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Early functional loading of sandblasted and acid-etched (SLA) Straumann implants following immediate placement in maxillary extraction sockets.

Clinical and radiographic results.

Running title: Nordin et al. Loading implants placed in extraction sockets

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Title: Nordin T., Graf J., Frykholm A., Helldén L. Early functional loading of sandblasted and acid-etched (SLA) Straumann implants following immediate placement in maxillary extraction sockets. Clinical and radiographic results.

Key words: dental implant; extraction socket; early loading; primary stability; splinting; precision; passive fit; SLA surface; Cresco precision method.

Abstract:

Objectives: To present the clinical and radiographic outcome of early loading (<10days) of implants inserted into fresh extraction sockets and to present a treatment protocol for early loading of the implants by "passively fitting" abutment free permanent fixed complete dentures (implant FCD:s).

Material and Methods: The study included 19 dentate patients treatment planned for extraction of all remaining maxillary teeth. In all 116 Straumann-implants with SLA surface were placed: 77 (66%) inserted in fresh extraction sockets and 39 (34 %) in healed bone. At least 6 implants were placed in each maxilla. One hundred and ten implants were loaded by permanent FCD:s within 10 days after placements and 6 after 14 days. The patients were reexamined clinically and radiographicaly after 2–3 years of clinical function. All FCD:s were removed for control of implant stability and evaluation of the peri-implant status.

Results: Due to framework fracture 2 implants were lost corresponding to a failure rate of 2%. The radiographic measurements after 2-3 years did not reveal any difference in bone height mesial and distal of the implants placed in extraction sockets vs. in healed bone. This was **interpreted as** a bone gain around the implants placed in extraction sockets and a slight bone loss around the implants placed in healed bone.

Conclusion: Early functional loading of SLA-surfaced implants following immediate placement in maxillary extraction sockets by rigid and passively fitting permanent implant FCD:s is a reliable treatment alternative.

Introduction

Implant treatment is – especially for dentate patients who need full arch implant supported restorations – often combined with considerable discomfort, anxiety and inconvenience. The classical treatment protocol includes a healing period of several months after tooth extraction (during which a transitional denture has to be worn), the surgical placement of the implants followed by another healing period of 3-6 months. This implies almost 1 year of reduced life quality and for many individuals great psychological stress. In order to reduce these problems, loading implants early after their placement has come into focus during the last years. Thus, many experimental (for review see Nkenke et al. 2003) and clinical studies dealing with shorter healing periods before loading the implants, and even immediate loading directly after the placement, have been carried out (for review see Gapski et al. 2003; Morton et al. 2004). Based on these results it seems that there is a consensus about a success-full outcome of immediate loading of implants placed in the edentulous parasymphyseal mandible, i.e. in a normally dense bone leading to a good primary stability. Even if there are data available from several clinical studies (e.g. Tarnow et al. 1997; Fischer & Stenberg 2004; Nikellis et al. 2004; Salvi et al. 2004; Östman et al. 2005) indicating that the outcome of early loading in other parts of the jaws is good, there is still some hesitance to recommend this therapy for general use in the maxilla and the lateral mandibular regions. This is due to the “softer” and more trabecular bone in these positions, i.e. factors that might directly or indirectly influence the primary stability of the implants.

Primary (initial) implant stability and stability during the early phase of the healing period has been proposed as the key factor for further treatment success (For review see Gapski et al. 2003). A micro-movement up to 50-150 μm (For review see Szmukler-Moncler et al. 1998; 2000) appears to be tolerated without jeopardizing healing. Above this threshold level, fibrous encapsulation might prevail over osseointegration. To maintain the primary (initial) stability of implants intended to become immediately/early loaded, the common opinion is to recommend stabilizing splinting by rigid precisely fitting superstructures and to place the implants in favorable cross-arch positions. Thus, e.g. Tarnow et al. (1997) proposed a protocol that would allow immediate/early loading in the maxilla, but only for edentulous arches with cross-arch stability. Results from recently published clinical studies have however shown good results after splinting without cross-arch implant positioning (e.g. Glauser et al. 2003; Rocci et al. 2003; Nordin et al. 2004; Salvi et al. 2004).

Splinting by temporary acrylic prostheses is the most commonly used method. Even if they are reinforced by metal, they do not have the same strength and rigidity as a well-dimensioned metal framework and the precision of fit is difficult to control. This type of splinting hence increases the risk for complications. It is also likely to assume that misfit between prosthesis and supporting implants involves an increased risk for jeopardizing the essential primary stability of not yet osseointegrated implants. Therefore, the optimal splinting device seems to be a permanent metal framework/prosthesis with maximum precision of fit which can be connected to the implants very soon after insertion.

