Purpose: To evaluate the efficacy of immediate loading versus early loading at 6 weeks of bar-retained mandibular overdentures supported by two implants placed with a flapless technique.

Materials and methods: Sixty patients were randomised: 30 to the immediately loaded group and 30 to the early loaded group. To be immediately loaded, implants had to be inserted with a minimum torque > 48 Ncm. Outcome measures were prosthesis and implant failures, biological and biomechanical complications, patient satisfaction, and Implant Stability Quotient (ISQ) assessed with a resonance frequency analysis instrument.

Results: Sixty implants were placed in each group. Flaps had to be raised in nine patients to check drill direction or to better visualise the area after multiple teeth extraction. Two implants in two patients did not reach the planned insertion torque and were immediately replaced by larger diameters ones. After 1 year no drop out occurred and two early loaded implants failed in two patients. There were no statistically significant differences between groups for prosthesis failures, implant losses, complications, and mean ISQ values; however, patients in the immediately loaded group were significantly more satisfied than those loaded early. When comparing mean ISQ values taken 6 weeks after placement with 1-year data within each group, values decreased significantly.

Conclusions: Mandibular overdentures can be successfully loaded the same day of implant placement with a minimally invasive surgery, increasing patient satisfaction while decreasing treatment time and patient discomfort. No apparent advantages were seen when loading the overdentures at 6 weeks.

Introduction

Early or immediate implant loading are common procedures, particularly in good bone quality. A Cochrane systematic review of randomised controlled clinical trials (RCTs), evaluating timing for loading of dental implants, suggested that immediately and early loaded dental implants in selected patients can be as effective as waiting for a conventional healing period when high insertion torques are used to place the implants. It was also suggested that more research would be needed that compared the efficacy of immediate with early loaded implants, since only two RCTs were identified that evaluated such comparisons.
Implant placement without flap elevation is becoming more popular among dentists. The main advantages of flapless procedures are the reduced post-operative pain and oedema experienced by patients4,5. However, the evidence supporting the safety of flapless procedures is still scarce, and they should be performed only by experienced clinicians in adequately selected cases6. The use of guided surgery aided with customised surgical templates derived from CT scans has been proposed to help clinicians to minimise the risk of perforation and incorrect implant alignment when placing implants flapless7,8, but reliable evidence of the advantages of computer-guided surgery is still lacking6.

Nevertheless, from a patient perspective, it would be ideal to obtain a functional overdenture on the same day as implant placement, with a minimal surgical intervention, reducing discomfort, treatment time and costs, if the risks of implant failures are not increased.

The aim of the present RCT was to compare the efficacy of immediate loading (test group) with early loading (control group) of mandibular overdentures supported by two implants placed with a flapless technique and rigidly connected with a bar. The null hypothesis was that there would be no difference in the outcomes the two procedures, against the alternative hypothesis of a difference. The present article is reported according to the CONSORT statement for improving the quality of reports of randomised trials (http://www.consort-statement.org/).

Materials and methods

Any patient requiring a mandibular overdenture who was 18 or older and able to sign an informed consent form was eligible for inclusion in this trial. Eligible patients needed to have bone volumes allowing the placement of two implants with at least a diameter of 3.7 mm and length of 10 mm.

Patients were not accepted into the study if any of the following exclusion criteria were present:
- general contraindications to implant surgery
- poor oral hygiene and motivation
- uncontrolled diabetes
- pregnancy or lactation
- substance abuse
- psychiatric problems or unrealistic expectations
- lack of opposing occluding dentition/prosthesis
- acute infection in the area intended for implant placement
- need for bone-augmentation procedures
- participation in another trial.

Patients were grouped into three groups according to what they declared: non-smokers, light smokers (up to 10 cigarettes per day) or heavy smokers (more than 10 cigarettes per day).

All patients had to sign a written informed consent form to be recruited in this trial. Patients were recruited and treated in one Italian private practice with extensive experience in immediate loading and flapless procedures. One experienced dentist (GC) performed all the operations.

