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The use of reduced healing times on ITI® implants with a sandblasted and acid-etched (SLA) surface:

Early results from clinical trials on ITI® SLA implants

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Summary: ITI® dental implants are available with two bone-anchoring surfaces, a titanium plasma-sprayed (TPS) surface, and a recently introduced sandblasted and acid-etched (SLA) surface. Cell culture and animal tests demonstrate that the SLA surface stimulates bone cell differentiation and protein production, has large amounts of bone-to-implant contact, and results in large removal torque values in functional testing of the bone contact. As a result of these studies, a prospective human clinical trial was initiated to determine whether the 4.1 mm diameter SLA ITI® solid screw implants could be predictably and safely restored as early as six weeks after implant placement surgery. The protocol restricted the use of the reduced healing time to a) healthy patients with sufficient bone volume to surround the implant, and b) those patients who had good bone quality (classes I-III) at the implant recipient site. Patients with poorer bone quality (class IV) did not have restorations until 12 weeks after implant placement. The clinical trial is an ongoing multicenter trial, with six centers in four countries, and with follow-up over five years. The primary outcome variable was abutment placement with a 35 Ncm force, with no counter torque and no pain or rotation of the implant. A secondary outcome was implant success, as defined by no mobility, no persistent pain or infection, and no peri-implant radiolucency. To date, 110 patients with 326 implants have completed the one-year post-loading recall visit, while 47 patients with 138 implants have completed the two-year recall. Three implants were lost prior to abutment connection. Prosthetic restoration was commenced after shortened healing times on 307 implants. The success rate for these implants, as judged by abutment placement, was 99.3% (with an average healing time of 49 days). Life table analyses demonstrated an implant success rate of 99.1%, both for 329 implants at one year and for 138 implants at two years. In the 24-month period after restoration, no implant losses were reported for the 138 implants. These results demonstrate that, under defined conditions, solid screw ITI® implants with an SLA endosseous surface can be restored after approximately six weeks of healing with a high predictability of success, defined by abutment placement at 35 Ncm without counter torque, and with subsequent implant success rates of greater than 99% two years after restoration.

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Endosseous root-form dental implants are currently the predominant dental implant used clinically (Cochran 1996). Support for the implant is maintained by direct contact between the osseous tissue and the surface oxide of the titanium (Brånemark et al. 1969; Schroeder et al. 1981). Initially,

stability of the implant is obtained through primary contact with the cut bone tissue and depends on congruency and press-fitting during placement. In one canine study, the degree of primary contact was between 52% and 72% after three months of unloaded healing, depending on the implant

surface characteristics (Cochran et al. 1998). Over time, bony remodeling takes place at the surface, and bone formation can occur on osteoconductive titanium surfaces. This results in secondary bone contact with the titanium implant; in the study referred to above, this was between 59% and 72% after 15 months of healing, which included one year of loading. Primary bony contacts had decreased to approximately 5% of the surface area. The results from this and other studies suggest that the characteristics of the implant surface can not only influence early contact between the bone and the implant, but continue to affect bone-to-implant contact long after implant placement (Roberts et al. 1984, 1987, 1989).

Various publications over the last 16 years have demonstrated that bone contact differs when different titanium implant surfaces are used. These studies include both descriptive and functional assays of the bone-to-implant contact. For example, Kirsch & Donath (1984) showed that bone contact occurred earlier around a titanium plasma-sprayed implant surface in comparison to a machined implant surface. One year later Thomas & Cook (1985) evaluated variables that influenced bone contact to the implant surface, and showed that rougher implant surfaces had significantly greater bone contact than did smoother implant surfaces. Interestingly, these investigators found that only one variable (implant surface characteristics) had a significant effect on the integration of the implant. Buser et al. (1991) confirmed these earlier studies by demonstrating, with five different titanium surfaces, that a positive correlation existed between the percentage of bone-to-implant contact and the roughness values of the similarly shaped implants. Functional studies on the strength of the bone-to-implant contact have also indicated that rougher implant surfaces have significantly greater strength than smoother titanium surfaces and that, within the 'rough' or 'smooth' categories, significant differences can exist (Buser et al. 1998, 1999b; Wennerberg & Albrektsson 2000). The biological basis of a rough implant surface can be determined from *in vitro* cellular studies of growth, matrix production and enzyme and protein (including growth regulatory substances) synthesis, using titanium surfaces with various degrees of roughness (Cochran et al. 1994;

Martin et al. 1995, 1996; Kieswetter et al. 1996; Schwartz et al. 1996).

The *in vitro* and animal studies noted above suggest that significant advantages exist for roughened titanium surfaced implants in comparison to smoother titanium implant surfaces. While these studies allow comparisons to be made between various surfaces, however, a goal in implant therapy is to improve patient care. A meta-analysis of longitudinal descriptive implant experiences in patients has suggested that, in certain indications, these advantages of rough titanium surfaces can also be reflected in better success rates for patients (Cochran 1999). A further benefit for patient care (in addition to improved success rates) would be a shorter healing time than that historically recommended. This possibility was examined in the present multicenter, prospective human clinical trial. The success of early abutment placement was assessed, based on the documented advantages of a sandblasted and acid-etched titanium surface, which has both high percentages of bone-to-implant contact in descriptive histomorphometric studies (Cochran et al. 1998) and high removal torque values in functional studies on the strength of the bone-to-implant contact (Buser et al. 1998, 1999b).

Material and methods

A prospective human clinical trial was designed with the aim of evaluating whether restoration on ITI® SLA solid screw implants of 4.1 mm diameter could begin six weeks after implant placement in class I to III bone, and after 12 weeks in class IV bone (Lekholm & Zarb 1985). Since the restoration phase begins with abutment connection, the primary outcome variable was whether an abutment could be placed and torqued to 35 Ncm, without using counter torque, without rotation of the implant, and without the patient feeling pain. Implant success was additionally evaluated using criteria that have been previously outlined (Buser et al. 1990, 1997, 1999a) and which are described below.

