

Mauro Donati
Vincenzo La Scala
Mauro Billi
Biagio Di Dino
Paolo Torrisi
Tord Berglundh

Immediate functional loading of implants in single tooth replacement: a prospective clinical multicenter study

Authors' Affiliations:

Mauro Donati, Tord Berglundh, Department of Periodontology The Sahlgrenska Academy at Göteborg University, Göteborg, Sweden
Mauro Donati, Private Practice, Perugia, Italy
Vincenzo La Scala, Private practice, Pistoia, Italy
Mauro Billi, Private practice Montevarchi, Italy
Biagio Di Dino, Private practice Monsumano, Italy
Paolo Torrisi, Private practice Catania, Italy

Correspondence to:

Mauro Donati
Department of Periodontology
The Sahlgrenska Academy at Göteborg University
PO Box 450
SE 405 30 Göteborg
Sweden
Tel.: +46 31 786 3124
Fax: +46 31 786 37 91
e-mail: mauro.donati@odontologi.gu.se

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Abstract

Objectives: The aim of the present study was to evaluate the outcome of immediate functional loading of implants in single-tooth replacement using two different installation procedures.

Material and Methods: One hundred and fifty-one subjects, who required single-tooth rehabilitation in the area of 15–25 and 35–45, were enrolled in eight private clinics in Italy. The implant sites were randomly allocated to one of the following treatment groups. In the control group, in which a standard preparation procedure for implant placement and submerged healing of the implant was used, abutment connection and loading of the implants were performed 3 months after installation. In the test group 1, a standard preparation procedure for the implant placement and immediate functional loading of implant was carried out. In the test 2 group, however, a modified implant installation procedure (osteotome technique) was used followed by immediate functional loading of the implant. Clinical and radiographic examinations were performed at 3 and 12 months of follow-up at all sites.

Results: Three implants (5.5%) from the test 2 group (osteotome preparation) and one (2%) from the test 1 group (conventional drill preparation) failed to integrate and were removed one and three months after implant installation. The mean marginal bone loss assessed at 12 months was 0.31 mm (test 1), 0.25 mm (test 2) and 0.38 mm (control) (no statistically significant differences were found between the three treatment groups.)

Conclusion: It is suggested that immediate functional loading of implants that are placed with a conventional installation technique and with sufficient primary stability may be considered as a valid treatment alternative in a single-tooth replacement.

In long-term prospective studies, single-tooth replacement in implant therapy was demonstrated to be a predictable and successful treatment procedure (Jemt et al. 1990; Henry et al. 1996; Buser et al. 1997; Palmer et al. 2000; Berglundh et al. 2002; Wennstrom et al. 2005). The documentation was based on treatment methods in which the implants were left unloaded for different periods of time in order to provide osseointegration. For many

patients, however, early or immediate functional loading of implants may be an advantage, especially in anterior regions when the need to restore the esthetic appearance after tooth loss has a high priority. The definitions of immediate functional loading that were suggested in Consensus Conference Meetings (Aparicio et al. 2003; Cochran et al. 2004) relate to an implant-supported restoration, which is placed in occlusion with the opposing dentition

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within 48 h from implant placement. In this context, a critical evaluation of publications in the field of single-tooth replacement is required.

Thus, despite the use of an immediate or early-cemented crown restoration on an implant, functional loading was applied after an additional period of healing (Ericsson et al. 2000; Chaushu et al. 2001; Andersen et al. 2002; Proussaefs et al. 2002; Malo et al. 2003; Rocci et al. 2003; Drago & Lazzara 2004; Norton 2004; Abboud et al. 2005; Ottoni et al. 2005). There are a few studies on immediate functional loading of implants used for single-tooth replacement (Jo et al. 2001; Calandriello et al. 2003b; Cannizzaro & Leone 2003; Glauser et al. 2005; Lindeboom et al. 2006). The majority of these studies were prospective cohort studies and included about 20–50 subjects/implants.

An installation technique aimed at increasing the primary stability of dental implants in the posterior maxilla called the 'osteotome technique' was described by Summers (1994a; 1994b; 1995). The implant-shaped instruments in this technique are used to laterally compress trabecular bone. The technique was also applied in alveolar expansion and sinus elevation through a crestal approach (Horowitz 1997; Summers 1998; Zitzmann & Schärer 1998; Rosen et al. 1999). Histomorphometric data that were obtained in animal experiments indicated that implant sites prepared by the osteotome technique had a significantly higher degree of bone-to-implant contact than sites in which conventional drill preparation was used (Nkenke et al. 2002). The aim of the present study was to evaluate the outcome of immediate functional loading of implants in single-tooth replacement using two different installation procedures (osteotome and conventional).

Material and methods

This study was designed as a prospective, randomized, controlled, single masked parallel, multicenter trial. One hundred and fifty-one subjects, who required single-tooth rehabilitation in the area from position 15 to 25 and from 35 to 45, were enrolled in eight private clinics in Italy. A total of 70 males, mean age 46.7 (SD 18.3),

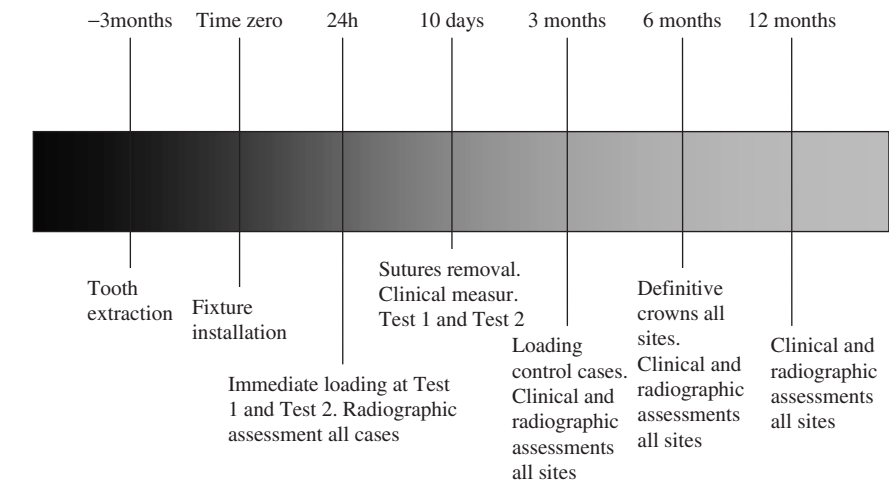


Fig. 1. Design of the study.

