Immediate Functional Loading of Implants Placed with Flapless Surgery Versus Conventional Implants in Partially Edentulous Patients: A 3-Year Randomized Controlled Clinical Trial

Gioacchino Cannizzaro, MD, DDS[1]/Michele Leone, MD, DDS[1]/Ugo Consolo, MD[2]/
Vittorio Ferri, MD, DDS[3]/Marco Esposito, DDS, PhD[4]

Purpose: *To compare the efficacy of immediate functionally loaded implants placed with a flapless procedure (test group) versus implants placed after flap elevation and conventional load-free healing (control group) in partially edentulous patients.* ***Materials and Methods:*** *Forty patients were randomized: 20 to the flapless immediately loaded group and 20 to the conventional group. To be immediately loaded, implants had to be inserted with a minimum torque > 45 Ncm. Implants in the immediately loaded group were provided with full acrylic resin temporary restorations the same day. Implants in the conventional group were submerged (anterior region) or left unsubmerged (posterior region) and were left load-free for 3 months (mandibles) or 4 months (maxillae). Provisional restorations were replaced with definitive single metal-ceramic crowns 1 month postloading. Outcome measures were prosthesis and implant failures, biological and prosthetic complications, postoperative edema, pain, and use of analgesics. Independent sample* χ^2 *tests, Mann-Whitney tests,* t *tests, and paired* t *tests were used with a significance level of .05.* ***Results:*** *Fifty-two implants were placed in the flapless group and 56 in the conventionally loaded group. In the flapless group, 1 flap had to be raised to control the direction of the bur and 1 implant did not reach the planned primary stability and was treated as belonging to the conventional group. After 3 years no dropouts or failures occurred. There was no statistically significant difference for complications; however, patients in the conventional group had significantly more postoperative edema and pain and consumed more analgesics than those in the flapless group. Osstell values were significantly higher at baseline in the flapless group (*P = *.033). When comparing baseline data with years 1, 2, and 3 within each group, mean Osstell values of the flapless group did not increase, whereas there were statistically significant increases in the Periotest values.* ***Conclusions:*** *Implants can be successfully placed flapless and loaded immediately without compromising success rates; the procedure decreases treatment time and patient discomfort.* Int J Oral Maxillofac Implants 2008;23:867–875

Key words: *dental implants, flapless, immediate loading, partial edentulism, randomized controlled clinical trial*

[1]Visiting Professor, Department of Dentistry and Maxillo-Facial Surgery, University of Modena and Reggio Emilia, and private practice, Pavia, Italy.
[2]Head and Professor, Department of Dentistry and Maxillo-Facial Surgery, University of Modena and Reggio Emilia, Italy.
[3]Visiting Professor, Department of Dentistry and Maxillo-Facial Surgery, University of Modena and Reggio Emilia, and private practice, Modena, Italy.
[4]Senior Lecturer, Oral and Maxillofacial Surgery, School of Dentistry, The University of Manchester, UK and Associated Professor, Department of Biomaterials, The Sahlgrenska Academy at Göteborg University, Sweden.

Correspondence to: Dr Gioacchino Cannizzaro, Viale Indipendenza, 58, 27100 Pavia, Italy. Fax: +39 0382568819. E-mail: gio_cannizzaro@libero.it

Osseointegrated dental implants have traditionally been placed in accordance with a 2-stage protocol.[1] Implants were submerged and left to heal for a period of 3 to 4 months in mandibles and 6 to 8 months in maxillae. Early attempts to load the implant earlier were associated with increased failure rates.[1] This meant that patients had to wait a significant time before prosthesis placement and often had to wear suboptimal provisional prostheses. In 1990 the first investigation was published suggesting that osseointegrated implants could be loaded early or immediately in mandibles of selected patients.[2] Early or immediate implant loading is now a common procedure, particularly in mandibles with good bone quality.[3]

A Cochrane systematic review of randomized controlled clinical trials (RCTs)[4] evaluating timing for loading of dental implants suggested that immediately loaded dental implants in selected mandibles can be as effective as those loaded after a conventional healing period. No RCT evaluating immediately loaded implants in edentulous maxillae was identified; however, several uncontrolled investigations showing very high success rates are available.[5–11]

While no increased failure rates for immediately loaded implants when compared to conventionally or early loaded implants were found in several RCTs,[12–15] immediately loaded implants occasionally have been associated with clinically relevant increased failure rates.[16,17] In an RCT of split-mouth design, single immediately loaded implants failed significantly more than conventionally loaded dental implants. Ten out of 23 immediately loaded implants failed versus only 1 of 23 of the conventionally loaded group.[16] The authors demonstrated a strong correlation between implant failures and the initial insertion torque of the implants. Nine of the 10 implants inserted with a 20-Ncm torque failed, versus only 10 placed with a 32-Ncm torque in the immediately loaded group.[16] These findings support the hypothesis that implant stability and lack of micromovement are 2 of the main factors associated with high success rates.[18] Various precautions are clinically used to minimize the risk of early failures for immediately loaded implants. The most common are: underpreparation of the implant site to achieve maximum primary implant stability,[14] nonoccluding temporary prostheses during the first 2 months of healing,[19] and progressive loading of the prostheses.