Immediate/early functional loading of implants inserted directly after tooth extraction is a treatment challenge, which involves several positive effects. In addition to the significantly reduced total treatment time, this treatment protocol includes other potential advantages such as less bone resorption, easier definition of the implant positions, and a good healing capacity of the fresh extraction site. Several experimental (for review see: Botticelli et al. 2003[a]) and clinical studies (for review see: Chen et al. 2004) have demonstrated that the immediate implant placement therapy directly after extraction might provide an osseointgration success rate similar to what has been reported for the placement of implants into ossified sites. Clinical documentation of the outcome of immediate/early functional loading of implants following direct placement in fresh extraction sockets has been lacking until the last years. Some of this documentation indicate that immediately loaded implants placed in fresh extraction sites carry a higher risk of failure compared to immediately loaded implants inserted in healed bone (Maló et al. 2000; Chaushu et al. 2001; De Bruyn & Collaert 2002). Those results contradict however results presented by others (e.g. Grunder 2001; Jo et al. 2001; Cooper et al 2002; Maló et al. 2003; Jaffin et al. 2004; Nordin et al. 2004; Bogaerde et al. 2005), who did not report any differences in implant survival rate or marginal bone loss between immediately/early loaded implants placed in healed bone and fresh extraction sockets, respectively.

The purpose of this article is to 1) present a clinical treatment protocol for immediate/early loading of dental implants and to 2) report and compare the clinical and radiographic outcome of early loading ($\leq$ 14 days) of SLA® surfaced Straumann implants (SLA: sandblasted, large grit and acid etched; Institute Straumann AG, Waldenburg, Switzerland) placed in either fresh extraction sockets or in healed bone.

Material and Methods

Patients

The 19 patients reported on in this explorative and retrospective study were the first patients who got treatment according to the clinical protocol described below (between June 2000 to March 2002). All of them had been treatment planned for extraction of their remaining maxillary teeth and they had urgently requested to get a fixed implant supported restoration in function as soon as possible after the extractions. The patients were presented a treatment protocol involving extraction of all their maxillary teeth, immediate placement of implants and then restoration by permanent implant supported fixed complete dentures (implant FCD; Simon & Yanase 2003) within < 14 days. Careful information was given that the predictability of the suggested therapy was not fully documented. The patients were also informed that the therapeutic team had long and favorable experiences of an identical treatment protocol, however with the difference that all implants were placed in healed ossified bone. All patients gave their consent to carry out the treatment according to the described protocol.

None of the patients suffered from any severe systemic disease and all accepted to have the surgical treatment done under local anesthesia. Any major bone augmentation procedure – which had been a contraindication for the treatment - was not anticipated. Seven of the patients were smokers and got therefore proper information about the potential negative effects of smoking on the outcome of the treatment. Smoking was however not an exclusion criterion for treatment.

In the choice of prosthetic restorations between a fixed “Toronto-bridge” (resin based tooth and alveolar replacement mounted on a metal framework) and a fixed metal-ceramic bridge all patients selected the less expensive “Toronto-bridge” alternative**.**

The distribution of the participants with reference to age, gender, mandibular dentition and indications for extraction is presented in Table 1. The surgeon (TN) and the prosthodontist (JG) examined all patients together. The radiographic examination included periapical- and panoramic radiographs and, if required tomography. Fig. 1 illustrates a case representative for the group.

Pre-surgical clinical/laboratory procedures (Fig.2)

Alginate impressions were taken, casts made and mounted in the articulator. The maxillary teeth were erased after which wax-up dentures were fabricated on acrylic baseplates. The baseplates were thickened in the anterior part and then hollowed out from inside to give space for the implants. Open custom impression trays were also fabricated.

Surgical treatment

Preoperatively the patients were sedated with benzodiazepam (Triazolam; Gerard Laboratories, Dublin, Ireland) and they were also given a prophylactic dose (2g) of phenoxymethylpenicillin (Kåvepenin; AstraZeneca, Södertälje, Sweden). The antibiotic treatment was continued (2g twice/day) postoperatively during a period of 5 days. The surgical procedures were carried out under local anesthesia (approximately 10 mL 2% Lidocaine with 12.5μg epinephrine; Xylocain-adrenalin™; AstraZeneca, Södertälje, Sweden).