Clinical protocol

This human clinical trial was designed as a longitudinal prospective study, with the aim of evaluating both abutment connection success, using descriptive analysis,

and implant success, using life table analysis (Cutler & Ederer 1958). The protocol required the implants to be placed in function with a temporary or permanent restoration, between 42 and 63 days after implant placement surgery. Implants were placed in bone of quality class I, II or III, at any location in the mouth.

The study was designed as a multicenter trial, using experienced implant investigators at six centers in four countries. These centers were: (1) the Department of Periodontics, University of Texas Health Science Center at San Antonio, USA; (2) the Department of Oral Surgery, School of Dental Medicine, Berne, Switzerland; (3) Rynland Hospital, Leiderdorp, Leiden, the Netherlands; (4) Katherinenhospital, Stuttgart, Germany; (5) the School of Dental Medicine, University of Connecticut, Farmington, USA; and (6) the Division of Stomatology and Oral Surgery, School of Dental Medicine, Geneva, Switzerland. The study protocol was approved at each center by the appropriate ethics committee or institutional review board.

Patients were recruited consecutively, and received a thorough oral clinical examination. Participating patients had to meet stated inclusion and exclusion criteria (Table 1) and also to self-report good health. Each patient should also desire an implant-supported restoration and be classified into one of the three treatment groups. Clinical and radiographic screening was used to limit the study to patients with sufficient bone quantity to completely encase the implant.

The patients participating in the trial were divided into three groups.

Group A: Patients with more than one tooth missing in the posterior mandible, and existing teeth that were healthy or adequately restored. In these cases, the missing teeth were to be replaced with a fixed implant-to-implant restoration on two or more implants in the posterior mandible. All centers except for Stuttgart recruited into group A.

Group B: Patients with more than one tooth missing in the posterior maxilla, and existing teeth that were healthy or adequately restored. In these cases, the missing teeth were to be replaced with a fixed implant-to-implant restoration on two or more implants in the posterior maxilla. All centers except for Stuttgart recruited into group B.

Table 1. Clinical study inclusion and exclusion criteria

Patient inclusion criteria:
1. Patient aged 18 years or older. 2. Ability to understand and sign the informed consent form prior to starting the study. 3. Ability and willingness to comply with all study requirements. 4. Adequate oral hygiene (defined as a Modified Sulcus Bleeding Index of 1 or less, and a Modified Plaque Index of 1 or less). 5. Adequate bone volume to accommodate the planned endosseous dental implants (i.e. sufficient height that the implant will not encroach on vital structures such as sinuses, and sufficient width that the implant can be placed within the confines of the existing bone, without dehiscence or fenestration). 6. More than one missing tooth in the mandible, plus existing teeth that are healthy and adequately restored, plus the desire for a fixed restoration on four or more implants, where each restoration should be supported on at least two implants, or a removable denture supported by four or more implants; – OR - More than one missing tooth in either the posterior maxilla or mandible, plus existing teeth that are healthy or adequately restored, plus the desire for a fixed restoration. The missing teeth must be able to be replaced with a fixed implant-to-implant restoration. 7. In the case of a woman of child-bearing age, a negative pregnancy test within one week prior to surgery.
Patient exclusion criteria:
1. Moderate or heavy smoking (more than ten cigarettes per day) or tobacco chewing use. 2. History of alcoholism or drug abuse within the past five years. 3. Severe bruxism or clenching habits. 4. Untreated periodontitis. 5. Tooth extraction at an intended implant site within the last six months. 6. Patient at risk from the surgical procedure. 7. Presence of residual roots at the implant site. 8. Presence of local inflammation or mucosal diseases such as lichen planus. 9. Patient at high risk for subacute bacterial endocarditis. 10. Uncontrolled diabetes. 11. Current hematological disorder or cumarin (or similar) therapy. 12. History of leukocyte dysfunction and deficiencies. 13. Metabolic bone disorders. 14. History of renal failure. 15. History of liver disease. 16. Immunocompromised patients, including HIV-positive. 17. Current steroid treatment. 18. Current chemotherapy. 19. History of radiation treatment to head or neck. 20. Any psychiatric contraindication, as judged by the investigator. 21. Previous graft at the intended surgical site (bone augmentation). 22. Physical handicap that would interfere with the patient's ability to exercise good oral hygiene on a regular basis. 23. Use of any investigational drug or device within the 30-day period immediately prior to implant surgery.

Group C: Patients with more than one tooth missing in the mandible, and existing teeth that were healthy or adequately restored. In these cases, either a fixed restoration was placed on four or more implants, with each restoration supported by at least two implants, or a removable denture restoration was fabricated and supported by four or more implants. Leiden, Stuttgart and Farmington recruited patients into group C.

Requirements for the potential implant site(s) included adequate bone volume to accommodate the planned endosseous dental implants. This meant that there should be both sufficient height, so that the implant would not encroach on vital structures such as sinuses, and sufficient width, so that the implant could be placed within the confines of the existing bone, without dehiscence or fenestration.

All implants were placed using a non-submerged technique, according to a strict surgical protocol following the manufacturer's instructions. Bone quality was determined at surgery by experienced investigators at the six centers participating in the study. For patients with class I-III bone (Lekholm & Zarb 1985), abutment placement and functional loading, with either a temporary or a permanent restoration, were required to be undertaken between 42 and 63 days after surgery. If class IV bone was determined at surgery, the patient was placed on a schedule which called for restoration between 84 and 105 days. All restorations were either cemented or screw-retained.

