According to previous studies, when an implant is exposed to the oral environment, a vertical repositioning of hard and soft tissues takes place.\(^1\) The usual amount of this peri-implant bone remodeling over time in physiologic conditions is 2 to 3 mm, depending on the patient’s smoking status, bone quality, and the implant surface and design.\(^6\) Several factors may affect this postrestorative biologic process: (1) local and systemic patient-related factors (eg, smoking habits, systemic disease, soft tissue thickness and biotype, individual bone pattern, oral microbiology); (2) implant and prosthetic factors (eg, implant micro- and macrogeometry, prosthetic material and configuration); (3) surgical factors (eg, flap design, drilling procedure, stage-two surgery technique), and (4) biologic and/or biomechanical factors (eg, biologic width reestablishment, occlusal loading). Focusing on this last group, bone resorption may be related to the reestablishment of biologic width that takes place following bacterial invasion of the implant/abutment interface.\(^7\) Although controversial, additional bone resorption seems to be related to occlusal loading, which transfers stresses along the coronal bone-implant interface.\(^8,9\) A different theory has been proposed that is not

**Objective:** This prospective randomized matched-pair controlled trial aimed to evaluate marginal bone levels and soft tissue alterations at implants restored according to the platform-switching concept with a new inward-inclined platform and compare them with external-hexagon implants.

**Materials and Methods:** Traditional external-hexagon (control group) implants and inward-inclined platform implants (test group), all with the same implant body geometry and 13 mm in length, were inserted in a standardized manner in the posterior maxillae of 40 patients. Radiographic bone levels were measured by two independent examiners after 6, 12, and 18 months of prosthetic loading. Buccal soft tissue height was measured at the time of abutment connection and 18 months later.

**Results:** After 18 months of loading, all 80 implants were clinically osseointegrated in the 40 participating patients. Radiographic evaluation showed mean bone losses of 0.5 ± 0.1 mm (range, 0.3 to 0.7 mm) and 1.6 ± 0.3 mm (range, 1.1 to 2.2 mm) for test and control implants, respectively. Soft tissue height showed a significant mean decrease of 2.4 mm in the control group, compared to 0.6 mm around the test implants.

**Conclusions:** After 18 months, significantly greater bone loss was observed at implants restored according to the conventional external-hexagon protocol compared to the platform-switching concept. In addition, decreased soft tissue height was associated with the external-hexagon implants versus the platform-switched implants.
aligned with the infection or adverse loading theories; this has been named the “compromised healing/adaptation theory,” in which failures are divided into three groups: preloading, early loading, and late loading.

Recently, published studies showed a different concept of implant-abutment connection: the platform-switching concept. The main characteristic of platform switching is the presence of a wider implant compared to the abutment selected. This configuration results in a mismatch at the implant/abutment interface, thereby moving the potentially infected interface away from the vital bone.

This concept has been investigated with different models and with implant-abutment horizontal mismatches between 0.35 and 1.0 mm, and decreased vertical bone loss compared to conventionally restored implants has been observed. Histologic analysis of platform-switched implants demonstrated less bone loss in a dog model and in humans compared to the conventional restoration protocol. The soft and hard tissue responses around platform-switched implants have also been assessed.

Additionally, a randomized controlled trial demonstrated a linear inverse correlation between implant/abutment mismatching and bone resorption. The outcome of that study demonstrated the assumption that a greater mismatch would be associated with less bone resorption. The biomechanical rationale for platform switching has also been analyzed. The platform-switching configuration, in fact, was demonstrated to shift the stress concentration away from the peri-implant bone, reducing the stress exerted on the abutment-implant interface.

There is evidence of improved bone preservation around platform-switched implants compared to the conventional design. However, a recently published pilot study with a small sample size highlighted poorer performance of platform switching when thin soft tissues were present and conventional healing/loading protocols (2 to 4 months) were followed.

In the literature, the platform-switching concept has been performed with horizontal flat or outward-inclined mismatching. However, no study has yet tested the benefits of an inward oblique mismatching. The aim of this multicenter prospective randomized controlled matched-pair trial was to evaluate the hard and soft tissue responses around a new implant concept with an inward inclined platform, which is believed to amplify the platform-switching concept, and compare them to the tissue response around an external-hexagon implant restored according to the traditional prosthetic concept. The null hypothesis was that an inward-inclined, platform-switched restoration does not benefit hard and soft tissues more than conventional prosthetic concepts.