and 81 females, mean age 44.2 (SD 12.9), participated in this study. Thirty-five (23.2%) subjects were smokers and 17 of these (11.3%) were heavy smokers (≥ 10 cigarette/day). The distribution of smokers including heavy smokers was similar in the three treatment groups. All subjects received detailed information on the study and signed a written consent before the start of the treatment. The recruited subjects had to fulfill the following criteria: good general health, absence of oral and dental disorders, single tooth loss with neighboring teeth in normal occlusion, recipient sites for implants that had healed for ≥ 3 months following tooth extraction, attainment of the insertion torque at the implant installation of at least 20 N cm (to allow screw retention of the abutment) and no bone wall dehiscence.

The design of the study is described in Fig. 1. The implants used in the current study were OsseoSpeed™ (Astra Tech Dental, Mölndal, Sweden) \varnothing 4.0 or 4.5 with lengths varying between 8 and 13 mm. The selection of implant type was based on existing bone dimensions. The implant sites were randomly allocated to one of the following treatment groups. In the control group, in which a standard preparation procedure for the implant placement and submerged healing of the implant was used, abutment connection and loading of the implants were performed 3 months after installation. In test group 1, a standard preparation procedure for the implant placement and immediate functional loading of the implant was carried out. In test group 2, however, a modified implant in-

stallation procedure with preparation of the implant bed using an osteotome technique (osteotome TM, Astra Tech Dental) was used followed by immediate functional loading of the implant.

A randomization protocol was produced from a computer-generated list for the distribution of subjects in the three treatment groups (control $n = 57$, test 1 $n = 50$, test 2 $n = 54$).

Surgical procedures

Each subject received an antibiotic prophylaxis 1 g of augmentin (amoxicillin 875 mg + clavulanate potassium 125 mg; Glaxo Smith Kline, Brentford, UK) 1 h before surgery. Following local anesthesia, sulcular incisions were made at the neighboring teeth and connected by a crestal incision over the edentulous area. Full thickness flaps were elevated to expose the bone ridge. For the installation of the implants in the control and test 1 sites, the preparation of the implant bed was performed according to the standards described in the manual for surgical procedures of the implant system (Astra Tech Dental). In the test 2 sites an initial preparation with a twist drill (\varnothing 2.5) was performed. Osteotomes (Astra Tech Dental) were subsequently used to widen the prepared canal to allow the placement of \varnothing 4.0 or 4.5 fixtures. All implants included in the study had an insertion torque of ≥ 20 N cm, and following implant installation no bone dehiscence or fenestration defects were present. After implant installation in the control sites the flaps were replaced and

secured with interrupted sutures to cover the implants.

Prosthetic procedures

Following the completion of the surgical procedure of the test 1 and test 2 sites, the prosthetic procedures were initiated. Thus, the position of the implant was transferred to a model using an impression-fixture-pick-up, which was attached to the surgical stent with an autopolymerising resin (Fig. 2). The implant was then protected with a healing abutment during a 12–24 h interval until the custom-made abutment and the temporary crown were placed. The flaps were adjusted and secured around the abutments with interrupted sutures.

A custom-made abutment (preparable abutment, Astra Tech Dental) and a temporary crown were produced within 24 h from implant installation. The healing abutment was removed and the custom-made abutment placed and tightened to 20 N cm. The temporary acrylic crown was cemented with a temporary cement (Temp Bond, Kerr Co., Orange, CA, USA). The crowns were in contact in centric occlusion (Fig. 3a). Suture removal was performed 10–14 days after implant surgery.

In the control sites, the abutment connection was performed in a second-stage surgical procedure 3 months after implant installation. A custom-made abutment and a temporary crown were produced. At 6 months from implant installation, new impressions were taken for all cases (tests and controls) and a gold–ceramic crown was produced and cemented.

Clinical and radiographic examination

Clinical and radiographic examinations were performed at 3 and 12 months of follow-up at all sites. Clinical examinations included the assessment of soft tissue dimensions. Thus, the width of the keratinized mucosa was recorded as the linear distance from the mucosal margin (mid-buccal) of the implant-retained crown to the mucogingival line. The height of the mesial and distal papilla was measured as the linear distance from the horizontal projection line connecting the mucosal margin of the implant-retained crown and the gingival margin of the neighboring tooth to the most coronal extension of the papilla at the mesial and distal aspect of the implant-retained crown. In addition,

assessments of plaque, mucositis and probing depth were carried out at four sites on each implant.

At implant installation and at 3 and 12 months of follow-up, standardized intraoral radiographs (Kodak Ektaspeed Plus, Eastman Kodak Co., Rochester, NY, USA) were obtained using a parallel technique with custom-made film holders. The radiographs were analyzed by an experienced radiologist who was blinded with regard to treatment groups. Measurements of the marginal bone level (the distance between the abutment/fixture junction and the marginal bone to implant contact level) were made at the mesial and distal aspects of the implants using a magnifying lens ($\times 7$) to the nearest 0.1 mm.