Evaluation and criteria for success

The primary aim of this study was to determine whether abutments could be placed

without complications in ITI® SLA implants, after 42–63 days for sites with class I-III bone and after 84–105 days for sites with class IV bone. Additionally, these implants were followed to determine the outcome of using a shorter healing time than that previously recommended for ITI® TPS implants of the same design (Buser et al. 1999a). Success for abutment placement was defined as described in the previous section. An implant was considered successful when: (i) a free-standing implant was immobile when tested with instrument pressure; (ii) a periapical radiograph did not show evidence of continuous peri-implant radiolucency; and (iii) there was an absence of persistent or irreversible signs and symptoms, such as pain and infection (Buser et al. 1990, 1997, 1999a).

Implant mobility was only measured when the implant was available for direct measurement. The prostheses were not routinely removed at post-loading follow-up visits, but were removed only in cases where the prosthesis itself was mobile or where the patient experienced discomfort on function or percussion. Other variables that were assessed, and which will be reported after three and five years, included: (i) periapical radiographic vertical bone loss, and (ii) gingival health, which was assessed by bleeding tendency, using a modified Sulcus Bleeding Index (Mombelli et al. 1987), and by the assessment of plaque accumulation, using a modified Plaque Index (Mombelli et al. 1987).

Patients were scheduled for follow-up examinations at abutment placement and at 3, 6, 12, 18 and 24 months post loading. Further follow-ups will include annual visits up to five years post loading. All evaluations were made at each visit, except for radiographs, which were not scheduled at the 3, 18 and 48-month follow-ups.

Results

The numbers of patients and implants evaluated at the different follow-up visits are shown in Table 2. One hundred and thirty-three patients entered into the clinical trial, with slightly more women than men being treated. A total of 383 implants were placed, and 380 abutments were inserted. Two patients were lost to follow-up, one in group A with two implants, and one in group C with 4 implants. Both of these

Table 2. Patient recruitment and follow-up status

No. of patients	133
% Female/Male	57.1/42.9
No. of implants	
Placed during surgery	383
With abutments inserted	380
At 3-month follow-up	376
At 6-month follow-up	371
At 1-year follow-up	326
At 1.5-year follow-up	249
At 2-year follow-up	138
At 3-year follow-up	16

Table 3. Distribution of implant length

Implant Length	
8 mm	18.3%
10 mm	38.6%
12 mm	39.4%
14 mm	3.7%

patients were last seen at the 6 month follow-up and no adverse events or other complications were reported at that time. The age distribution of patients in the trial is shown in Figure 1. The youngest patient at implant placement was 20 years old, while the oldest was 82 years old. Most patients were aged between 40 and 69 years of age.

The distribution of implant lengths is shown in Table 3. Approximately 78% of the implants were either 10 mm or 12 mm in length. Figure 2 shows the position of the implants for group B (posterior max-

Table 4. The number of implants placed at each study center, by treatment group

Center	No. of implants in each treatment group			
	Group A	Group B	Group C	Total
Berne	40	10	–	50
Farmington	37	8	27	72
Geneva	42	12	–	54
Leiden	25	5	64	94
San Antonio	54	11	–	65
Stuttgart	–	–	48	48

illa), while Figure 3 shows the position of the implants for both groups A (posterior mandible) and C (edentulous mandible). The numbers of patients and implants in each group were as follows: group A, 80 patients with 198 implants; group B, 21 patients with 46 implants; and group C, 32 patients and 139 implants (Table 4). In the maxilla, the majority of implants were placed in the first molar and premolar positions. In the mandible, the first molar and premolar positions also dominated; however, in group C, many implants were also placed in the mandibular lateral incisor positions. Table 5 shows that, in groups A and B, most fixed partial dentures were supported by two implants, while four implants were usually used in group C. Over 85% of the implants were placed in bone of quality class I-III, with the majority (77%) in class II and III bone (Table 6).

Three types of adverse events were reported (Table 7).

Early implant loss. In these cases, the implant was mobile when the patient presented either before or at the abutment placement visit. Mobile implants were considered to be implants which had failed to osseointegrate. They were therefore explanted and counted as failures. None of these early implant failures occurred in the maxilla.

Implant rotated on abutment placement. In these cases, the implant rotated on abutment tightening. The implant was stable in the vertical axis, and thus it was not mobile. Two of these implants were restored immediately and one was restored four days later. These implants were considered as failures for shortened restoration (abutment placement failures), but were considered as implant successes at the recall appointments.

Pain on abutment placement. In these cases, the patient experienced discomfort or pain on abutment tightening. These implants were either restored immediately (five cases) or were left unrestored (one case) to allow a few more weeks of healing. These implants were considered as failures for shortened restoration (abutment placement failures), but were considered as implant successes at the recall appointments.

In 99.0% of cases, the implant resisted without incident the torque required for abutment placement, despite the shortened healing times. Three implants failed to osseointegrate and were removed. Three cases of implant rotation occurred, and there were six implants where the patient complained of pain on abutment insertion. All implants that initially had rotation or pain were eventually loaded within the time required by the protocol (Table 8), except for one case in class IV bone, where the clinician decided to leave the implant for a further 55 days before placing the implant into function. All of these implants were seen at later follow-up visits and were rated as implant successes (Table 7).

