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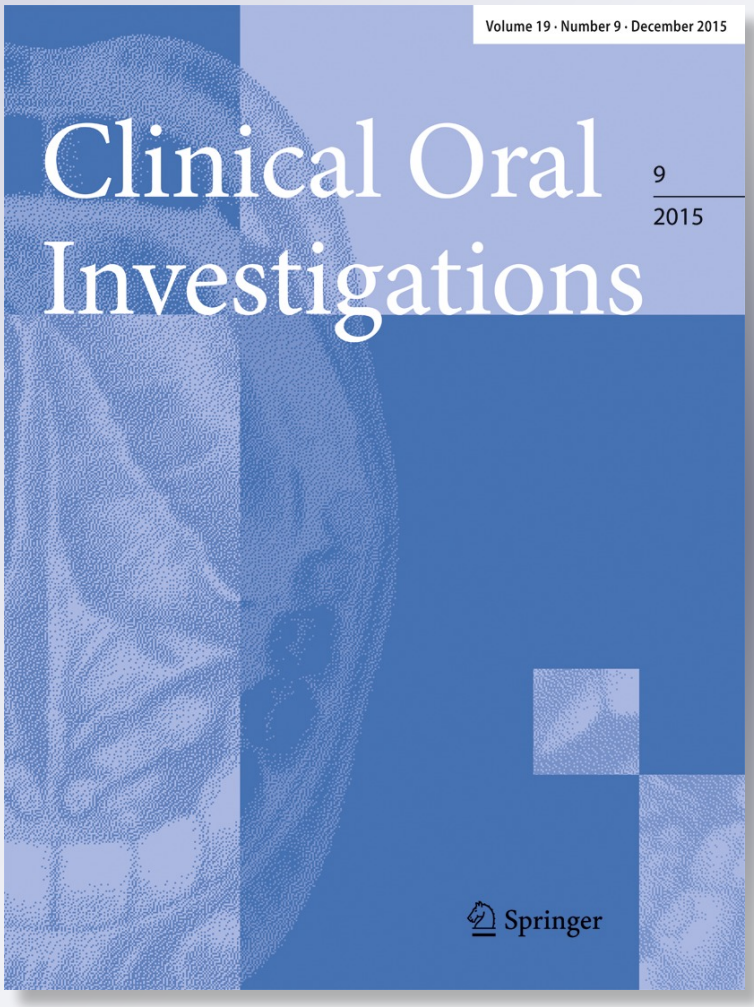

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ORIGINAL ARTICLE

Platform switching vs standard implants in partially edentulous patients using the Dental Tech Implant System: clinical and radiological results from a prospective multicenter study

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Abstract
Objectives The main objective of this study was to evaluate clinical and radiographic outcomes of implant-supported fixed partial prostheses, comparing platform switching and standard platform concepts.
Materials and methods Patients with single or multiple partial edentulism were included in this prospective multicenter study. Success rate, as well as crestal bone loss and occurrence of complications were evaluated over time, for a minimum of 3 years after prosthesis delivery. Radiographic and clinical examination served to evaluate implant and prosthesis conditions.
Results A total of 51 patients with 117 implants (55 in the centralized platform group and 62 in the standard platform group) were considered in the analysis. After 3 years of loading, the cumulative implant survival in test group was 90.3 %, while in the control group, it was 96.5 % without any statistically significant difference. After 3 years of function, the bone loss was 0.33±0.19 mm in the test group and 0.48±0.26 mm, revealing a significant difference.
Conclusions Platform switching concept may lead to a reduction of marginal bone loss over time if compared to standardized one. Such effect seemed not to be related to a reduction of overall success rate of the treatment.
Clinical relevance Platform switching could be a viable prosthetic option for implant treatment of partial edentulism.

Keywords Dental implant · Bone resorption · Bone loss · Platform switching

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Introduction

The use of osseointegrated implants is considered an effective and reliable technique for the treatment of partial and complete edentulism. The excellent long-term success rate of implant therapy is supported by a number of experimental and clinical evidence.

The crestal bone level around implants has long been considered one of the most important factors for evaluating implant success [1]. Apical shifting of such level up to 1.5 mm respect to the implant-abutment junction (IAJ) has been commonly observed after 1 year of prosthesis delivery and is considered one of the criteria for successful implants. Such value, however, is dependent upon the location of the IAJ relative to bony crest at placement [2, 3]. The remodelling of crestal bone that takes place after transgingival abutment installation has been recently addressed by modification of the implant design. Several theories have been proposed for explaining such phenomenon, which could be related to stress concentration at the coronal region of the implant or being a result of localized inflammation within the soft tissue located at the implant-

abutment interface, which could be a consequence of the soft tissue's attempt to establish a mucosal barrier (biologic width) around the coronal portion of the implant [3, 4]. According to the biologic width hypothesis, a static colony of microorganisms exists in the implant-abutment microgap. The metabolic waste materials from these microorganisms trigger an inflammatory reaction that may hinder osteogenic activity, and within such inflammatory infiltrate zone, the crestal bone may recede. At a given distance from the microgap, the concentration of inflammatory substances decreases due to dilution in the interstitial fluids reaching a threshold level that allows osteogenic cellular activity to take place again. At this point, no further bone loss is expected to occur, in the absence of pathological events or biomechanical overload [3, 4].

Several experimental studies have shown that peri-implant mucosa must have a minimum thickness (about 3 mm) to provide adequate protection to the underlying tissues [5, 6]. The crestal bone remodelling process therefore can be seen as a biologic response to create adequate space for such biological seal around implants [5, 6].

