Preliminary results of a prospective clinical study on the Friadent plus surface

A two-year follow-up

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Implant surface characteristics are widely recognized as being of fundamental importance in achieving long-term implant success. It has been suggested that implants with micro-roughened surfaces produce a more rapid bone response and more bone to implant contact. The aim of the present study was an evaluation of the clinical outcome of the new grit-blasted and high-temperature acid-etched Friadent plus surface.

Introduction

As such, extensive research has been performed in order to determine the surface texture necessary to attain an optimal bone-implant biomechanical interlock. Four interrelated properties of an implant surface affect osteogenic activity: chemical composition, surface energy, surface roughness, and surface morphology.[1,2] Osseointegration and its underlying mechanisms of cell attachment, migration, proliferation, and differentiation are sensitive to one or more of these properties.[3,4] Methods of enhancing the implant surface include alteration of the microstructure and modification of its physiochemical parameters, including surface-free energy and wettability. Data from several studies suggest that implants with microstructered surfaces produced by grit-blasting and/or acid etching lead to a more rapid bone response and/or more bone to implant contact than ones with smooth or turned surfaces.[5] Recently, a novel enhanced implant surface has been introduced obtained by grit-blasting and a new acid-etching technique at elevated temperatures (Fig. 1). Previous in vitro and animal studies, investigating this biopore structure (BPS) surface, have shown that its surface morphology, -wettability, and -energy influences a number of events in the process of osseointegration.[12-22] These study results suggest that significant advantages exist for grit-blasted and high-temperature acid-etched titanium surfaced implants. While in vitro assays allow comparisons to be made between various surface modalities, however, the primary target in implant therapy is to improve patient care with regard to function, reduction of treatment time and comfort. Human histological and histomorphometrical assays of the plus surface on the bone response around unloaded implants inserted in poor bone sites, and immediately loaded implants retrieved after 8 weeks have suggested a better success rate for patients as a result of the microstructured implant surface.[6,7] Based on the experimental results, a human clinical trial was initiated. The aim of the present study was an evaluation of the preliminary results of a two-year, prospective, multicenter trial that used 155 grit-blasted and high-temperature acid-etched Friadent plus implants placed in 77 patients.

Material and methods

In the period between July 2003 and July 2005, 77 patients (36 men, 41 women, between the ages of 17.3 to 78.7) were enrolled in this study at 10 private and university centers. Informed written consent was obtained from patients to use their data for research purposes. Subjects were screened according to the following inclusion criteria: controlled oral hygiene, the absence of any lesions in the oral cavity, and sufficient

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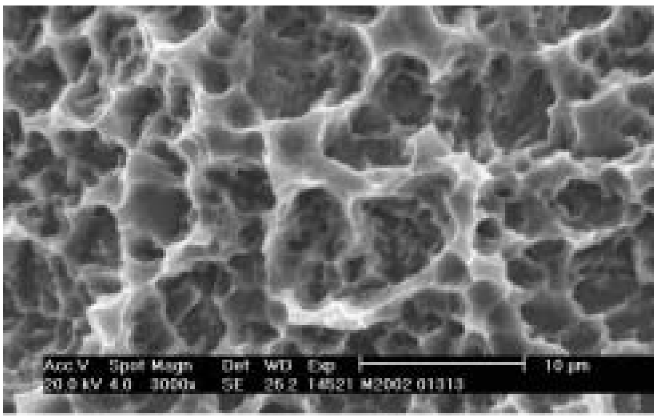
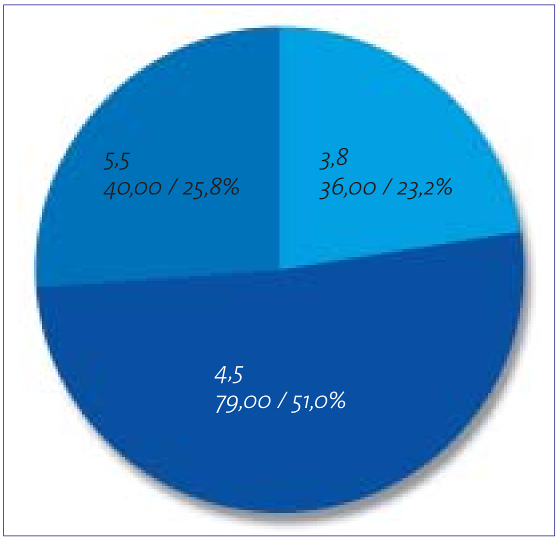
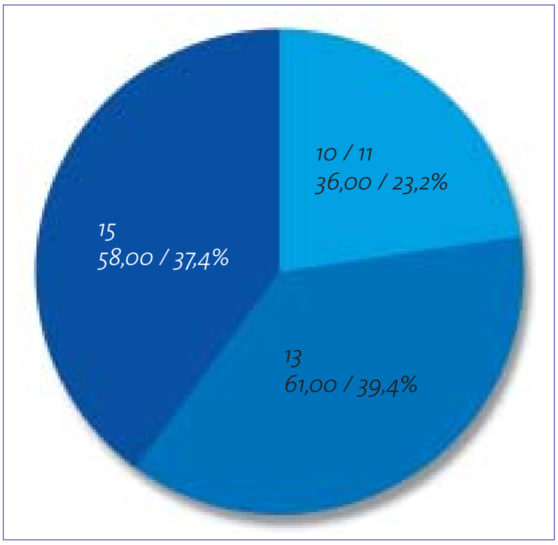


