A Noninterventional Study Documenting Use and Success of Implants With a New Chemically Modified Titanium Surface in Daily Dental Practice

Giuseppe Luongo, MD, DDS[1]*
Giacomo Oteri, DDS, MD[2]

A new chemically modified titanium surface, SLActive, has recently been developed. The results obtained in controlled clinical trials indicate that this implant can be safely used and that it offers predictable results. The goal of this noninterventional study was to verify that the success rates of implants used in daily dental practice are comparable to those reported in controlled clinical trials. This study was a prospective, noninterventional study using implants with a chemically modified surface according to the daily dental practice procedures applied by private practitioners. The choice of the implantation procedure and the loading protocol were the responsibility of the investigator and were chosen according to the patient's needs. Thirty clinical centers actively participated in this study, and 226 patients were treated, of which, 8 patients were lost to follow-up. Because of the noninterventional design of the study, the patients were not selected according to strictly defined inclusion/exclusion criteria. Thus, the study included individuals with risk factors such as smoking (24%), untreated gingivitis or periodontitis (9%), and bruxism (6%). The implants were equally distributed between mandible (46%) and maxilla (54%). A bone augmentation procedure was done in 31% of the cases. Early loading (functional loading between 48 hours and 3 months after implant insertion) was applied most frequently (48%), followed by the conventional loading protocol (3 to 6 months after implant placement, 34%). Immediate restoration and immediate loading were rare (7% and 2%, respectively). Of 276 implants inserted and documented, 5 implants failures were reported, all of which were associated with a sinus floor augmentation procedure. The survival rate was 98.2% at the 1-year follow-up visit. The results showed that implants with a chemically modified surface can be successfully restored with success rates similar to those reported in formal clinical trials under more controlled conditions.

Key Words: noninterventional study, SLActive surface, daily dental practice

[1] Private practice, Rome, Italy.
[2] Department of Dentistry, University of Messina, Messina, Italy.
* *Corresponding author*, e-mail: giuseppeluongo@studioluongo.it
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Introduction

Endosseous dental implants have demonstrated excellent survival rates and provide predictable and reliable long-term support for dental prostheses.[1–3] For more than 20 years, the successful use of dental implants as foundations for treatment of completely and partially edentulous patients has been extensively documented in the literature. Longitudinal studies have demonstrated that the survival rate of dental implants can exceed 95% over 8 to 10 years.[4–6]

Implant surface properties are likely to be of particular relevance to the chemical and biological interface processes in the early healing stages after implantation. It is generally accepted that these early stages are likely to have an effect on the host response to the implant and therefore the long-term outcome and success of the treatment.[7,8] Currently, titanium is the standard material for dental implants because of its excellent biocompatibility and osseointegration properties.[9–12] Because modifications of the titanium surface topography and roughness can have a substantial effect on osseointegration,[13] such modifications have been successfully exploited to influence bone integration and long-term stability of the implant,[3,14–16] and many such modifications, developed with the intention of achieving a bioactive surface (eg, through modification with fluoride ions or calcium phosphate ceramics), are now commercially available.[17]

A new chemically modified titanium surface (SLActive, Straumann AG, Basel, Switzerland) has been developed, using the well-documented topography of the sandblasted, large-grit, acid-etched (SLA; Straumann) surface. This chemically modified surface has a high surface free energy, has reduced atmospheric hydrocarbon contamination, and is strongly hydrophilic compared with the standard SLA surface.[18,19]

Recently, a randomized-controlled multicenter study investigating the differences in survival rates and bone-level changes between immediately and early (28–34 days) loaded implants characterized by the new chemically modified surface has been initiated. With more than 260 patients included in the study and more than 380 implants inserted, this randomized controlled clinical trial represents the largest study of this kind. The interim results obtained after 5 months,[20] which were confirmed by the 12-month primary endpoint analysis,[21] showed implants survival rates of 98% and 97% in the case of immediate and early loading, respectively. Despite the more aggressive loading protocol, these rates are comparable to those observed for SLA implants in conventional loading procedures.[3,22,23] In line with this, interim results of a recent study show that implants with the new chemically modified surface are suitable for early loading 3 weeks after surgery, even in low-density bone, as found in the posterior maxilla.[24] These data also support the fact that implants with the chemically modified surface are safe and predictable in early and immediate loading procedures with results comparable to those achieved by conventional loading.