The literature describing postrestorative crestal bone level changes apical to IAJ is based on a precise implant-abutment relationship, meaning that implant seating surface and abutment component have matching diameters. In this case, the inflammatory cell infiltrate associated with the IAJ is located at the outer edge of the IAJ in direct approximation to the crestal bone at the time of abutment connection phase [4, 5]. This may in part explain the biologic and radiographic observation of crestal bone loss around exposed and restored two-piece implants.

An assumption can be made that by moving centripetally the microgap of the IAJ, the threshold level of inflammatory substances (and consequently the crestal bone level) is moved proportionally. The placement of smaller-diameter healing and prosthetic components on implants having wider-diameter platform has been proposed recently as a means to minimize crestal bone loss around implants, by relocating the IAJ at a more distant position from the bone crest [7–12]. This "centralizing" approach, commonly known as "platform switching concept" has clinical, biological and biomechanical rationale, and early radiographical evidence showed very promising results, suggesting that such configuration can be an effective method for preserving crestal bone around the top of wide-diameter implants. This is also accompanied by positive effects on the aesthetic outcome.

The main purpose of this investigation was to evaluate in partially edentulous patients the crestal bone level changes around implants with wide, centralizing platform and compare them to matched implants with standard design. Further objectives were to assess other implant-related parameters such as implant survival, soft tissue health, aesthetic outcome and patient-related parameters such as prosthesis success and satisfaction.

Materials and methods

Study design

This was a multicenter prospective clinical study. Partially edentulous patients were rehabilitated by prostheses supported by both centralizing platform implants (test) and standard (control) implants, randomly allocated to implant sites. For patients that had to receive two or more implants, both test and control implants were assigned. For patients that had to receive one single-tooth rehabilitation, the use of either centralizing platform or standard implants was randomized.

All implants used in this study were produced by Dental Tech Srl, Misinto (Milan), Italy. They were made of grade 5 titanium (TiAl6V4) and had a cylindric, self-tapping body with sandblasted acid-etched surface (blasted wrinkled surface (BWS®)) and internal hexagon implant-abutment connection. For this study, they were available in two configurations: ImpLassic (standard platform, control implants) and ImpLassic CP (centralizing platform, test implants). Implants were available with diameter between 3.75 and 4.75 mm, equal to the external diameter of the platform, and length from 8 to 16 mm. Both implant types had a 0.3-mm-high polished coronal portion and microthreads in the implant neck. In ImpLassic CP implants, the polished coronal portion was bevelled and directed inward and upward (centralized platform) creating a circumferential gap around the IAJ. For the test implants, abutments with 3.25-mm diameter were used with fixtures of 3.75-mm diameter, and abutments of 3.50 mm were used with fixtures of 4.25 and 4.75 mm. This means that in the test group the radial mismatch between abutments and implants ranged from 0.25to 0.625 mm at platform level.

Hypothesis and sample size calculation

The main outcome for sample size calculation was radiographic peri-implant bone level change. The null hypothesis to be tested was of no difference in peri-implant bone level change between the two types of implants at 12 months. The number of cases was calculated based on the following question: how many cases are required in order to have 80 % power of detecting a difference of 20 % between the two groups at each follow-up, at a 5 % level of significance (alpha=0.05) with a single-sided test? Based on values reported in several previous studies, it was assumed a 40 % standard deviation for paired differences. The estimated sample size was n=50 implants for each group. Taking into account a drop-out rate of 20 %, a total of 60 implants were planned for each group.

Study objectives

The aim of this study was to evaluate clinically and radiographically the outcome of centralizing platform implants as compared to standard implants up to 3 years of function. In case of significant lower marginal bone loss around centralizing platform implants, the indication of using preferentially this type of implants will be clinically supported. Secondary objectives were to evaluate peri-implant tissues health, aesthetic outcomes and patients' satisfaction.

Patient's inclusion criteria

- Subjects of any race and gender older than 18 years, in good systemic health and physically able to tolerate conventional implant surgery (ASA 1-2folowing the American Society of Anesthesiologists classification).
- Partially edentulous patients or patients with hopeless teeth in need of extraction, for which a decision has been made to treat their condition with fixed implant-supported rehabilitation. In case of postextraction sites, a healing period of no less than 2 months was necessary before implant placement.

Patient's exclusion criteria

- Presence of active infection or inflammation in the areas intended for implant placement
- Presence of systemic diseases such as uncontrolled diabetes and of any bone disease or pathologies affecting bone metabolism
- Patients under therapy with bisphosphonates i.v.
- Patients irradiated in the head and neck regions within 12 month before surgery
- Pregnancy
- Inability or unwillingness to return for follow-up visits
- Inability or unwillingness to maintain a good level of oral hygiene throughout the study
- Edentulous patients that will clearly express a preference for being treated by means of rehabilitations other than those considered for this study(e.g. denture or overdenture)
- Patients submitted to immediate loading procedure (prosthesis delivered within 48–72 h of implant surgery)
- Need of using any type of bone regeneration techniques (autografts, allografts, xenografts, guided tissue regeneration with membranes, PRP or other blood derivatives, recombinant growth factors). All implants had to be placed in edentulous sites (or healed postextraction sockets), without augmenting the residual bone.
- Need of performing maxillary sinus augmentation (both lateral and crestal technique) or any other surgical procedure for increasing residual bone volume (bone height and/or width).
- Immediate implants in postextraction sockets and implants inserted earlier than 2 months of extraction were not included. Patients that received one or more immediate implants in postextraction sockets were included in the study only if they also received other implants placed according to the present inclusion criteria, and only the latter were considered for analysis.