Preliminary screening was performed on intraoral radiographs, panoramic orthopantomographs or CT scans. When CT scans were not deemed necessary, a bone caliper was used to determine clinically the thickness of the available bone. When satisfactory mandibular dentures (Fig 1) were not available, they were made prior to implantation. Patients received professional oral hygiene prior to the operation and were instructed to rinse with a chlorhexidine mouthwash 0.2% for 1 minute, twice a day, starting 2 days prior to the intervention and thereafter for 2 weeks. All patients received prophylactic antibiotic therapy: amoxicillin 2 g one hour prior to the operation and were instructed to rinse with a chlorhexidine mouthwash 0.2% for 1 minute, twice a day, starting 2 days prior to the intervention and thereafter for 2 weeks. Patients allergic to penicillin were given clarithromycin 500 mg 1 hour prior to the intervention. Local anaesthesia was obtained using articaine with adrenaline 1:100.000.
The choice of the implant diameter and length was left to the surgeon. Tapered SwissPlus (Zimmer Dental, Carlsbad, CA, USA) with diameters of 3.7 and 4.8 mm, and 10, 12 and 14 mm long were used. Implants were placed flapless by inserting a 2 mm diameter drill directly into the mucosa (Figs 2 to 4). A 2.7-mm diameter surgical drill was used and, if necessary, followed by a custom-made tapered drill (diameter of 3.2 or 3.9 mm) to prepare the upper 3 mm of the osteotomy site implant insertion. Implants were inserted in the under-prepared osteotomy sites (Figs 5 to 7) with a torque of 48 Ncm, and once the motor
stopped, manually with a ratchet until seated in the proper position. A placement was attempted in which the transition between the machined collar and the textured surface were at the same level as the alveolar bone crest.

Resistance to implant insertion was objectively recorded with a motor torque device (Elcomed 100, W&H Dentalwerk Buermoos, Salzburg, Austria). In the protocol-formulation phase, it was decided that implants that had not achieved the minimal torque resistance of 48 Ncm at insertion, should be replaced by a larger diameter implant, or an alternative site was to be prepared to achieve the minimal desired insertion torque.

After both implants had been inserted, the envelope containing the randomisation code was opened and the operator knew whether the patient would have the implants immediately loaded or loaded after 6 weeks. A non-submerged technique was employed for the early loaded implants.

After surgery, patients were instructed to avoid brushing and trauma at the surgical site. Ice packs were provided. A cold and soft diet was recommended for 7 days. Smokers were recommended to avoid smoking for 3 days post-operatively. Analgesics (nimesulide) 100 mg were prescribed to be taken twice a day during meals on patient’s demand. When placed, sutures were removed after about 10 days and oral hygiene instructions were given.

The prosthetic procedures were identical for both groups, but started just after placement for the subjects in the immediately loaded group. The mandibular denture was trimmed (Fig 8) and used as an individual tray. Impregum F (3M Espe, Seefeld, Germany) was used as the impression material, and the denture was blocked directly to the implant mounts (Fig 9) with Pattern Resin (GC America, Alsip, IL, USA). Once the implant mounts and the impression tray were removed, cover screws were placed onto the implants (Fig 10). Definitive casts were mounted in articulators...
using interocclusal records and casts of the opposing arch. Screw-retained gold bars without lateral extensions were cast, starting from preformed plastic bars (Hader Bar, Zimmer Dental; Figs 11 and 12), which were augmented in a vertical direction, and screwed onto the implants using a standard torque of 30 Ncm. The patient’s adapted denture or the newly fabricated denture with two yellow plastic riders (Hader Clip, Zimmer Dental) were positioned the same day as implant placement for patients of the immediately loaded group (Figs 13 to 16), and about 6 weeks after for the early loaded group. A panoramic orthopanto-
mograph was routinely taken after tightening of the gold bar to check bar precision (Fig 17).

Patients were recalled every 3 months for oral hygiene maintenance and prosthetic check-ups for the entire duration of the study (1 year after loading; Figs 18 and 19). All overdentures needing relining were relined about 3 months after placement.

The outcome measures evaluated for the present study were:

- Prosthesis failure: an overdenture that could not be placed because of implant failures or secondary to implant failure, or if the patient was not using it.
- Implant failure: the presence of any mobility of the individual implant and/or any infection dictating implant removal. Implant stability was measured 6 weeks and 1 year after implant placement, after having removed the bar, in three different ways:
  1) Measuring the resonance frequency analysis (RFA) with Osstell (Integration Diagnostics, Göteborg, Sweden). Results were expressed in ISQ (implant stability quotient) with values ranging from 1 (minimum stability) to 100 (maximum stability). Implants showing values ≤ 40 were considered failures.
  2) Manually by using the handles of two metallic instruments.
  3) By applying a reverse torque of 20 Ncm with the motor.

