A prospective noninterventional study to document implant success and survival of the Straumann Bone Level SLActive dental implant in daily dental practice

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Objectives: Clinical studies to assess dental implants are common in implantology, but such studies are usually performed for specific indications and following a specific protocol with strict inclusion and exclusion criteria. The aim of the current study was to evaluate the Straumann Bone Level SLActive dental implant in a prospective, multicenter, noninterventional trial. **Method and Materials:** The implant could be used in whatever manner was deemed suitable by the clinician, within approved indications. No particular placement or loading protocol was specified. A total of 1,532 implants were placed in 852 patients in 123 centers in nine countries in the US and Europe. After exclusion of three countries due to patient enrollment and data issues, 759 patients with 1,355 implants were analyzed. **Results:** Most patients received one or two implants (58.6% and 25.3% of patients, respectively), and 90% of cases were performed with a raised flap. A submerged healing protocol was significantly more prevalent in European centers, while transmucosal healing was significantly more prevalent in North American centers. After 1 year, 538 patients with 908 implants were available for evaluation. The cumulative implant survival and success rates were 98.5% and 96.0%, respectively. **Conclusions:** This prospective noninterventional study evaluated the use of Straumann Bone Level SLActive dental implants in a large number of patients. The cumulative survival and success rates were similar to those observed in controlled clinical trials, confirming this dental implant's clinical applicability in daily practice. *(Quintessence Int 2013;44:499–512; doi: 10.3290/j.qi.a29611)*

Key words: bone level dental implant, daily dental practice, noninterventional study, SLActive

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Endosseous dental implants have demonstrated excellent long-term survival and predictable support for dental prostheses, from single crowns to full-arch fixed dental prostheses and overdentures.[1-6] The success of dental implants in patients has been extensively demonstrated in clinical trials for over 20 years. Such clinical studies to assess dental implant survival rates are common in implantology, and the results are often cited by dental implant manufac-

turers as proof of the success of their products.[7,8] However, these studies are usually performed according to a protocol with strict inclusion and exclusion criteria, which dictates the enrollment of patients with specific dental situations, or aim to investigate a specific indication. One potential criticism of such studies, therefore, is that they may not accurately reflect the wide variety of patients and situations seen in normal daily dental practice. The clinicians involved in such formal clinical trials may potentially devote more time and attention to the patients in the trial, due to the study set-up. In addition, the clinicians involved in these clinical trials are usually specialists or have additional training in a particular dental discipline, and this may increase the likelihood of higher implant survival.[9] For these reasons, formal clinical trials may be biased towards more favorable outcomes.[10]

To minimize some of the criticisms levied as to the applicability of a highly controlled institution-based study to clinical private practice, a noninterventional study could be designed and initiated for the evaluation of a particular medical device. In a noninterventional trial, the product in question would be used in the manner for which it has been approved, but the assignment of patients to a particular therapeutic strategy would not be determined by a clinical trial protocol. Instead, treatment is determined according to the standard current practice of the clinician, independent of the decision to include the patient in the study. However, the usage of the product would be systematically documented and analyzed. The intention of such a noninterventional study in the context of dental implantology would therefore verify the results of controlled clinical studies in a real-world situation.

Implant outcomes are influenced by the implant design as well as the surgical procedure. There is a wide variety of implant designs and surfaces on the market, with an emphasis in recent years on implants and surgical procedures designed for improved esthetic results.[11,12] Esthetic outcomes depend mainly on the amount of peri-implant bone remodeling, which can be influenced by the implant design.[13] Following implant placement, the goal with esthetic implant treatment is therefore to minimize bone loss as much as possible.[14]

A bone level implant with a sand-blasted, large-grit, acid-etched, and hydrophilic surface (SLActive) has been developed with a view to obtaining more predictable outcomes in the esthetic zone. The Straumann Bone Level implant is designed to be placed with the neck of the implant at the same level as the crestal bone. Unlike soft tissue level implants, the bone level implant has no metallic tulip-shaped shoulder, so that the visibility of any gray metallic shadow through the soft tissue can be eliminated. Preclinical studies evaluating the platform switching concept with this implant have shown very little bone loss and no significant differences between submucosal and transmucosal healing approaches.[15] The results were in line with those observed in similar previous studies,[16,17] but with smaller crestal bone loss values; mean bone loss 6 months after loading was +0.17 mm, -1.32 mm, and -0.15 mm for submucosal implants placed above, below, or at the crestal bone level, respectively, and -0.20 mm, -1.40 mm and -0.47 mm for transmucosal implants placed above, below, and at the crestal bone level, respectively. A second study with a similar protocol showed bone-to-implant contact percentages 6 months after loading of 71.5%, 71.8%, and 73.3% for submucosal implants above, below, and at the bone crest level, and 76.0%, 74.5%, and 73.2% for transmucosal implants above, below, and at the bone crest level, respectively.[18]

The goal of the present study was to evaluate the success and survival of Straumann Bone Level SLActive implants in daily dental practice in normal clinical situations for up to 3 years; 1-year results are reported here.