Screening and informed consent

After diagnosis and treatment planning were formulated, the inclusion and exclusion criteria were checked and the patient's data were recorded.

Before being taken into the clinical study, each patient was informed that participation in the study was voluntary and that he/she could withdraw from the study at any time without giving reasons, and without this resulting in any disadvantage for him/her. The patient was informed by the investigator about the treatment procedures that were to be compared and the possible risks. At the same time, the nature, importance, significance, expected advantages and possible risks of the study and alternative treatments were explained to him/her. The patient was allowed sufficient time and was given the opportunity for the clarification of any open questions. In addition, the patient was handed an "Explanation for the Patient", which contained all the important information in written form. Patients that agreed to be included had to personally sign and date the consent form before the start of the study.

Randomization

Surgical sites were randomized using a 1:1 computer-generated randomized table so that each patient received a similar number of test and control implants, when possible, according to a split-mouth design.

One implant For patients in need for one single-tooth rehabilitation, the choice of using a test or a control implant was defined by centralized randomization: once the surgical intervention had been planned, the clinicians asked for the type of implant to be used directly to the sponsor that provided indications into a closed opaque envelope, according to a randomized table. Implants of proper size according to the indications of the clinicians were provided by the sponsor together with the envelope. The latter was open soon before surgery.

Two implants In case of need of two single-tooth rehabilitations or of a partial prosthesis supported by two implants, either implant types (test and control) were placed. The

allocation to implant sites was randomized and indicated in a closed opaque envelope, provided by the sponsor.

Three implants In case of need of three single-tooth rehabilitations or of a partial prosthesis supported by three implants, either implant types (test and control) were placed but the choice of using one test/two controls or two test/one control was randomly determined, as well as the allocation of test/control implants to implant sites. The information was provided by the sponsor in a closed opaque envelope.

Four implants Analogue to what indicated for two implants

One envelope was prepared for each clinical case (prosthesis). As an example, for patients rehabilitated by means of two partial prostheses supported by two implants each for a total of four implants, three envelopes were prepared, while for patients receiving one prosthesis supported by four implants, a single envelope was prepared.

The content of envelopes was based on computer-generated randomized tables that were prepared before starting the study and provided to the sponsor. The latter was contacted time-to-time by each centre and had to take care for assigning similar proportions of test and control implants to each centre.

Clinical procedures

The present study was conducted in conformity with the principles embodied in the Helsinki Declaration of 1975 for biomedical research involving human subjects, as revised in 2000 [13]. The study protocol was approved by the Review Board of the Research Centre for Oral Health of the University of Milan. The patients were recruited during an 18-month period, from April 2008 to September 2009.

Both short-span fixed bridges and single-tooth reconstructions were included in the study. Three surgeons at different clinical centres followed the same standard protocol, conforming to the manufacturer's instruction. A collegial meeting before starting the study served to define the common operative procedures.

Implant surgery was performed under local anaesthesia, according to standard clinical protocols. Implant site preparation and implant insertion was performed according to the implant manufacturer's guidelines. Centralizing platform implants were inserted with the coronal portion of the implant at the same level (mesially and/or distally) as the bone crest. During preparation of each implant site, the operator scored the density of bone as dense (type I), normal (type II–III) and soft (type IV).

Clinicians were free to leaving implants to heal in a submerged way, with flap closure and suturing after application of a cover screw or to use transmucosal one-stage implants. At the end of the surgical phase, a standardized X-ray was taken with the paralleling technique. This served as the baseline control.

Prosthesis were attached to the implants according to either early (2 months ± 1 week after surgery) or delayed (4 to 6 months after surgery) loading protocol.

At the surgical re-entry procedure, partial thickness flaps was elevated to allow access to the marginal portion of the implant sites. The healing cap was replaced with a healing abutment. Another standardized X-ray was taken at this stage. All centres standardized as much as possible on the impression procedures and the prosthetic procedures for the delivery of temporary and final restorations. The latter could be screw or cement retained. Patients were recalled for follow-up control visits as described on following sections.

Variables assessed

1. Prosthesis success: when the prosthesis can be released as planned and its function is maintained without complications, even in case of the loss of one or more implants. Prosthesis were considered as failed whether it was not possible to place it as planned or its function was compromised due to implant failure or for other reasons. In case of prosthesis failure, the case was terminated, without further controls.
2. Implant survival, based on the following criteria (1): no evidence of peri-implant radiolucency; no recurrent or persistent peri-implant infection; no complaint of pain; no complaint of neuropathies or paraesthesia; implant stability, assessed for each implant (if possible) by means of opposing instruments' pressure. As an adjunct to the survival criteria, additional criteria for implant success were also imposed. Implants were considered successful if the following conditions were met at the time of evaluation, in adjunct to those specified for survival: no crestal bone loss exceeding 1.5 mm by the end of the first year of functional loading, and no bone loss exceeding 0.2 mm/year in the subsequent years.
3. Plaque index and bleeding index: the presence or absence of plaque, independent of the amount of plaque, was recorded at implant level. The same was made for bleeding index considering positive any implant that showed spontaneous bleeding.
4. Aesthetics: gingival appearance was evaluated by means of the papilla index score (PIS) as proposed by Jemt in 1997 [14]. Four different index scores were used to assess papilla aspect: PIS = 0, no papilla and no curvature of the soft tissue contour; PIS = 1, less than half the height of the papilla in the proximal teeth and a convex curvature of the soft tissue contour; PIS = 2, at least half the height of the papilla in the proximal teeth, but not in complete harmony with the interdental papilla of the proximal teeth; and PIS

= 3, papillae able to fill the interproximal embrasure to the same level as in the proximal teeth and in complete harmony with the adjacent papillae.