- Any biological or prosthetic complications. Complications were grouped in three categories:
  1) Intra-operative and post-operative biological complications, such as haemorrhage, numbness of the lower lip and chin, etc.
  2) Biological complications in maintenance, such as peri-implant mucositis (heavily inflamed soft tissue without bone loss), peri-implantitis (bone

![Fig 17](Panoramic radiograph taken after bar delivery.)

![Fig 18](Peri-implant tissues after 1 year of function with the mandibular overdenture.)

![Fig 19](Panoramic radiograph taken after 1 year of function of the overdenture.)
loss with suppuration or heavily inflamed tissues), fistulas, etc.

3) Prosthetic complications, such as fracture of the implant, abutment screw, overdentures, etc.

- Patient satisfaction: assessed 1 year after loading by asking patients whether they were satisfied with the overall overdenture treatment. Patients had to indicate one of the following answers:
  1 – completely satisfied
  2 – partially satisfied
  3 – unsure
  4 – unsatisfied
  5 – completely unsatisfied.

The final follow-up was at 1 year after loading. Complications were assessed by the treating dentist (GC), who was not blinded, but implant stability and ISQ values were recorded by an independent dentist who was not aware of patient allocation (ML).

The sample size was calculated to compare 10% of failures with 20%. A two-group chi-square test with a 0.050 two-sided significance level will have 90% power to detect the difference of a proportion of 0.200 and a proportion of 0.100 (odds ratio of 0.444) when the sample size in each group is 286. Thirty patients were included in each group.

A computer-generated restricted randomisation list was used to create two groups with equal numbers of patients by Dr Marco Esposito, who was not involved in patient recruitment or treatment and had access to the randomisation list stored in a password-protected portable computer. The randomised codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Envelopes were opened sequentially only after the two implants were inserted, therefore treatment allocation was concealed to the investigator (GC) in charge of enrolling and treating the patients included in the trial.

All data analysis was carried out according to a pre-established analysis plan. The patient was the statistical unit of the analyses. A biostatistician (Prof Helen Worthington) with expertise in dentistry analysed the data, without knowing the group allocation. Fisher’s exact probability test was used to compare the relative numbers of patients who had at least one prosthesis failure, implant failure or complication. Mann–Whitney U test was used to compare the medians of the two groups for patient’s satisfaction. Independent sample t tests were used to compare the mean ISQ values at 6 weeks after implant placement and 1 year after loading between the two groups. Paired t tests were conducted to compare changes between 6 weeks after implant placement and 1 year after loading, for each treatment group. All statistical comparisons were conducted at the 0.05 level of significance.

Results

At screening, four patients were found not eligible for this trial: two patients had unrealistic expectations from the treatment, one patient had a crest too thin to undergo flapless surgery and one patient had undergone coronary bypasses 3 months earlier. All patients eligible for this trial agreed to participate. Sixty patients were consecutively enrolled in the trial and randomised immediately after implant placement: 30 to the immediately loaded group and 30 to the early loaded group. All patients were treated according to the allocated interventions. No patient dropped out and the data of all patients were evaluated in the statistical analyses. No deviation from the operative protocol occurred.

Patients were recruited and treated from November 2004 to December 2005. The follow-up focused on the time between implant placement and 1 year after loading. The last overdenture was delivered in January 2006, and the last patient was recalled in January 2007 for the 1-year check-up.