Statistical analysis

Mean values, SDs and cumulative frequencies were calculated for each variable. Pri-

mary outcome variables were implant loss and marginal bone level changes. Fisher’s exact test was used to evaluate differences in frequencies of plaque, gingivitis and probing pocket depth (PPD) categories between the treatment groups as well as differences in implant loss between treatment groups and between implant types (4.0 vs. 4.5). The Student–Newman–Keuls Test (ANOVA) was applied to evaluate differences between the three treatment groups regarding marginal bone level changes and differences in soft tissue changes from baseline to 12 months. Differences in marginal bone level changes between implant types (\varnothing 4.0 and 4.5) were analyzed using Student’s *t*-test. A multifactorial ANOVA was carried out to



Fig. 2. Custom-made surgical stent used for registration of the implant position at the end of the surgical phase.

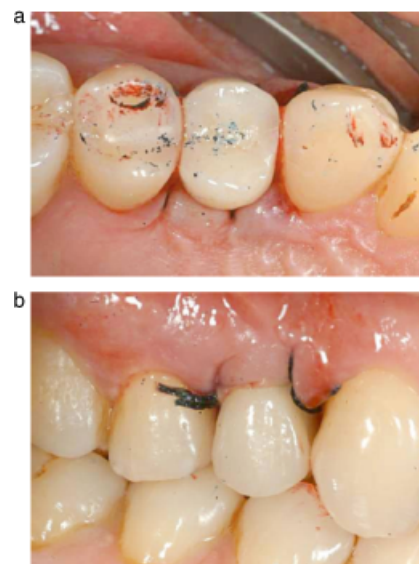


Fig. 3. Occlusal (3a) and lateral view (3b) of the temporary acrylic crown (14) in full contact in centric occlusion within 24 h from implant installation.

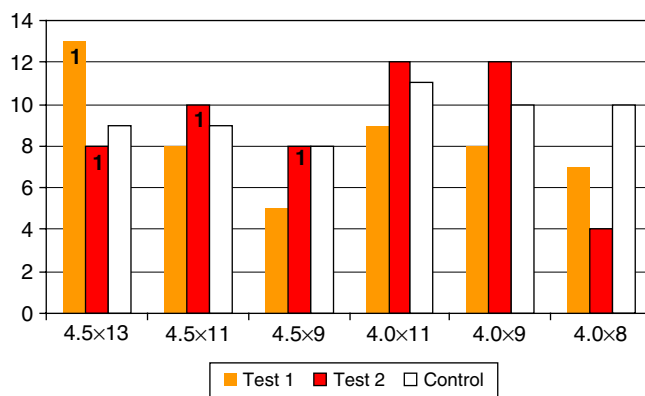


Fig. 4. Distribution of the type and length of implants placed in the different groups. Number and type of implants lost.

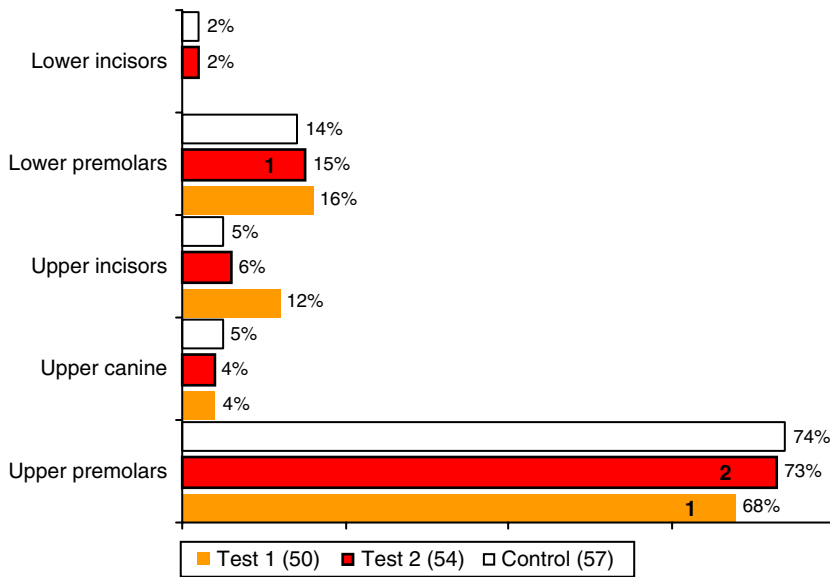


Fig. 5. Distribution of implant position, i.e. tooth sites restored, in the different groups. Number of implants lost according to tooth sites restored.

Table 1. Life-table for the number of patients and implants at the various time intervals

Time intervals	No patients	No implants	Reasons for loss of implants to follow up		
			Not fulfilling inclusion criteria	Drop out	Explanted
Implant placement	149	159	2 (test 2)		
1 month	147	156			3 (test 2)
3 months	145	154		1 (control)	1 (test 1)
6 months	145	154			
12 months	144	153		1 (control)	

Table 2. Clinical measurement at 12 months. Frequencies (%) of sites with plaque, mucositis, PPD <3 mm, 4–5mm and ≥ 6 mm

	Mesial (%)	Buccal (%)	Distal (%)	Lingual (%)
Plaque				
Test 1	8.16	10.2	12.24	11.08
Test 2	4.08	4.08	4.08	6.12
Control	3.64	7.27	10.91	7.27
Fisher's exact test; P-value NS.				
Mucositis				
Test 1	12.24	8.16	10.2	6.12
Test 2	4.08	2.04	4.08	2.04
Control	7.27	9.09	12.73	0
Fisher's exact test; P-value NS.				
PPP ≤ 3 mm				
Test 1	79.59	95.92	87.76	89.8
Test 2	89.80	100	93.88	100
Control	80%	92.73	74.55	90.91
Fisher's exact test; distal sites: Test 2 vs. control.				
PPD 4–5 mm				
Test 1	14.29	4.08	10.2	10.2
Test 2	10.2	0	6.12	0
Control	18.18	5.45	25.45	9.09
Fisher's exact test; distal sites: Test 2 vs. control.				
PPD ≥ 6 mm				
Test 1	6.12	0	2.04	0
Test 2	0	0	0	0
Control	1.82	1.82	0	0
Fisher's exact test; P-value NS. NS, nonsignificant.				

evaluate differences in mean values of marginal bone loss in relation to implant types and treatment groups. Multilevel regression analysis was applied to evaluate the influence of different variables on marginal bone level changes. In all analyses, a P-value of <0.05 was considered to represent a statistical significance.

