 mm; $P = 0.966$), and 3-year post-loading (difference = 0.03 mm; CI 95%: -0.67, 0.73; $P = 0.926$).
- No association could be found between less than 2 mm of keratinised mucosa height at delivery of definitive prostheses (4 months after loading) with peri-implant marginal bone loss (difference (< 2 mm - ≥ 2 mm) = 0.10, CI 95%: -0.28, 0.48, $P = 0.590$) and buccal recession (difference (<2 mm - ≥2 mm) = 0.11, CI 95%: -0.43, 0.66, $P = 0.674$) at 3 years after loading. In the definitive abutment group the height of keratinised mucosa at loading was < 2 mm for 7 out of 33 patients (21.2%, CI 95% = 9.0%-38.9%).

Table 6 Comparison between different centres at 3 years post-loading.

	Luongo (n = 18)	D'Avenia (n = 17)	Bressan (n = 19)	Grusovin (n = 19)	*P*-value
Patients with remade prostheses N = 73	0 (0%)	5 (29.4%)	3 (15.8%)	0 (0%)	0.007*
Patients with implant failures N = 73	0 (0%)	0 (0%)	1 (5.3%)	0 (0%)	1
Patients with complications N = 73	0 (0%)	4 (23.5%)	4 (21.1%)	1 (5.3%)	0.066
Pink esthetic score (PES) N = 73	11.1 (1.6)	12.7 (1.4)	10.4 (1.6)	12.1 (1.3)	< 0.001*
Buccal recession N = 73	0.10 (1.41)	-0.43 (1.02)	-0.46 (0.76)	0.24 (0.54)	0.075
Patient function satisfaction N = 74 (very satisfied/satisfied/uncertain)	18/0/0	17/0/0	17/1/1	18/1/0	1
Patient aesthetic satisfaction N = 74 (very satisfied/satisfied/uncertain)	18/0/0	17/0/0	19/0/0	16/3/0	0.055
Patients willing to redo the therapy N = 74	100%	100%	100%	100%	Non estimable
Bone loss N = 73	0.66 (0.64)	0.21 (0.48)	0.25 (1.12)	0.10 (0.17)	0.089
Keratinised mucosa height N = 73	1.82 (0.51)	2.62 (1.56)	3.54 (1.76)	3.13 (1.27)	0.002*

*Statistically significant differences

One value was missing. In the repeated abutment changes group the height of keratinised mucosa at loading was < 2 mm for 13 out of 39 patients (33.3%, CI 95% = 9.1%-50.2%). The difference was not significant (difference = 12.1%, CI 95% = -8.2%-32.5%, $P = 0.379$).

- The comparison between the four centres 3 years after loading is presented in Table 6. There were no statistically significant differences in the number of patients experiencing complications ($P = 0.066$), patient satisfaction ($P = 1$ for functional and $P = 0.055$ for aesthetic outcome), buccal recession ($P = 0.075$), or peri-implant marginal bone loss ($P = 0.089$) between centres. On the contrary, the number of remade crowns ($P = 0.007$), the pink esthetic score ($P < .001$) and the keratinised mucosa ($P = 0.002$) differed significantly between centres.

■ Discussion

The study was designed to evaluate whether a non-abutment removal approach including immediate non-occluding loading could play a clinically significant role in maintaining bone levels, compared with repeated abutment disconnection and conventional loading. With the exception of 0.43 mm bone loss and 0.26 difference in the soft tissue contour of the PES score at 3 years post-loading favouring implants that received definitive abutments that were no longer removed, no other significant differences were observed. While such differences are indicative of some biological impact on the peri-implant tissues, such impact had no perceivable or visible consequences on the patients. Given no clinically significant differences were observed, clinicians can choose the procedure they find more convenient.

Another important finding of this trial was that immediate loading procedures did not affect the implants success negatively which is in agreement with the finding of a Cochrane systematic review[8].

Finally no increased peri-implant marginal bone loss and buccal recessions were observed at implants with less than 2 mm of keratinised mucosa height, meaning that future trials should be conducted to evaluate the effectiveness of the soft tissue augmentation procedure to prophylactically increase the keratinised mucosa in order to prevent future bone loss and soft tissue recessions.

Our results are in slight disagreement with another controlled, but non-randomised study, in which the same implant, although not indexed, was used[4]. No statistically significant difference in marginal bone loss 3 years after implant placement was found at implants placed in posterior mandibles. Our results were also in slight disagreement with a small RCT including only 16 patients[7], in which again no difference was noticed. However, other RCTs using different implant systems reported statistically significant differences of 0.2[3], 0.3[5] and 0.5[6] mm in

favour of those implants whose abutments were not disconnected, which are in agreement with the findings of the present trial. From a clinical point of view, differences in bone loss from 0.2 to 0.5 mm may not have a clinically noticeable impact, therefore it should not discourage clinicians to change abutments, if needed, though the empiric rule that the less you manipulate the abutments the better they are, still appears to be valid.

The comparison among centres revealed some statistically significant differences. For instance, one centre had to remake more crowns (corresponding to 25% of the delivered prostheses), than the other centres. This was due mainly to the specific prosthetic procedures used by that centre for rehabilitating single implants from the repeated disconnection abutment group. The use of the correct type of indexed abutments would have minimised, if not eliminated, this problem. The differences between centres observed in bone loss and keratinised mucosa height may not have a clinically significant impact; on the contrary an average difference of in PES score of 2.6 out of a maximum score of 14 between the best and worst performing centre may have an impact on the aesthetic outcome. It is difficult to explain such differences. This observation is in contradiction with what is generally believed and reinforces once more the need and urgency to properly study the actual role of the keratinised mucosa on the long-term health of the soft tissue.

The main limitations of the present trial are the small sample size and the used of non-indexed abutments on indexed implants. Unfortunately the planned sample size could not be achieved due to the loss of two centres, thought the sample size was large enough to detect some significant differences at 3-year post-loading (peri-implant marginal bone loss and soft tissue contour) between the two procedures. Such differences, however, may not have any clinical impact. The problem of using non-indexed abutments on indexed implants was present only if abutments were removed, since it was difficult to reposition them exactly in the same position. In ordinary clinical practice this problem is easily avoidable by using the correct and dedicated indexed abutments. Another limitation was the invalidation of the allocation concealment procedure in one of the centres. Despite verbal and written instructions and explanations on why not opening the envelopes to know the randomisation code before implant installation, some clinicians still do it. This problem is definitively underestimated since it is difficult to control when sealed envelopes, used to conceal allocation, are actually open. Therefore centrally computerised random allocation concealment after patients' data is entered on digital case report forms should be preferred. Finally, in the present study, implants of the two groups were loaded at different time points (immediately and after 3 months), which could be a confounding factor. In a Cochrane systematic review comparing immediate vs conventional loading, this issue was considered and it was found that patients with conventionally loaded implants lost 0.1 mm more peri-implant marginal bone than patients subjected to immediate loading procedures[8]. While this difference was found to be statistically significant, from a clinical point of view such a difference is unnoticeable. With regard to the generalisation of the present results, if operators use the correct abutment types on indexed implants they could obtain better results than those reported in this study, in terms of having to remake fewer of prostheses.

Conclusions

The 3-year post-loading data showed that repeated abutment disconnections significantly increased bone loss of 0.43 mm, but this difference cannot be considered clinically relevant, therefore clinicians can use the procedure they find more convenient for their specific patient. Immediately non-occlusally loaded dental implants are a viable alternative to conventional loading and no increased bone loss or buccal recessions were noticed at implants with less than 2 mm of keratinised mucosa.

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