**Fig. 1.** Distribution of patient age.

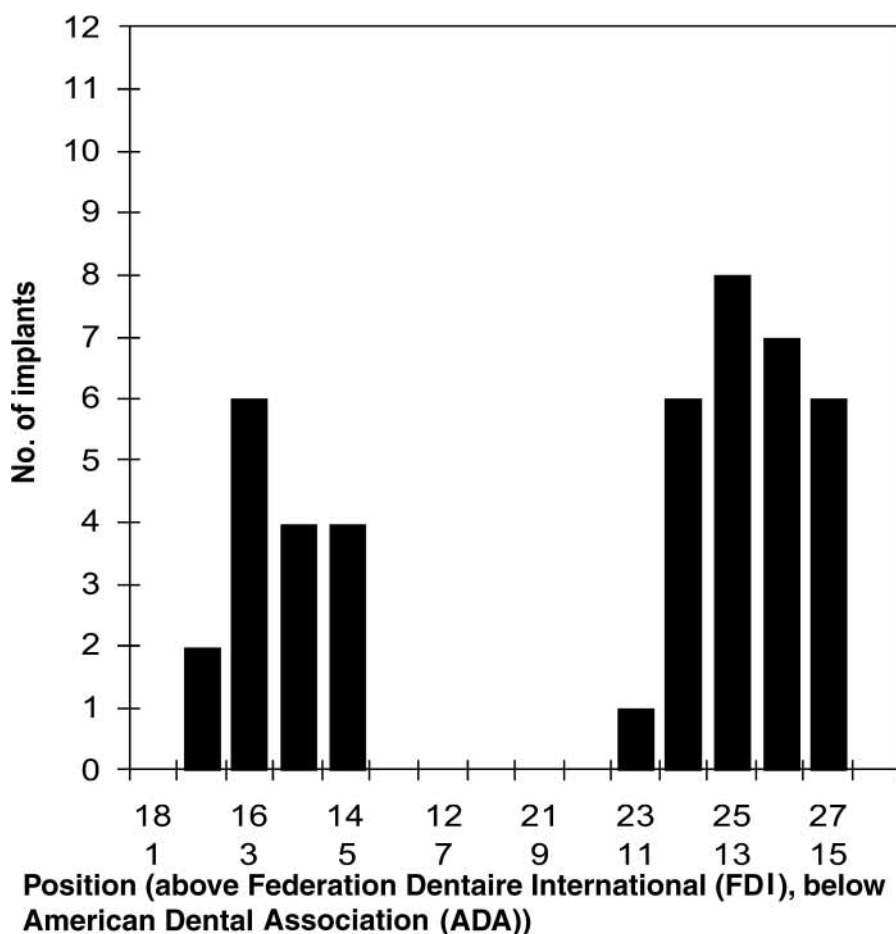


Fig. 2. Positions of implants inserted in group B (maxilla).

Figure 4 shows the time of abutment placement for the 307 implants restored in bone of quality class I-III, within 63 days of surgery. A further 24 implants had the abutment inserted later than 63 days post surgery and are not shown in this figure. This later placement occurred either because the patient also had an implant in class IV bone (thus requiring that all implants be left for the longer healing times for class IV sites) (five cases), or because the patient or the site failed to comply with the protocol (19 cases). In contrast, although the protocol stated that implants placed in class IV bone should be given a longer healing time, nine implants placed

in class IV bone were restored within 63 days after surgery. For one of these nine implants, pain on abutment insertion was recorded at 47 days; after restoration on the same day, however, the implant was rated as successful at the 6, 12 and 18-month follow-up visits. In total, 49 implants in class IV bone had abutments placed later than 63 days after implant surgery. In one case, the patient complained of pain on abutment insertion at 91 days post surgery; this implant was therefore left for a further 55 days before restoration. The implant and restoration has passed the 6-month follow-up without complications.

No implant failures or other implant-re-

lated adverse events were reported at any of the patient follow-ups after abutment placement. All adverse events, except one case of pain on abutment placement, occurred in the group having abutment placement within 63 days of surgery.

Life table analyses (Table 9) showed an overall implant success rate of 99.1% at one year after loading. Three implant losses occurred out of the 329 implants which were at risk after one year. As no implants were lost after one year, the cumulative implant success rate for 138 implants remained unchanged at 99.1% at the 2-year evaluation point. The 1-year implant success rates for the three groups separately were 99.4% (166 implants, posterior mandible), 100% (35 implants, posterior maxilla) and 98.4% (128 implants, anterior and edentulous mandible) for groups A, B and C, respectively.

Discussion

The purpose of this study was to evaluate the placement and restoration of endosseous dental implants that had a sandblasted and acid-etched surface, where the implant was in contact with osseous tissue and the abutment was placed after approximately six weeks of healing. The design of the study was a prospective human multicenter clinical trial, which involved six centers in four countries. The implants, which were one-part implants without an interface (microgap) at the osseous crest, were placed using a non-submerged surgical technique. The short-term results demonstrate a high success rate for abutment connection, using 35 Ncm without countertorque, as well as a high rate of implant success after one and two years of loading.

The primary outcome variable in this

Table 5. Number of implants supporting the restorations within each treatment group

No. of restorations in each group	No. of supporting implants						
	2	3	4	5	6	7	8
Group A	81	12	–	–	–	–	–
Group B	19	3	–	–	–	–	–
Group C	–	1	25	3	1	1	1

Table 6. Distribution of bone quality among implant sites, as determined at surgery at each study centre

Center	Bone quality ^a				
	I	II	III	IV	Total
Berne	2	28	17	3	50
Farmington		51	9	12	72
Geneva	7	32	10	5	54
Leiden	5	29	51	9	94
San Antonio	4	11	26	24	65
Stuttgart	12	12	20	4	48
Total	30	163	133	57	383

^aBone quality according to Lekholm & Zarb (1985)