The patients got all their remaining maxillary teeth and root rests removed, after which meticulous efforts were accomplished to eliminate all soft tissue from the extraction sockets before preparation of the implant sites. Straumann solid screw SLA-surfaced implants were then placed into some of the extraction sockets but also into feasible healed bone sites lateral of the sockets. One trained oral surgeon (TN) carried out all surgical procedures. In all, 116 implants were placed. Of those, 77 implants were inserted into extraction sockets and 39 into healed bone (Table 2). The length and dimension of the implants as well as bone quality (Lekholm & Zarb 1985) and primary stability are also presented in Table 2. All implants were placed anterior to the maxillary sinus cavity. The surgeon exploited bone apical and occasionally lateral of the extraction sockets to obtain deeper implant site preparations and better primary stability. This implies that some of the implants ended up in inclined positions. As illustrated in Fig. 3 the implants inserted into healed bone were placed according to the manufacturer's recommendations, i.e. to the border between the smooth implant neck and the rough SLA surface (SRB). However, in sites with insufficient crestal bone width, they were occasionally placed below the SRB mesially and distally in order to get the SLA surface covered with bone on the buccal and/or palatal aspects as well. The implants placed in extraction sockets were inserted to a depth where the implant platform often was in level with or occasionally even lower than the bone crest adjacent to the socket (Fig. 3). Bone harvested by the use of a suction trap (Bone Trap™; Astra Tech, Mölndal, Sweden) during the drilling preparation of the implant site was placed in the extraction sockets to fill out some of the space between implant and socket walls (Fig. 3). If the surgeon experienced that the primary stability of the implant was insufficient, the implant was removed. The intention was to place at least 6 implants in each maxilla. This could be achieved in all cases (Table 2). The surgeon estimated that all implants but 6 (Case 15) got fair to good primary stability. Before suturing the flaps, impression copings were screw-tightened to the implants in preparation for the impression (Fig.4). The patients were instructed to rinse with 0.2 % chlorhexidine gluconate (Hexident™; Ipex Medical AB, Danderyd, Sweden) for at least 1 minute twice a day for 2 weeks post-surgery.

Post-surgical clinical/laboratory procedures

In direct conjunction with the closure of the surgical procedures impressions (Impregum™, 3M ESPE Dental Ag, Seefeld, Germany) were taken by custom impression trays (See Fig 4; inset). After removal of the impression trays together with the disconnected impression copings, conical abutments ("index-abutments"; AstraTech, Mölndal, Sweden) were carefully screw-connected to the implants (Fig. 5A). The individually designed pre-prepared wax-up dentures (Fig 2) were then used as impression trays over the index-abutments (Fig. 5B). The position of the individual denture was directed of the predetermined occlusal relation to the opposite jaw. Registration paste secured this relation (Fig. 5C). After removal of the "impression denture", the index-abutments were unscrewed and replaced by conventional healing caps and the patients were dismissed.

The laboratory procedures started with conventional fabrication of master-casts. The index-abutments were screw-connected to the implant analogues (Fig. 6A) in the same way and order as in the mouth. The "dentures" were then carefully placed on top of the index-abutments. In order to get visual control that the "dentures" were correctly positioned some impression material had to be cut away. The mastercast/denture-assemblies could then be mounted in the articulator in an identical relation to the opposing dentition as in the mouth by use of the registration index (Fig. 6B). The conventional lost-wax casting technique was utilized for the fabrication of titanium frameworks. The inevitable casting-distortion of the frameworks was corrected to "passive fit" by use of the Cresco Precision method® (CP-method). By use of this technology conventional abutments (even angulated abutments) can be excluded, i.e. the FCD:s used in this retrospective study were abutment free and passively fitting to the implants. The principles for achievement of passive fit are illustrated in Fig. 7 A-F. Detailed descriptions of the CP-method have been presented elsewhere (Helldén & Dérand 1998; Helldén et al. 2005).

<u>Delivery of the implant FCD:s</u>

Eighteen of the FCD:s were screw-retained (Fig. 8) to the implants within 10 days (Range: 8-10 days). Due to illness, 1 patient did not get her restoration until 14 days after surgery. Radiographic examination of all implants was carried out before the final screw-tightening (35 Ncm). The patients were seen 2 weeks after the delivery of the FCD:s for control and thorough oral hygiene (OH) instructions**.** After 2 months the FCD:s were unscrewed for inspection and eventually minor correction of the soft tissues. In 10 cases the prostheses were relined for compensation of soft tissue shrinkage. Depending on their OH-compliance the patients were re-called on individual intervals for controls and if necessary removal of newly formed calculus.

Retrospective follow-up data collection:

The clinical and radiographic follow-up data, which are reported in this article, were collected during the period between April to October 2004. All patients had worn their FCD:s for > 24 months at the time of the follow-up examinations (Table 3). Eighteen patients attended these examinations. One patient had deceased (Table 1) i.e. the attendance rate was 95%. The examinations followed a predetermined protocol described below.

Assessments at the follow-up examination:

a) Patient satisfaction according to a VAS-scale from 1-10 (Visual Analogue Scale). The patients answered a questionnaire anonymously.
b) Review of clinical and mechanical complications (from the records) during the observation time (e.g. retention screw loosening, screw fracture, veneer fracture, framework fracture etc.).
c) Observed mechanical complications.
d) Peri-implant mucosal status after removal of the FCD was discriminated between “normal mucosa”, “minimal inflammation”, “moderate inflammation” and “severe inflammation” (Apse et al. 1991). After evaluation of the mucosal status, probing around the implants was performed to measure sulcus depths and check for infrabony defects.

e) Tests for stability of each individual implant at 35 Ncm rotational torque and by resonance frequency analysis (RFA; Meredith et al. 1996). An Ostell™ instrument (Integration Diagnostics AB, Sweden) was used for the RFA-measurements.

f) Radiographic examination (see below)

Radiographic examinations.