METHOD AND MATERIALS

Clinicians, patients, and implants

This study was a prospective, multicenter, noninterventional study using Straumann Bone Level SLActive implants (Institut Straumann). The implants were allowed to be used in all approved indications and all implant therapies at the discretion of each

individual clinician. Clinicians were allowed to take part in the study provided that they were generally familiar with and legally allowed to perform dental implant treatment. The experience and educational background of participating clinicians was assessed by internet-based background searches. Patients were eligible to participate if their general medical condition was sufficient to allow an oral surgical procedure and if dental implant treatment was indicated for tooth restoration. No specific inclusion or exclusion criteria were applied, and there was no general medical condition where oral surgical procedures were contraindicated. Patient willingness to consent to participation in the study was necessary, and data collection and analysis were designed to preserve the anonymity of the patients. All aspects of the study were performed according to the 'World Medical Association Declaration of Helsinki' for patients participating in clinical studies. The study has been independently reviewed and approved by the respective ethics committees of each participating country, where applicable.

The implants (Bone Level SLActive, Institut Straumann) had a body diameter of 4.1 mm and lengths of 8, 10, 12, or 14 mm. A variety of abutments were allowed to be used, including provisional abutments, solid abutments, Meso abutments, anatomic abutments, gold abutments, and Locator abutments. All prosthetic components were to be used within their standard indications and recommendations for use. No particular implant placement or loading protocol was specified; all surgical protocols from immediate implant placement in extraction sockets to placement in sites healed for 16 weeks and over were allowed, and all loading protocols from immediate (within 48 hours after placement) to delayed (> 6 months after placement) were allowed, at the discretion of each participating clinician. All implants were to be placed according to normal treatment protocols and the manufacturer's recommendations.

Surgical procedures and assessments

Patient examination was performed at a presurgery visit, and informed consent was obtained. Demographic data (age, sex, and race), oral hygiene score (based on the investigator's clinical experience [1 = excellent, 2 = good, 3 = satisfactory, 4 = bad]), dental situation (number and position of missing teeth), and reasons for tooth loss were recorded. Patients were also evaluated for dental/oral risk factors (untreated periodontitis, insufficient oral hygiene, bruxism, and horizontal/vertical bone defects) and systemic risk factors (smoking, metabolic diseases, medication, alcohol or drug abuse, radiotherapy, tumor surgery, chronic sinusitis, and physical disability).

Types and sites of implants placed were documented at implant placement (first stage surgery), and the type of healing procedure (submerged, nonsubmerged, or semi-submerged) and abutment/healing abutment used was recorded. The time since the tooth to be replaced was lost or removed was recorded and categorized according to the Proceedings of the ITI Consensus Conference:[19]

- type 1: immediate placement as part of the same surgical procedure
- type 2: early placement with soft tissue healing (4 to 8 weeks)
- type 3: early placement with partial bone healing (12 to 16 weeks)
- type 4: late placement in fully healed site (≥ 6 months).

Implant loading

In the event of second-stage surgery (for submerged implants), the type of secondary component and any complications were recorded. Loading protocols followed the normal time schedules followed in each center. Implants were loaded with single crowns, splinted crowns, or fixed partial dentures, or full- or partial-arch prostheses. For temporary and final restoration, the type of restoration was recorded, implant success and survival criteria were evaluated, complications were noted, and subjective radiographic bone level examination was performed. Implant loading was performed according to the individual patient situation, and the loading protocols were categorized according to the criteria by Cochran et al[20]:

- Immediate restoration: restoration placed out of occlusion within 48 hours of implant surgery

- Immediate loading: restoration placed in occlusion within 48 hours of implant surgery
- Early loading: restoration placed at least 48 hours after implant surgery, but within 3 months
- Conventional loading: restoration placed in a second procedure after a healing period of 3 to 6 months after implant surgery
- Delayed loading: restoration placed in a second procedure at least 6 months after implant surgery.

Follow-up evaluations

Follow-up evaluations, examining periapical radiography, implant success and survival, radiographic bone level measurement, and complications, were performed after 1 year, with further follow-up visits planned after 2 and 3 years. Radiography and radiographic measurement of bone level were strongly recommended; where performed, these were not standardized throughout the study, but were performed according to each clinic's standard procedure.

Implant success was defined according to the criteria by Buser et al[21]:

- absence of pain
- absence of recurrent peri-implant infection
- absence of tactile mobility
- absence of continuous peri-implant radiolucency.

Surviving implants were those that were still in place, whether functionally successful or not. Implant failure was defined by implant removal, fracture beyond repair, or classification other than successful or surviving.