Results

The distribution of the implant types and length categories and the position of the tooth sites that were restored in the three treatment groups are presented in Figs 4 and 5. Table 1 describes the number of subjects and implants recorded at the time of implant insertion and follow-up examinations. Two implants (test 2 group) were defined as not fulfilling the inclusion criteria because of a dehiscence of the buccal bone wall after the placement. At the 1-year follow up examination, two patients exited from the study because of general medical disorders. Three implants (5.5%) from the test 2 group (osteotome preparation) and one (2%) from the test 1 group (conventional drill preparation) failed to integrate and were removed after 1 and 3 months, respectively, from the time of implant installation. The results from the clinical assessments at the 12-month examination are reported in Table 2. No major differences were found between the three treatment groups with respect to frequencies of plaque and mucositis. The evaluation of the frequencies of PPD categories revealed small differences between the groups. Thus, the distal aspect of the control sites had significantly higher frequencies of 4–5 mm PPD than distal aspects of test 2 implants. No differences were detected between the treatment groups in changes of the papilla height or in the width of the keratinized mucosa from baseline to 12 months (Table 3).

The results from the radiographic measurements are reported in Tables 4 and 5 and in Figs 6–8. The mean marginal bone loss at 3 months of follow-up for implants of the test 1 group was 0.32 mm at the mesial site and 0.34 mm at the distal site. The corresponding figures for the test 2 and control implants were 0.19 and 0.21 mm, and 0.27 and 0.32 mm, respectively. Between 3 and 12 months of follow-up, only

Table 3. Clinical measurement. Changes in the papilla height (mesial and distal) and width of keratinized mucosa from the time of crown placement to 12 months. Mean values and standard deviation

	Mesial papilla	Distal papilla	Keratinized mucosa
Test 1	-0.43 ± 1.2	-0.21 ± 1.27	0.21 ± 1.41
Test 2	-0.20 ± 1.44	-0.28 ± 1.66	0.30 ± 1.33
Control	-0.55 ± 1.14	-0.50 ± 0.95	0.26 ± 1

Student–Newman–Keuls test; *P*-value NS.
NS, nonsignificant.

Table 4. Marginal bone level changes from baseline (T0) to 3 months (T3) and from baseline to 12 months (T12) according to treatment groups

Time intervals	Test 1		Test 2		Control		Student–Newman–Keuls test
	Mesial	Distal	Mesial	Distal	Mesial	Distal	
T0–T3	-0.32 (± 0.61)	-0.34 (± 0.51)	-0.19 (± 0.72)	-0.21 (± 0.73)	-0.27 (± 0.91)	-0.32 (± 0.73)	NS
T0–T12	-0.32 (± 0.87)	-0.31 (± 0.50)	-0.25 (± 0.81)	-0.26 (± 1.13)	-0.33 (± 0.89)	-0.43 (± 0.88)	NS

Mean values and SD (site as unit).

Table 5. Marginal bone level changes from baseline (T0) to 3 months (T3) and from baseline (T0) to 12 months (T12) according to the implant type

Time intervals	Type of implants		<i>T</i> -test
	4.0	4.5	
Bone level alteration T0–T3	-0.19 ± 0.6	-0.53 ± 1.28	<i>P</i> <0.05
Bone level alteration T0–T12	-0.17 ± 0.66	-0.48 ± 1	<i>P</i> <0.05

Mean values and SD.

The marginal bone level changes from baseline to 3 and 12 months for the two implant types are presented in Table 5. The Ø 4.5 implant type showed a significantly larger amount of bone loss than the Ø 4.0 implant type both at 3 months and 12 months of follow-up. The different amount of marginal bone loss from baseline to 12 months between the two implant types was also confirmed in the analysis of cumulative frequencies of sites with marginal bone loss ≥ 1 mm (Fig. 8). Thus, the Ø 4.5 implant type had a significantly larger frequency of sites showing marginal bone loss ≥ 1 mm (20.5%) than the Ø 4.0 implant type (11.3%).

The results from the multifactorial ANOVA, which was used to evaluate the differences in marginal bone loss in relation to implant diameter and treatment group, are reported in Fig. 9. In the control group, the Ø 4.5 implant type had a significantly larger amount of bone loss than the Ø 4.0 implant (*P*<0.01). The differences between the two implant types within the test groups were less pronounced than in the control group.

A multilevel regression model was applied to identify influencing factors when using marginal bone level change as a dependent variable (Table 6). Thus, treatment groups, implant types, smoking habits, insertion torque (N cm), reasons of tooth failure, tooth position restored, plaque, mucositis and PPD category were introduced and tested stepwise. Only the interaction between the Ø 4.5 implant