The main baseline patient characteristics are presented in Table 1. Patients with various medical conditions and pathologies were included in both groups. Flaps had to be raised in nine patients to check drill direction (six patients) or to better visualise the area after multiple teeth extraction (three patients), as illustrated in Table 1. At placement, all but two implants achieved the minimal implant insertion torque required (48 Ncm). These two 3.7-mm diameter implants were immediately replaced by larger diameter implants, one in the same implant site and one in a newly prepared adjacent site. Both of these implants were subsequently randomised to the immediately loaded group. No intra-operative complication occurred. The lengths and diameters of the inserted implants are presented in Table 2.
Two implants in two patients of the early loaded group failed. Both implants were found to mobile and their failures were compatible with an overload aetiology. One implant was found to be mobile 15 days after loading, placed in a post-extractive socket of a male suffering from controlled diabetes and hypertension. The other implant was detected mobile 4 months after loading and was slightly painful. It was placed in a female with unknown pathologies. Both patients declared to be non-smokers. Both failed implants were successfully replaced. There were no statistically significant differences in prosthesis and implant failures between the two interventions (Fisher’s exact test \( P = 0.492 \); difference in proportions = 0.067, 95% confidence intervals –0.057 to 0.213). The use of the reverse torque of 20 Ncm to evaluate implant stability did not identify additional implant failures.

There were no statistically significant differences for mean ISQ values from baseline to 1 year (Table 3). Nineteen post-operative complications occurred in 19 patients during the 1-year follow-up (Table 4). Eleven patients belonged to the immediate loading group and eight to the early loaded group. All complications were successfully treated. There were no statistically significant differences in post-operative complications between the two interventions (Fisher’s exact test \( P = 0.580 \)).

Patients who received immediately loaded overdentures were significantly more satisfied than those who had to wait for 6 weeks \( (P < 0.001, \text{Mann–Whitney U test}; \text{Table 5}) \). In particular, 24 patients of the immediately loaded group were completely satisfied, compared with seven of the early loaded group.

**Discussion**

The present RCT was designed to evaluate whether two flapless inserted and immediately loaded implants...
supporting a bar-retained mandibular overdenture could provide a reliable treatment alternative to early-loaded implants, since patients do appreciate less invasive surgery and shorter treatment periods. The findings of the present trial are encouraging, since no immediately loaded implants failed compared with only two early-loaded implants over a 1-year period. Implant placement was intended to be flapless, but in nine patients a flap had to be raised to allow proper implant insertion. This indicates that flapless implant placement is not always a simple procedure and should be used in adequately selected cases. However, the elevated flaps were smaller than conventional flaps and may have caused less discomfort to the patients than conventional ones.

It has been shown that a high insertion torque is a prerequisite for successful immediate loading of dental implants. All implants were placed with a high insertion torque (> 48 Ncm). Only for two implants could the desired primary stability not be obtained. They were immediately replaced with larger diameters implants, obtaining the desired insertion torque. To achieve a high insertion torque, implant sites were under-prepared to a various degree according to bone quality. This could be the most relevant aspect to explain the good results obtained in this trial. The hypothesis that a high primary implant stability is a prerequisite for success of immediately loaded implants finds support from another RCT\(^9\), in which single implants were either non-occlusally immediately or conventionally loaded. A strong correlation was found between low insertion torque values and implant failures. Nine of the ten implants inserted with a 20 Ncm torque failed, versus only one out of ten placed with a 32 Ncm torque in the immediately loaded group.

| Table 3 | Comparison between mean ISQ (SD) values at baseline and one year for the two study groups, and for changes from baseline within each group. |
|--------|--------|--------|
| Immediate loading (n = 30) | Early loading (n = 30) | P value from independent sample t test |
| 6 weeks post-implantation | 71.95 (1.91) | 71.42 (2.12) | 0.311 |
| 1 year post-implantation | 70.22 (1.25) | 70.43 (1.34) | 0.519 |
| P value from paired t test from 6 weeks to 1 year | < 0.001 | 0.012 |

| Table 4 | Post-operative complications. |
|--------|--------|--------|
| Complication type | Immediate (n = 30) | Early (n = 30) |
| Soft tissue ulcers within 30 days | 4 (13%) | 4 (13%) |
| Clip lost retention | 6* (20%) | 4 (13%) |
| Peri-implantitis | 1 (3%) | 0 (0%) |

*In one patient the same problem occurred three times during the first 4 months and the bar was remade with longer extensions (1 cm). All complications were successfully treated.

| Table 5 | Comparison between patients’ satisfaction at 1 year after loading for the two groups. |
|--------|--------|--------|
| Immediate loading (n = 30) | Early loading (n = 30) |
| Completely satisfied | 24 (80%) | 7 (23%) |
| Partially satisfied | 5 (17%) | 12 (40%) |
| Unsure | 1 (3%) | 7 (23%) |
| Unsatisfied | 0 (0%) | 4 (13%) |
| Completely unsatisfied | 0 (0%) | 0 (0%) |