As described above, radiographic documentation of each individual implant was taken at the time of delivery (Day F = Function =Base line) of the FCD:s and at the follow-up examinations. Digital radiographic technique was used for the baseline examinations, while conventional periapical- and panoramic radiographs were used for the follow-up examinations. The baseline radiographs were used as a reference to the radiographs taken at the follow-up examinations (Fig. 9). A special effort was made to get a perpendicular projection towards the implant. It shall be pointed out that it was not the purpose of the radiographic examinations to depict the entire implant, as the marginal bone was the area of interest. This made it impossible - in a few extraction socket sites - to determine the bottom of the extraction socket, i.e. the bone-implant contact level (Point C; Fig. 3) as the “apical” part of the implant ended up outside the radiographs. In those cases the radiograph was recorded non-measurable.

The marginal bone level (MBL) assessed mesial and distal of the implants was recorded as the distance from a reference point (R) to the bone-implant contact level (C). The outer rim of the implant shoulder (2.8 mm from the border between the implants smooth and rough surface: SRB) was used as reference point (Figs. 3 and 10). To compensate for distortion in the radiographs due to different x-ray projection, the distance between threads 1 and 3 on each implant was measured. This value was then used to calculate the enlargement and the true distances. The average of the measured mesial and distal “true” values for each implant was used to calculate the mean MBL at “base-line” and at the follow-up examinations as well as the mean changes in MBL during the observation period for the implants placed in extraction sockets (test sites) and in ossified healed bone (control sites), respectively.

The same examiner (AF) analyzed all radiographs. The measurements from the digital radiographs were made in the VixWin PRO (Dentsply, Gendex, Milano, Italy) computer program, while the measurements from the conventional radiographs were made to the nearest one tenth of a mm using an eyepiece magnifying loupe (x 7) with a built in mm-scale. The radiographic data are presented as mean values and standard deviation (SD). Due to the skew distribution of implants placed in the various patients (Table 2) the comparisons had to be done for the whole groups, i.e. an intra-individual comparison between test- and control sites was not accomplished.

Statistical methods.

Fisher’s permutation test (Good 2000) was used to compare the radiographic measurements (distances) for the implants placed in healed bone and implants placed in extraction sockets, respectively. Fisher’s test for pair comparison was applied to analyze the change from baseline within groups. Both tests are non-parametric. All p-values were two-sided and $p < 0.05$ was considered as significant. The 95% confidence interval for the difference between “healed bone” and “extraction sockets” regarding bone loss or bone gain was calculated using the duality between tests and confidence sets.

Results

Two implants failed (1.7%) and had to be removed (Table 3). These failures were directly linked to fractures of 2 frameworks. The implants constituted the most distal supports for the frameworks. Both fractures were located between the loose implant and the next anterior implant. This made it possible to remove the failing implants together with the connected fractured part of the prostheses. The fractured surfaces of the remaining part of the prostheses were then trimmed. The patients were offered replacement of the lost implants and new FCD:s, but they did not experience the reduced extension of the prostheses as functionally or aesthetically disturbing, i.e. they accepted the situations. All remaining implants (107) were stable as tested by rotation at 35 Ncm. after removal of the FCD:s at the follow-up examinations. The resonance frequency analysis (RFA) did not reveal any difference in implant stability between implants placed in extraction sockets and in healed bone (mean 57.1 $\pm$ 4.9 vs 57.2 $\pm$ 4.5).

The over-all oral hygiene status evaluated after removal of the prostheses was judged good around 38% of the implants, fair around 38% and poor in the remaining 24%. The results from the examinations of the peri-implant mucosal status around the implants placed in healed bone and extraction sockets, respectively are presented in Table 4. The probing of the sulcus revealed depth of $\geq$ 4 mm (range 4 – 10; Average: 5.6 mm) around 9 implants. A slight suppuration could be observed around 2 implants after probing. Following debridement and improved oral hygiene these inflammatory symptoms disappeared and local surgical interventions could be avoided. The probing did not reveal any infrabony pockets.

The “mechanical” complications during the observation period are listed in Table 3. Two of the retention screws were found loose when the FCD:s were removed at the follow-up examinations. The most frequent complication was fracture (7) of resin teeth. In addition to the relining of the FCD:s done 2 months after the delivery, 3 prostheses had to be rebased due to soft tissue shrinkage

The patients expressed a very high level of treatment satisfaction (Table 5). The average satisfaction level for the 4 variables was 9.3 on a scale from 0-10.