5. Patient's satisfaction: once the prosthesis was finalized, the patient will compile a questionnaire for satisfaction evaluation regarding aesthetics, phonetics, ease of maintenance and functional efficiency (mastication). The scoring for each item was between 0 and 100 on a VAS scale. The same questionnaire was proposed at the 1-year evaluation and at the end of the study. Since satisfaction is measured using the patient as the unit of analysis, it cannot be related to the outcome of a specific implant type as most patients will receive either types of implants. However, this parameter is of importance to the overall evaluation of the success of implant therapy.
6. Marginal bone level change: control periapical radiographs were performed using a long-cone paralleling technique and an individual X-ray holder (bite block) to ensure reproducibility. Radiographs were taken at baseline, at the stage of prosthesis delivery, and at any subsequent follow-up visit. Radiographs taken soon after implant placement served as the baseline for evaluation of the marginal bone level change over the study period. The distance between the most coronal bone-to-implant contact and the apical portion of implant neck at both mesial and distal aspect was measured. For digital radiographs, measures were performed directly by the operator and recorded on the data collection form. In case of conventional films, the original or a copy was sent to the study monitor: each periapical radiograph was digitized at 600 dpi with a scanner (Epson Perfection Pro, Epson) and the marginal bone level assessed with a dedicated image analysis software (UTHSCSA Image Tool version 3.00 for Windows, University of Texas Health Science Center in San Antonio, TX, USA) by an independent blinded evaluator. The apical portion of implant neck was used as the reference for each measurement and the known distance between threads served for calibration. Mesial and distal values were averaged so as to have a single value for each implant.

Follow-up

No specific diet was recommended to the patients. The patients were scheduled for follow-up evaluation at 6, 12, 24, and 36 months postsurgery. At each scheduled follow-up, clinical evaluation was performed by assessing the following: plaque and bleeding indexes, gingival inflammation, implant mobility and mobility of the prosthetic structure. Standardized periapical radiographs were taken to assess proper healing and bone levels around implants as described above. Finally, patient's satisfaction was assessed. Any biological or prosthetic complication occurring throughout the study, such as numbness of the lower lip and chin, peri-implant mucositis (heavily inflamed soft tissue in the absence of bone loss), peri-implantitis (bone loss with suppuration or heavily inflamed tissues), fistulas, or fracture of the implant, of the abutment screw, of the framework, etc., was recorded any time they occur.

Statistical evaluation

Bone level changes over time intra-group and between-groups at each time point were statistically evaluated by a blinded statistician using repeated measures two-way analysis of variance (ANOVA). For patients receiving both types of implant, a single bone loss value was considered for each implant type. Such value was calculated by averaging mesial and distal values from one or more implants of the same group type inserted in the single patient. Mean bone level changes around centralizing platform and standard implants were thus compared considering the patient as the analysis unit. A probability value of $P=0.05$ was used as the significance level. The possible effect of some additional variables (e.g. submerged or non-submerged healing, cemented or screw retained abutments, early or delayed loading mode, different mismatch between implant and abutment diameter) on marginal bone loss and implant failure was investigated.

Differences in the proportion of failures at each follow-up between the two groups of implants were compared by means of the Fisher's exact test. In this case, the analysis was performed at both patient and implant level.

Life table analysis was also performed to determine the cumulative implant survival rate throughout the study. Conventional non-parametric tests were used to evaluate other variables.

In order to keep a consistent level of homogeneity among the information provided by the different centres, it was decided to leave out from the radiographic analysis regarding marginal bone level change all centres that could not be able to treat at least ten patients within the established recruitment period (20 months) and/or that did not provide the 1-year outcomes for at least 80 % of the patients treated.

Results

Fifty-one patients (26 men and 25 women) were recruited in three clinical centres from May 2008 to December 2009. Their mean age at surgery was 55.4±13.8 years (range 18–82 years). Six patients were smokers (they declared to smoke <10 cigarettes/die). Another one was a former smoker. Table 1 resumes patients' characteristics at baseline. Patients have been rehabilitated by means of 68 prostheses supported by a total of 117 implants, of which 55 CP (test) and 62 standard (control)

Table 1 Patients' characteristics

Baseline characteristics	No. (%)
No. of patients	51
males	26 (51 %)
Females	25 (49 %)
Smokers	6 (12 %)
Total implants	117
Total test implants	55 (47 %)
Test failed	5 (9 %)
Total control implants	62 (53 %)
Control failed	2 (3 %)
Bone quality	
Soft	32 (27.4 %)
Mormal	77 (65.8 %)
Dense	8 (6.8 %)
Post-extractivesites	21 (18 %)
Mean follow-up (months)	47.7
Min	37.9
Max	56.0

implants. There were 31 single-tooth rehabilitations and37 partial prostheses (Table 2). Implant distribution in maxilla and mandible is presented in Figs. 1 and 2, respectively. Twenty-one implants (17.9 %) were inserted in healed postextraction sockets (after a period of at least 3 months since extraction). Bone quality at implant insertion sites was 27.4 % soft, 65.8 % normal and 6.8 % dense. Sixty implants (51.3 % of cases, 30 tests and 30 controls) were left to heal in a submerged way (with their platform in an apical position respect to the bone crest) and 57 (48.7 %, 25 tests and 32 controls) in a non-submerged way (levelled with the bone crest). Forty-six patients achieved the 36-month follow-up. Five patients dropped out due to personal reasons.