**MATERIAL AND METHODS**

**Study Design and Patient Selection**

Between February 2007 and February 2008, patients referred to four private clinics in Rome and Piacenza, Italy, and São Paulo and Caxias do Sul, Brazil, were examined. To be included, a patient had to meet the following criteria:

- A need for a fixed implant-supported prosthesis in the posterior maxilla (from the first premolar to the second molar)
- Age at least 18 years
- No relevant medical conditions
- Nonsmoking or smoking ≤ 10 cigarettes/day (all pipe or cigar smokers were excluded)
- Full-mouth plaque score and full-mouth bleeding score ≤ 25%
- Availability for follow-up for 18 months after prosthetic loading
- Presence of a ridge wide enough to allow the insertion of a 4-mm-diameter implant according to the Brånemark protocol

Subjects with acute infections at the planned treatment sites, a need for horizontal bone regeneration, current pregnancy or lactation, or a history of bisphosphonate therapy were excluded from participation.

All patients received two adjacent implants: one with a traditional external-hexagon configuration (EH, P-I Branemark Philosophy, control group) and one with an inward-inclined platform (Amplified, P-I Branemark Philosophy, test group) (Fig 1). Both implants presented the same implant body and the same neck and were made of grade IV titanium. A hybrid geometry that featured a conical apex (with a bone-collecting chamber) and a parallel body with special threaded profiles was present. The body was 4.0 mm in diameter, with the platform opening to a final diameter of 4.3 mm, resulting in a conical coronal region. The surfaces of both implants featured nanotopographic characteristics. The semirough surface was obtained after a subtraction process by mechanical ultrasonic cleaning. Thus, differences from the two groups were restricted to the abutment connection and design.

The mesiodistal positions of the two implants (control and test) were assigned randomly according to predefined randomization tables. A balanced random permuted block approach was used to prepare the randomization tables to avoid unequal balance between the treatment groups. To reduce the chance of unfavorable splits between the test and control groups in terms of key prognostic factors, the randomization process took into account the following variables: presence of adjacent teeth, distal-extension sites, and site
location in dental arch. Assignment was performed using a sealed envelope.

The present study was performed following the principles outlined by the Declaration of Helsinki on experimentation involving human subjects. All procedures and materials in the present prospective study were approved by the local ethical committees, and all patients provided informed consent.

**Surgical and Prosthodontic Protocol**

Before the surgical procedure, full-mouth professional prophylaxis was conducted. Patients received 1 g of amoxicillin clavulanate 1 hour prior to surgery and continued with 2 g per day for 6 days. A crestal incision was performed after anesthesia had been induced (Fig 2a). When required, sinus elevation was performed, but the coronal part of all implants was always placed in at least 4 mm of native bone.

After the implant site was prepared (round and 2-mm drills at 1,500 rpm; pilot drill at 1,000 rpm; and surgical site finalization at 1,000 rpm with drills of 2.8 mm for soft bone, 3.0 mm for normal bone, and 3.3 mm for dense bone, all under abundant saline irrigation), surgeons’ assistants were asked to open the sealed envelope containing the information regarding implant positions, ie, the surgical site was prepared by the surgeon without previous knowledge of the type of implant to be placed. According to the randomization, two 13-mm-long implants (one control and one test) were inserted at the crestal level (Fig 2b).

Before implant insertion, buccolingual width of the buccal bone wall was measured using a surgical probe as the distance from the implant platform to the most external bone.

All implants were inserted with the platform at the bone level (Figs 2c and 2d). Tension-free sutures were placed with a 5.0 monofilament to prevent any early exposures of cover screws.

Patients were instructed to eat a soft diet and to avoid chewing in the treated area until the sutures were removed. Oral hygiene at the surgical site was limited to soft brushing for the first 2 weeks postsurgery. Regular brushing in the rest of the mouth and rinsing with 0.12% chlorhexidine were prescribed for 2 weeks. Thereafter, conventional brushing and flossing were permitted. After 2 weeks, the sutures were removed. Implants were allowed to undergo submerged healing.

Two to three months later, the implants were uncovered. The cover screws were exposed and removed via a crestal incision placed just over the area corresponding to the implant. Attached keratinized mucosa was present on both the palatal and buccal aspects around all implants. Subsequently, the corresponding healing abutment was inserted. After 1 week, a corresponding coping transfer was used and an impression was made.

For prosthetic restoration, in the control group, a matching-diameter abutment was used. In the test group, according to the platform-switching concept, the selected abutment resulted in a horizontal mis-
match of 0.35 mm (corresponding to a total of 0.50 mm because of the inward-inclined platform) between the implant and abutment diameters (Figs 3a and 3b).

To prevent unequal loading of the implants, the test and control implants restorations were splinted. Cemented restorations were adopted, and the margins were positioned approximately 1 mm below the soft tissue margin to ease the removal of excess cement. The crowns were luted with temporary cement (Temp Bond, KerrHawe).

**Radiographic and Clinical Assessments**

An individual customized digital film holder was fabricated for each patient to ensure reproducible radiographic analysis. At the time of the connection of the definitive abutment and crown, implant stability and soft tissue conditions were assessed. Furthermore, digital periapical standardized radiographs were obtained to ensure perfect adaptation of the abutment on the implant.