The results from the radiographic measurements are presented in Table 6. Due to 1 patients death (7 implants), 2 implant failures and 14 not readable radiographs the assessment of MBL could not be performed for 23 implants (see Tables 2 and 6). **The mean (± SD; 95% CI) distance at base-line from the reference point (R; Fig. 3) to the point at which the bone met the surface of the implants (C) was 2.4 ± 0.9 mm for the "healed bone group" (control) and 4.0 ± 1.3 mm for the "extraction socket group"(p< 0.001). Corresponding measurements from the radiographs obtained at the follow-up examinations after 2-3 years functional loading revealed almost equal (p> 0.30) marginal bone levels (C) in relation to the reference point (R) between the groups (Table 6; Fig.10): The mean distance (R–C) for the control sites was 3.2 ± 1.1 mm and for the extraction socket sites 3.0 ± 0.6 mm. As the smooth implant neck measures 2.8 mm, this corresponds to an average distance of 0.4 and 0.2 mm below SRB, respectively. The mean bone loss was 0.8 ± 1.2 mm mesial/distal of the implants placed in healed bone (p= 0.021), while a mean bone gain of 1.0 ± 1.0 mm could be measured mesial/distal of the implants placed in extraction sockets (p< 0.001). This difference between the groups was statistically significant (p< 0.001).**

Discussion

The present clinical and radiographic retrospective follow-up study demonstrated that the described 3-visits treatment protocol makes it possible to offer patients a permanent implant supported FCD within < 10 days following extraction of their maxillary teeth and with favorable results. This implies that many patients' intense desire to reduce the number of surgical procedures and to avoid long edentulous periods with transitional dentures can be met. The results might justify the claim that the treatment outcome is predictable**.** It shall however be reminded that the reported results are coupled to the used implants with a SLA-surface and to the CP-technology for the fabrication of "passively fitting" and abutment free superstructures (Fig. 7A-F). The patient's perception of the treatment they had gone through was very positive in all aspects (Table 5). Their satisfaction with the treatment combined with the successful clinical outcome (98% implant success rate) might also justify qualifying the treatment protocol as "patient-friendly" and reliable. Furthermore, the reduced number of clinic visits in combination with the exclusion of a temporary removable denture and abutments makes also the treatment concept highly cost effective. This is mainly linked to the careful pre-surgical laboratory preliminaries, the well thought-out clinical prosthodonic procedures and the rational CP framework fabrication method. As there were virtually no exclusion criteria there are reasons to believe that the obtained results are applicable for most patients with similar clinical status and desire. It shall be reinforced that the described treatment protocol primarily is designated for patients, whose primary demand is to get fixed teeth and good function as soon as possible. For patients with high esthetic demands it is to recommend 4-8 weeks healing before placement of the implants. This increases the volume of soft tissue for flap adaptation around the implants and flap coverage if local bone augmentation is required.

The primary stability of the implant is generally considered as the most important factor for successful osseointegration (Gapski et al. 2003). It may be assumed that good stability is more critical for implants, which are loaded immediately or early after their insertion, even more so for those immediately/early loaded implants placed in fresh extraction sockets. The main focus of the present treatment protocol was to establish optimal primary stability of the implants during placement and then utilize all possible stabilizing factors to secure the obtained stability during the following phase of bone resorption adjacent to the implant surface and the later phase of bone apposition (Berglund et al 2003; Raghavendra et al. 2005). The most evident way to attain optimal initial stability is to use implants as long and wide as possible. In the present study 95 (82%) of the totally 116 inserted implants had a length/diameter of 14 x 4.1 mm (Table 2), which in healed bone constitutes more than sufficient implant/bone interface. Seventy-seven of the implants (66%; Table 2) were placed in extraction sockets, with a reduced but obviously sufficient part of the total implant surface in close contact with bone as indicated by the surgeon's estimation of no stability difference between implants placed in healed bone and in extraction sockets (Table 2). The immediate insertion of the relatively long and wide implants after tooth extraction in this study (Table 2) was possible due to the preserved height and width of the alveolar ridge. Normally, resorption of the ridge occurs after extraction resulting in reduced bone quantity for implant placement. The immediate/early placement of the implants may prevent some of this resorption.

Early splinting of the newly inserted implants by a permanent passively fitting superstructure is a significant part of the actual treatment protocol. High precision of fit reduces the potential risk for development of stresses and strains, during and after the screw connection of the superstructure to the implants, that might otherwise be transmitted to the interface between implant and bone during an early critical phase of the healing process. Therefore, all frameworks utilized in the present study were fabricated by use of the CP method (Helldén et al. 2005). This fabrication technology leads to a “passive fit” between implants and framework/prosthesis (Helldén & Dérand 1998). The fit made it possible to screw tighten/retain all prostheses in this study by 35 Ncm within 14 days after implant placement without any symptoms of pain or implant movement (Fig. 8).

Two frameworks fractured (Table 3). As a consequence 2 implants were overloaded, lost their stability and failed. The fractures and indirectly the implant failures could be related to under-dimensioned frameworks. This was explained by a compromised inter-arch space, a fact that regretfully had not been realized and consequently not compensated for during the fabrication of the frameworks. The occurred fractures reinforce the urgent recommendation to splint the implants by well dimensioned, stabile permanent metal frameworks and indirectly the statement that temporary acrylic prostheses constitute a raised risk for complications (e.g. micro-motion, fracture of prosthesis, misfit) as they do not have the same strength and rigidity as a correctly dimensioned metal framework. The occurred mechanical complications (Table 3) also point out the advantages to use screw-retained prostheses instead of cement retained for early functional loading cases. The screw retention makes it possible to remove the prosthesis for repair, checking the implant stability, relining/rebasing the prosthesis to compensate for soft tissue shrinkage etc.