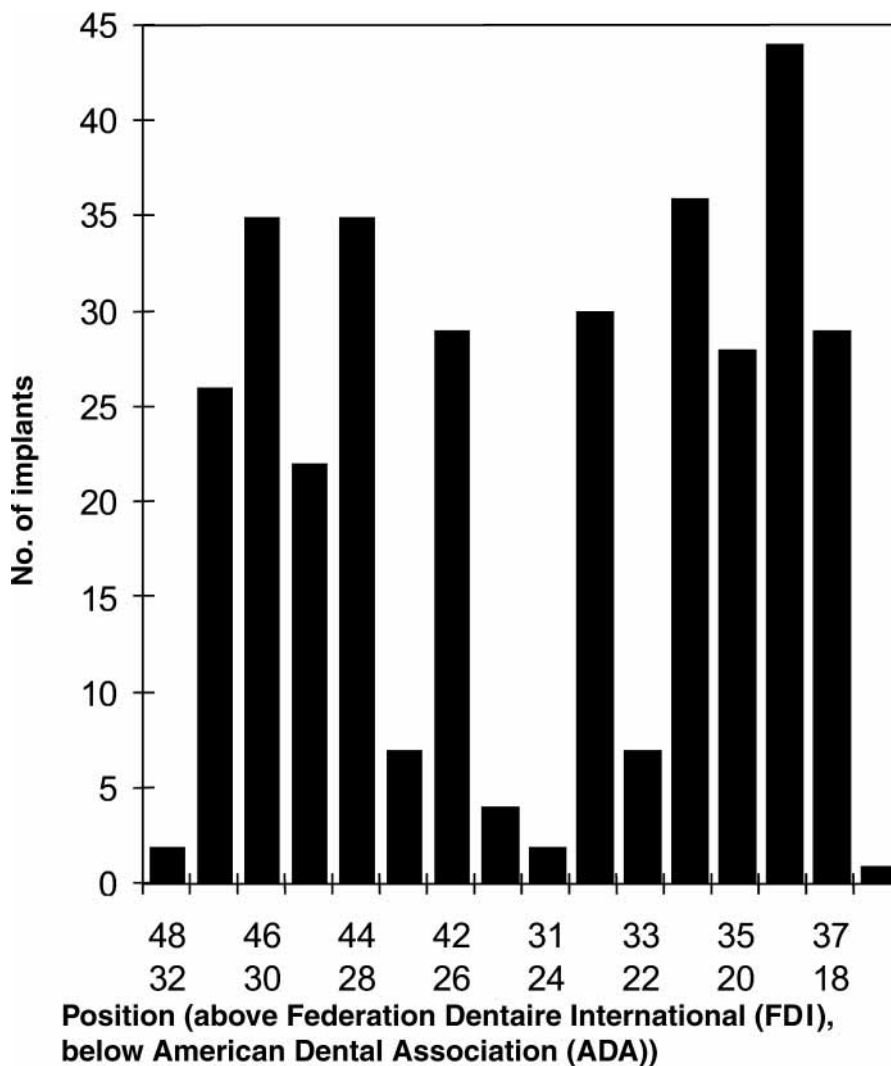


Fig. 3. Positions of implants inserted in groups A and C (mandible).

study was the success of abutment connection to the implant after a shorter healing time than that conventionally used in patient implant studies. While implant restoration typically begins three to six months after implant placement, it was started earlier in this study, i.e. after six weeks of healing if the implant was placed in sites with bone quality of class I-III, and after 12 weeks if the bone quality was judged to be class IV. The purpose of a healing period after implant placement is to allow healing of the cut bone surfaces that lie adjacent to the implant surface, which are created during osteotomy preparation. Upon healing of the bone, the implant becomes more stable and a restoration can be supported. The time at which bony healing is sufficient for implant restoration has not yet been precisely determined. This is particularly relevant in regard to single-tooth

implant restorations and multiple implant restorations that are not connected to one another. The recommended three to six months healing time was empirically derived, but was then verified as being sufficient to allow most implants to be restored. Even after these healing times, however, some implants have not been stable when an abutment was tightened in the implant. If the implant demonstrates lateral mobility at this stage, most investigators consider this implant an 'early' failure, and the implant is typically explanted. If, however, the implant rotates slightly, many clinicians either continue with the restoration or wait for further healing to occur, prior to restoration. Some investigators (and manufacturers) also recommend that a counter torque is used when an abutment is inserted into the implant (Sullivan et al. 1996).

The implants in the present study had abutments placed without using counter torque. The implant manufacturer recommends the use of a torque control device to place a 35 Ncm force on the abutment. In the present multicenter study, therefore, all implants had abutments placed with a controlled force and with no device to resist rotation, other than the bone-to-implant contact. In addition, no anti-rotational features exist on the solid screw implants used, other than the roughness created by the sandblasted and acid-etched surface. It is apparent from one study that bone tissue does form within the sandblasted areas (20–40 µm pits) on

Table 7. Summary of adverse events

Group ^a	Tooth position FDI (ADA)	Bone quality ^b	Implant length (mm)	Time of abutment insertion ^c	Time of loading ^c	Status at last follow-up (months)
Early implant loss						
C	46 (30)	III	8	–	–	Failure (0)
C	42 (26)	II	8	–	–	Failure (0)
A	35 (20)	III	12	–	–	Failure (0)
Implant rotation						
A	35 (20)	III	8	46	50	Success (36)
B	16 (3)	III	8	57	57	Success (24)
A	37 (18)	I	12	42	42	Success (18)
Pain						
C	36 (19)	III	8	43	43	Success (12)
C	46 (30)	II	8	51	51	Success (24)
C	43 (27)	II	10	43	43	Success (24)
C	31 (24)	II	12	43	43	Success (24)
B	17 (2)	IV	12	47	47	Success (18)
B	27 (15)	IV	14	91	146	Success (6)

^aGroup A, posterior mandible; Group B, posterior maxilla; Group C, mandible

^bAccording to Lekholm & Zarb (1985)