Seven implants (five test implants in four patients and two control implants in another patient) had to be removed and were classified as failure. All these implants were successfully replaced without further complications. Table 3 lists the characteristics associated with the failed implants. Three failures (of which one single tooth) occurred during the healing phase prior to prosthesis delivery, between 2 weeks and 5 months from implant placement. The other four failures (of which one single tooth) occurred within the first year of loading. Table 4 shows the life table analysis for the overall data and for test and control implants separately. The overall cumulative implant survival up to 36 months of follow-up was 93.7 %. It was 90.3 and 96.5 % for the test and control implants, respectively. At implant level, the difference was not significant (P=0.78). Of patients, 90.2 % did not experience implant failure. Also, at patient level, no significant difference was found between test and control groups (P=0.53). Prosthesis success was 93.5 % for single-tooth and 100 % for partial prosthesis, for a total of 97.1 %.

Peri-implant bone level change was significantly lower in the test implants as compared to control at all follow-up times (P<0.0001, Fig. 3 and Table 5). Such finding was particularly evident around single crown restorations, even though the sample size in this subgroup was rather low. Regarding this parameter, a post hoc analysis of the study power yielded a value of over 80 % at the 36-month follow-up. For other parameters evaluated (cemented vs screw-retained fixation, submerged vs non-submerged healing, early vs delayed loading mode, different abutment-implant mismatch), no significant influence on marginal bone loss could be detected.

The radiographs of one representative case in test and control group are presented respectively in Figs. 4, 5 and 6, and 7, 8 and 9.

Table 6 reports the results of the clinical parameters assessment. Plaque index and bleeding index showed a trend towards increase; such trend was not different between test and control implants. PIS did not show marked changes throughout the study. No implant showed mobility at follow-up visits, and very few showed peri-implant radiolucency.

Patient satisfaction was very high with an average score of 91.2/100 for aesthetics, 91.6/100 for mastication function and 90.8/100 for phonetics at the 36-month follow-up, with 87.5 % of participant considering the result "better than expected" and the remaining 12.5 % "as expected".

Table 2 Demographics of the implants and cases

Prosthesis type (no. of implants)	Number of prosthesis	Total number of implants	Number of test implants	Number of control implants
Single	31	31	13	18
Partial (2)	27	54	26	28
Partial (3)	8	24	12	12
Partial (4)	2	8	4	4
Total	68	117	55	62

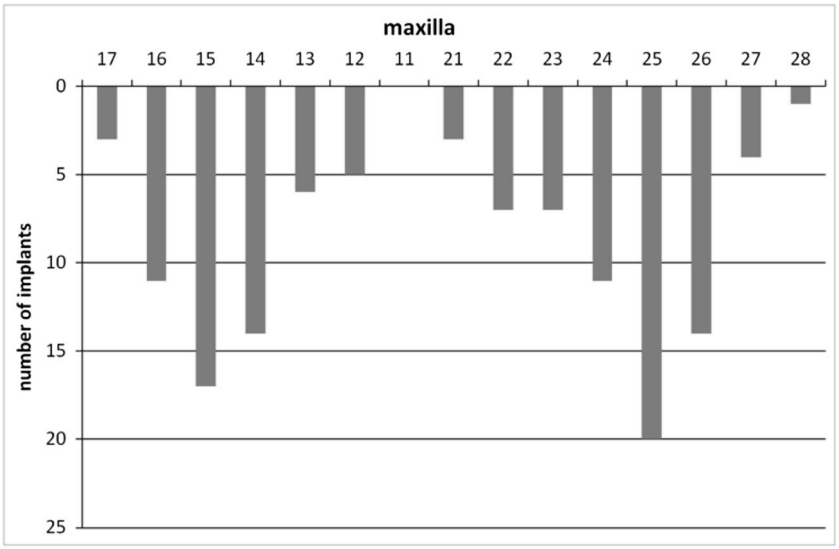

Fig. 1 Implant distribution in the maxilla

Discussion

The use of abutments with a diameter smaller than that of their corresponding implant platform (initially defined platform switching) has been introduced in the late 1990s with the main purpose of reducing peri-implant bone loss. Several modifications of the initial model have been developed by different manufacturers and launched on the dental implants market. While in the first implants adopting the platform switching concept, the platform was widened with respect to the fixture body [9], in the implants evaluated in the present study, the strategy for creating a gap between the abutment connection and the platform border is different. The platform in fact is not expanded but is bevelled and tends to centralize towards the connection with the abutment, whose diameter is reduced respect to the fixture body. In this way, no modification to the drilling procedure for implant site preparation is required.

Recent systematic reviews have analyzed the literature on the clinical and radiographic outcomes of implants adopting the platform switching concept [15, 16].

The meta-analysis by Atieh et al. [15] evaluated ten controlled studies with a total of 1239 implants. They found that the marginal bone loss around platform-switched implants was significantly lower than around platform-matched implants, while no significant difference was found regarding implant failure in the two groups.