The over-all oral hygiene standard among the participants was not optimal, which might explain the less favorable mucosal status around some of the implants at the follow-up examinations (Table 4). In spite of this, the healing results around the implants, evaluated from the clinical examinations and the radiographs, were predominantly good. Due to the skewed distribution of implants placed in extraction sockets and healed bone in the individual patient's jaws, it was considered not meaningful to test for any correlation's between the peri-implant mucosal data with the 2 alternatives for implant insertion. The distribution of the peri-implant mucosal status (Table 4) is more probably a function of the individual patients oral hygiene standard than related to how the implants were inserted.

When an implant is placed in an extraction socket, a part of its surface is not in contact with bone. This implies a quite different healing situation as compared to the healing at a surface with initial bone contact (Berglundh et al. 2003; Abrahamsson et al. 2004). Botticelli et al. have recently (2003[a,b], 2004[b,c]) published the results from 4 experimental studies in the dog. In these studies they created defects lateral to the implants to simulate implants placed in extraction sockets. The histological analysis disclosed that defects lateral to implants with a SLA-surface heal with proper osseointegration**.** The experimental studies were followed up by a clinical human study (Botticelli et al. 2004[a]). SLA-surface implants were placed in extraction sockets, both in the maxilla and the mandible, in a way similar to the present study. These implants were, however, not loaded. Four months later surgical re-entry procedures were performed and it could then be observed that the majority of the extraction sockets were almost completely filled out by bone. Based on these results, the authors concluded that marginal gaps following installation of SLA-surface implants into extraction sockets may predictably heal with bone formation and defect resolution. This conclusion is in agreement with clinical and histological results reported by Paolantonio et al. (2001) from a human study on immediate implantation in fresh extraction sockets. The outcome of the present study is in agreement with the above-described results and with results reported from other similar clinical studies (e.g. Grunder 2001; Jaffin et al. 2004; Nordin et al. 2004; Bogaerde 2005). These studies and also the report coming out from a recent consensus meeting (Chen et al.

2004; Hämmerle et al. 2004) seem to support a "bone gain" interpretation of the measurements from the radiographs in the present study (Table 6).

An extraction socket is normally asymmetric with a wider distance between the buccal and the lingual wall than between the mesial and distal walls (Fig. 3). Due to this asymmetry the bone-implant contact is most often located higher mesially and distally than buccally and lingually. This statement is in agreement with data reported by Botticelli et al. (2004[a]), who measured the depths of the defects around implants inserted in extraction sockets. They found that the defects buccaly and lingually of the implants were approximately 2 –3 times deeper than mesially and distally. **As a planar conventional radiograph image only give information about the bone level on the mesial and distal part of the socket, the base-line values for the test sites presented in Table 6 are therefore most probably underestimates and not representative for the widely varying circumferential contact levels**. As a consequence the bone gain values at the follow-up examinations are most likely also underestimates. The **distance from the reference point (R) as well as from the SRB to the implant-bone contact point** (C) mesial and distal of the implants – as measured from the radiographs taken 2-3 years after the insertion - did not show **any difference** (Table 6; Fig. 10) between the implants originally placed in extraction sockets (tests) as compared to the implants placed in healed bone (controls). This **indicates** the occurrence of a marginal bone loss with a simultaneous new bone formation starting from the bottom of the defect/space around the implants placed in the extraction sockets and a slight loss of marginal bone around the implants placed in healed bone (Table 6**;** Fig. 10). As no virtual vertical "infra-bony" defects could be probed around the implants it might be assumed that the "osseointegrated" implant areas circumferential around the test- and control implants also were about the same. **In spite of the described shortcomings in the use of conventional radiographs for**

measures of the bone contact levels around implants making the evidence level of the method medium to low and not confirmatory from a statistical aspect, there are still reasons from a clinical point of view to consider the present results as a relatively strong indicator of bone regeneration especially as they are supported by results from the experimental studies in dogs as well as from the clinical studies referred to above. The relatively large standard deviation observed for the bone-gain in the case of implants placed in the extraction sockets may be explained by the differences in the non-contact space lateral to the implants at base-line (Table 6). Different implant placement depths at surgery might be another explanation as new bone apposition on the smooth and concave Straumann implant neck is unlikely (Botticelli et al. 2005**). The also large standard deviations for the control implants can be explained in a similar way, as these -in the case of thin alveolar ridges – were placed deeper than to the SRB mesially and distally.**

The definitions for “immediate” and “early loading” used in this report follow the recommendations coming out from a recent consensus conference. According to the final document from that conference, “immediate loading” implies loading within 2 days after implant insertion while “early loading” implies loading within 3 months (Cochran et al. 2004). The wide time span for the “early loading” (from 48 hours to 3 months) makes the definition unspecific and vague. Therefore the “early loading” nomenclature used in this study might be misleading as all prostheses but one were delivered within 10 days. By using the simplified and rational prosthetic/laboratory method described in this paper, it is quite possible to deliver permanent abutment-free implant supported prostheses within 2 days. However, logistic aspects make it difficult (though not impossible) to keep this time frame.