The trials were performed under controlled clinical conditions and in adherence to a precise protocol that foresees inclusion/exclusion criteria for patient selection. The aim of the present investigation was therefore to assess the use and success of implants characterized by the new chemically modified surface in a larger number of patients treated in private-practice settings in Italy. The products were used as they are in the typical dental office, but the usage was documented in a systematic way and the results were analyzed. The goal of this study was to verify that the success and survival rates of implants used in daily dental practice are comparable to those reported in controlled clinical trials.

Materials and Methods

This study was designed as a prospective noninterventional cohort study using implants of the Straumann Dental Implant System (Institut Straumann, Basel, Switzerland) with a chemically modified SLA surface (SLActive, Institut Straumann) within the indications recommended by the manufacturer. These implants are composed of 2 regions: the apical rough modified SLA part to be incorporated in the bone and a coronal machined titanium collar. The aim was to document the use of the implants in daily dental practice 1 year after implant insertion and to assess implant success and survival rates compared with results obtained in controlled clinical trials. Thirty private practitioners in Italy participated in this study. All investigators received a file containing a case report form to be filled out for every treated patient in order to collect the data in a standardized and complete way.

Clinical protocol

In this study, patients made up to 5 visits: screening, surgery, temporary loading (optional), final restoration, and follow-up 1 year after implant placement. The relationship between the dentist and the patient was not to be influenced by the study protocol. The dental implants were to be used within their approved indication and in situations where the dentist would normally use them. Decisions on treatment (implantation procedure, loading protocols) were left to the dentist's own discretion and were chosen according to the given situation and the patient's needs. The pharmacologic protocol, before and after surgical treatment, was also at investigator judgment.

Implant surgery was performed according to the standard practice of each center. Implant mobility was evaluated by recording whether the implant was a spinner (rotation movements during screwing or unscrewing secondary parts) or mobile (horizontal movements). Radiographic bone loss was measured at each center at the temporary loading, final restoration, and 1-year follow-up visits according to the center's standard methodology for bone-level measurement. All radiographic analysis was performed by the same clinician at each center. All participating investigators applied the same criteria to judge implant success: (1) the absence of implant mobility, (2) the absence of persistent or irreversible pain, (3) no recurrent peri-implant infection, (4) no bone loss greater than 2 mm, and (5) no radiolucency.

Inclusion and exclusion criteria

Patients were consecutively enrolled into the study and were eligible if their general medical condition allowed an oral surgical procedure and if dental implants were indicated for the restoration of their teeth. Before surgery, the investigator informed each patient of the measurement, and patients had to sign an informed consent. Patients could withdraw from the study at any time.

Results

Thirty clinical centers in Italy participated in this study. A total of 226 patients were enrolled. One center dropped out of the study because of investigator illness; no data were provided after the surgery visit for the 8 patients enrolled in this center. Because these patients contributed no postsurgery data relating to implant success or complications, they were considered lost to follow-up and therefore excluded from the data analysis. The final data analysis was performed on 218 patients. The centers recruited 4 to 9 patients each; one center enrolled 12 patients. Of the patients, 160 received 1 implant, and 58 received 2 implants, for a total of 276 implants documented. All 29 centers actively involved in

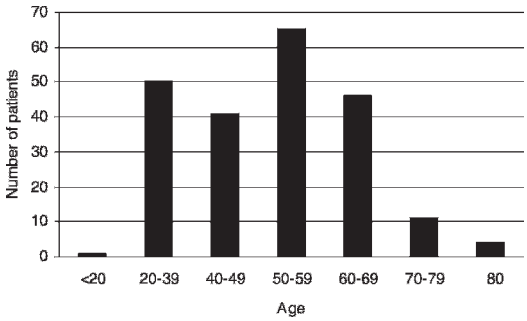

FIGURE 1. Patient age at surgery.

the study delivered the data for the 1-year follow-up visit.

Study population and implants used

The study population analyzed in this study consisted of 218 patients, 114 (52.3%) men and 104 (47.7%) women. Patients ranged in age from 19 to 89 years (Figure 1), with a mean age of 51 years. Approximately two-thirds of the patients were recorded as having good (58%) or excellent (8%) oral hygiene (Table 1). Another 28% of patients were reported to have fair oral hygiene, and 6% of the patients had poor oral hygiene. The most common risk factor was smoking (24% of patients), followed by untreated gingivitis or periodontitis (9%) and bruxism (6%; Table 1). Four patients were affected by osteoporosis, and the following risk factors were experienced by 1 patient each: not strictly controlled diabetes, postextraction bone infection, rheumatoid arthritis, previous myocardial infarction, atherosclerosis, hypertension, microcytemia, and mild depression.