^cNumber of days post surgery

FDI, Federation Dentaire Internationale; ADA, American Dental Association

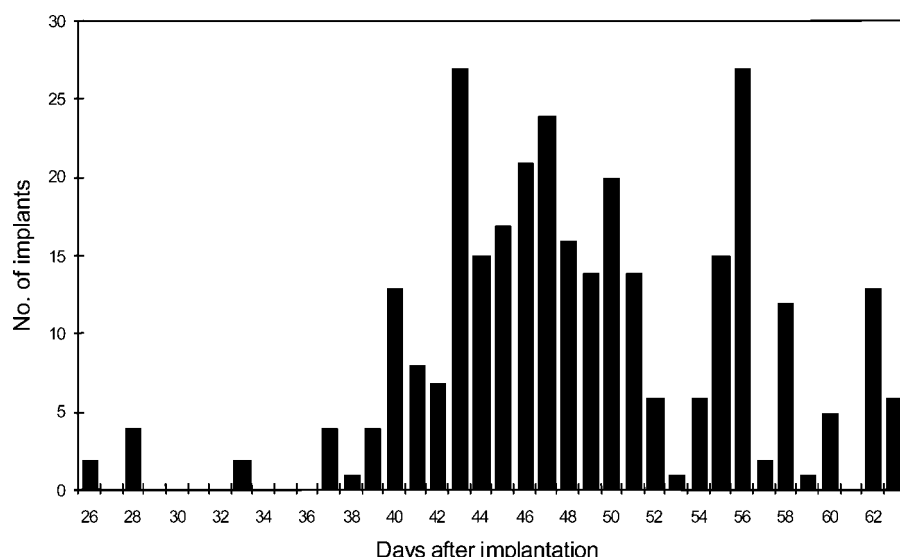


Fig. 4. Time of abutment placement in bone of quality class I-III. The mean placement time was 49 days after implantation.

the surface, and it is possible that this bone may serve to stabilize the implant against rotation forces (Wong et al. 1995).

It is difficult to determine the time at which an implant has sufficient stability in bone to resist lateral forces or a rotational force of 35 Ncm. One criteria that has been used during implant placement is 'stability' during the osteotomy preparation. In these cases, stability has typically been de-

fined by the surgeon as the lack of clinically detectable motion when two opposing instruments are used in a lateral direction. In experimental studies, this rather crude evaluation of mobility has been replaced by attempts to quantify the lateral movement of the implant. One instrument used in such studies is the Periotest®, which uses a plunger to strike the side of the implant and allows the damping mo-

tion to be determined (Walker et al. 1997; Meredith et al. 1998). A more recently developed instrument to detect lateral mobility uses resonance frequency (Meredith et al. 1997a, 1997b; Meredith 1998; Sennerby & Meredith 1998; Friberg et al. 1999). Both of these devices, which provide a quantitative value of lateral motion under a controlled force, represent improvements in detecting lateral movement, in comparison to the more subjective clinical evaluation without a controlled force. However, they do not evaluate resistance to rotation of the implant, which is an indication of the strength of the implant-to-bone contact. Therefore, the present study used a controlled rotational force of 35 Ncm and two subjective evaluation criteria, which were clinically detectable rotation of the implant and patient discomfort. Interestingly, in all cases of rotation or patient discomfort, the implants were either restored immediately or restored after a further healing period, and all implants and restorations remain functional and successful. These data suggest that either implant rotation or patient discomfort on rotation may be an indication of premature osseous integration of the implant, rather than an indicator of implant failure as in the case of lateral mobility of an implant.

Because the process of wound healing around titanium implants is not yet sufficiently understood, it is difficult to determine when an implant is capable of resisting a 35 Ncm force without counter torque. Eriksson & Albrektsson (1983) demonstrated that osseous preparation for the surgical placement of an implant involves a variable amount of bony necrosis at the cut bone surface. In some cases, such as when the temperature increases beyond a certain point, the level of damage to the surrounding cells is such that the tissue

Table 8. Adverse events occurring prior to or at abutment placement after reduced healing time, as a function of bone class

Bone class ^a	Early implant loss	No. of implants with abutment placement ≤63 days	Implant rotation on abutment placement ^b	Pain on abutment placement ^b
I	0	29	1	0
II	1	144	0	3
III	2	125	2	1
IV	0	9	0	1
I-IV	3	307	3	5

^aAccording to Lekholm & Zarb (1985)

^bAll implants had restoration ≤63 days

Table 9. Life table analyses

Group	Interval (mo)	No implants at start of interval	No. drop-outs during interval	No. implants not completing interval	No. implants at risk	No. implants lost during interval	Success rate for interval	Cumulative implant success
A,B,C	0-12	383	6	48	329	3	99.1%	99.1%
	12-24	326	0	188	138	0	100%	99.1%
A	0-12	198	2	30	166	1	99.4%	99.4%
	12-24	165	0	104	61	0	100%	99.4%
B	0-12	46	0	11	35	0	100%	100%
	12-24	35	0	19	16	0	100%	100%
C	0-12	139	4	7	128	2	98.4%	98.4%
	12-24	126	0	65	61	0	100%	98.4%

is destroyed, and thus bone healing (a cellular phenomena) does not occur. Cochran et al. (1998) demonstrated that, immediately after placement, the implant is stabilized by a press-fit of the slightly larger diameter of the implant (in the case of the ITI® implant) against the cut native bone surface, referred to as primary bone contact. If reversible bony damage occurs during osteotomy preparation, bone healing will gradually occur adjacent to the titanium surface, resulting in secondary bone contact. During this healing process, woven bone becomes lamellar bone, and secondary bony contact increases, while primary contact decreases. The point at which the implant can resist a 35 Ncm rotational force remains to be determined, however. For example, in order to resist rotation, is secondary woven bone contact required over a certain amount of the surface? If so, what is this threshold amount? It seems likely that primary bony contact is responsible for lateral stability of the implant, but even this stability is dependent on the location of the primary contact (for example, whether it occurs on the apical or the coronal surface). The amount and location of cortical and cancellous bone around the implant certainly appear to be important factors in providing resistance to lateral mobility.