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Legends.

Fig. 1 Clinical appearance of a representative case. Advanced periodontal disease.

Fig. 2 Casts mounted in the articulator. Maxillary teeth erased and replaced by a wax-up denture on acrylic base plate. The buccal part of the alveolar ridge is only partly covered by the denture.

Fig. 3 **Highly** schematic illustration of implant placed in "healed bone" (left) and in an extraction socket (right). In healed bone, the smooth-rough border of the implant (SRB) is located at the alveolar crest level. The reference point (R) for the measurements is the rim of the implant shoulder. In the extraction sockets (right), the implant is placed deeper and consequently the SRB is **lower in relation to** the alveolar crest. C marks the base of the "defect" (bone-implant contact level). The "spongy" material in the space lateral of the implant in the right picture represents harvested bone material. The inset illustrates the normal situation when a circular implant is placed into an oval extraction socket. Bone-implant contact at a higher level mesially and distally.

Fig. 4 The surgeon mounts the impression copings before suturing. Impression can be taken by use of a customized individual tray directly after flap closure (inset).

Fig 5 A After disconnection of the impression copings and removal of the tray, 4 conical "index abutments" (see inset and arrows) are screw-connected to 4 properly distributed implants. It is crucial to check by x-ray that the "index abutments" fit accurately on the implants. Healing caps on remaining 2 implants.

Fig. 5B The wax-up denture filled with impression material is placed over the index-abutments.

Fig. 5C The maxillo-mandibular relationship is secured by registration paste. After removal of the “denture” together with the registration paste, the index abutments are replaced by healing caps.

Fig. 6A Master-cast fabricated in the laboratory. The index abutments are screw-connected to the implant analogues in the same positions as in the mouth. Soft tissue masking material removed.

Fig. 6B Master-cast with wax-up denture mounted in the articulator. Note that a most of the impression material and the soft tissue mask are removed: This allows an adequate control that the “denture” rests perfectly on the abutments. A cast framework is then fabricated according to the Cresco Precision method®.

Fig. 7 A-F Schematic illustration of the Cresco Precision method® for correction of casting distortion and achieve “passive fit”.

A. Mis-fitting framework (due to casting distortion) placed on the implant analogues.
B. Master-cast and framework mounted (by plaster) in an articulator-like “fixator”, which secures the relation between the units.
C. Framework “legs” are cut in a defined horizontal plane.

D. Prefabricated “bridge supports” fitting the utilized implant brand are screw-connected to the implant analogues.

E. The “bridge supports” are then cut in the same horizontal plane as the framework “legs”.

F. Precision of fit between framework and “bridge supports”. Laser welding reassembles the surfaces. The end result is an abutment free “passively fitting framework/prosthesis. A computerized milling machine in the laboratory is utilized for the described “precisioning” procedures.

Fig. 8 Delivery and screw-tightening (35 Ncm) of the permanent passively fitting and abutment free prosthesis (FCP) to the implants (after 8 days). Note the positions of the retention-screw entrances. By use of the Cresco prosthetic method implant inclination and/or divergences between implants (see Fig. 6) can be corrected without need for angulated abutments.

Fig 9 Radiographs demonstrating status at delivery of prosthesis (upper row: April 2003) and after 33 months (lower row: Febr. 2005). The 4 anterior implants were placed in extraction sockets and the 2 most distal (1 on each side) were placed in healed bone. Marginal bone levels marked by arrows.

Fig. 10 **Highly** schematic illustration of the status around the implants after 2-3 years functional loading. The distance between the smooth/rough border (SRB) and the bone-implant contact level (C) is similar in the case of implants inserted in healed bone (left) and in extraction sockets (right). This indicates a certain bone loss in the first situation simultaneously with bone loss/bone apposition in the second (compare with Fig. 3).

Table 1. Distribution of patients with reference to age, gender, reasons for extraction of the teeth, situation in opposite jaw and reason for not follow-up attendance.

Patient	Age	Gender	Mandibular dentition	Reason for extractions	Reason for not attending follow-up examination.
1.	58	Female	Left: Natural teeth Right: Impl. FPD*	C. rel. ¶	
2.	59	Female	Impl. FCD	PD. rel.¶¶	
3.	55	Male	Natural teeth	PD. rel.	deceased
4.	57	Male	Impl.FCD**	PD. rel.	
5.	66	Male	Natural teeth	PD. rel.	
6.	77	Male	Natural teeth	C. rel.	
7.	73	Male	Natural teeth	PD. rel.	
8.	60	Male	Natural teeth	PD. rel.	
9.	58	Male	Impl.FCD	PD. rel.	
10.	65	Male	Impl.FCD	PD rel.	
11.	53	Female	FCD***	PD. rel.	
12	64	Female	Front: Natural teeth Bilat.: Impl. FPDs	C. rel.	
13.	77	Female	Impl.FCD	PD. rel.	
14.	69	Female	Front: Natural teeth Bilat.: Impl. FPDs	PD. rel.	
15.	87	Female	Impl. FCD	PD. rel.	
16.	80	Female	Impl. FCD	PD. rel.	
17.	64	Male	Impl. FCD	PD. rel.	
18.	61	Male	Impl. FCD	PD. rel.	

