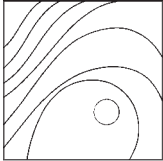


A Prospective Longitudinal Clinical Trial Evaluating the Preservation of the Peri-implant Hard and Soft Tissues



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This prospective longitudinal clinical trial aimed to evaluate the success of a bone-level implant with an integrated platform-switched connection by assessing peri-implant soft tissue and marginal bone level. Twenty-six patients were treated in two different centers with implants placed in healed partially edentulous ridges. Implant success rate and marginal bone level were evaluated with photographs, radiographs, and clinical measurements, with a 6-month postloading follow-up. The esthetic appearance of the photographed peri-implant soft tissue was evaluated at 6 months via the Pink Esthetic Score applied by two calibrated operators. All of the implants except for one placed in the mandible demonstrated successful osseointegration, resulting in a success rate of 97.8% at the 6-month follow-up. Compared to historical controls, no detectable differences in peri-implant marginal bone loss or esthetic outcome were seen.
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The rehabilitation of the masticatory function with the use of osseointegrated implants is a routine option in dental practice. The success of this treatment has been widely documented for different edentulous conditions.^{1–4}

In the last 10 years, a new generation of implants has been introduced with the main purpose of reducing the complexity of the surgical steps while maintaining or improving the final outcome and stability of the treatment. In particular, the new implant geometries seem to significantly influence and improve primary stability, and the emergence profile is designed to reduce marginal bone loss over the years in use, resulting in better clinical and esthetic outcomes.^{5,6}

Both conical/cylindrical and cylindrical implants, even when placed in fresh extraction sockets, allow proper soft and hard tissue healing to occur. With both implant types, mucosal inflammation was infrequent, marginal bone levels were maintained, and soft tissue volume increased gradually after the placement of the permanent restoration.⁷

Over time, different indices for evaluating esthetic results in implant rehabilitations have been proposed. Among these methods, the Pink Esthetic Score (PES) by Fürhauser et al⁸ has been considered a valuable method to define the different

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parameters of soft tissue outcomes and to follow them over long-term observation. PES is related to seven variables: mesial papilla, distal papilla, level of the soft tissue margins, soft tissue contour, alveolar process deficiency, soft tissue color, and soft tissue texture. A score of 0, 1, or 2 is assigned to each parameter, and all parameters were assessed by direct comparison with the natural, contralateral reference tooth, analyzing the presence of match or mismatch.

This study primarily aims to evaluate the clinical outcome of using a new implant specifically designed to obtain a high primary stability. This was done by objectively analyzing the peri-implant soft and hard tissue stability.

Materials and Methods

All clinical procedures and data analyses conducted for this prospective longitudinal clinical trial have been conducted in full accordance with ethical principles of the Declaration of Helsinki. During recruitment, all patients read, understood, and signed the informed consent for all clinical procedures and gave their written permission to anonymously have their clinical data, clinical pictures, and radiographs used.

All clinical procedures were conducted in two private clinics located in Milan (Italy) and Rome (Italy) between October 2017 and July 2019, performed by two previously calibrated operators (M.S. and G.L.).

Selection Criteria

Patients were consecutively enrolled in this study if all the following inclusion criteria were met: man or woman between 18 and 75 years of age; presence of one or more adjacent missing teeth in the anterior or posterior maxilla or mandible; and adequate bone quality and quantity at the implant site to permit the insertion of an implant (The Marc Nevins, Little Implant Co) with a 3.85-, 4.2-, or 5-mm diameter and 8-, 10-, 11.5-, 13-, or 15-mm length. Patients who demonstrated willingness to return to the clinical center for the follow-up visits were included, and written informed consents were signed.

The following systemic and local exclusion criteria for patients were observed: medical conditions requiring prolonged use of steroids or using medications that can interfere with bone metabolism; history of neoplastic disease, uncontrolled endocrine disorders, leukocyte disorders, or immunodeficiency syndromes; metabolic bone disorders or renal failure; physical handicaps that would interfere with the ability to perform adequate oral hygiene; alcoholism or drug abuse; and smoking ≥ 10 cigarettes per day or cigar equivalents.

Local exclusion criteria also included the following: any bone augmentation on the implant site done performed in the previous 2 months; local inflammation, including untreated periodontitis or other intraoral infection; mucosal diseases, such as erosive lichen planus; unhealed extraction sites (less than 6 weeks postextraction of teeth in

intended sites); and severe bruxing or clenching habits.