P value from Mann–Whitney U test < 0.001.
The only two failures in the present RCT occurred in the early loaded group and were compatible with an overload aetiology\textsuperscript{10}. A similar trend was observed in another concurrent RCT evaluating immediate versus early loading of cross-arch implant-supported maxillary prostheses (unpublished results). Other authors also reported increased failures rates (42%) for mandibular overdentures loaded early, at 6 weeks\textsuperscript{11}. It might be hypothesised that a 6-week healing period may not be ideal for loading mandibular dental implants. A possible explanation is that the loading forces may interfere with the bone healing process at the bone-to-implant interface. However, more data are needed to confirm or reject this hypothesis.

The high success rates of immediately loaded implants observed in the present study are in agreement with other RCTs evaluating immediate loading in fully edentulous mandibles\textsuperscript{12,13}.

While it might have been expected that patients in the immediately loaded group expressed a higher degree of satisfaction, the highly significant statistical and clinical difference that resulted exceeded any expectations. The combination of two factors might have contributed to such different degrees of satisfaction. One factor is that the two patients who had a failed implant were unsatisfied with the procedure, despite that both implants were successfully replaced and immediately loaded for one patient and early loaded at 6 weeks for the other patient. The second but possibly more determinent factor was that patients were informed that they were participating in a RCT, and that they would have been randomised to either group despite their preference. It is likely that the preferred patient option was immediate loading, therefore patients in the early loaded group became less satisfied because they did not obtain their preferred treatment choice.

When evaluating the Osstell data, no difference between the two groups was observed at the 6-week and 1-year time points. This finding is expected since implants were inserted with high insertion torque and the clinician was not yet aware which loading strategy was to be used. It is interesting to observe that there was a highly statistically significant decrease in ISQ values from the baseline to 1-year assessment. While from a clinical perspective this difference is unlikely to have any significance, this observation may be some-what surprising since in some other studies (unpublished results)\textsuperscript{14-16}, ISQ values tended to increase at least during the first year. The decrease in ISQ values may be explained by the fact that implants were inserted with a high insertion torque that induced significant bone compression. After bone healing and remodelling, the ISQ values decreased slightly as a consequence of the diminished bone-to-implant contact area.

Implant stability of each implant was assessed 6 weeks after placement and 1 year after loading with three different methods: first with the Ossstell device, then using the handles of two metallic instruments, and finally with a reverse torque of 20 Ncm delivered by the motor. The results were identical. Therefore, it is difficult to recommend any method as the most appropriate one to discriminate mobile implants.

The major limitation of the present study is that the number of included patients may be too low to detect a statistically significant difference in prosthesis/implant failures, if any. Unfortunately, the centre in the present study did not have the capacity to recruit the number of patients suggested by the sample size calculation in a reasonable period. It can be estimated that the recruitment period should have been prolonged for 12 years in order to achieve the requested numbers. However, this is the largest RCT so far published for this specific indication. Larger RCTs are still needed to confirm whether immediate loading could be a more successful procedure than early loading. Based on the present data (about 6% of implant failures in the early-loaded group), sample sizes in the order of 300 patients per group may be needed to detect a difference in prosthesis or implant failures. However, precise sample sizes are difficult to calculate when considering, for instance, that 42% of patients in the early loaded group of another similar RCT\textsuperscript{11} experienced implant losses. Such large numbers of study participants can be only obtained in a reasonable time with multicentre trials and pooling reliable data from different RCTs in systematic reviews.

The flapless procedures were conducted without the help of any software for optimal planning of implant placement\textsuperscript{7}. Pre-surgical evaluations were generally made by assessing the bone width clinically, and less frequently with CT scans, when necessary.

Generalisation (external validity) of the findings of the present trial to other settings should be made with
great caution, since the operator was highly experienced with the flapless and immediate loading procedures. However, both techniques were tested in real clinical conditions, using relatively broad patient inclusion criteria.

### Conclusions

Mandibular overdentures can be successfully loaded the same day as implant placement with minimally invasive surgery, increasing patient satisfaction while decreasing treatment time and patient discomfort. No apparent advantages were seen when loading the overdentures at 6 weeks.

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