A flap is usually elevated to visualize better the bone sites where the implants will be placed. Flap elevation ensures that some anatomic landmarks (eg, foramina, lingual undercuts, or maxillary sinuses) are clearly identified and protected. When the amount of available bone is limited, flap elevation will facilitate implant placement, maximizing bony contact while minimizing the risk of bone fenestrations. However, flaps are associated with some degree of morbidity and discomfort and require suturing. There are situations where flap elevation may be not necessary, since the amount of bone is sufficient and the risk of complications is minimal. Under these circumstances, flapless implant placement may be indicated. When placing implants with a flapless procedure the surgeon is working blindly and bone perforations are more likely to occur. Guided surgery aided with customized surgical templates derived from CT scans can help clinicians to minimize the risk of perforation and incorrect implant alignment.[20]

Retrospective[21,22] and prospective studies[20,23] showed that it is possible to place dental implants successfully without raising a flap, even when loading the implants immediately.[11,17] An RCT[24] showed that patients treated with flapless implant placement experienced less pain for shorter time than those subjected to flap elevation. From a patient perspective it would be ideal to obtain a functional fixed prosthesis the same day of implant placement, with a minimal surgical intervention, as this would reduce discomfort, treatment time, and costs, if the risk of implant failures is not increased.

The aim of this RCT was to compare the efficacy of immediate functionally loaded implants placed with a flapless procedure (test group) versus implants placed after flap elevation and conventional load-free healing (control group) in partially edentulous patients. The null hypothesis was that there would be no difference in prosthesis/implant success rates and complications between the 2 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 parallel-group randomized trials (http://www.consort-statement.org/).

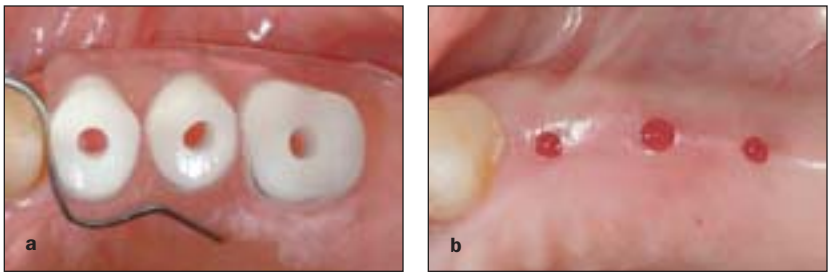
MATERIALS AND METHODS

Any partially dentate patient requiring dental implants 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 implants with a diameter of at least 3.7 mm and a length of at least 10 mm. Patients with multiple edentulous areas to be restored were included in the trial, but they could be treated only with single definitive crowns, so no pontics were allowed.

Patients were not accepted into the study if any of the following exclusion criteria were present: *(1)* general contraindications to implant surgery; *(2)* irradiation in the head and neck area within 1 year before implant surgery; *(3)* poor oral hygiene and motivation; *(4)* uncontrolled diabetes; *(5)* pregnancy or lactation; *(6)* substance abuse; *(7)* psychiatric problems or unrealistic expectations; *(8)* lack of opposing occluding dentition in the area intended for implant placement; *(9)* severe bruxism or clenching; *(10)* active infection or severe inflammation in the area intended for implant placement; *(11)* need for bone augmentation procedures, including sinus augmentation; *(12)* very soft bone at drilling (type 4) according to the classification of Lekholm and Zarb[25]; *(13)* untreated periodontal disease; *(14)* immediate postextractive implants.

Fig 1a Surgical template in position.

Fig 1b Holes through the mucosa made with the aid of the surgical template.