Every 6 months for 18 months after definitive restoration, clinical examinations were performed to evaluate peri-implant and periodontal parameters at implants and the neighboring (mesial and distal) teeth, respectively. Every 6 months, periapical standardized digital radiographs were also obtained to evaluate changes in marginal bone levels after loading (Digital Sensor Schick 1, Schick Technologies). Digital periapical radiographs were standardized using the previously mentioned individualized mouthpiece to ensure a consistent technique. Exposure parameters were conducted according to the manufacturer’s recommendations and standard clinical protocols (Fig 4).

A computerized measurement technique was applied to the digital periapical radiographs. Evaluation of the marginal bone level around implants was performed using image analysis software (Autocad 2006, version Z 54.10, Autodesk) that could compensate for radiographic distortion (21). The software calculated bone resorption at the mesial and distal aspects of the implants. Since each implant was inserted at the level of the bone crest, the distance was measured from the mesial and distal margins of the implant neck to the most coronal point of bone contact with the implant. For each implant, separate mesial and distal values were recorded. All measurements were made and collected by two calibrated calibrated.
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examiners who had not placed the implants. For each pair of measurements, mean values were used. Calibration of the blinded examiners was performed on triplicate measurements before the study began.

Soft Tissue Measurements
At the time of abutment connection and after 18 months of prosthetic loading, the buccal soft tissue height was measured and recorded. A modified periodontal probe, accurate to within 0.5 mm, was selected for this purpose. The probe was positioned at the margin of the platform. The distance from the platform to the gingival margin was recorded. To facilitate measurements, crowns and abutments were removed at the 18-month examination.

Statistical Analysis
To evaluate the differences in bone height between the paired control and test implants the Wilcoxon sign rank test was used. The differences in bone height with respect to implant site and the type of grafting (or no grafting performed) was calculated by the Kruskal-Wallis test. To determine the degree of association between buccal bone width and bone loss, the Pearson correlation coefficient was selected. Correlations (r) between 0 and 0.25 were considered low, those between 0.25 and 0.5 were considered fair, those between 0.5 and 0.75 were considered moderate, and those greater than 0.75 were considered strong. The significance level was set at $P < .05$.

RESULTS

A total of 63 patients presented with the anatomical conditions required for the present trial. Of these patients, 23 did not fulfill the inclusion criteria; thus, 40 patients were included. Twenty-four patients were men and 16 were women, and the average age of the participants was 58.2 years.

A total of 19 patients (38 implants) required major sinus elevation with a buccal approach. The implants were placed and the sinus membrane was elevated during the same procedure, according to the guide-
Table 1  Patient and Site-Specific Data of the Patients Enrolled in the Study

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<th>Loss (mm)</th>
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<th>Buccal bone thickness (mm)</th>
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*FDI tooth-numbering system.

Age = patient age at the time of implant insertion; site = implant site; + = mesial adjacent tooth; - = distal adjacent tooth; SD = standard deviation.
lines suggested by Wallace and Froum. Another 10 patients (20 implants) underwent minor sinus elevation with a crestal approach using osteotomes. Nanostructured hydroxyapatite was used as the only grafting material (Nanobone, Artoos).

No patients dropped out and all were followed for a period of 18 months after prosthetic loading. All implants belonging to the control and test groups were clinically osseointegrated, stable, and free of signs of infection. Table 1 displays the mean marginal bone level changes around control and test implants during the study period. For each time point evaluated (6, 12, and 18 months), bone loss around the control implants was significantly greater than around the test implants (Fig 5). At the last follow-up assessment, control implants exhibited an average of 1.63 mm of bone loss, compared to 0.49 mm for the test implants (Fig 6).

A total of 11, 29, 33, and 7 implants from both groups were placed in the first premolar, second premolar, first molar, and second molar regions, respectively. The bone loss was different around control implants depending on the implant location; more bone resorption was demonstrated at the first premolar compared to the second premolar and first molar but was similar to that seen at second molar sites. No difference was observed in control implants with respect to implant site (Fig 6). A total of 19 implants in each group was associated with sinus graft elevation from the lateral wall (major procedure) and 10 implants from each group were associated with sinus elevation by a crestal approach (minor procedure); 11 implants from each group were placed without any bone augmentation procedure. No difference in bone height was seen regardless of whether grafting (major or minor) was performed, both for control (P = .3) and for test (P = .6) implants. The buccal bone width was similar for both control and test implants, and no correlation was found between buccal bone width measured at surgery and marginal bone level alterations after 18 months in the control (r = .03, P = .81) or test (r = .13 and P = .41) groups (Fig 7).