Endpoints

The primary endpoints were the implant survival and success rates 1 year after abutment placement. Secondary endpoints were change in crestal bone level and evaluation of loading protocol. Descriptive statistics (means and standard deviations) were used to report the data. To evaluate any potential differences between the US and European patient groups, a Student's *t* test with a two-tailed distribution and two-sample unequal variance was performed; *P* values less than .05 were considered statistically significant.

RESULTS

Patients, clinicians, and implants

Patients were enrolled at 123 centers in nine countries (Belgium, Canada, Germany, Italy, The Netherlands, Spain, Switzerland, United Kingdom, and the United States). A total of 852 patients received 1,532 implants (Fig 1). The mean patient age was 53.7 ± 15.0 years (range 16.3 to 88.8 years); 55.6% were women and 44.2% were men (data were missing for 0.1%). The reasons for tooth loss are detailed in Table 1.

A total of 102 clinicians took part in the study, each placing 13.3 implants on average (range, 1 to 76 implants; mode, 10 implants). The educational background of the participating clinicians is presented in Fig 2. Fifty-two clinicians were identified as oral and maxillofacial surgeons, 6 were periodontists, and 44 were classified as general dentists. In addition to the academic education it was also evaluated that 19 clinicians were specialists in oral implantology.

Upon analyzing the results, it was apparent that several problems were encountered in centers from three of the countries (Belgium, The Netherlands, and Spain). Due to the incomplete recording of data (eg, only 32 of a total of 90 patients in these countries had a documented final restoration) and inconsistent follow-up analyses (only 11/90 patients were available at the 1-year follow-up), data analysis was incomplete for these countries. Thus, it was decided to exclude these countries from the analysis. In the remaining six countries, a total of 759 patients received 1,355 implants (Fig 1); the mean patient age was 54.2 ± 15.0 years (range 18.0 to 88.8 years). This patient population was used for all subsequent results.

No dental or systemic risk factors were reported for 60.9% and 84.6% of patients, respectively. The most common dental risk factor was horizontal or vertical bone defect (20.9% of patients), followed by bruxism (6.9%), and insufficient oral hygiene or periodontitis (1.7% each). The main systemic risk factor was the use of concomitant medication (2.8%), followed by diabetes mellitus and osteoporosis (1.1% each). The prevalence of other risk factors (metabolic

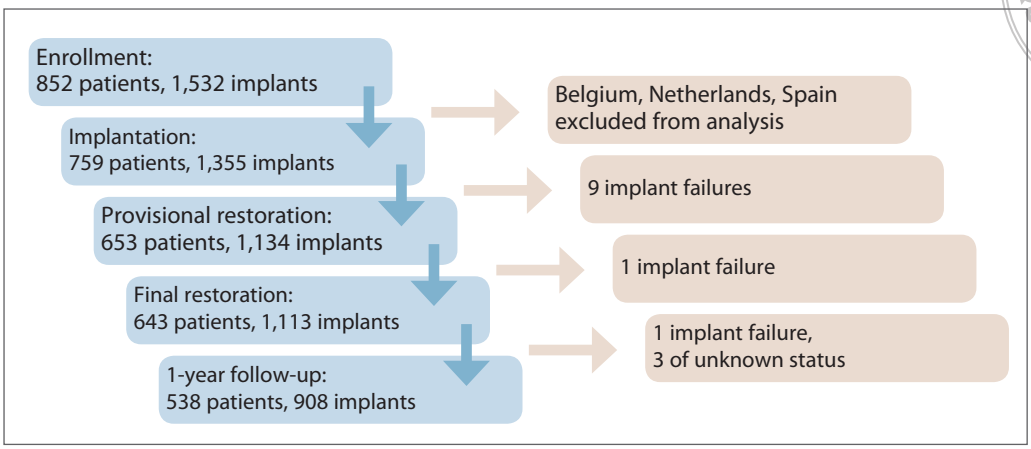

Fig 1 Number of patients and implants. The number of patients and implants are depicted from the patient enrollment until the 1-year follow-up: 759 patients received a total number of 1,355 implants at the implantation visit. After 1 year, 538 patients and 908 implants were still included in the study. The implant failures between the visits are presented. In total, 11 implants failed during the first year after placement and 3 were of unknown status.