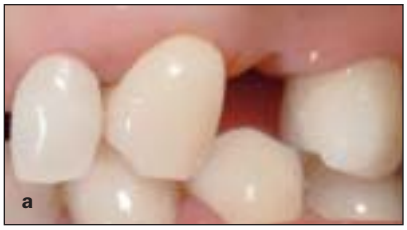
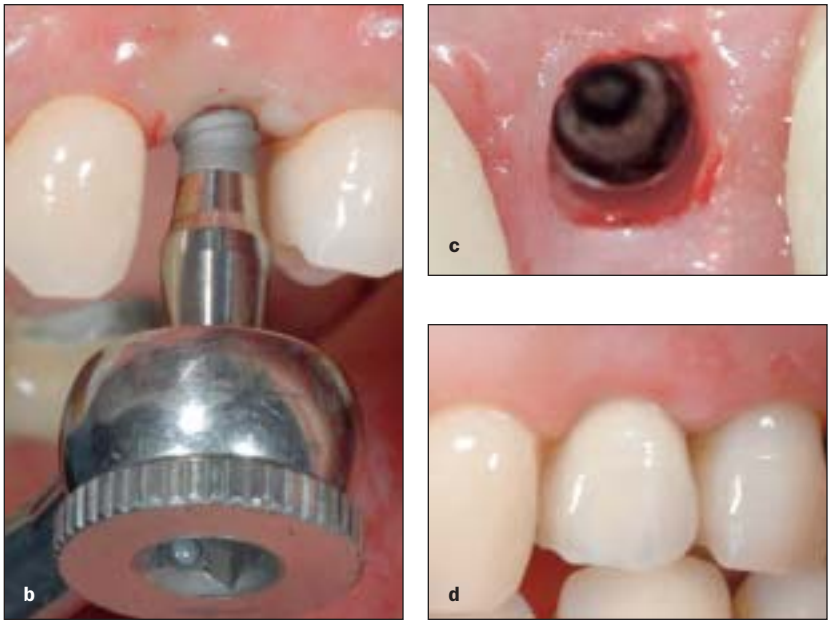


Fig 2a A first premolar is missing.

Fig 2b Flapless implants being seated in the final position with the aid of a manual ratchet.

Fig 2c Final position of an implant placed with a flapless technique.

Fig 2d Provisional restorations were placed within 4 hours after implant placement, with 2 exceptions. Shown here is a full occluding definitive metal-ceramic crown placed the day after implantation (one of the 2 exceptions).



All patients signed a written informed-consent form. Patients were recruited and treated in a single Italian private practice by a single surgeon with extensive experience in immediate loading and flapless procedures.

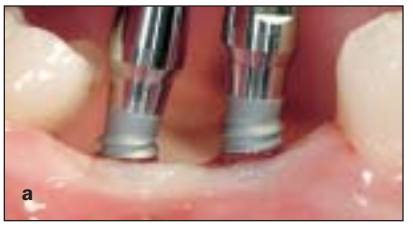
Partially edentulous patients requiring dental implants were randomized to have implants placed with a flapless procedure and immediately loaded (test group) or placed after flap elevation and conventionally loaded (control group).

Preliminary screening was performed on intraoral radiographs, panoramic radiographs, or computerized tomographic (CT) scans. When CT scans were not deemed necessary, a bone caliper was used to clinically determine the thickness of the available bone. Diagnostic tooth arrangements and surgical templates to guide implant insertion were made (Fig 1a).

Patients received professional oral hygiene 1 day before the operation and were instructed to use chlorhexidine mouthrinse 0.2% for 1 minute, 4 times a day, starting 3 days prior to the intervention and thereafter for 10 days. All patients received prophylactic antibiotic therapy: Augmentin (amoxicillin + clavulanic acid, GlaxoSmithKline, Verona, Italy) 2 g 1 hour prior to the intervention and 1 g twice a day for 3 days postoperatively. Local anesthesia was obtained using Articain with adrenaline 1:100,000 (Dentsply, Rome, Italy).

The choice of the implant diameter and length was left to the surgeon. Tapered SwissPlus (Zimmer Dental, Carlsbad, CA) with diameters of 3.7 and 4.8 mm and lengths of 10, 12, and 14 mm were used.

According to the randomization procedures, implants were placed flapless or not with the aid of templates (Fig 1a). For flapless implants, drills were inserted directly into the mucosa (Fig 1b; Figs 2a to 2c; Figs 3a and 3b). Bone density at drilling was subjectively evaluated, and the bone at the implant site was classified as either "hard," "medium," "soft," or "very soft."[25] Patients with "very soft" bone sites were excluded from the study. Resistance to implant insertion was objectively recorded with a motor torque



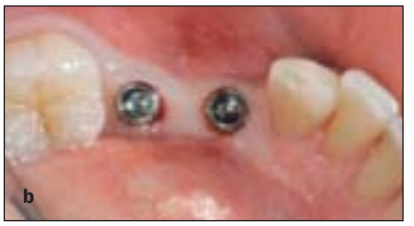


Fig 3a Placement of 2 flapless implants.

Fig 3b Occlusal view of 2 implants placed using a flapless technique.

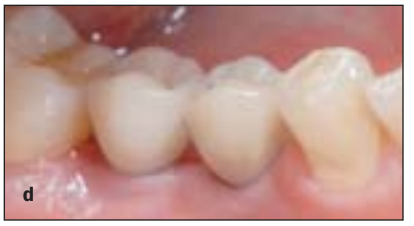


Fig 3c Abutments on implants placed using a flapless technique.