The results of this prospective multicenter human clinical trial demonstrate that ITI® implants, with a sandblasted and acid-etched surface, can be restored after approximately six weeks of healing with high success, as determined by the resistance to abutment placement with 35 Ncm and no counter torque. Experimental animal studies have shown that this particular titanium surface results in a high degree of bone-to-implant contact and high removal torque values. Furthermore, *in vitro* studies have shown that osteoblasts grown on this surface exhibit properties of highly differentiated bone cells, which suggests that this surface is osteoconductive. The results from these experimental studies reinforce the concept of enhanced bone formation around the sandblasted and acid-etched surface, and the possibility of reduced clinical healing times prior to restoration. The successful abutment placement that has been demonstrated in this clinical trial, and the subsequent implant success, provides further evidence that the ITI® SLA surface has significant clinical advantages,

such as shorter restoration times than those used in earlier studies on implant restoration.

Résumé

Les implants dentaires T® sont disponibles avec deux surfaces d'ancrage à l'os: une surface plasma-spray en titane (TPS) et une surface récemment présentée, soufflée et mordancée (SLA). La culture cellulaire et des tests sur l'animal ont démontré que la surface SLA stimulait la différenciation des cellules osseuses et la production de protéines, qu'elle la différenciation des cellules osseuses et la production de protéines, qu'elle possédait de grandes quantités de contact os-implant et résultait en des valeurs importantes de contre-torsion. Un essai clinique prospectif chez l'être de 4,1 mm en forme de vis pouvaient être utilisés six semaines après la chirurgie. Le protocole restreignait l'utilisation du temps de guérison chez les patients sains avec un volume osseux suffisant pour entourer l'implant et chez des patients qui avaient une bonne qualité osseuse (Types -) au niveau du site receveur de l'implant. Des patients ayant un os de qualité moindre (type V) n'avaient des restaurations commencées que douze semaines après l'insertion des implants. L'essai clinique était une recherche multicentrique qui se déroule encore actuellement dans six centres dans quatre pays avec un suivi de cinq années. La première variable a été le placement des piliers avec une force de 35 Ncm sans contre-torsion et douleur ou rotation de l'implant. Une seconde découverte a été le succès de l'implant défini par l'absence de mobilité. L'absence de douleur persistante ou d'infection, et aucune radioclarité paromplantaire. Jusqu'à présent 110 patients avec 326 implants ont achevé leur visite de rappel d'une année et 47 patients et 138 implantsterminaient leur visite de rappel de deux années. Trois implants ont été perdus avant la connexion du pilier. La restauration prothétique a été entreprise après la restriction du temps de guérison sur 307 implants. Les résultats démontrent que la diminution du temps de guérison jugé par les taux de succès au moment du placement du pilier était de 99,3%. Le temps de guérison moyen pour ces implants était de 49 jours. Les analyses de succès des implants présentaient 329 implants avec un taux de succès d'une année de 99,1% et un taux de succès à deux ans de 99,1% pour 138 implants. Aucune perte implantaire n'a été rapportée après restauration. Sous des conditions définies les implants T® vis solides avec une surface endosseuse SLA peuvent être restaurés après environ six semaines de guérison avec un taux de prévision important de succès défini par le placement du pilier à 35 Ncm sans contre-torsion et avec des taux de succès implantaire de 99% après deux années d'observation.

Zusammenfassung

Die T®-Zahnimplantate sind mit zwei Oberflächen für den Knochenbereich erhältlich, der Titanplasmasprayschicht (TPS) und der kürzlich eingeführten sandgestrahlten und säuregeätzten Oberfläche (SLA). Untersuchungen mit Zellkulturen und Tieren zeigen, dass SLA-Oberflächen eine Knochenzellendifferenzierung und Proteinproduktion induzieren, eine sehr hohe Knochen-implantatkontrakte haben und in der Folge in funktionellen Tests auch hohe Ausdrehwiderstände zeigen. Auf Grund dieser

Resultate regten wir eine prospektive klinische Studie am Menschen an, die mithelfen soll festzustellen, ob SLA T®-Vollschraubeimplantate mit einem Durchmesser von 4,1 mm 6 Wochen nach der chirurgischen Implantation voraussagbar und sicher rekonstruiert werden können. Das Protokoll beschränkte die verkürzte Einheilphase auf gesunde Patienten mit genügend Knochenvolumen um die Implantate und auf solche, die eine gute Knochenqualität (Typ -) um die Implantationsstelle aufwiesen. Patienten mit qualitativ weniger gutem Knochen (Typ V) erhielten die Rekonstruktion frühestens nach 12 Wochen. Diese klinische Studie ist eine über 5 Jahre laufende Multizenterstudie an 6 Zentren in vier Ländern. Die erste Frage der Untersuchungen betraf die Fixation des Sekundärteils mit einer Kraft von 35 Ncm. Dabei sollte weder ein Wiederausdrehen des Implantates, noch Schmerzen oder Rotationen des Implantates vorkommen. Die zweite Frage betrifft den Erfolg der Implantation, definiert durch Stabilität, Schmerzfreiheit, Infektionsfreiheit und keine Radiotransluzenz um den Implantatkörper. Zurzeit stehen 110 Patienten mit 326 Implantaten mindestens ein Jahr nach Rekonstruktion und funktioneller Belastung, 47 Patienten oder 138 Implantate davon bereits zwei Jahre. Die Resultate zeigen, dass eine reduzierte Heilphase bis zum Tag der Fixation des Sekundärteils eine Erfolgsrate von 99,3% hat. Die durchschnittliche Einheilphase dieser Implantate betrug 49 Tage. Der auf Überlebens Tabellen analysierte Erfolg zeigte für die 329 Implantate eine Erfolgsrate von 99,1% nach einem Jahr und für die 138 Implantate eine von 99,1% nach zwei Jahren. Nach 24 Monaten harren wir auf den 138 Implantaten keine Rekonstruktionsverluste. Die Resultate zeigen, dass unter definierten Bedingungen ein T®-Vollschraubenimplantat mit einer SLA-Oberfläche nach einer Einheilphase von etwa 6 Wochen mit gut voraussagbaren Erfolgsaussichten rekonstruiert werden kann. Dabei wird der Erfolg definiert durch eine Fixation des Sekundärteils mit 35 Ncm ohne Retentionsverlust und einer anschließenden Erfolgsrate von über 99% zwei Jahre nach der Rekonstruktion.