Fig. 1 REM of grit-blasted and high-temperature acid-etched Friadent plus surface. x 3000 magnification

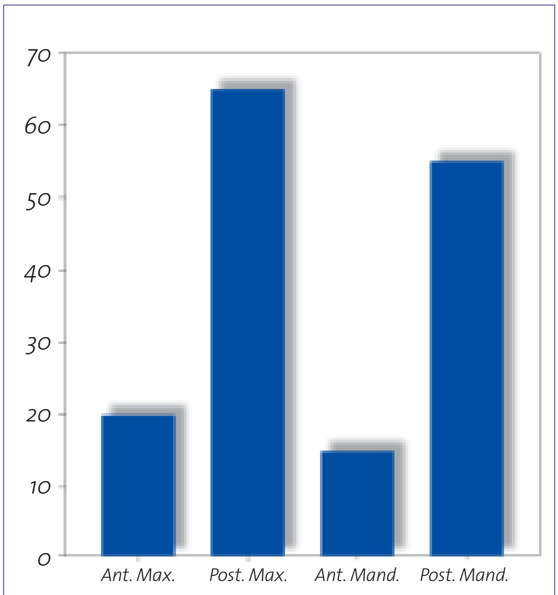
Tab. 1
Distribution
Implant
Diameter



Tab. 2
Distribution
Implant Length



Tab. 3
Localisation of
implant



residual bone volume to receive implants of at least 3.8 mm in diameter and 10 mm in length. Immediate implant loading was performed when implant insertion torque values were above 30 Ncm (26 implants). Alternatively a conventional two-stage surgical protocol with 3 to 6-month healing time was used (129 implants). In cases of insufficient bone volume, augmentation procedures were performed prior to (19 cases), and / or at the same time of implant placement (39 cases). Exclusion criteria were as follows: A high degree of bruxism or parafunction, smoking more than 20 cigarettes/day, excessive consumption of alcohol, localized radiation therapy of the oral cavity, antitumor chemotherapy, liver diseases, kidney diseases, blood diseases, immunosupressed patients, corticosteroid treatment, pregnancy, inflammatory and autoimmune diseases of the oral cavity, poor oral hygiene.

Data Collection

Prior to surgery, patients were monitored by periapical radiographs and orthopantomographs. If possible, periapical radiographs were used during follow-up. For each patient, peri-implant crestal bone levels were evaluated by calibrated examination of periapical x-rays. Measurements were recorded after surgery, at the time of re-opening, and at 12 and 24 months. They were carried out mesially and distally to each implant, calculating the distance between the edge of the implant and the most coronal point of contact between the bone and the implant. The bone level was recorded right after implant placement as reference point for the subsequent measurements. Peri-implant probing was not performed, because of the ongoing controversy regarding the correlation between probing depth and implant success rates.[14-16]

Implants

A total of 155 root-analog Friadent plus implants (DENTSPLY Friadent, Mannheim, Germany) were inserted; 36 (46.7 %) in men and 41 (53.3 %) in women. Implant diameters were distributed in the following manner: 36 (23.2 %) of 3.8 mm, 79 (51.0 %) of 4.5 mm, and 40 (25.8 %) of 5.5 mm (Table 1). Implant lengths were placed as follows: 36 (23.2 %) of 10 and 11 mm, 61 (39.4 %) of 13 mm, and 58 (37.4 %) of 15 mm (Table 2). 20 (12.9 %) were placed in the anterior maxilla, 65 (41.9 %) were placed in the posterior maxilla, 15 (9.7 %) were placed in the anterior mandible, and 55 (35.5 %) were placed in the posterior mandible (Table 3). 26 (17 %) implants were immediately loaded and 129 (83 %) were loaded delayed. In this case a submerged, two-stage technique was used.