Fig 3d Provisional full-resin partial prosthesis placed a few hours after implantation.

device (Elcomed 100, W & H, Dentalwerk Buermoos Ges.M.Bh; Buermoos, Salzburg, Austria). In the protocol formulation phase, it was decided that implants randomized to the flapless group with a torque resistance inferior to 45 Ncm should instead be treated as belonging to the conventional group and kept load-free for 3 to 4 months. For implants placed flapless in hard bone, the manufacturer's instructions were followed. For implants placed in medium or soft bone, underpreparation of the sites was always performed using drills with smaller diameters than the final implant diameter. Bicortical implant engagement was always sought for maxillary implants by perforating completely the upper cortical bone, raising the nasal or sinus mucosa, and placing implants 2 mm longer than the available bone. Implants were inserted with a speed of 15 rpm using a torque of 45 Ncm. Once the motor stopped, they were tightened manually with a ratchet until seated in the proper position (Fig 2b). It was attempted to place the transition between the machined collar and the textured surface level with the alveolar bone crest (Fig 2c).

Implants of the conventional group were placed after a midcrestal incision and full-thickness flap elevation. For implant placement, the manufacturer's instructions were followed, and no subpreparation or bicortical engagement procedures were implemented. Flaps were closed with single sutures (Vicryl 3-0; Ethicon, Somerville, NJ). A nonsubmerged technique was employed for implants in posterior areas, whereas implants placed in esthetic anterior areas were submerged. Implants were kept load-fee for 3 months in mandibles and 4 months in maxillae. Submerged implants were exposed via a flap, and healing abutments were placed and kept load-free for about 20 days to allow complete healing of the peri-implant soft tissues.

After surgery, patients were instructed to avoid brushing and trauma on the surgical site. Ice packs were provided. A cold and soft diet was recommended for 7 days. Smokers were instructed to avoid smoking for 3 days postoperatively. No painkillers were prescribed. When placed, sutures were removed after about 1 week.

The prosthetic procedures were identical for both groups. Impression copings were attached to the implants, and impressions were made with individual trays using Impregum F (Espe Dental, Seefeld, Germany). Definitive casts were mounted in articulators using interoccusal records and casts of the opposing arch. Provisional full occluding acrylic resin restorations were manufactured and cemented on prepared abutments screw-tightened at 30 Ncm (Figs 3b and 3c). In the flapless immediately loaded group, when multiple adjacent implants were placed, provisional prostheses were constructed as partial prostheses to splint the implants (Fig 3d). Provisional restorations were placed within 4 hours after implant placement, with 2 exceptions (Fig 2d). Definitive metal-ceramic single crowns were cemented 1 month after delivery of the provisional restorations with a temporary cement. Patients were recalled every 3 months for oral hygiene maintenance and prosthetic check-ups for the entire duration of the study.

The outcome measures evaluated for the present study were:

1. *Prosthesis failure.* A prosthesis that could not be placed because of implant failures or a failed prosthesis.
2. *Implant failure.* The presence of any mobility of the individual implant and/or any infection dictating implant removal. Implant stability was measured using Periotest (Siemens, Bensheim, Germany) and Osstell (Integration Diagnostics,

Göteborg, Sweden) after removal of the prostheses. Periotest measurements were performed positioning the device perpendicularly to the implant abutment on the buccal side. For each implant, 4 measurements were taken and the value that occurred at least twice was recorded. Implants showing Periotest values (PTV) between −8 and 0 were considered successful, values between +1 and +3 borderline, and values ≥ 4 as failed. The resonance frequency analysis (RFA) was measured with Osstell. Results were expressed as an implant stability quotient (ISQ) with values ranging from 1 (minimum stability) to 100 (maximum stability). Implants showing values ≤ 40 were considered failures. Assessments were done at implant placement (baseline—flapless group) or at implant exposure (baseline—conventional group) and at 1, 2, and 3 years after loading.

3. *Any biological or prosthetic complications.* Complications were grouped in 3 categories: *(1)* intraoperative and postoperative biological complications, such as hemorrhage, 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) or peri-implantitis (bone loss with suppuration or heavily inflamed tissues, fistulas); and *(3)* prosthetic complications, such as fracture of the implant, abutment screw, framework, or occlusal material.
4. *Edema*. The level of postoperative edema was assessed at the first control visit 2 to 3 days after implant placement by the surgeon according to the following scale: 1 = no visible edema; 2 = moderate edema; 3 = severe edema and/or visible hematoma.
5. *Postoperative pain.* The level of postoperative pain was assessed at the first control visit 2 to 3 days after implant placement by the surgeon. Patients were asked whether they felt postoperative pain. They could answer "yes" or "no." Patients who reported feeling postoperative pain were also asked if the pain was tolerable or not, and their answers were recorded.
6. *Consumption of analgesics*. No analgesics were prescribed. At the first control visit 2 to 3 days after implant placement, the surgeon asked whether any analgesics were used to control pain. The answer could be "yes" or "no."