The following intrasurgical exclusion criteria were also applied: lack of primary stability implant at the surgery; augmentation of vertical dehiscence > 3 mm; and inability to place the implant according to the prosthetic requirements.

Clinical Procedures

Baseline demographic data were collected before implant surgery for each patient. All implant surgical procedures were performed under local anesthesia with or without conscious sedation according to the patient needs. An appropriate prophylactic antibiotic therapy (eg, 1 g amoxicillin twice a day for 3 days) was prescribed to each patient, together with the proper administration of nonsteroidal anti-inflammatory drugs (eg, 50 mg ketoprofen twice a day for 3 days) to relieve postsurgical pain. Briefly, a single crestal incision was made on the edentulous ridge, continuing to one adjacent tooth with an intrasulcular incision. A full mucoperiosteal flap was raised, and the exposed bone was prepared under abundant saline-solution irrigation using multiple drills of increasing diameter (Surgery Kit, Little Implant Company) according to the bone quality (Fig 1). Every selected implant was placed in the osteotomy without irrigation until the correct implant position was accomplished with sufficient primary stability (Fig 2). A cover screw was positioned on the implant, and submerged healing was obtained with

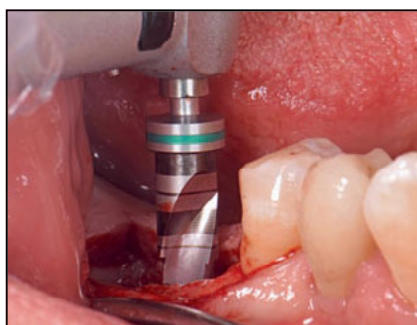


Fig 1 Preparation of the implant site with the multi-drill surgical drilling protocol.

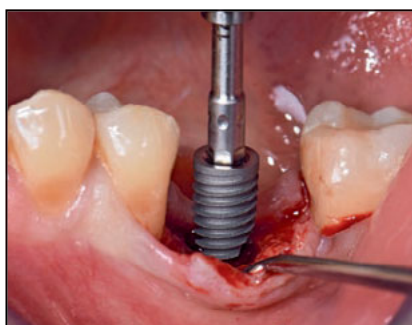


Fig 2 The implant was placed following osteotomy preparation.



Fig 3 Using a digital image, the PES was evaluated 6 months after crown delivery.

primary wound closure using Vicryl 4-0 sutures (Ethicon). Intraoperative clinical variables were recorded. The surgery was considered successful when all planned implants were placed in the correct position and achieved sufficient primary stability (at least 30 Ncm). Any adverse event was recorded.

After surgery, all patients were followed-up at 2 and 12 weeks to evaluate the soft tissue healing through the Wound Healing Index (WHI). After 12 to 16 weeks, the implants were uncovered. Under local anesthesia, a small crestal incision was performed to replace the cover screw with a proper healing screw. The mucoperiosteal flap was sutured with 4-0 silk simple sutures, which were removed after 7 days.

Three to 4 weeks after suture removal, a high-quality dental impression was taken with elastomeric material to fabricate the final restoration. In some cases, a temporary restoration was applied before the final one until complete and satisfactory soft tissue healing was achieved. After delivery of the final restoration, the baseline prosthetic data were recorded. All patients fol-

lowed specific training on personalized self-performed oral hygiene.

All patients were followed up at 3 and 6 months after crown delivery. At 6 months, clinical photographs and periapical radiographs were used to register the PES, peri-implant clinical parameters, and marginal bone loss (MBL; Figs 3 and 4). Standardized digital periapical radiographs were taken with a photostimulable phosphor plate (Vista-Scan, Dürr Dental) and a film holder (Rinn System, Dentsply Sirona), applying the parallel ray technique. All intraoral radiographs were saved as a high-resolution JPEG file and subsequently analyzed with an open-source software (ImageJ, National Institutes of Health).