Table 1 **Reasons for tooth loss: the reason for tooth loss was recorded for all patients enrolled in the study**

Reason	No. of implants (%)
Periodontitis	519 (33.9%)
Caries	347 (22.7%)
Unsuccessful endodontic treatment	200 (13.1%)
Tooth fracture	174 (11.4%)
Loss due to trauma	75 (4.9%)
Congenitally missing	68 (4.4%)
Excessive internal root resorption	13 (0.8%)
Previous implant lost	12 (0.8%)
Root resorption following re-implantation	3 (0.2%)
Fracture of previous implant	1 (0.1%)
Other	120 (7.8%)
Total	1,532 (100%)

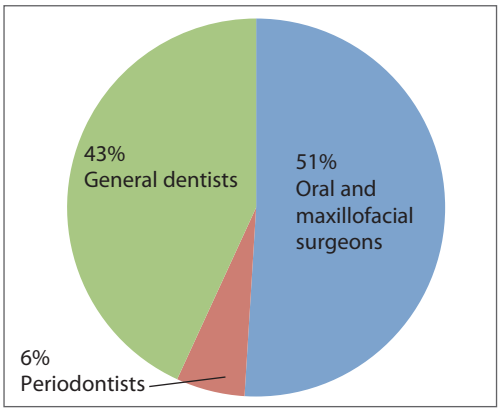

Fig 2 Educational background of the 102 participating clinicians. Among the 102 participating clinicians from 6 countries, the academic education was evaluated by internet-based background checks; 52 were identified as oral and maxillofacial surgeons based on reported comprehensive education in this field, 6 were periodontists, and 44 were classified as general dentists. Clinicians were classified as general dentists if not reported otherwise. Besides the academic background, 19 clinicians could be classified as specialists in dental implantology due to reported education.

disease other than diabetes mellitus, tumor surgery and/or radiation therapy, and physical disability) was lower than 1% each. The majority of patients showed good (59.4%) or satisfactory (26.0%) oral hygiene scores, with excellent scores in 12.5%; only 1.8% showed a bad oral hygiene score. The majority of the patients (87.6%) were nonsmokers.

Most patients received one or two implants (58.6% and 25.3% of patients, respectively), while 5.4% and 5.3% received three and four implants, respectively. The remaining patients received between five and eight implants (2.0%, 2.4%, 0.5%, and 0.5% for five, six, seven, and eight implants, respectively). Implant lengths of 12 mm and 10 mm were most commonly used (48.6% and 34.2% of implants, respectively); 9.7% were 14-mm long and 7.2% were 8-mm long. In total, 70.8% of the implants were placed in the maxilla and 29.2% were placed in the mandible. The detailed implant distribution according to the tooth position is shown in Fig 3. In total, 649 implants (47.9%) were placed in the esthetic region (positions 14 to 24 according to FDI World Dental Federation notation).