The final follow-up was at 3 years of loading. Outcome measures, with the exception of implant stability, were assessed by the treating dentist, who was not blinded. The Osstell and Periotest values were recorded by an independent dentist who was not aware of patient allocation. No sample size calculation was performed.

A computer-generated restricted randomization list was used to create 2 groups with equal numbers of patients by an independent external party. Just before each implant placement operation, the surgeon called the external party to know group allocation; therefore treatment allocation was concealed to all the investigators of this trial.

The patient was the statistical unit of the analyses. A biostatistician with expertise in dentistry analyzed the data without knowing the group allocation. Independent sample χ^2 tests were used to compare the relative numbers of patients who had at least 1 prosthesis failure, implant failure, or complications or consumed analgesics. The Mann-Whitney test was used to compare the medians of the 2 groups for edema and pain. Independent sample *t* tests were used to compare the mean Periotest and Osstell values at baseline, 1, 2, and 3 years between the 2 groups. Paired *t* tests were conducted to compare changes between baseline and year 1, 2, and 3, for each treatment group. All statistical comparisons were conducted at the .05 level of significance.

RESULTS

All patients eligible for this trial agreed to participate. Forty-three patients were consecutively enrolled in the trial and randomized: 22 to the flapless group and 21 to the conventional group. However, at implant placement, 2 patients from the flapless group and 1 from the control group were excluded because the implant sites had very soft bone (type 4). Therefore, this trial presents data from 20 patients from each group. All patients were treated according to the allocated interventions; however in 1 patient of the flapless group, the planned minimal primary implant stability of 45 Ncm could not be obtained, and the implant was loaded after 4 months according to an intention-to-treat analysis and the research protocol. No patient dropped out, and all were followed up to 3 years postloading. The data of all patients were evaluated in the statistical analyses. The only significant deviations from the operative protocol was that 2 patients of the flapless group requested immediate final crowns which were delivered the day following implantation (Fig 2d).

All implants were placed between March 2002 and July 2002. The main baseline patient characteristics are presented in Table 1. In the flapless group, 2 patients suffered from cardiac disease, 1 from hypertension, and 1 from controlled diabetes. In the conventional group, 2 patients suffered from cardiac

Table 1 Patients' and Interventions' Characteristics

	Flapless (n = 20)	Conventional (n = 20)
Females	10	11
Mean age at implant insertion (range)	40.1 (18–62)	37.4 (19–64)
Smokers	8	9
Total number of inserted implants	52	56
Implants inserted in mandibles	27	32
Implants inserted in anterior areas (canine to canine)	13	22
No. of patients receiving 1 implant	5	6
No. of patients receiving 2 implants	8	3
No. of patients receiving 3 implants	1	5
No. of patients receiving 4 implants	3	2
No. of patients receiving 5 implants	2	3
No. of patients receiving 6 implants	1	1

disease, 1 from hypertension, 1 from depression, and 1 was HIV positive.

Fifty-two implants were placed in the flapless group and 56 in the conventional group. The lengths and diameters of the inserted implants are presented in Table 2, whereas the bone density, which was subjectively evaluated, appears in Table 3. There were no apparent significant baseline imbalances between the 2 groups.

No prosthesis or implant failed. There were no statistically significant differences in the occurrence of complications among the 2 groups. The following complications occurred:

1. *Intraoperative and postoperative biological complications.* In the flapless group, 1 patient had a transient disturbance of the inferior alveolar nerve, and in another the maxillary sinus membrane was perforated, with no clinical consequence. Wound dehiscence occurred in 2 patients of the conventional group.
2. *Biologic complications in maintenance.* Peri-implant mucositis affected 1 implant from each group; 2 implants in 2 patients from each group developed peri-implantitis. All patients with peri-implantitis presented with 3 to 4 mm of peri-implant marginal bone loss and purulent exudate and were successfully treated with a surgical intervention to debride and smoothen the affected surface portions and by bone osteoplasty.
3. *Prosthetic complications.* In the flapless group, 4 patients had complications: 1 crown had to be redesigned for esthetic reasons, porcelain fractured from 2 crowns, 1 crown needed occlusal adjustment, and 1 abutment became loose. In the conventional group, 3 patients had complications: 2 crowns had to be redesigned in 2 patients for esthetic reasons, and 2 crowns needed occlusal adjustment in another patient.

Six patients in the flapless group had moderate postoperative edema. The remaining 14 patients showed no visible edema. In the conventional group, 4 patients had no edema, 12 had moderate edema, and 4 had severe edema. The difference was statistically significant ($P = .001$; Mann-Whitney test).

Eleven patients in the flapless group did not report any postoperative pain, whereas the remaining 9 patients reported they felt some postoperative pain. In the conventional group, 4 patients reported they felt no postoperative pain, whereas the remaining 16 reported pain, and in particular 4 subjects stated that they felt severe pain. The difference was statistically significant ($P = .008$; Mann-Whitney test).