Demographic and Primary Outcome Variables

The following demographic parameters were registered: age, gender, ethnicity, and smoking status. A smoker was defined as patient smoking < 10 cigarettes per day (persons smoking ≥ 10 cigarettes per day were not included in the

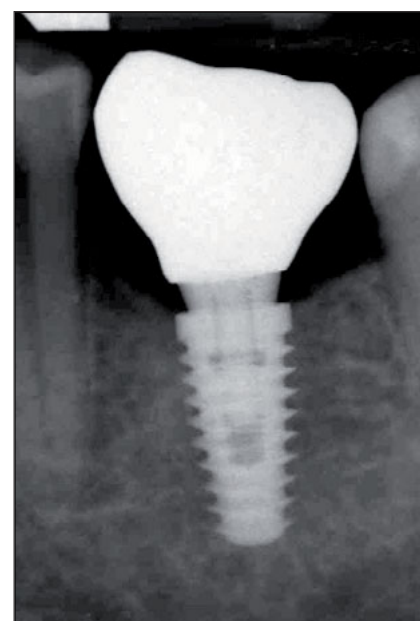


Fig 4 Radiographs were used to measure the MBL 6 months after crown delivery.

present trial). The primary outcome variables were the implant success rate and MBL.

Implant survival and success rates

The implant-supported restoration was evaluated to determine the success or survival of the given therapy. **Survival was defined as the absence of implant mobility, peri-implant radiographic radiolucency, recurrent peri-implant infection with suppuration,** and structural implant failure at the 6-month follow-up. Success was defined as a survived implant-supported restoration that did not present any biologic technical complications or patient complaint at the 6-month follow-up.

Marginal bone loss

MBL was defined as the vertical distance between the implant shoulder and the location of the first bone-to-implant contact as seen on the 6-month radiograph, assessed by a previously calibrated operator (L.F.) at the mesial and distal aspect of each target site. The known implant length was used for calibration purposes and to determine the exact magnification of the images. Measurements were rounded up to the nearest 0.01 mm.

Secondary Outcome Variables

The following secondary outcomes were analyzed: intrasurgical variables (bone fenestrations, bleeding, lack of primary implant stability, etc); number of implants placed in each patient; implant sites; implant diameter and length; diameter and

depth of the final drill used; and soft tissue healing.

The WHI⁹ evaluates soft tissue wound healing with scores from 1 (absence of gingival edema, erythema, suppuration, patient discomfort, and flap dehiscence) to 3 (poor wound healing with significant gingival edema, erythema, suppuration, patient discomfort, and **flap dehiscence, or any suppuration**).

Prosthetic outcome variables were the crown material and type of restoration (screwed vs cemented). The following peri-implant clinical outcome variables were recorded at the 6-month follow-up:

Probing depth (PD): the measurement of the peri-implant sulcus depth from the level of the peri-implant soft tissue margin.

Recession (REC): because there is no cemento-enamel junction, the abutment-crown junction was used as a measurement point to define the peri-implant mucosal recession.

All clinical PD and REC data were determined on six points per implant using a manual periodontal probe (PCP-UNC-15). All measurements were rounded up to the nearest 0.5 mm.

Esthetic outcome variables

The esthetic evaluation was based on the PES. The PES evaluates the esthetic appearance of the peri-implant soft tissue according to the following seven variables, assessed on clinical images taken at the **6-month follow-up** by two previously calibrated operators (M.S and F.L.): mesial papilla; distal papilla; level of the soft tissue margin; soft tissue contour; alveolar process de-

ficiency; soft tissue color; and soft tissue texture.

Each variable was assessed with a score ranging from 2 to 0, with 2 being the optimal esthetic outcome and 0 being the poorest one. Whenever possible, the reference tooth should be the contralateral natural tooth.

Data Analysis

All data were inserted in a digital database sheet and checked for entry errors. Qualitative variables were described as proportions, whereas quantitative variables were presented as means, SDs, and ranges. For primary outcome variables, the 95% confidence intervals (95% CIs) were reported. The implant was considered the statistical unit.

Results

A total of 26 patients (14 from the clinic located in Rome, 12 from Milan) were included in this clinical trial and received a single or multiple implant-supported restoration. The baseline demographic characteristics of the patients are summarized in Table 1.

Surgical and prosthetic outcomes are depicted in Table 2. A total of **46 implants** were placed: **2 in the anterior mandible**, 24 in the posterior mandible, and 20 in the posterior maxilla. The mean number of implants placed for each patient is 1.8, ranging from 1 to 4. All implant surgeries healed uneventfully (ie, showing a WHI score of 1) except

for one mandibular implant that showed mucosal inflammation and whose cover screw was exposed at 2 weeks of healing. At second-stage surgery, all implants demonstrated successful osseointegration and were restored with a final porcelain-fused-to-zirconia fixed restoration. Forty-three percent of the implant-supported prostheses were screw-retained.