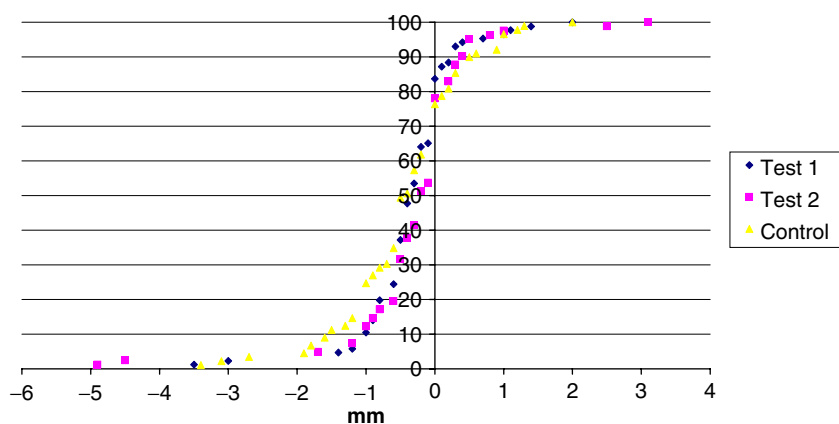


Fig. 6. Cumulative frequencies of the marginal bone level changes at mesial and distal sites of the implants in the three groups (site as unit). Sites showing ≥ 1 mm of marginal bone loss at 12-month examination. Student–Newman–Keuls test; *P* = 0.01.

small changes in mean marginal bone level occurred in the three groups. Thus, the data describing the overall marginal bone loss over the entire 12-month period were almost similar to those reported for the first 3 months (Table 4).

The cumulative frequencies of the marginal bone level changes are presented in Fig. 6. In 24.2% of the mesial or distal

sites of the control implants, the marginal bone level decreased ≥ 1 mm during the 12 months of follow-up. The corresponding figures for the test 2 and test 1 groups were 11% and 11.6%, respectively. The differences in the cumulative frequencies of sites with marginal bone loss ≥ 1 mm between tests (1 and 2) and control groups were statistically significant (Fig. 7).

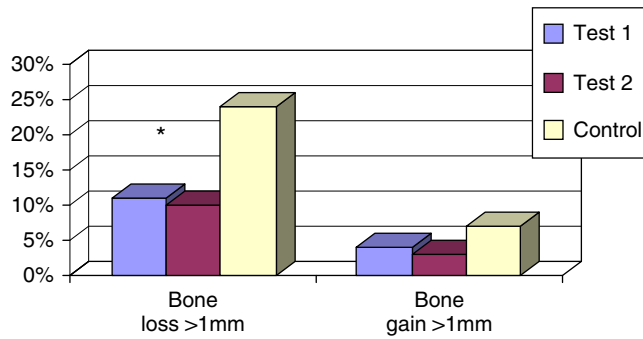


Fig. 7. Distribution (%) of sites (mesial or distal) with ≥ 1 mm of bone loss and sites with ≥ 1 mm of bone gained at 12 months in the three different groups (site as unit). Student–Newman–Keuls test; $P=0.01$.

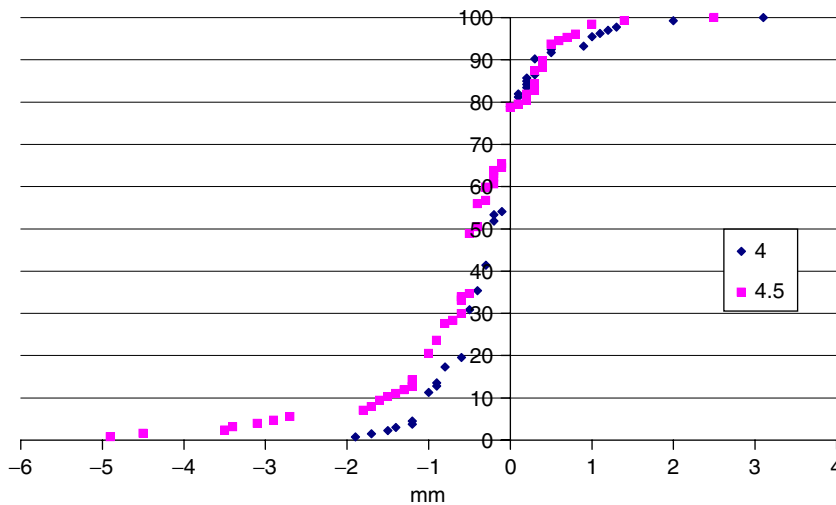


Fig. 8. Cumulative frequencies of the marginal bone level changes at mesial and distal sites of the implants in relation to the implant diameter (site as unit). Sites showing ≥ 1 mm of marginal bone loss at 12-month examination. Student–Newman–Keuls test; $P=0.042$.

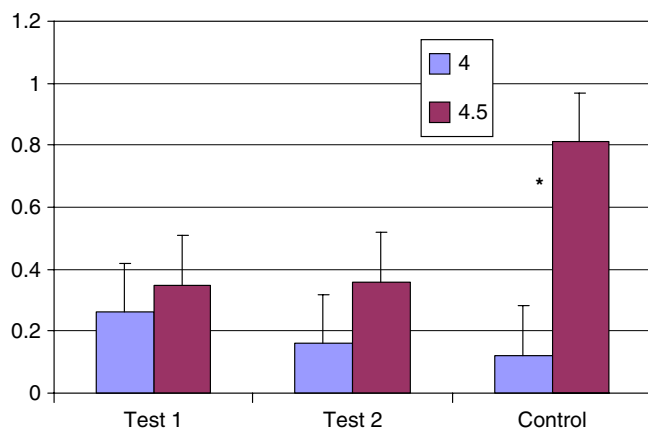


Fig. 9. Mean values of marginal bone loss in relation to implant diameter and treatment groups (implant as unit). $P<0.01$ * Multifactorial ANOVA.

type and the control procedure ($P<0.01$) had a significant impact on marginal bone loss. The multilevel model also evaluated the influence of different factors on the

residual variance that was confined to three levels, i.e. operator level, implant level and site level. The variance in the final model at the operator level was negligible. The

residual variance (unexplained variability) had a distribution of about 50% at the implant level (differences between different implants) and 50% at the site level. The multilevel model failed to demonstrate any association between the differences in the % of PPD category 4–5 mm of the control and test 2 implants on the one hand and the differences in marginal bone level changes between the control and tests implants on the other.