Surgical and Prosthetic Technique

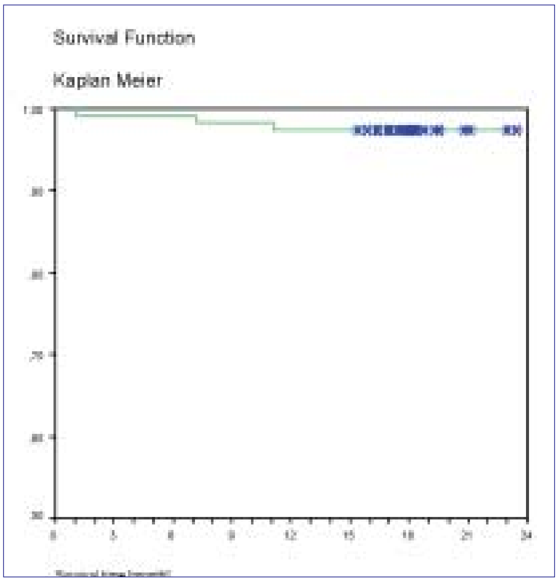
All patients underwent the same surgical protocol. Antimicrobial prophylaxis was obtained for a minimum of five days, starting one hour before surgery. Local anesthesia was induced and post-surgical analgesic treatment was performed. Oral hygiene instructions were provided to the patients. After crestal incision a mucoperiosteal flap was elevated and implant site preparation was performed according to the recommendations of the implant manufacturer. Bone quality had the following distribution: in 12 cases the bone quality was D I, in 24 cases D II, in 29 cases D III, and in 12 cases D IV. If a conventional two-stage surgical protocol was used, a fixed or removable provisional restoration, avoiding pressure on the submerged implants, was fabricated. In case of immediate loading, a temporary restoration was relined with acrylic, trimmed, polished and cemented or screw-retained at the day of implant placement. Occlusal contact was avoided in centric and lateral excursions whenever possible. After placement of the provisional restoration, a periapical radiograph was taken. In cases due for prosthetic rehabilitation, the provisional restoration was removed and an impression of the abutments were recorded. The final restoration was screw-retained or cemented. Restorative treatments included 20 single-tooth restorations (26 %), 42 short span fixed bridges (55 %), 10 full-arch reconstructions (13 %), and 5 overdentures (6 %). All patients were included in a strict recall with follow-up visits at 1, 6, 12 and 24 month examinations. All implants were evaluated for mobility, peri-implant radiolucency, gingival health, signs and symptoms of infection, neuropathies, paresthesia. Measurements of crestal bone level were recorded after surgery, at the time of re-opening, and at 12 and 24 months.

Statistical Analysis

Descriptive statistical analyses were performed by SPPS for windows 11.0. Tukey-Box plots for visualizing the development of the crestal bone level were used. Implant survival rate was calculated according to *Kaplan-Meier*.

Results

Of the 155 implants placed, a total of 152 implants osseointegrated, 3 implants failed. One implant failed after 35 days, prior to loading, and was categorized as early implant failure. One implant failed at 4 months, and one at 8 months post loading. An implant success rate of 97.37 % was achieved for a period of 24 months post placement (Table 4). The mean crestal bone loss after one year was 0.99 mm, respectively 1.16 mm after two years. While 148 implants could be recorded for crestal bone level measurements after one-year post-loading recall visit, 114 implants could be registered at the two-year recall visit. 12 implants were lost to follow-up at two-year interim evaluation, because the respective patients did not comply with the scheduled



Tab. 4

recall appointment. 29 implants could not be evaluated, since their second recall appointment was after the time of all-over data collection.

Discussion

A successful protocol for implant reconstructions are dependent upon several factors acting in concert: Beside defined surgical and prosthetic approaches, macro- and micro design of the implant is of utmost importance.