19.	57	Female	Natural teeth	PD. rel.

Nomenclature according to Simon & Yanase (2003):
* Impl. FPD = Implant supported Fixed Partial Denture.
** Impl. FCD = Implant supported Fixed Complete Denture
*** FCD = Fixed complete denture (tooth supported)

¶ : C. rel. = Caries related; ¶¶ : PD. rel. = Periodontal disease related.

Table 2. Number of implants placed in ossified bone and in extraction sockets, implant lengths, bone quality (Lekholm & Zarb 1985) and "primary stability". Of the totally placed 116 implants 107 had a diameter of 4.1 mm, 6 had a diameter of 3.3 and 3 a diameter of 4.8 mm.

Patient	**No. of placed implants**	**Implant lengths**				**Bone**	**Primary**	
	In ossified quality	In extraction stability		6mm bone	10mm sockets	12mm	14mm	
1.	2	5				7	3	good
2.	1	5				6	3	good
3.	1	6				7	2	good
4.	3	3				6	3	good
5.	2	4				6	2	good
6.	4	2				6	2	good
7.	3	3				6	2	good
8.	1	5		1		5	2	good
9.	2	4			1	5	2	good
10.	3	3			3	3	2	good
11.	1	5		2		4	4	fair
12.	0				6	6	4	fair
13.	2				4	6	3	good
14.	5			1	2	4	4	good
15.	2	4	1	4	1		4	poor
16.	2	4				6	2	good
17.	2	4			6		2	good

18.	1	5				6	2	good
19.	2	4				6	3	good
Total	39	77	1	7	13	95		

Table 3. Complications during "observation period".

Patient		Complications: Observation period:
1.MLA		2 retention screws
loose.		36 months
2.UA		Minor resin tooth
fractures x 3		36 months
3.ED		- Deceased
4.DP	-	
	36 months	
5.TB		Framework fracture.
		Implant failure x 1
		29 month
6.OW		- 30 month
7.FB		- 34 months
8.CL		Framework fracture
		Implant failure x 1.
		29 months
9.RH		- 28 months
10.SW		- 28 months
11.BMW		Prosthesis rebased
		28 months

12YJ Prosthesis rebased

28 months

13.ALA Minor resin tooth

fracture 28 months

14.RJ - 32

months

15.ALE - 26 months

16.BL - 28 months

17.HK - 33

months

18.AR Bruxism: Fracture of
several resin teeth. 24 months
Teeth replaced.

Prosthesis rebased.

19.AB - 29 months

Table 4. Percentage distribution of peri-implant mucosal status at the follow-up examinations. Evaluated after removal of the prostheses. Figures within parenthesis denote number (n) of implants.

Implant inserted in:	Normal mucosa	Minimal inflammation	Moderate inflammation	Severe inflammation
Healed bone	21% (8)	36% (13)	36% (13)	
Extraction sockets	10% (7)	46% (32)	43% (30)	

Table 5. Patient satisfaction level visualized on a VAS-scale (Visual Analogue Scale) from 0-10. A high value represents high satisfaction level. The results are presented as average values (and range) for the 19 patients at the follow-up examinations.

Question:	Average: (VAS-scale 0-10)	Comments
1. Any complaints?	8.1 (range: 1-10)	10 = No complaints
2. Satisfaction with prosthesis function?	9.8 (range: 9-10)	10 = Very good
3. Satisfaction with aesthetics?	9.5 (range: 6-10)	10 = Very satisfied.
4. Satisfaction with treatment procedures?	9.8 (range: 9-10)	10 = Very satisfied

Table 6. Mean (± standard deviation) distances between reference point (rim of implant shoulder) and level at which the bone met the surface of the implants placed in healed bone and in extraction sockets, respectively. The measurements were done from radiographs taken at the delivery of the prostheses (base-line) and at the follow-up examinations. The bone loss as well as the bone gain within the groups were statistically significant ($p = 0.021$ and $p = 0.0013$, respectively).

Distance from reference point:

Implants placed in:	**At base-line**	**At follow-up examination**	**Bone loss/bone gain:**
healed bone:	**2.4 ± 0.9 mm**	**3.2 ± 1.1 mm**	
extraction sockets:	**4.0 ± 1.3 mm**	**3.0 ± 0.6 mm**	
Difference between groups	**p < 0.001**	**p > 0.30**	**p< 0.001**
		c.i.: 1.77 (0.99, 2.55)	