Discussion

The present investigation was carried out to study immediate functional loading of implants in single-tooth replacement using two different surgical procedures (osteotomes vs. conventional drill preparation). It was demonstrated that four implants were lost in the immediate functional loading groups while no loss occurred in the control group. Three of the lost implants were placed using the osteotome preparation procedure (test 2). Furthermore, no statistically significant differences in mean marginal bone loss were detected between the treatment groups. It is suggested that immediate functional loading of implants that are placed with a conventional installation technique and with sufficient primary stability may be considered as a valid treatment alternative in a single-tooth replacement.

There is limited information on immediate functional loading of implants used for single-tooth rehabilitation. Jo et al. (2001) reported on 36 single expandable implants which were immediately provided with provisional restorations in full occlusal contact. Three implants (8.3%) were lost during 13–40 months of follow-up period. In a prospective study, Cannizzaro & Leone (2003) compared 23 single-tooth implants that were subjected to immediate loading with 24 delayed loading implants. No implants were lost at the test and control groups at 2 years of follow-up. The radiographic examination revealed that 91.3% of the test implants and 87.5% of the controls showed a marginal bone loss ≤ 1 mm. The remaining implants, 8.7% of the test group and 12.5% of the controls, demonstrated marginal bone loss that varied between 1 and 2 mm. The results presented by Cannizzaro

Table 6. Multilevel regression model. Marginal bone level changes at 12 months as outcome variable

Predictors	Null model			Final model		
	Value	SE	P	Value	SE	P
Implant type						NS
Treatment group						NS
Smoking						NS
Insertion torque						NS
Tooth failure reason						NS
Tooth position						NS
Plaque						NS
Mucositis						NS
PPD category						NS
Treat. Group × implant type						
4.5 × control				- 0.68	0.21	<0.01
Intercept	- 0.39	0.09		- 0.13	0.15	
Variance						
Operator	0.03	0.03		0.02	0.03	
Implant	0.36	0.07		0.32	0.06	
Site		0.36	0.05		0.36	0.04
- 2 × loglikelihood	618.46		P<0.001		606.78	
ICC				0.3		
R ²				0.07		

SE, standard error; ICC, intra-class correlation; R², total variability; NS, nonsignificant.

zaro & Leone (2003) are in line with the data reported in the present study. Thus, the percentage of implants that had ≥ 1 mm of marginal bone loss was higher in the control group than in the test groups. Calandriello et al. (2003a) evaluated 20 implants used for single-tooth rehabilitation and exposed to immediate loading. At the 12-month re-examination, no implants were lost and the mean marginal bone loss was 1.22 mm. The amount of bone loss reported by Calandriello et al. (2003a) is considerably larger than that presented in the current study. In a subsequent prospective multicenter trial, Calandriello et al. (2003b) evaluated immediate functional loading of implants used in single-tooth replacement in the molar segments of the mandible. The survival rate recorded at 6 months was 100%, and the overall marginal bone loss was 1.0 mm. Glauser et al. (2003) analyzed 20 implants used for single-tooth replacement with immediate functional loading. No implant loss was recorded at the 12-month evaluation and the mean marginal bone loss was 1.2 mm.

In the present study, the mean marginal bone loss assessed at 12 months was 0.31, 0.25 and 0.38 mm for the test 1, test 2 and control implants, respectively. The corresponding amounts of marginal bone loss that occurred during the first 3 months, however, were 0.33, 0.2 and 0.29 mm. Thus, regardless of treatment group, the

largest amount of marginal bone loss took place during the initial 3-month period after fixture installation, and only minor changes occurred subsequently. This observation corroborates data presented in an experimental study in dogs by Berglundh et al. (2005). They analyzed marginal bone level alterations following implant installation, abutment connection and functional loading. It was reported that the largest amount of bone loss occurred following implant installation and abutment connection and that almost no bone level alterations occurred during a period of 10 months of functional load. The finding that the marginal bone loss is more pronounced in the initial period after implant installation than during the following period of implants in function is also supported by data presented in clinical trials. Cooper et al. (2001) studied early loading on implants placed using a one-stage procedure. It was reported that about 0.4 mm bone loss occurred during an initial 6-week period, while no further bone level changes were observed at the subsequent 12-month follow-up.

The results in the present study also revealed that the conical-shaped 4.5-mm-wide implants exhibited a higher frequency of implant loss and a larger amount of bone loss than the 4.0 mm cylindrical-shaped implant. The reason for this difference between the conical and cylindrical type

of implants is presently not understood but may be related to differences in primary stability and geometry within the marginal portion of the implant. The data describing mean values of marginal bone loss around the conical 4.5 MicroThread™ (Astra Tech-Dental, Mölndal, Sweden) implant in the present study, however, are in agreement with results previously reported. Thus, Norton (1998) and Puchades-Roman et al. (2000) reported that the mean marginal bone loss around the conical 4.5 MicroThread™ implant varied between 0.42 and 0.6 mm, respectively, using conventional loading time conditions. Furthermore, Cooper et al. (2001) and Norton (2004) presented a mean marginal bone loss of 0.4 and 0.54 mm in early and immediate restoration protocols at the conical 4.5 MicroThread™ implant.