The good clinical outcome of the present study can be attributed to the use of implants with a microstructured surface.[8-10] Beside the investigated Frialit plus implants (Fig. 2 to 5), the new surface is available on Xive and Ankylos implants (all Dentsply Friadent, Mannheim,Germany). Previous studies have demonstrated that it is possible to influence the strength and extent of osseointegration by altering the micromorphologic and physiochemical properties of the implant surface structure. In vitro and animals results demonstrated that the grit-blasted and high-temperature acid-etched Friadent plus surface, correlating with increased wettability, facilitates cellular adhesion, promotes mechanical interlocking of the tissue, and increases direct bone-to-implant contact (BIC); thereby enhancing the stability of the implant-bone interface. Rapid cell attachment and spreading, as a pre-requisite for cell-division, may be important for healing and subsequent osseointegration and consequent early establishment of a bone interface. This fact is important especially for exclusion of infection and essential for the success of early and immediate-loaded implants.[11] While cell tests of Sammons et. al.[12-14] revealed significantly enhanced rates of cell spreading for the biopore structured Friadent plus surface in comparison with machined-, solely double-acid-etched-, and anodic-oxi-

Fig. 2 Immediate implant placement of Frialit plus D 5,5/L 15 mm after trauma of central incisor

Fig. 3 Provisional acrylic resin crown for initial treatment

Fig. 4 Periapical radiograph prior to final restoration

Fig. 5 Final restoration of central incisor (11) with full ceramic crown in-situ and healed peri-implant soft-tissue.

dized implant surfaces, Di Iorio et al.[15] demonstrated a correlation between surface morphology and fibrin clot extension. Increasing the complexity of the surface microtexture seems to determine the formation of a more extensive and three-dimensionally complex fibrin scaffold. These facts are considered to be dominant prerequisites for direct bone apposition.[1] A porous microstructure may enhance cell attachment and spreading, while grit-blasting may promote mechanical interlocking.[14] An animal investigation of Weinländer et al.[16] showed high rates of bone-to-implant contact (BIC) with clear traces of contact osteogenesis using fluorochrome intravital labeling. Higher removal torque values compared to solely acid-etched implants and anodic oxidized textured implants were demonstrated by the authors. These results were confirmed by Novaes et al. [17,18] placing immediate implants in periodontally infected sites of mongrel dogs. A study in mini pigs conducted by Neugebauer et al.[19] revealed no statistically significant differences with regard to BIC, peri-implant bone and bone mineralization rate for loaded and unloaded implants with the plus surface. The collagen fiber orientation after four month of loading presented a better bone quality around the immediate loaded implants. Wettability tests showed that the new surface is initially hydrophobic (contact angle 140.94°) but on second contact with water this changes to an extremely hydrophilic behavior. [20,21] This could be related to the presence of overhangs in the microstructure and the hierarchical levels of microporosity. The unique wettability characteristic has been hypothesized to lead to an advanced adhesion of non-collagenous proteins like sialoprotein and osteopontin, which are the preconditions of contact osteogenesis.[12] Changes in surface wettability properties during cell spreading could interfere with filopodial attachments and might explain the multifocal attachments and extended

appearance of osteoblasts on the Friadent plus surface. Moreover, higher amounts of fibronectin adsorbed on the plus surface may improve host responses such as osteoblast adhesion.[14] In other investigations the Friadent plus surface has been shown to enhance fibrin and SAOS-2 cell adhesion and to promote cell proliferation[22], thus demonstrating further biological consequences of the alterations in surface properties due to the differential acid etching conditions.[21] The success rate of the present clinical study is confirmed by histological and histomorphometrical results on bone response to the plus surface with high BIC values for immediately loaded and submerged implants in humans.[6,7] Degidi et al.[23] reported an implant success rate of 99.6% for a period of twelve months post placement for 802 immediately loaded and two-stage submerged implants with the plus surface.

Surface micromorphology and wettability will maintain a matter of primary interest within the research of implant micro-design.[24] Recent pre-clinical reports on the influence of a chemically modified and hydroxylated surface on the bone response, by storing the implant in an isotonic salt solution, lack the evidence of long term clinical documentation.[25,26] Caution must be exercised when these laboratory data and animal results are extrapolated to predict human clinical response.

Conclusions

The two-year interim report indicates that Friadent plus implants achieved a high rate of integration that remained stable during the course of implant function. In addition, the plus surface has provided a high level of prosthetic predictability. With an implant success rate of 97.37 % and a mean marginal bone loss of 1.16 mm after two year post-loading recall visit, the investigated implants demonstrated a predictable clinical outcome of implant-supported treatment concepts for the rehabilitation of partially and totally edentulous patients. ■

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