At the 6-month radiographic examination, the mandibular implant with unpaired soft tissue healing at the 2-week follow-up showed an important radiolucency surrounding two-thirds of the implant body. Therefore, it was considered a failed implant and was excluded from further analysis.

Primary Outcome Variables

The 6-month implant survival rate was 97.8% (95% CI: 88.5% to 99.9%). No biologic or technical complication or patient complaint was reported for the 45 surviving implants, meaning that the success rate at the 6-month follow-up was the same as the survival rate (97.8%).

The primary outcome variable MBL was evaluated on the 45 surviving implants. Frequency distribution of radiographic MBL is shown in Fig 5. The mean value of MBL at the 6-month follow-up was 1.16 mm (95% CI: 0.98 to 1.34 mm). None of the implants showed a radiographic MBL ≥ 3 mm except the early failed implant.

Table 1 Baseline Patient Demographics

Patients, n	26
Mean age (range), y	57 (27–77)
Gender, n	
Male	11
Female	15
Ethnicity (Caucasian), %	100
Light smokers, n	5

Table 2 Baseline Surgical and Prosthetic Outcomes

Placed implants, n	46
Mean implants per patient (range), n	1.8 (1–4)
Implant position, n	
Anterior mandible	2
Posterior mandible	24
Posterior maxilla	20
Restoration type, n	
Screw-retained	20
Cement-retained	26

Secondary Outcome Variables

Clinical outcome variables

Regarding the clinical parameters, none of the implants showed mucosal recession at 6 months; the mean PD was 2.9 ± 0.7 mm (range: 1.7 to 4.7 mm). Figure 6 shows the frequency distribution of the peri-implant PD.

Esthetic outcome variable

The PES scores are presented in Fig 7. The mean PES score at 6 months was 11.6 (range: 7 to 14). Sixty-one percent of the implant-supported restorations showed a PES score ≥ 12 .

Discussion

It is well known that different factors influence the marginal bone changes around implants as years pass. Among these aspects, the implant design and the hard and soft tissue architecture seem to play critical roles.¹⁰

Loss of bone and soft tissue are strictly related to the stability of the esthetic outcome, which is part of the overall success of the whole implant treatment.

In the present study, implant success and survival rates were evaluated according to the original principles suggested by Albrektsson et al,⁴ revisited in 1991 by the same author.³ The parameters were

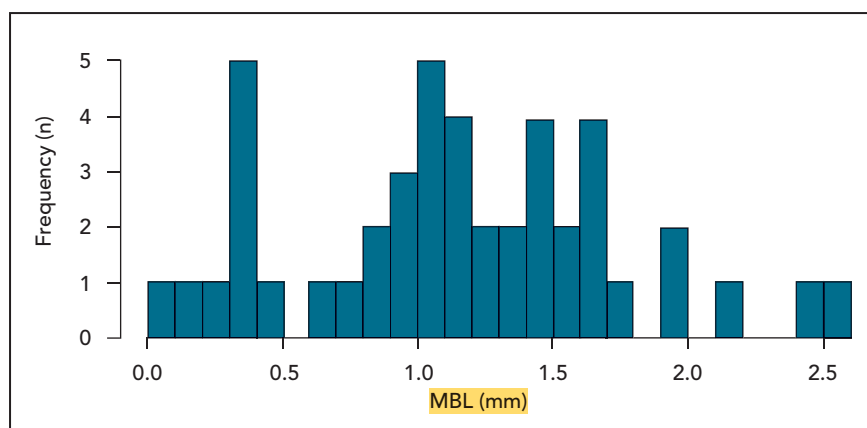


Fig 5 Frequency distribution of MBL (in mm) for the 45 surviving implants at the 6-month follow-up.

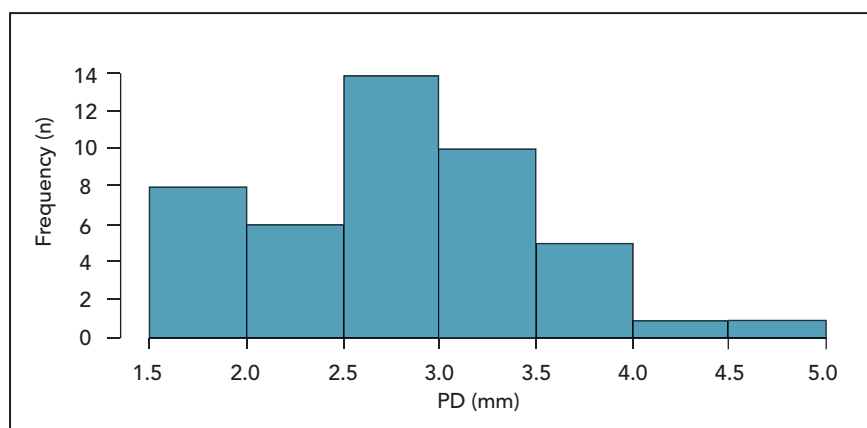


Fig 6 Frequency distribution of PD (in mm) for the 45 surviving implants at the 6-month follow-up.