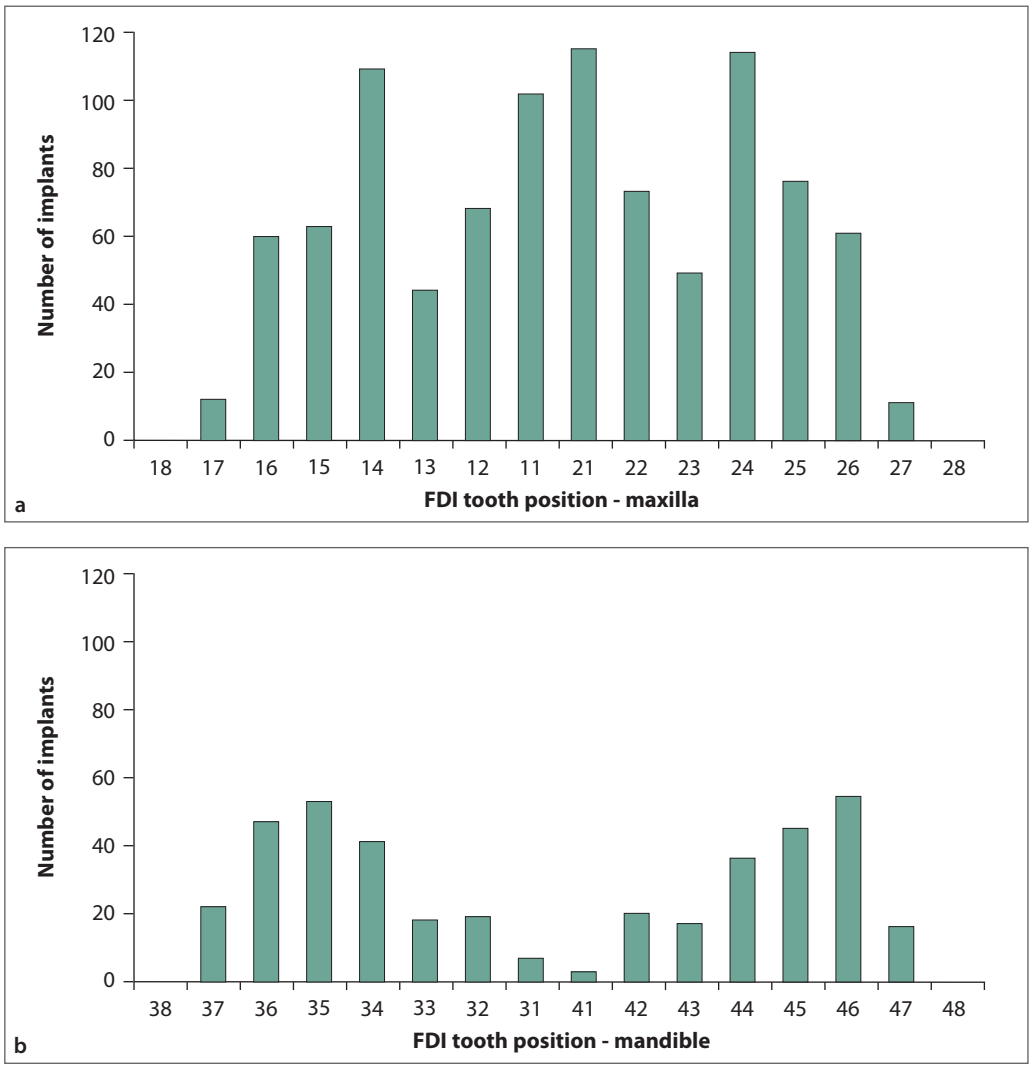

Fig 3 Implant distribution according to tooth position. The number of implants per tooth position is depicted in the maxilla *(a)* and in the mandible *(b)*, according to the FDI World Dental Federation notation. A total of 649 implants (47.9%) were placed in the esthetic region (positions 14 to 24).

Surgical procedures

The time between tooth loss or tooth extraction and implantation was recorded for the 1,355 inserted implants. The timing of implant placement was categorized as type 1 to 4, according to the Proceedings of the ITI Consensus Conference (Table 2).[19] There was a difference evident between the European and North American centers. In European centers implants were preferably placed late after tooth extraction (60.4% type 4; ≥ 6 months after tooth extraction), while only a minority of implants were placed immediately after tooth extraction (10.5% type 1: immediately after tooth extraction). In contrast, in North American centers the majority of implants were preferably placed either immediately (42.9% type 1) or late after tooth extraction (44.4% type 4). Thus, there were significant differences in the timing of implant placements between the European and North American centers (*P* values shown in Table 2). Figure 4 shows an exemplary case of a patient whose mandibular right first premolar was extracted 4 weeks prior to implant placement.

A surgical procedure where a flap was elevated was performed in 90% of cases, while a flapless procedure was performed in only 9.1% of cases; for the remaining cases the surgical procedure was not recorded. The bone quality recorded at the position of each implant is shown in Table 3. Primary stability was achieved for 98.6% of implants placed.

The healing protocol used is shown in Table 4. Similar to the timing of implant placement, there was a difference observed in the healing protocol between the European and North American centers; European centers predominantly used a submerged protocol (65.8% of implants), while North American centers predominantly employed transmucosal healing (74.8% of implants). These healing protocols were significantly different ($P < .01$) between Europe and North America. However, there was no significant difference for semi-submerged healing (7.1% in European centers compared to 10.7% in North American centers; $P = .20$).

Provisional and final restoration

Of 1,134 implants in 653 patients where data were available for evaluation at the provisional restoration stage, there were nine implant failures (Fig 1). Provisional restoration was performed for 278 implants (24.5%). Data from a total of 1,113 implants in 643 patients were available for analysis at the final restoration stage (Fig 1), and one additional implant failure was noted (ie, all

Table 2 **Classification for the timing of implant placement. The time between tooth loss or extraction and implantation was categorized according to the Proceedings of the ITI Consensus Conference.[19] Absolute numbers of implants and percentages (in parentheses) are shown according to region.**

Classification	United States/Canada	Europe	Overall
Type 1: directly after tooth extraction (immediate placement)	57* (42.9%)	128* (10.5%)	185 (13.7%)
Type 2: 4–8 weeks postextraction (early placement with soft tissue healing)	6* (4.5%)	184* (15.1%)	190 (14.0%)
Type 3: 12–16 weeks postextraction (early placement with partial bone healing)	11† (8.3%)	172† (14.1%)	183 (13.5%)
Type 4: ≥ 16 weeks (late placement)	59* (44.4%)	738* (60.4%)	797 (58.8%)
Total	133 (100%)	1,222 (100%)	1,355 (100%)

*Statistically significant difference ($P < .01$) between the regions; †statistically significant difference ($P = .03$) between the regions.