Resumen

Los implantes dentales T®-están disponibles en dos superficies de anclaje óseo, una superficie de plasma de titanio pulverizado (TPS), y una superficie recientemente introducida chorreada por arena y grabada con ácido (SLA). Los cultivos celulares y los tests en animales demuestran que la superficie SLA estimula la diferenciación de células óseas y la producción de proteínas, tiene unas amplias zonas de contacto hueso-implante, y, resulta en altos valores de torque de remoción en los tests funcionales de contacto óseo. Como resultado de estos estudios, se inició un ensayo clínico humano prospectivo para determinar si los implantes roscados macizos de 4,1 mm de diámetro SLA T® podrían ser restaurados con predictibilidad y seguridad tan temprano como a las 6 semanas de la cirugía de colocación del implante. El protocolo restringió el uso del periodo reducido de cicatrización a pacientes sanos con suficiente volumen de hueso para rodear el implante y aquellos pacientes que tenían una buena calidad de hueso (tipo -) en el lugar receptor del implante. Los pacientes con una peor calidad de hueso (tipo V) recibieron las restauraciones tras 12 semanas de la colocación del implante. El ensayo clínico que continúa multicéntricamente con 6 centros en 4 países con un seguimiento de 5 años. La primera variable resultante fue la colocación del pilar con una fuerza de 35 Ncm sin contratorque y sin dolor o

rotación del implante. La segunda resultante fue el éxito del implante definido por ninguna movilidad, ningún dolor persistente o infección y ninguna radiolucencia periimplantaria. hasta la fecha 110 pacientes con 326 implantes han completado un año de visitas de mantenimiento tras la carga y 47 pacientes con 138 implantes han completado los dos años de mantenimiento. SE perdieron tres implantes antes de la conexión del pilar. La restauración protésica comenzó tras el tiempo reducido de cicatrización en 307 implantes. Los resultados demuestran que el tratamiento con tiempo reducido de cicatrización valorado por el índice de éxito de colocación de pilares fue del 93%. La media de tiempo de cicatrización para estos implantes fue de 49 días. El análisis de la tabla de éxito de implantes muestra 329 implantes con un índice de éxito de un año del 99.1% y de dos años del 99.1% para 138 implantes. Estos resultados demuestran que bajo unas condiciones definidas, los implantes resacados macizos T[®] con una superficie endoósea SLA pueden ser restaurados después de aproximadamente 6 semanas de cicatrización con una alta predictibilidad de éxito definida por colocación del pilar con 35 Ncm sin contratorque y con un índice de éxito de implantes subsecuente mayor del 99% a los 2 años tras la restauración.

要旨

ITI[®] インプラントには、チタン・プラズマ溶射(TPS)表面と、最近導入されたサンドブラストと酸エッチングを施した(SLA)表面の2種類の表面がある。細胞培養と動物試験は、SLA表面は骨細胞の分化と蛋白の産生を刺激し、骨インプラントの接触面積を増加させ、骨接触の機能的試験では、高い抜去トルクの値となる事を示している。これらの研究結果をふまえて、SLA表面を施した、直径4.1mmのITI[®]充実型スクリュー・インプラントを埋入後6週間という早期の補綴治療開始の安全性と予知性を調べるために、前向きヒト臨床試験が実施された。プロトコルは、治療期間の短縮はインプラント周囲に十分な骨量があり、インプラント受給床の骨質が良好である(タイプ1-3)健全な患者に限定した。骨質が劣る(タイプ4)患者では、補綴治療の開始はインプラント埋入後12週間後とした。

現在進行中の同臨床試験は4カ国の6施設が参加する多施設試験であり、追跡期間は5年間である。一次目標は、カウンター・トルクをつけず、痛みやインプラントの回転なく35Ncmの力でアバットメントを連結することであった。二次目標は、動揺性なし、持続的な疼痛あるいは感染なし及びインプラント周囲の放射線透過像なしとい

う定義に基づく、インプラントの成功であった。今日まで患者110名、インプラント326本が、荷重1年後のリコール来院を済ませており、患者47名138本のインプラントは2年目のリコールを済ませた。3本のインプラントがアバットメント連結前に失われた。307本のインプラントにおいて、短縮した治療期間後に補綴物が装着された。

結果は治療期間を短縮した治療におけるアバットメント連結の成功率は99.3%であった。これらのインプラントの平均治療期間は49日であった。インプラント成功率の生命表分析は、329本のインプラントは1年間の成功率が99.1%、138本のインプラントは2年間の成功率が99.1%であった。24ヶ月後に138本のインプラントの中で、補綴治療後に失われたものはない。これらの結果は、定義された条件下では、骨内にSLA表面を施したITI[®]充実型スクリュー・インプラントは、アバットメントの連結は35Ncmで、カウンター・トルクをつけないで行うという条件下で、高い成功の予知性をもって治療期間約6週間後に補綴治療を開始することができ、さらに補綴治療2年後のインプラント成功率は99%以上である事を示している。

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