Five patients of the flapless group reported that they took postoperative analgesics versus 13 patients of the conventional group. The difference was statistically significant ($P = .026$; χ^2 test).

With respect to Osstell and Periotest measurements comparing flapless immediately loaded with conventionally loaded implants, Osstell values were statistically significantly higher (Table 4) at baseline in the flapless group ($P = .033$). However, no difference was detected at year 1, 2, and 3 between the groups (Table 4). No statistically significant differences were observed for Periotest values at any time interval (Table 5).

When comparing baseline data with year 1, 2, and 3 within each group, Osstell values remained stable in the flapless group but increased in a statistically significant manner in the conventionally loaded group (Table 4). Periotest values increased in a statistically significant manner in both groups (Table 5).

DISCUSSION

The present RCT was designed to evaluate whether flapless immediately loaded implants in partially

Table 2 Length and Diameters of the Implants

	Flapless (n = 52)	Conventional (n = 56)
Implant length		
10 mm	17	8
12 mm	27	39
14 mm	8	9
Implant diameter		
3.7 mm	38	51
4.8 mm	14	5

Table 3 Bone Density Evaluated Clinically

	Flapless (n = 52)	Conventional (n = 56)
Hard	8	9
Medium	27	31
Soft	17	16

Table 4 Comparison Between Mean Osstell (SD) values at Baseline, 1, 2, and 3 Years for the 2 Study Groups and for Changes from Baseline Within Each Group

	Flapless (n = 20)		Conventional (n = 20)		
	Mean	SD	Mean	SD	*P**
Baseline	69.15	3.16	66.60	4.09	.033
Year 1	69.83	1.94	69.64	2.55	.80
Year 2	69.30	1.96	69.57	1.93	.66
Year 3	69.38	1.31	69.75	2.14	.52
P					
Baseline to year 1†	.29		<0.001		
Baseline to year 2†	.83		.003		
Baseline to year 3†	.76		.003		

*Independent sample *t* test.
†Paired *t* test.

Table 5 Comparison Between Mean Periotest (SD) Values at Baseline, 1, 2, and 3 Years for the 2 Study Groups and for Changes from Baseline Within Each Group

	Flapless (n = 20)		Conventional (n = 20)		
	Mean	SD	Mean	SD	*P**
Baseline	−2.08	0.70	−1.82	0.94	.34
Year 1	−2.72	1.02	−2.91	0.99	.55
Year 2	−3.25	0.97	−3.28	0.89	.92
Year 3	−4.07	0.85	−3.98	0.96	.76
P					
Baseline to year 1†	.005		< .001		
Baseline to year 2†	< .001		< .001		
Baseline to year 3†	< .001		< .001		

*Independent sample *t* test.
†Paired *t* test.

edentulous patients could provide satisfactory results, since patients appreciate less invasive surgery and shorter treatment periods. The findings of this trial are encouraging, since not a single implant failed over a 3-year period. Only 2 significant deviations from the protocol occurred in the flapless group. In 1 patient, during the flapless procedure, a flap had to be raised to allow proper implant placement. In another patient the flaplessly placed implant did not reach the planned primary implant stability (45 Ncm) and was conventionally loaded instead. There were no differences in complications among flapless immediately loaded implants and conventionally placed implants. However, when evaluating the data on postoperative edema, pain, and consumption of analgesics, it emerged clearly that the flapless approach decreased the postoperative discomfort associated with flap elevation, without any other appreciable negative consequences. The present findings are in agreement with another recent RCT,[24] where it was also found that patients treated with a flapless approach experienced less pain for shorter time periods than those subjected to flap elevation.

The high success rates observed in this study are in agreement with some trials evaluating immediate loading in partially edentulous patients,[14,15,26–28] but are in disagreement with other studies which reported failure rates of immediately loaded implants ranging from 25%[17] to 44%.[16] One aspect which may explain the good results obtained in this trial is that all immediately loaded implants achieved high primary stability at placement, since a minimum insertion torque of 45 Ncm was to be obtained for flapless placed implants to qualify for immediate loading. Only for 1 implant was the desired primary stability not obtained, in which case the implant was allowed to heal unloaded for 4 months as in the control group. The hypothesis that a high primary implant stability is a prerequisite for success of immediately loaded implants finds support from another RCT[16] in which single implants were either nonocclusally immediately or conventionally loaded. A strong correlation was found between low insertion torque values (20 Ncm) and implant failures.