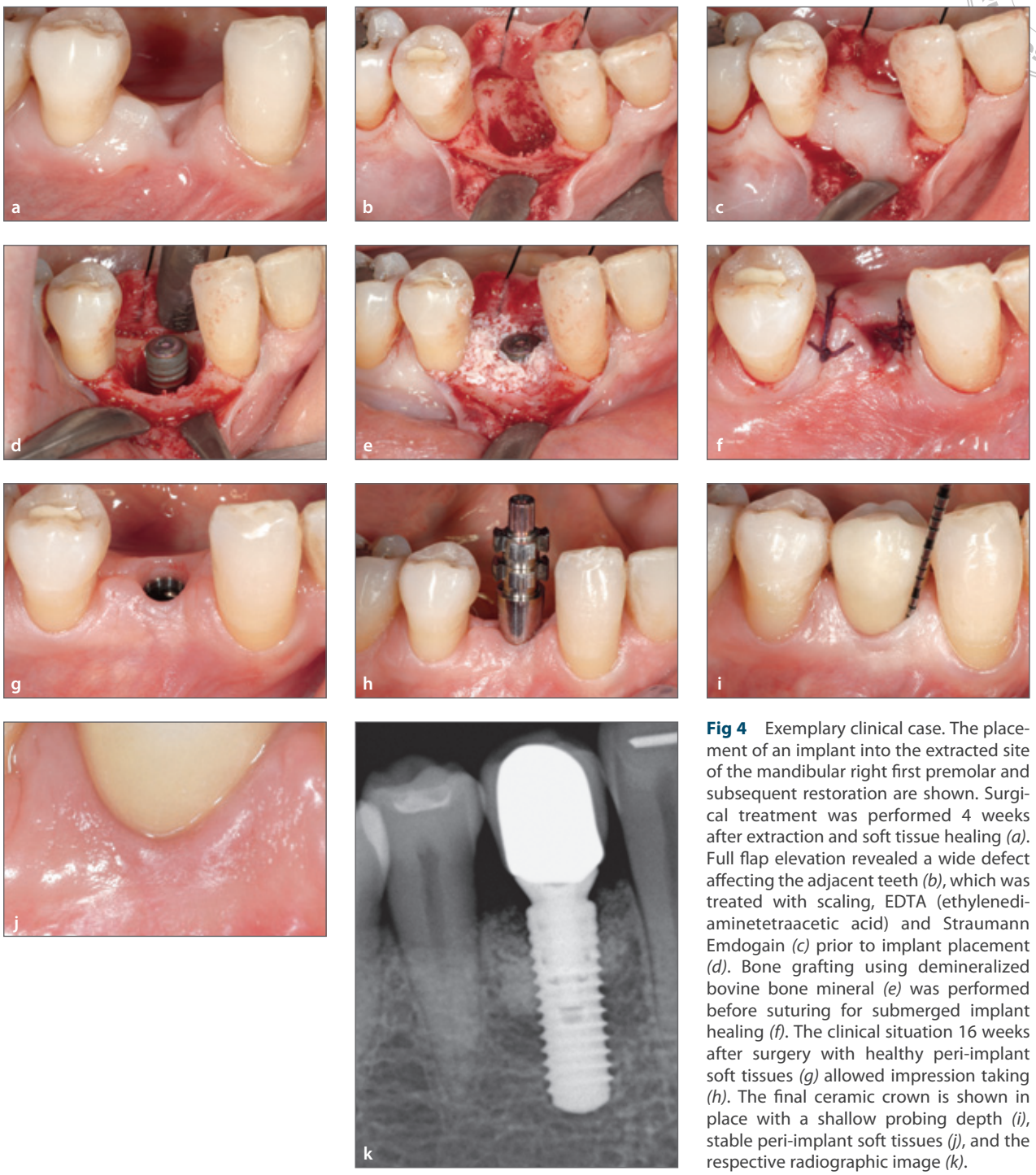

Fig 4 Exemplary clinical case. The placement of an implant into the extracted site of the mandibular right first premolar and subsequent restoration are shown. Surgical treatment was performed 4 weeks after extraction and soft tissue healing *(a)*. Full flap elevation revealed a wide defect affecting the adjacent teeth *(b)*, which was treated with scaling, EDTA (ethylenediaminetetraacetic acid) and Straumann Emdogain *(c)* prior to implant placement *(d)*. Bone grafting using demineralized bovine bone mineral *(e)* was performed before suturing for submerged implant healing *(f)*. The clinical situation 16 weeks after surgery with healthy peri-implant soft tissues *(g)* allowed impression taking *(h)*. The final ceramic crown is shown in place with a shallow probing depth *(i)*, stable peri-implant soft tissues *(j)*, and the respective radiographic image *(k)*.

failures had been previously recorded at the provisional restoration visit). The cumulative implant survival rate was therefore 99.1% at this stage. Problems with the implants were noted in 14 cases, including eight cases of radiolucency (0.7%) and four cases of peri-implantitis (0.3%).