Similar mean buccal soft tissue height (3.0 mm) was measured at the time of abutment connection around both types of implants. However, after 18 months of loading, significantly lower soft tissue height was seen around the external-hexagon implants (0.6 mm) than around the platform-switched (2.4 mm) implants.
DISCUSSION

Over a period of 18 months, the present study demonstrated that implants restored according to the "amplified" platform-switching concept experienced significantly less marginal bone loss and better soft tissue preservation compared to implants with matching implant and abutment diameters and a conventional external-hexagon configuration.

All patients enrolled in the present study received the same treatment: one implant with an external hexagon with a matching-diameter abutment and one implant with the "amplified" platform-switching configuration. To ensure that the results would be comparable, both control and test implants presented the same macroscopic and microscopic design and the same surface, varying only in the connection. Thus, the different results would seem to be related to the differences in the design of the abutment and connection.

Additionally, many factors associated with bone loss are patient related, which may influence the results of a clinical trial. A matched-pair design was therefore selected to exclude the patient as a variable. Test and control implants were placed adjacent to each other to minimize differences in bone site pattern. Moreover, to prevent variations in occlusal loading, the two implants were restored with a single two-unit prosthesis.

Additionally, it should be highlighted that, in fact, the observed differences cannot be related to soft tissue thickness, since implants were inserted in the same environment. The most extensive marginal bone level alterations were seen at the first follow-up (6 months after prosthetic loading), whereas during the 1-year observation period thereafter, minor bone loss was observed. Previous experimental and clinical studies in fact observed the most pronounced marginal bone level changes after the surgical trauma resulting from implant placement and abutment connection, whereas after functional loading, only minor signs of bone loss occurred.7,24,25 During the first year of loading, two-piece implants in particular have frequently been associated with crestal bone loss of about 1.5 to 2.0 mm.26–28 The result of the present study, in which control implants exhibited mean marginal bone loss of 1.63 mm after 18 months, are in line with these previous findings. Several explanations for these observed changes in crestal bone height have been suggested. Some authors have discussed the potential role of the microgap at the implant-abutment interface, which could act as site for bacterial colonization at the implant sulcus.22,29,30 Others described the establishment of an adequate dimension of the biologic width associated with marginal bone resorption at sites with a thin mucosa25 and in conjunction with abutment connection.31 Butt-joint connections associated with matching-diameter implant-abutment configurations have linked inflammation (an inflammatory cell infiltrate) to bone loss of 1.5 to 2.0 mm.7,32

The reasons for the observed reduced bone loss at platform-switched implants in the present study can only be speculated upon. The horizontal inward repositioning of the implant-abutment interface has been suggested to overcome some of the problems associated with two-piece implants. The platform switching may increase the distance between the gap of the implant-abutment interface (which is associated with inflammatory cell infiltrate) and the marginal bone, thereby decreasing the potential bone-resorptive effect. Also, there might be a reduction in the amount of marginal bone loss necessary to expose a minimum amount of implant surface to which the soft tissue can attach.11 These assumptions are supported by recent animal studies13,26,33 and human histologic observations.18

Clinical case series of immediate implants34,35 and prospective controlled studies have evaluated the bone responses14,36–38 as well as the soft tissue responses16 to platform-switched implants, although positive outcomes are believed to be dependent on the soft tissue biotype.22 The magnitude of the observed marginal bone level alterations varied among the studies. This may be a result of different observation periods (6 to 24 months), implant types, study populations, and radiographic analysis methods. However, compared to control implants with matching abutment-implant dimensions, these studies all demonstrated significantly less marginal bone loss as assessed on radiographs at implants restored according to the platform-switching concept.

The differences in bone loss may also be related to the different mechanics of the implant-abutment connections analyzed. In fact, the connection type exerts a significant influence on the stress distribution in bone because of different load transfer mechanisms and differences in the size of the contact area between the abutment and the implant; controversially, the stress distribution around the peri-implant area was shown to be higher in an external-hex compared to an internal-hex configuration.39–41 [AU: Do you mean that the *stresses* themselves were higher (around external vs internal hex), not the *stress distribution*? Or did you mean that the stress was distributed over a larger area in external vs internal hex? Please clarify.] Tolerance between components and a resulting instability of the connection could also affect bone resorption because of the bidirectional bacterial flow into and out of the implant-abutment interface during functional loading.42 However, the importance of this influence might be minimized by the fact that the two implants were restored with a single two-unit prosthesis in the present study.
CONCLUSION

Decreased bone loss was observed around platform-switched implants compared to traditional external-hexagon implants at three different intervals over 18 months in a matched-pair controlled trial. After 18 months, the conventional external-hexagon implants exhibited bone loss that was more than 1 mm greater than that seen around the platform-switched implants. This difference was not related to grafting procedures, and no correlation with baseline buccal bone width could be observed. Future experimental and clinical studies will help to unravel the biologic processes involved as well as establish the significance of these findings for long-term implant success. [AU: Reference #43 was not cited. Please indicate where it should be cited, or delete it.]

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