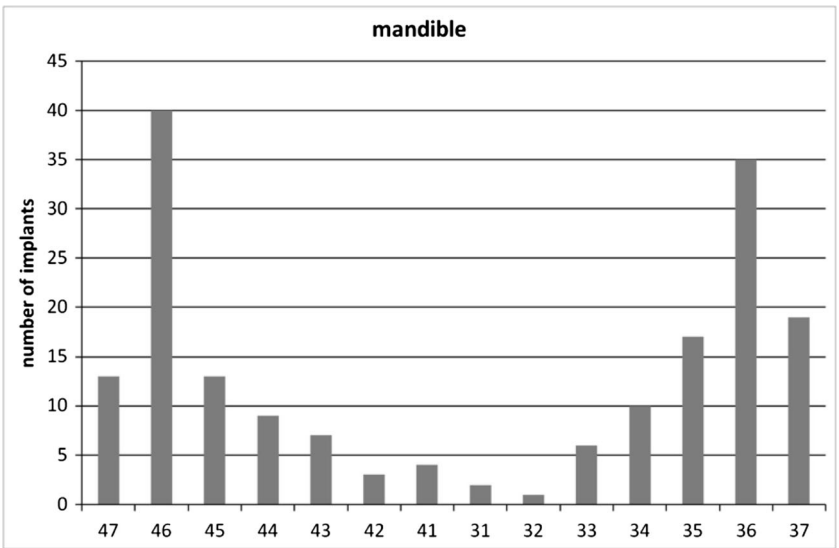

Fig. 2 Implant distribution in the mandible

Table 3 Characteristics associated with failed implants

Centre	Failure time	Implant site	Test/ control	Size (mm)	Insertion torque (N cm)	Prosthesis type	Bone quality	Patient age/ gender	Smokerpatient	Post extraction site	Surgical complications
3	2 weeks	13	Test	3.75×13	30	Single	Normal	50 years/ female	No	Yes	None
3	5 months	14	Test	3.75×11.5	40	Partial (2)	Normal	82 years/ male	No	Yes	None
3	8 months	16	Ctrl	3.75×11.5	<30	Partial (3)	Normal	64 years/ female	No	No	None
3	8 months	26	Ctrl	3.75×10	<30	Partial (3)	Normal	64 years/ female	No	No	None
3	9 months	28	Test	4.25×8	<30	Partial (3)	Soft	44 years/ male	No	No	None
3	10 months	46	Test	4.25×8	<30	Single	Normal	44 years/ male	No	No	None
5	3 weeks	13	Test	4.25×13	40	Partial (3)	Normal	62 years/ male	Yes	No	None

The review by Al-Nsour et al. [16] selected nine studies (seven randomized controlled trials and two prospective comparative studies). Seven of the nine studies demonstrated that platform switching was effective in preserving marginal bone around implants. However, no randomized studies with at least 3 years of follow-up were found and only one RCT with low risk of bias reported the results on a total of more than 100 implants [17]. No meta-analysis was conducted due to heterogeneity among studies. The review concluded that platform switching appear to be a promising tool in preserving peri-implant bone, though several factors like the depth of implant placement, implant microstructure, the extent of the difference between abutment and platform diameter, and the examination method might influence the interpretation of results.

Another systematic review of the literature confirmed that platform switching is related to a significantly lower bone loss if compared to centralized platform [18].

One recent study investigated through histomorphometric analysis the characteristics of peri-implant bone when platform switching concept was applied [19]. The authors observed a growth of novel bone in presence of platform switching that was not observed in control sites.

With regard to the amount of bone loss associated to platform switching, a number of clinical trials evaluated such parameter with results comparable to those reported in the present study [20–23].

Some authors postulated that the position of implant-abutment interface might be a fundamental factor affecting

Table 4 Life table analysis

Time (months)	No. paz	No. of implants	Test/ control	Drop-out (implant)	Failed implants	IFR (test/control) (%)	ISR (total) (%)	CSR (total) (%)	CSR (test/control) (%)
0–6	51	117	55	5	Test 3	2.6	97.4	97.4	94.5
			62	5	Control 0	0.0			100
6–12	49	104	47	3	Test 2	4.2	96.2	93.7	90.3
			57	5	Control 2	3.5			96.5
12–24	46	92	42	0	Test 0	0.0	96.2	93.7	90.3
			50	0	Control 0	0.0			96.5
24–36	46	92	42	0	Test 0	0.0	96.2	93.7	90.3
			50	1	Control 0	0.0			96.5
>36	46	91	42	0	Test 0	0.0	96.2	93.7	90.3
			49	0	Control 0	0.0			96.5

IFR implant failure rate, *ISR* implant survival rate, *CSR* cumulative survival rate

Table 5 Details of the analysis of marginal bone loss

		T-6 m	C-6 m	T-12 m	C-12 m	T-24 m	C-24 m	T-36 m	C-36 m
Overall	Mean (mm)	0.20	0.31	0.29	0.42	0.33	0.47	0.33	0.48
	SD (mm)	0.19	0.20	0.23	0.21	0.25	0.24	0.19	0.26
	N	44	48	41	46	42	42	37	38
P value (ANOVA)	T vs C	<0.0001							
Single tooth	Mean (mm)	0.09	0.27	0.13	0.38	0.14	0.44	0.18	0.53
	SD (mm)	0.04	0.15	0.05	0.17	0.05	0.19	0.05	0.31
	N	9	16	8	14	7	13	6	13
P value (ANOVA)	T vs C	<0.0001							
Partial prosthesis	Mean (mm)	0.23	0.33	0.33	0.44	0.37	0.49	0.36	0.46
	SD (mm)	0.21	0.22	0.24	0.23	0.25	0.26	0.19	0.23
	N	35	32	33	32	35	29	31	25
P value (ANOVA)	T vs C	0.0003							

T test, *C* control, *SD* standard deviation, *N* number of implants

the bone loss rate. In fact, the point of conjunction between abutment and implant neck could be a site of colonization due to the microgap between the surfaces. This can induce a local inflammatory process that can promote bone resorption [24].