Bone type II (according to the definition of Lekholm and Zarb[27]), present in 39% of the patients (Table 2), and bone type III, present in 37% of patients, were the most common. Only 10% of the implants were inserted into bone type I, and 15% were inserted into bone type IV.

Extraction/loss of the tooth at the site of implantation had occurred in most of the patients more than 6 months before implant surgery (48%). Another 22% had lost the tooth 8 weeks to 6 months previously, indicating that the clinicians used a rather cautious treatment plan.

The vast majority of the implants used were the Standard Plus type (92%), characterized by a titanium collar part of 1.8 mm and a diameter of 4.1 mm (76%; Table 3). The implants were equally distributed be-

TABLE 2
Bone quality at surgery (N = 276)

Bone Type*	n	%
Type I	27	9.8
Type II	107	38.8
Type III	101	36.6
Type IV	41	14.9

*According to Lekholm and Zarb.[27]

TABLE 1
Oral hygiene and risk factors in 218 patients

Characteristic	n	%
Oral hygiene		
Excellent	17	7.8
Good	127	58.3
Fair	62	28.4
Poor	12	5.5
Risk factors		
Uncontrolled diabetes	1	0.5
Bruxism	14	6.4
Untreated gingivitis, periodontitis	19	8.7
Smoking	52	23.9
Osteoporosis treatment	4	1.8
Other	9	4.0

TABLE 3
Implants used in the study (N = 276)

Implant	n	%
Type		
Standard	19	6.9
Standard Plus	254	92.0
TE	2	0.7
Missing	1	0.4
Length (mm)		
8	28	10.1
10	162	58.7
12	86	31.2
Diameter (mm)		
3.3	10	3.6
4.1	211	76.4
4.8	55	19.9

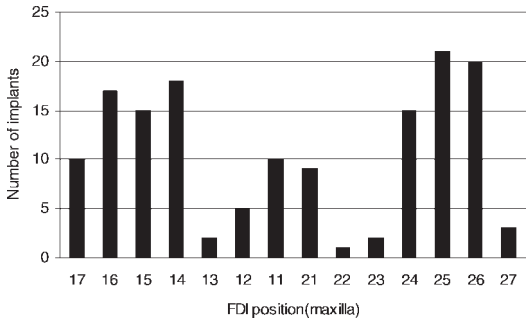

FIGURE 2. Position of implants in the maxilla according to the FDI nomenclature.

tween mandible (46%) and maxilla (54%), and most were inserted in the posterior region of the mouth (Figures 2 and 3).

Bone augmentation procedures

At the time of the surgery the investigators were asked to document whether they performed bone regenerative techniques simultaneously with the implant placement. A bone augmentation procedure was applied in 86 of all inserted implants (31%); in 23 (8%) of these cases a membrane was also used (Table 4). The frequencies of the indications for which a bone augmentation was performed were as follows: 38 cases of sinus floor elevation, 6 cases of vertical ridge augmentation, 29 cases of horizontal ridge augmentation, and 22 cases of extraction socket preservation.

Loading protocols

Early loading, which recognized international implantological societies define as functional

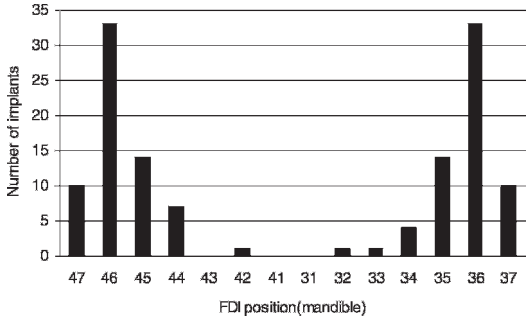

FIGURE 3. Position of implants in the mandible according to the FDI nomenclature.