Based on the results of the present trial and those from the aforementioned studies, it can be concluded that immediate loading of dental implants can be successful if some clinical precautions are taken. Such precautions may include: underpreparation of the implant sites, particularly in the presence of soft bone, to achieve high insertion torque (30 Ncm or more), and the use of implants promoting a stronger and faster osseointegration. It should be stressed that the present trial was conducted without the help of any software for optimal planning of implant placement.[20] Presurgical evaluations were done on CT scans, when necessary, though templates were always used as aids to achieve ideal implant placement for the prosthetic rehabilitation. Therefore, the generalization (external validity) of the findings of the present trial to other settings should be done with great caution, since the operator was highly experienced with the flapless and immediate loading procedures. On the other hand, both techniques were tested in real clinical conditions, using relatively broad patient inclusion criteria. It may be suggested to surgeons interested in performing flapless surgery to use one of the commercially available presurgical planning software packages with the aid of customized surgical templates derived from CT scans, at least for the most challenging cases.

The limitations of the present study were *(1)* that the number of included patients may still be too low to detect a statistically significant difference in prosthesis/implant failures, if any; and *(2)* that the assessments of edema, pain, consumption of analgesics, and complications were done by the operator. It is recognized that there is a risk of bias when operators assess their own interventions.[29] However, the Osstell and Periotest measurements were made by an independent dentist who was not aware of group allocation of the patients and had no access to the clinical records.

When evaluating the Osstell and Periotest data, it is interesting to observe that a statistically significant difference was found, for Osstell values alone, when comparing the baseline data of the groups. There was a similar trend, though not statistically significant, for the Periotest values. This baseline difference can be easily explained by the fact the implants placed flapless to be immediately loaded were inserted with higher insertion torque values than those conventionally loaded. When comparing baseline with 1-, 2-, and 3-year data in the flapless group, a statistically significant difference was found for Periotest values but not for Osstell values. These findings are difficult to explain. In the conventionally loaded group, a statistically significant difference, meaning an increased bone stability, was found for both Osstell and Periotest values when comparing follow-up values with baseline ones. It can be concluded that at 1 year a sort of steady state was achieved, even though the Periotest values tended to increase over the years, whereas Osstell values remained stable. Possible explanations for the observed difference between Osstell and Periotest values can only be conjectural, however. Either the Periotest is more sensitive to changes from baseline than Osstell, as shown by the significant difference found in the flapless group, or Periotest and Osstell measure 2 different aspects of bone integration. However, the clinical utility, if any, for both measurements, remains questionable.

CONCLUSIONS

Both techniques achieved 100% success rates, though the immediate loading flapless procedure of implants that achieved a high primary stability did so in a shorter period of time and with less discomfort for the patients than the placement of implants after flap elevation and kept for 3 to 4 months load-free. Therefore, a flapless immediate loading procedure may be preferable in properly selected and planned cases.

ACKNOWLEDGMENTS

The authors wish to thank Mr Ferla Massimo for his help with the randomization procedures, Dr Giuseppe Fontana for recording Periotest and Osstell values, Mrs Daria Laini for the assistance during the clinical procedures and data recording, and Prof Helen Worthington of the University of Manchester for statistical support. No commercial support in any form has been received by the investigators.