With the application of platform switching concept, the implant abutment interface is positioned far from the peri-implant bone and this aspect was considered as a protective factor preventing bone resorption [9, 25]. Moreover, the presence of a wide and robust portion of soft tissue around the interface between the abutment and the implant neck was advocated to be a further factor improving peri-implant sealing and reducing the amount of bone loss [26, 27].

The beneficial effect on bone loss rate of platform switching concept were hypothesized to be also related to a biomechanical advantage that might lower the compressive stresses located at the implant-bone interface in the neck area.

Liu and coworkers in a recent finite element analysis reported that a platform-switched configuration might allow a more uniform stress distribution in the bone than a centralized one [28]. The higher amount of stress observed at the implant-abutment interface could be considered negligible, considering the mechanical characteristics of the materials used.

One biomechanical evaluation by Pessoa et al. found that the higher the difference between the diameter of abutment platform and implant neck, the higher the reduction of the stress observable in peri-implant bone, in simulated conditions [29].

A number of biomechanical studies based on finite element simulations confirmed that platform switching can significantly influence the stress on implant surrounding bone, reducing the extent of acting forces [30–34].

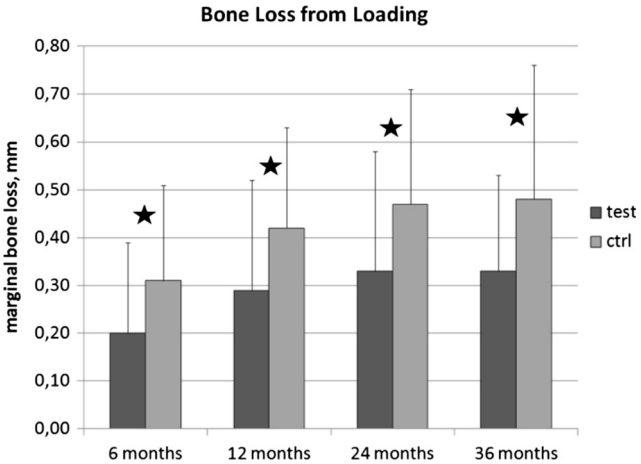

Fig. 3 Trend of bone loss in test and control implants from the loading time. The *star* indicates significant difference between test and control implants

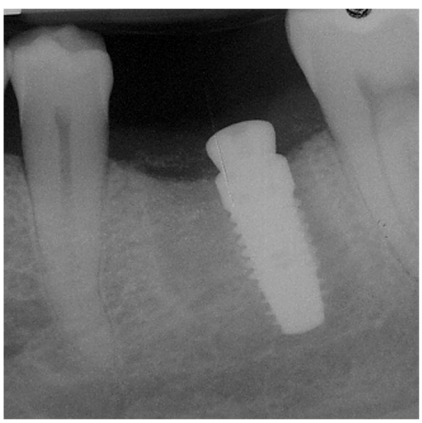

Fig. 4 A test implant of size 4.75×11.5 mm is placed in site 46 in 60-year-old male

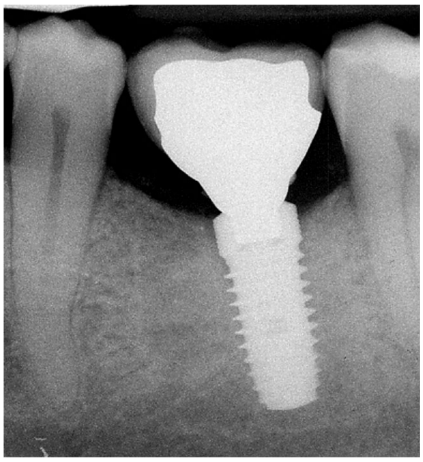

Fig. 5 One-element prosthesis is delivered 16 weeks after implant placement

The outcomes of the present randomized study, based on a sample of more than 100 implants, followed for at least 3 years of function, are in line with the results of the literature, confirming that platform switching contributes to keep low the marginal bone loss around implants, especially around single-tooth restorations. The latter aspect, however, deserves further studies since the low sample size of that subgroup (single crown) does not allow a generalization of the results. The use of implants with a switched platform therefore can be important for the restoration longevity in different prosthesis types.

Regarding the implant survival rate, a value of 90.3 % for the test implants, with five failures out of 55 implants placed, and an overall 93.7 % could seem a rather scarce result. However, one might consider that this study was designed so as to be as close as possible to the daily practice, without specific restrictions to the clinicians in the treatment choice and in the surgical procedures. Therefore, even though the implant system was the same for all centres, centre-related variability might have affected the outcomes. From Table 3, one can note that most of the failures (6 out of 7) occurred in one single centre. That private centre has adopted the present implant system for the first time. However, this does not necessarily mean that failures might be related to the inexperience of the clinician. Some of the patients treated in this centre had a critical systemic condition that might have been related to implant

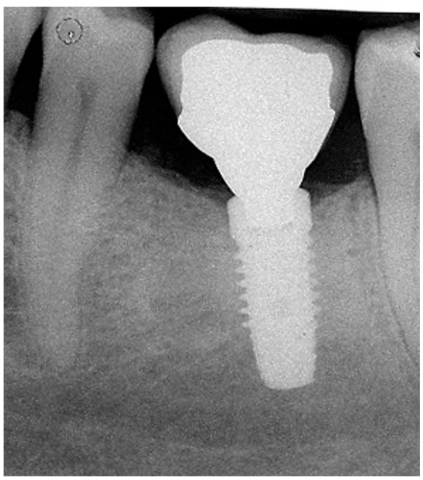

Fig. 6 Radiograph taken after 3 years of function shows very low marginal bone loss as compared to prosthesis delivery stage