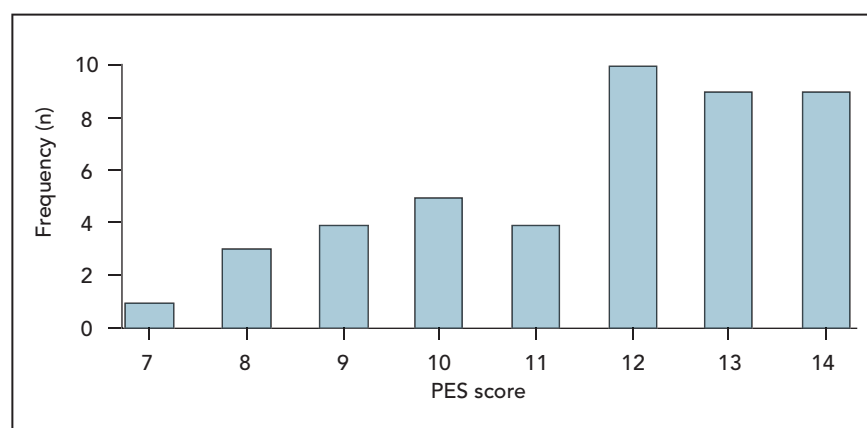


Fig 7 Frequency distribution of PES scores for the 45 surviving implant sites at the 6-month follow-up.

integrated with the esthetic analysis by the use of the PES.

The results at the 6-month evaluation showed a survival rate of 97.8%. Only one complication was reported among the 46 implants included in the study, so the success rate was also 97.8%.

These results might be related also to the surgical protocol, which includes positioning the implant 1 to 2 mm below the crestal bone level, leaving 2 mm of buccal bone. Together with the emergence profile of this particular implant, this allows new bone growth at the implant-abutment connection, creating a tighter soft tissue sealing.

In fact, an ideal implant design has high primary stability and low bone compression on the bone-implant interface.

The design of deep, squared threads influences the stress that the implant transfers to the bone during the placement procedure, achieving greater bone-to-implant contact and increasing the functional surface area in contact with bone.^{11,12} Thus, the macro- and micro-design features of an implant, particularly that of the implants used in the present study, may influence overall success.¹³ In particular, an increased taper design and sharp cutting threads help achieve high primary stability in varying bone densities.

The particular morphology of the drills used to insert this specific implant may also play a role. The sharp cutting of the multi-drills is more gentle to the bone, reducing the stress transferred during the preparation procedure. Moreover, it allows for a simplified drilling se-

quence, requiring only two drills for each implant.

The implant used in this study incorporates a platform-switched design. This design is widely recognized as a factor in the maintenance of the marginal bone over time. Canullo et al,¹⁴ analyzing implants restored with platform-switched protocol, showed better peri-implant alveolar bone-level stability and an absence of continuous soft tissue shrinkage after 10 years of prosthetic loading. Additionally, the implant-abutment connection technology appears to have a significant impact on peri-implant crestal bone levels.¹⁵

Evaluation of the peri-implant soft and hard tissue stability around the implants included in this study showed a marginal bone loss of 1.16 mm (95% CI: 0.98 to 1.34 mm) at the 6-month follow-up, which is in line with recent observations.¹⁶

No implant complications or failures were seen in the present study, including the five patients who were light smokers (< 10 cigarettes per day).

The esthetic outcomes of all 45 implants were assessed through the PES. All the cases showed quite a good result at the 6-month follow-up, as 61% of the implant-supported restorations presented a PES score > 12 (mean: 11.6).

Conclusions

Within this study's limitations of a short observation period, the clinical outcome seems to be in accordance with ones reported from the

literature. Further, compared to the historical controls, no detectable differences were seen in terms of peri-implant marginal bone loss and esthetic outcome.

Acknowledgments

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