REFERENCES

1. Brånemark P-I, Hansson BO, Adell R, et al. Osseointegrated implants in the treatment of the edentulous jaw. Experience from a 10-year period. Stockholm: Almqvist & Wiksell International, 1977.
2. Schnitman PA, Wöhrle PS, Rubenstein JE. Immediate fixed interim prostheses supported by two-stage threaded implants: Methodology and results. J Oral Implantol 1990; 16:96–105.
3. Brånemark P-I, Engstrand P, Öhrnell LO, et al. Brånemark Novum: A new treatment concept for rehabilitation of the edentulous mandible. Preliminary results from a prospective clinical follow-up study. Clin Implant Dent Relat Res 1999;1: 2–16.
4. Esposito M, Worthington HV, Thomsen P, Coulthard P. Interventions for replacing missing teeth: Different times for loading dental implants. Cochrane Database of Systematic Reviews 2004; Chichester, UK: John Wiley & Sons.
5. Tarnow DP, Emtiaz S, Classi A. Immediate loading of threaded implants at stage 1 surgery in edentulous arches: Ten consecutive case reports with 1- to 5-year data. Int J Oral Maxillofac Implants 1997;12:319–324.
6. Balshi SF, Wolfinger GJ, Balshi TJ. A prospective study of immediate functional loading, following the Teeth in a Day protocol: A case series of 55 consecutive edentulous maxillas. Clin Oral Implants Res 2005;7:24–31.
7. Bergkvist G, Sahlholm S, Karlsson U, Nilner K, Lindh C. Immediately loaded implants supporting fixed prostheses in the edentulous maxilla: A preliminary clinical and radiologic report. Int J Oral Maxillofac Implants 2005;20:399–405.
8. Degidi M, Piattelli A, Felice P, Carinci F. Immediate functional loading of edentulous maxilla: A 5-year retrospective study of 388 titanium implants. J Periodontol 2005;76:1016–1024.
9. Maló P, Rangert B, Nobre M. All-on-4 immediate-function concept with Brånemark System implants for completely edentulous maxillae: A 1-year retrospective clinical study. Clin Implant Dent Relat Res 2005;7(suppl 1):S88–S94.
10. Östman PO, Hellman M, Sennerby L. Direct implant loading in the edentulous maxilla using a bone density-adapted surgical protocol and primary implant stability criteria for inclusion. Clin Implant Dent Relat Res 2005;7(suppl 1):S60–S69.
11. Cannizzaro G, Leone M, Esposito M. Immediate functional loading of implants placed with flapless surgery in the edentulous maxilla. One year follow-up of a single cohort study. Int J Oral Maxillofac Implants 2007;22:87–95.
12. Chiapasco M, Abati S, Romeo E, Vogel G. Implant-retained mandibular overdentures with Brånemark System MKII implants: A prospective comparative study between delayed and immediate loading. Int J Oral Maxillofac Implants 2001; 16:537–546.
13. Romeo E, Chiapasco M, Lazza A, et al. Implant-retained mandibular overdentures with ITI implants. Clin Oral Implants Res 2002;13:495–501.
14. Cannizzaro G, Leone M. Restoration of partially edentulous patients using dental implants with a microtextured surface: A prospective comparison of delayed and immediate full occlusal loading. Int J Oral Maxillofac Implants 2003;18: 512–522.
15. Romanos GE. Immediate loading of implants in the posterior mandible. A 2-year prospective study. J Periodontol (in press).
16. Ottoni JM, Oliveira ZF, Mansini R, Cabral AM. Correlation between placement torque and survival of single-tooth implants. Int J Oral Maxillofac Implants 2005;20:769–776.
17. Oh TJ, Shotwell JL, Billy EJ, Wang HL. Effect of flapless implant surgery on soft tissue profile: A randomized controlled clinical trial. J Periodontol 2006;77:874–882.
18. Albrektsson T, Brånemark P-I, Hansson H-A, Lindström J. Osseointegrated titanium implants. Requirements for ensuring a long-lasting, direct bone-to-implant anchorage in man. Acta Orthop Scand 1981;52:155–170.
19. Testori T, Bianchi F, Del Fabbro M, Szmukler-Moncler S, Francetti L, Weinstein RL. Immediate non-occlusal loading vs. early loading in partially edentulous patients. Pract Proced Aesthet Dent 2003;15:787–794.
20. van Steenberghe D, Glauser R, Blomback U, et al. A computed tomographic scan-derived customized surgical template and fixed prosthesis for flapless surgery and immediate loading of implants in fully edentulous maxillae: A prospective multicenter study. Clin Implant Dent Relat Res 2005;(7 suppl 1): S111–S120.
21. Dominguez Campelo L, Dominguez Camara JR. Flapless implant surgery: A 10-year clinical retrospective analysis. Int J Oral Maxillofac Implants 2002;17:271–276.
22. Rocci A, Martignoni M, Gottlow A. Immediate loading in the maxilla using flapless surgery, implants placed in predetermined positions, and prefabricated provisional restorations: A retrospective 3-year clinical study. Clin Implant Dent Relat Res 2003;5(suppl 1):29–36.
23. Becker W, Goldstein M, Becker BE, Sennerby L. Minimally invasive flapless implant surgery: A prospective multicenter study. Clin Implant Dent Relat Res 2005;7(suppl 1):S21–S27.
24. Fortin T, Bosson JL, Isidori M, Blanchet E. Effect of flapless surgery on pain experienced in implant placement using an image-guided system. Int J Oral Maxillofac Implants 2006; 21:298–304.
25. Lekholm U, Zarb GA. Patient selection and preparation. In: Brånemark P-I, Zarb GA, Albrektsson T (eds). Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chicago: Quintessence, 1985:199–209.
26. Hall JA, Payne AG, Purton DG, Torr B. A randomized controlled clinical trial of conventional and immediately loaded tapered implants with screw-retained crowns. Int J Prosthodont 2006; 19:17–19.
27. Lindeboom JA, Frenken JW, Dubois L, Frank M, Abbink I, Kroon FH. Immediate loading versus immediate provisionalization of maxillary single-tooth replacements: A prospective randomized study with BioComp implants. J Oral Maxillofac Surg 2006;64:936–942.
28. Testori T, Galli F, Capelli M, Zuffetti F, Esposito M. Immediate nonocclusal versus early loading of dental implants in partially edentulous patients: 1-year results from a multicenter, randomized controlled clinical trial. Int J Oral Maxillofac Implants 2007;22:815–822.
29. Schulz KF, Chalmers I, Hayes RJ, Altman DG. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. J Am Med Assoc 1995;273:408–412.