The osteotome technique was recently evaluated in a review by Shalabi et al. (2007). They reported that the survival rate of implants placed using this procedure and with a conventional loading protocol was about 99% up to 56 months of loading. No clinical data appear to be available on the osteotome technique combined with an immediate functional loading protocol in single-tooth replacement. In an experimental study Nkenke et al. (2005) analyzed implants placed in the maxilla of minipigs. The implants were placed using either an osteotome technique or conventional drill preparation. The survival rate of implants that were subjected to immediate loading was significantly lower in both osteotome and drill preparation (50% and 58%) than for implants exposed to load at 5 months after implant installation (94.5 for osteotome and 89% for drill preparation). In the present study, it was found that implants immediately loaded and installed with the osteotome technique had a higher frequency of implant loss than implants placed with conventional drill preparation (5.5% vs. 2%). Büchter et al. (2005), in an experimental study in minipigs, reported on fractures of the trabeculae of the peri-implant bone around implants at 7 days after placement using the osteotome procedure. At 28 days no signs of fractured trabeculae were observed. At sites in which a conventional drilling technique was used, signs of fractured trabeculae in the peri-implant bone area were absent both at 7 and at 28 days. This finding may add to our

understanding on the higher risk of implant loss when applying immediate load on implants placed using an osteotome technique.

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References

- Abboud, M., Koeck, B., Stark, H., Wahl, G. & Paillon, R. (2005) Immediate loading of single-tooth implants in the posterior region. *International Journal Oral & Maxillofacial Implants* **20**: 61–68.
- Andersen, E., Haanaes, H.R. & Knutsen, B.M. (2002) Immediate loading of single-tooth ITI implants in the anterior maxilla: a prospective 5-year pilot study. *Clinical Oral Implants Research* **13**: 281–287.
- Aparicio, C., Rangert, B. & Sennerby, L. (2003) Immediate/early loading of dental implants: a report from the Sociedad Espanola de Implantes World Congress consensus meeting in Barcelona, Spain, 2002. *Clinical Implant Dentistry Related Research* **5**: 57–60.
- Berglundh, T., Abrahamsson, I. & Lindhe, J. (2005) Bone reactions to longstanding functional load at implants: an experimental study in dogs. *Journal of Clinical Periodontology* **32**: 925–932.
- Berglundh, T., Persson, L. & Klinge, B. (2002) A systematic review of the incidence of biological and technical complications in implant dentistry reported in prospective longitudinal studies of at least 5 years. *Journal of Clinical Periodontology* **29** (Suppl 3): 197–212.
- Büchter, A., Kleinheinz, J., Wiesmann, H.P., Kerken, J., Nienkemper, M., Weythorher, H., Joos, U. & Meyer, U. (2005) Biological and biomechanical evaluation of bone remodelling and implant stability after using an osteotome technique. *Clinical Oral Implants Research* **16**: 1–8.
- Buser, D., Mericske-Stern, R., Bernard, J.P., Behneke, A., Behneke, N., Hirt, H.P., Belsler, U.C. & Lang, N.P. (1997) Long-term evaluation of non-submerged ITI implants. Part 1: 8-year life table analysis of a prospective multi-center study with 2359 implants. *Clinical Oral Implants Research* **8**: 161–172.
- Calandriello, R., Tomatis, M. & Rangert, B. (2003a) Immediate functional loading of Branemark System implants with enhanced initial stability: a prospective 1- to 2-year clinical and radiographic study. *Clinical Implant Dentistry & Related Research* **5** (Suppl 1): 10–20.
- Calandriello, R., Tomatis, M., Vallone, R., Rangert, B. & Gottlow, J. (2003b) Immediate occlusal loading of single lower molars using Branemark System Wide-Platform TiUnite implants: an interim report of a prospective open-ended clinical multicenter study. *Clinical Implant Dentistry & Related Research* **5** (Suppl 1): 74–80.
- Cannizzaro, G. & Leone, M. (2003) Restoration of partially edentulous patients using dental implants with a microtextured surface: a prospective comparison of delayed and immediate full occlusal loading. *International Journal Oral & Maxillofacial Implants* **18**: 512–522.
- Chaushu, G., Chaushu, S., Tzohar, A. & Dayan, D. (2001) Immediate loading of single-tooth implants: immediate versus non-immediate implantation. A clinical report. *International Journal Oral & Maxillofacial Implants* **16**: 267–272.
- Cochran, D.L., Morton, D. & Weber, H.P. (2004) Consensus statements and recommended clinical procedures regarding loading protocols for endosseous dental implants. *International Journal Oral & Maxillofacial Implants* **19** (Suppl 1): 109–113.
- Cooper, L., Felton, D.A., Kugelberg, C.F., Ellner, S., Chaffee, N., Molina, A.L., Moriarty, J.D., Paquette, D. & Palmqvist, U. (2001) A multicenter 12-month evaluation of single-tooth implants restored 3 weeks after 1-stage surgery. *International Journal Oral & Maxillofacial Implants* **16**: 182–192.
- Drago, C.J. & Lazzara, R.J. (2004) Immediate provisional restoration of Osseotite implants: a clinical report of 18-month results. *International Journal Oral & Maxillofacial Implants* **19**: 534–541.
- Ericsson, I., Nilson, H., Lindh, T., Nilner, K. & Randow, K. (2000) Immediate functional loading of Branemark single tooth implants. An 18-months' clinical pilot follow-up study. *Clinical Oral Implants Research* **11**: 26–33.
- Glauser, R., Lundgren, A.K., Gottlow, J., Sennerby, L., Portmann, M., Ruhstaller, P. & Hammerle, C.H. (2003) Immediate occlusal loading of Branemark TiUnite implants placed predominantly in soft bone: 1-year results of a prospective clinical study. *Clinical Implant Dentistry & Related Research* **5** (Suppl 1): 47–56.
- Glauser, R., Ruhstaller, P., Windisch, S., Zembic, A., Lundgren, A., Gottlow, J. & Hammerle, C.H. (2005) Immediate occlusal loading of Branemark System TiUnite implants placed predominantly in soft bone: 4-year results of a prospective clinical study. *Clinical Implant Dentistry & Related Research* **7** (Suppl 1): S52–S59.
- Henry, P.J., Laney, W.R., Jemt, T., Harris, D., Krogh, P.H., Polizzi, G., Zarb, G.A. & Herrmann, I. (1996) Osseointegrated implants for single-tooth replacement: a prospective 5-year multicenter study. *International Journal Oral & Maxillofacial Implants* **11**: 450–455.
- Horowitz, R.A. (1997) The use of osteotomes for sinus augmentation at the time of implant placement. *Compendium Continuing Education in Dentistry* **18**: 441–447, 442–450; quiz 454.
- Jemt, T., Lekholm, U. & Gröndahl, K. (1990) 3-year followup study of early single implant restorations ad modum Branemark. *International Journal of Periodontics & Restorative Dentistry* **10**: 340–349.
- Jo, H.Y., Hobo, P.K. & Hobo, S. (2001) Freestanding and multiunit immediate loading of the expandable implant: an up-to-40-month prospective survival study. *Journal of Prosthetic Dentistry* **85**: 148–155.
- Lindeboom, J.A., Frenken, J.W., Dubois, L., Frank, M., Abbink, I. & Kroon, F.H. (2006) Immediate loading versus immediate provisionalization of maxillary single-tooth replacements: a prospective randomized study with BioComp implants. *Journal of Maxillofacial Surgery* **64**: 936–942.
- Malo, P., Friberg, B., Polizzi, G., Gualini, F., Vighagen, T. & Rangert, B. (2003) Immediate and early function of Branemark System implants placed in the esthetic zone: a 1-year prospective clinical multicenter study. *Clinical Implant Dentistry & Related Research* **5** (Suppl 1): 37–46.
- Nkenke, E., Kloss, F., Wiltfang, J., Schultze-Mosgau, S., Radespiel-Troger, M., Loos, K. & Neukam, F.W. (2002) Histomorphometric and fluorescence microscopic analysis of bone remodelling after installation of implants using an osteotome technique. *Clinical Oral Implants Research* **13**: 595–602.
- Nkenke, E., Lehner, B., Fenner, M., Roman, F.S., Thams, U., Neukam, F.W. & Radespiel-Troger, M. (2005) Immediate versus delayed loading of dental implants in the maxillae of minipigs: follow-up of implant stability and implant failures. *International Journal Oral & Maxillofacial Implants* **20**: 39–47.
- Norton, M.R. (1998) Marginal bone levels at single tooth implants with a conical fixture design. The influence of surface macro- and microstructure. *Clinical Oral Implants Research* **9**: 91–99.
- Norton, M.R. (2004) A short-term clinical evaluation of immediately restored maxillary TiOblast single-tooth implants. *International Journal Oral & Maxillofacial Implants* **19**: 274–281.
- Otoni, J.M., Oliveira, Z.F., Mansini, R. & Cabral, A.M. (2005) Correlation between placement torque and survival of single-tooth implants. *International Journal Oral & Maxillofacial Implants* **20**: 769–776.
- Palmer, R.M., Palmer, P.J. & Smith, B.J. (2000) A 5-year prospective study of Astra single tooth implants. *Clinical Oral Implants Research* **11**: 179–182.
- Proussaefs, P., Kan, J., Lozada, J., Kleinman, A. & Famos, A. (2002) Effects of immediate loading with threaded hydroxyapatite-coated root-form implants on single premolar replacements: a pre-