Table 5 shows the types of restorations used at the final restoration stage. Most restorations were cemented (78.6% of

Table 3 Bone quality: at the implantation visit, bone quality was recorded at the position of each implant

Bone quality	No. of implants	Frequency (%)
Type 1	91	6.7
Type 2	641	47.3
Type 3	532	39.3
Type 4	79	5.8
Unknown/missing	12	0.9
Total	1,355	100

Table 4 Implant healing protocol according to region: implants were allowed to heal according to one of the three healing protocols indicated

Healing protocol	United States/Canada	Europe	Overall
Submerged	19* (14.5%)	806* (65.8%)	825 (60.9%)
Semi-submerged	14† (10.7%)	87† (7.1%)	101 (7.5%)
Transmucosal	98* (74.8%)	327* (26.7%)	425 (31.4%)
Unknown/missing	0 (0.0%)	4 (0.3%)	4 (0.3%)
Total	131 (100%)	1,224 (100%)	1,355 (100%)

*Statistically significant difference ($P < .01$) between the regions; †difference not statistically significant ($P = .20$) between the regions

Table 5 Type of restoration recorded at the final restoration visit

Type of restoration	No. of implants	Frequency (%)
Single crown	608	54.6
Fixed partial dentures (including cantilever)	358	32.1
Full-arch prosthesis	105	9.4
Partial-arch prosthesis	25	2.2
Unknown/missing	17	1.5
Total	1,113	100

implants); screw retention was used in only 11.4% of cases, and other types of retention were used in 8.7% of cases. Conventional implant loading was predominantly used (68.6% of implants), followed by delayed loading (14.6%), and early loading (12.4%) (Table 6). Conventional loading was significantly more prevalent in the European centers than the North American centers (70.0% compared to 57.5%; $P = .01$). Immediate loading and restoration were more prevalent in the North American centers, however the differences were statistically not significant compared to the European centers (3.3% vs 0.2% [$P = .06$] for immediate loading and 6.7% vs 2.2% [$P = .05$] for immediate restoration).

Implant survival and success and bone measurements after 1 year

After 1 year, a total of 538 patients with 908 implants were available for evaluation (Fig 1). At this stage, there was one additional implant failure recorded (due to loss of osseointegration) and three implants where data were unknown or missing. Taken together, a total of 14 implants either failed or had a lack of documented survival

within the first year after implant placement, resulting in a cumulative survival rate of 98.5%, based on 908 implants after 1 year.

Few problems with the implants were noted at the 1-year follow-up, including five cases of peri-implantitis (0.6% of implants) and one case of radiolucency (0.1%). The overall success rate of the bone level implants was calculated based on the success criteria as published by Buser et al.[21] Therefore, if an event such as pain, peri-implantitis, mobility, or radiolucency was reported, they were counted as unsuccessful implants, irrespective of whether the event was transient or persistent. No distinction in the persistence of an event was made during data acquisition. A total of 36 complications, problems and/or failures that applied to the success criteria were reported within the first year after implant placement, which resulted in a cumulative success rate of 96.0%, based on 908 implants after 1 year.

Where radiographic bone level was evaluated, there was no change in crestal bone level at the majority of implants (62.2% and 61.8% mesial and distal) (Table 7). Change in bone level of greater than 1 mm was observed at less than 5% of implants (4.5% and 3.9% mesial and distal), while bone growth was observed in around 3% of cases (3.3% and 3.0% mesial and distal). Due to the noninterventional nature of the study, no radiographs were acquired for the remaining implants because this was not part of the standard procedure of the respective dental practitioners.

Table 6 **Implant loading protocol: numbers of implants and percentages (in parentheses) according to region**

Loading protocol	United States/Canada	Europe	Overall
Immediate loading	4* (3.3%)	2* (0.2%)	6 (0.5%)
Immediate restoration	8† (6.7%)	22† (2.2%)	30 (2.7%)
Early loading	14‡ (11.7%)	124‡ (12.5%)	138 (12.4%)
Conventional loading	69§ (57.5%)	695§ (70.0%)	764 (68.6%)
Delayed loading	21# (17.5%)	142# (14.3%)	163 (14.6%)
Unknown/missing	4 (3.3%)	8 (0.8%)	12 (1.1%)
Total	120 (100%)	993 (100%)	1,113 (100%)

*Difference not statistically significant ($P = .06$); †difference not statistically significant ($P = .05$); ‡difference not statistically significant ($P = .80$); §difference statistically significant ($P = .01$); #difference not statistically significant ($P = .38$).