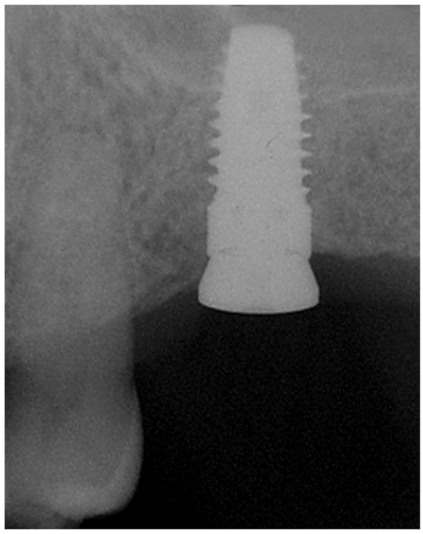

Fig. 7 A control implant of size 4.75×10 mm is placed in site 16 in 54-year-old female

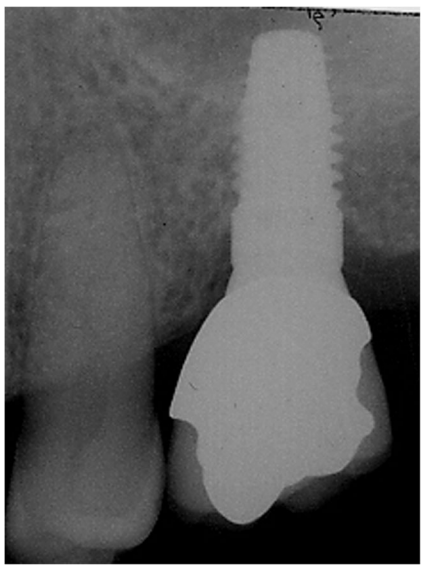

Fig. 8 One-element prosthesis is delivered 20 weeks after implant placement

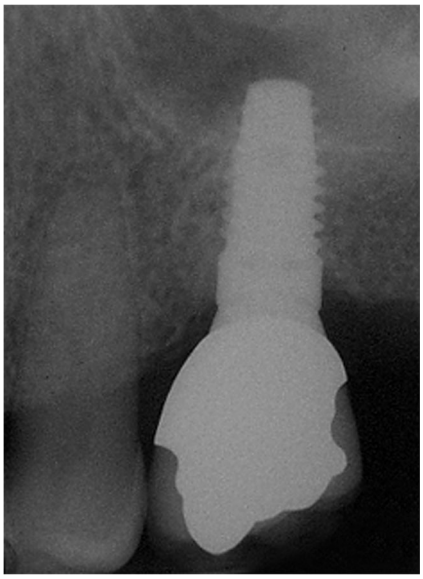

Fig. 9 Radiograph taken after 3 years of function shows a low marginal bone loss as compared to prosthesis delivery stage

failure. For example, the woman who lost two control implants (in two different partial prostheses) had been affected by breast cancer, and the man who lost two test implants in two different rehabilitations (one single tooth and one partial prosthesis) had a severe periodontal condition. Another failure of a test implant occurred in an 82-year-old woman who had been under oral bisphosphonates for osteoporosis since long. This could mean that the clinical centre experiencing most failures often had to deal with difficult cases, which increased the overall risk of failure. Since no particular restriction in patient selection criteria was placed in the present study, such risk had to be accepted. At the same time, the findings of the present study might reflect the treatment outcomes obtained in the daily practice, where clinicians have to deal with a highly heterogeneous population of patients.

Further randomized studies may help to gain more insight in some aspects of the platform switching devices that have been suggested but not completely clarified by previous studies. For example, if the use of platform switched implants may significantly contribute to decrease marginal bone loss around implants immediately placed in fresh postextraction sockets, and if the level of the platform with respect to the ridge level at placement, the implant location and angulation, or the distance between platform border and the abutment may affect the marginal bone loss in the long term.

This study confirmed that platform switching contributes to reduce the marginal bone loss around implants. Further randomized studies may help to gain more insight in some aspects of the platform switching concept, which have been suggested but not completely clarified by previous studies. For example, if the use of platform switched implants may significantly contribute to decrease marginal bone loss around implants immediately placed in fresh postextraction sockets, and if the level of the platform respect to the ridge level at placement, the implant location and angulation, or the distance between platform border and the abutment may affect the marginal bone loss in the long term.

Table 6 Evaluation of clinical parameters

		Prosthesis delivery (%)	6 months (%)	12 months (%)	24 months (%)	36 months (%)
Plaque	Yes	5.0	7.7	13.8	20.5	23.0
	No	95.0	92.3	86.3	79.5	77.0
Bleeding	Yes	5.9	0.0	1.2	9.6	19.7
	No	94.1	100.0	98.8	90.4	80.3
Inflammation	Yes	5.0	4.8	1.2	8.4	6.6
	No	95.0	95.2	98.8	91.6	93.4
Papilla index	0	48.3	50.0	64.2	65.1	59.0
	1	16.9	20.2	14.8	7.2	11.5
	2	27.0	21.2	13.6	16.9	18.0
	3	7.9	8.7	7.4	10.8	11.5
Mobility	Yes	0.0	0.0	0.0	0.0	0.0
	No	100.0	100.0	100.0	100.0	100.0
Peri-implant radiolucency	Yes	5.2	3.1	2.5	2.5	8.2
	No	94.8	96.9	97.5	97.5	91.8

All results are expressed as percentage.

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Conflict of interest Authors declare they are free from any conflict of interest. The company providing the implants (Dental Tech S.R.L.) did not interfere at all with designing and carrying out of the study, and none of the authors received any compensation for their contribution to this study.

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