- liminary report. *International Journal Oral & Maxillofacial Implants* **17**: 567–572.
- Puchades-Roman, L., Palmer, R.M., Palmer, P.J., Howe, L.C., Ide, M. & Wilson, R.F. (2000) A clinical, radiographic, and microbiologic comparison of Astra Tech and Branemark single tooth implants. *Clinical Implant Dentistry & Related Research* **2**: 78–84.
- Rocci, A., Martignoni, M. & Gottlow, J. (2003) Immediate loading in the maxilla using flapless surgery, implants placed in predetermined positions, and prefabricated provisional restorations: a retrospective 3-year clinical study. *Clinical Implant Dentistry & Related Research* **5** (Suppl 1): 29–36.
- Rosen, P.S., Summers, R., Mellado, J.R., Salkin, L.M., Shanaman, R.H., Marks, M.H. & Fugazzotto, P.A. (1999) The bone-added osteotome sinus floor elevation technique: multicenter retrospective report of consecutively treated patients. *International Journal Oral & Maxillofacial Implants* **14**: 853–858.
- Shalabi, M.M., Manders, P., Mulder, J., Jansen, J.A. & Creugers, N.H. (2007) A meta-analysis of clinical studies to estimate the 4.5-year survival rate of implants placed with the osteotome technique. *International Journal Oral & Maxillofacial Implants* **22**: 110–116.
- Summers, R.B. (1994a) A new concept in maxillary implant surgery: the osteotome technique. *Compendium* **15**: 152, 154–156, 158 passim; quiz 162.
- Summers, R.B. (1994b) The osteotome technique: part 2—the ridge expansion osteotomy (REO) procedure. *Compendium* **15**: 422, 424, 426, passim; quiz 436.
- Summers, R.B. (1995) The osteotome technique: part 4—future site development. *Compendium Continuing Education in Dentistry* **16**: 1080, 1092 passim; quiz 1099.
- Summers, R.B. (1998) Sinus floor elevation with osteotomes. *Journal of Esthetic Dentistry* **10**: 164–171.
- Wennstrom, J.L., Ekestubbe, A., Grondahl, K., Karlsson, S. & Lindhe, J. (2005) Implant-supported single-tooth restorations: a 5-year prospective study. *Journal of Clinical Periodontology* **32**: 567–574.
- Zitzmann, N.U. & Scharer, P. (1998) Sinus elevation procedures in the resorbed posterior maxilla. Comparison of the crestal and lateral approaches. *Oral Surgery Oral Medicine Oral Pathology Oral Radiology & Endodontics* **85**: 8–17.