TABLE 4
Bone augmentation procedures performed at implant placement (N = 276)

Procedures	n	%
Bone augmentation only	63	22.8
Membrane only	1	0.4
Bone augmentation and membrane	23	8.3
Neither	189	68.5

loading of the implant between 48 hours and 3 months after implant insertion,[25,26] was the loading protocol applied most frequently (48% of the implants), whereas 34% of the implants were loaded according to the conventional loading protocol (implants loaded 3 to 6 months after implant placement; see Table 5). Immediate restoration (ie, a restoration within the initial 48 hours, out of occlusion) and immediate loading (restoration done within 48 hours, in occlusion) were relatively rare (7% and 2%, respectively).

A temporary restoration was made in 167 patients in whom 206 implants (75% of total) had been inserted. The type of restoration most frequently performed was the single crown, which was used in more than two-thirds (68%) of the patients. Of these, 97 cases were single molars. Splinted crown and implant-borne bridges accounted for 20% and 11% of the restorations, respectively, while only 2 cases (1%) of overdenture were reported.

TABLE 5
Loading protocol (N = 273)*

Protocol	n	%
Immediate restoration (within 48 h, no occlusion)	18	6.6
Immediate loading (within 48 h, in occlusion)	5	1.8
Early loading (48 h to 3 mo)	132	48.4
Conventional loading (3–6 mo)	93	34.1
Delayed loading (>6 mo)	25	9.2

*In total 276 implants were inserted in the patients enrolled in the study. At the time of loading (either temporary or final) 3 implants were lost to follow-up.

TABLE 6
Implant success: Life table analysis*

Time Interval (Visits)	Implants at Baseline	Failures Occurred at the Specified Time Interval	ISR (%)	CSR (%)
Surgery to temporary loading	276	2	99.3	99.3
Temporary loading to final restoration	274	3	98.9	98.2
Final restoration to 1-y follow-up	271	0	100	98.2

*ISR indicates interval survival rate; CSR, cumulative survival rate.

Implant survival and success rates

Of 276 implants inserted and documented, 2 implants (0.7%) were reported as not being successfully osseointegrated by the time of the temporary loading visit (FDI positions 26 and 16, respectively; Table 6). A further 3 implants (1.1%) failed before final restoration (1 implant in FDI position 15 and 2 in position 16; Table 6). The survival rate calculated using the Kaplan-Meier method was 98.2% at the 1-year follow-up visit after implant insertion. Because all the remaining implants in situ were functional and fulfilled the success criteria considered in the study (absence of mobility, absence of persistent or irreversible pain, no recurrent peri-implant infection, no bone loss greater than 2 mm, and no radiolucency) it can be said that the overall implant success rate was also 98.2%.

In 2 of the failure cases the investigator reported that the implant was spinning or mobile during surgery, and in the other 3 failures primary stability of the implants was reached at the time of placement. In 4 of the patients experiencing implant failures, the bone type belonged to class IV (defined according to Lekholm and Zarb[27]), and in 1 patient the bone was class III, which was in line with the fact that all of these implants were placed in the posterior regions of the maxilla. Only 1 patient in 5 presented a risk factor (smoking). In all cases of implant failure a simultaneous bone augmentation procedure was performed for the indication of sinus floor elevation.

Complications

Two complications were reported at surgery: a spinning implant and a mobile implant. Both of these implants were subsequently removed and are part of the 5 implant failures reported previously.

At the temporary loading visit, 3 complications were reported: bone loss around the implant in 1 patient (<2 mm), 1 case of loosening of the abutment, and 1 case of paresthesia.

At the 1-year follow-up visit, 1 patient showed loosening of the abutment, 1 patient reported acrylic/porcelain fractures, and non–implant-related serious adverse events were reported in 2 patients.

DISCUSSION

The restoration of missing teeth with endosseous dental implants has become a well-accepted dental treatment modality. A characteristic of the procedure has been a relatively long unloaded healing period after implant placement into the bone to minimize the risk of healing and osseointegration complications. In recent years, patient demands have increased in terms of esthetics and regaining gain function as soon as possible after surgery. To respond to these needs, several companies have put much effort in the development of new implant surfaces and/or in the modification of old ones with the aim of shortening restoration times. The chemically modified surface used in this investigation was developed using the

well-documented topography of the SLA surface.[19]

A large randomized controlled clinical trial reported a survival rate for the new chemically modified surface implants of 98% and 97% in the case of immediate and early loading, respectively.[20] The purpose of the current study was to compare the high survival and success rate of these type of implants reported in that controlled clinical trial with those obtained under common practice conditions where patient selection is not restrictive and technique is not controlled.

High survival and success rates were documented in this noninterventional study. One year after implant placement the cumulative survival and success rates, as defined in the protocol, were both 98.2%. Noninterventional trials are inherently less controlled than formal clinical trials. According to the protocol, no strict inclusion/exclusion criteria had to be applied in the selection of the patients besides the usual contraindications observed in routine implant therapy. As a result, the patients enrolled in the study were more heterogeneous and as such represent those seen more typically in routine practice. Thus, although many variables were uncontrolled, the predictability of the procedure with implants characterized by the new chemically modified surface was not affected.

Several reasons may explain why the survival and success rates are very high in spite of the variability in patient selection and the heterogeneity of the clinicians participating in the study. One possibility is that implant placement and restoration are less dependent on the particular patient selected, restorative technique, and follow-up and are more dependent on other variables. All 5 implants that failed in this noninterventional trial were placed concomitantly with bone augmentation in a sinus floor elevation procedure. Implant placement can be performed either simultaneously to the sinus lift procedure or in a 2-step approach. In 2 systematic reviews no differences have been reported between these 2 procedures.[28,29] However, because implant primary stability is essential for the success of implant treatment, it is recommended to adopt a simultaneous procedure when at least 5 mm of residual bone is available. This basal bone allows the implants to be stabilized while the graft is maturing. In 2 of the failures, no primary stability was achieved at the time of implant placement and simultaneous sinus floor elevation; both of these failures were in bone type IV, which may be associated with greater implant mobility at placement.[30] In these cases the critical clinical situation cannot be compensated by any surface property, because secondary stability is hardly dependent on surface characteristics when implant micromovements are present. In addition, some evidence suggests that implant survival is more variable in the grafted sinus[31] and that implants placed with sinus augmentation may not have the same long-term survival as those placed in native bone.[32]

In the other 3 cases of implant failure, although primary stability was achieved, the bone quality was low (type IV in 2 cases and type III in 1 case). This unfavorable characteristic might have led to implant loss because poor bone quality may be a primary predictor of implant failure.[33,34]

In nearly half of the cases (48%; Table 5) the clinicians followed an early loading protocol, which is defined as a functional loading of the implant between 48 hours and 3 months after placement. High success rates in early loading procedure with SLA implants have been reported in cases of partial edentulism restored with splinted crowns and 3-units fixed prosthesis.[35] In the current study, most of the early loaded implants were single teeth, which are known

to be more prone to failure than splinted restorations. In this view, the use of an implant surface that can promote and accelerate bone formation is of particular importance. The new chemically modified surface has been shown to promote osteoblast differentiation.[18] A study in miniature pigs demonstrated an increased bone apposition to the implant surface in the early healing stages with 60% greater bone formation at the chemically modified surface compared with the SLA surface. Additionally, there was earlier formation of more mature bone,[36,37] with mean removal torque values consistently higher in the first 8 weeks.[38]

Histologic and immunohistochemical evaluations have shown enhanced bone formation, significantly increased cellular activity, and proliferation of vascular structures with the chemically modified surface compared with SLA.[39] Greater subepithelial connective tissue attachment, with well-organized collagen fibers and numerous blood vessels, were also evident.[40] Taken together, these processes are likely to translate to faster osseointegration and more stability of implants with the new chemically modified surface. Results of a recently published randomized controlled pilot clinical study conducted in 31 patients, each of whom received 1 SLA and 1 chemically modified surface implant, support this theory. Implant stability was measured weekly over the first 6 weeks after implant placement using the resonance frequency analysis method. Results of the analysis suggested significant stability improvements with the new chemically modified surface; increased stability was seen at an earlier stage, and the change from decreasing to increasing stability in the mandible (ie, from primary to secondary stability) occurred earlier with the chemically modified surface—at 2 weeks compared with 4 weeks with SLA.[41]

In summary, this prospective, human, noninterventional trial resulted in successful restoration of implants characterized by the new chemically modified surface. The cumulative rates are similar to formal clinical trials under more controlled conditions. Known characteristics of the new chemically modified implant surface include enhanced bone cell differentiation, large amounts of bone apposition, and strong bone-to-implant contact at early time points resulting in a high predictability of the clinical outcome.

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Abbreviation

SLA: sandblasted, large-grit, acid-etched

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