Table 7 **Crestal bone level: the number (%) of implants with mesial and distal radiographic bone level changes is indicated at the 1-year follow-up**

	Mesial	Distal
No change	565 (62.2%)	561 (61.8%)
< 0.5 mm	108 (11.9%)	100 (11.0%)
0.5–1 mm	43 (4.7%)	63 (6.9%)
1–2 mm	32 (3.5%)	26 (2.9%)
2–3 mm	5 (0.6%)	5 (0.6%)
3–4 mm	4 (0.4%)	2 (0.2%)
> 4 mm	0 (0%)	2 (0.2%)
Bone growth	30 (3.3%)	27 (3.0%)
Not evaluated or unknown	121 (13.3%)	122 (13.5%)
Total	908 (100%)	908 (100%)

Complications

Complications were documented throughout the entire study. The following complications were reported at second stage surgery: formation of fistula (3 cases), complications with regenerative procedures (2 cases), and excessive bone resorption (1 case). At provisional restoration, complications with prosthetics (8 cases), excessive bone resorption (4 cases), complications with soft tissue management (3 cases), pain (1 case), and implant mobility (1 case) were reported. At final restoration, complications with soft tissue management (4 cases), complications with prosthetics (3 cases), formation of fistula (1 case), and implant mobility (1 case) were reported. Finally, at the 1-year follow-up, the following complications were reported: complications with prosthetics (3 cases), soft tissue inflammation (2 cases), radiolucency (1 case), pain (1 case), complications with soft tissue management (1 case), and excessive bone resorption (1 case).

DISCUSSION

The use of dental implants for the restoration of missing, lost, or extracted teeth has become a widely accepted treatment solution, and patient demands in terms of esthetics and timely restoration of function have dramatically increased in recent years. Clinicians and industry have therefore tried to develop new techniques and products to achieve this, including both new surgical procedures and implant designs.

The purpose of this large prospective multicenter noninterventional trial was to evaluate the performance of Straumann Bone Level SLActive implants in daily clinical dental practice. The results demonstrated the excellent performance of these implants in all indicated clinical situations. From the 1,355 inserted implants, a total of 11 implant failures were reported within the first year of implant placement, and survival was not documented for three additional implants. Therefore, a total of 14 implant failures were considered. Based on the remaining 908 implants that could be assessed at the 1-year follow-up, this resulted in a cumulative survival rate of 98.5%. Since the cumulative survival rate includes all failed or undocumented cases out of the initial 1,355 implants, it is a conservative measure of the effective survival rate. In terms of implant success, 36 complications, problems, and/or failures were reported that apply to the success criteria of Buser et al[21] within the first year after implant placement, which resulted in a cumulative success rate of 96.0%. As with the cumulative survival rate, this percentage is likely to underestimate the effective rate, because all reports from the initial 1,355 implants were counted and then related to the remaining 908 implants. These rates were comparable with those observed in formal controlled clinical trials with more restrictive patient selection methods. For example, 1-year results from a randomized, controlled clinical study with 127 Straumann Bone Level SLActive implants placed in 127 patients with either submerged or transmucosal healing showed implant survival rates of 100% and 98.3% for the submerged and transmucosal groups, respectively.[22] Survival and success rates of 100% were also found in a single cohort study evaluating Straumann Bone Level SLActive implants placed in 20 consecutive patients in single tooth gaps in the esthetic zone after a healing period of 4 to 8 weeks.[23] In this study, success and survival remained unchanged up to 3 years.[24]

The present study revealed certain differences in the surgical protocol between European and North American study centers; European centers predominantly employed late implant placement (60.4%) and a submerged healing protocol (65.8%), while North American centers predominantly used either immediate or late implant placement (42.9% and 44.4%, respectively) in combination with transmucosal healing (74.8%). Similarly, loading of implants was performed differently in the two regions. Conventional loading was significantly more prevalent in the European centers than the North American centers (70.0% vs 57.5%), and immediate loading and restoration were significantly more prevalent in the North American centers (3.3% and 6.7% vs 0.2 % and 2.2%). Hence, there may be tendency for European implantologists to rely on a

more conventional procedure, while North American implantologists favor a more condensed procedure. The motivation for the different procedures was not evaluated in this study and potential clinical implications therefore remain unclear. Unfortunately, due to the heterogeneity of the data as a result of the noninterventional nature of the study (eg, lack of defined inclusion/exclusion criteria), it was not possible to perform a differential analysis of the outcomes of the respective surgical protocols according to region. Such an analysis would require a controlled clinical trial with all other parameters (eg, patient demographics, indications) equalized, and was obviously outside the scope of the present study.

The results of the present study showed that the majority of implants showed no change in crestal bone level up to 1 year, with less than 5% of implants showing crestal bone loss of greater than 1 mm. This appears to mirror the results from a recent clinical study in 127 patients with Straumann Bone Level implants in the anterior maxilla and mandible.[22] Similar clinical outcomes with both submerged and transmucosal healing and a minimal mean change in crestal bone level of < 0.5 mm (-0.47 mm and -0.48 mm for submerged and transmucosal implants, respectively) were observed over 12 months.[22] Moreover, good esthetic results with the Straumann Bone Level implant have been demonstrated in a prospective case series conducted over a 12-month period.[23] These results remained stable up to 3 years, at which time the mean bone loss was 0.18 mm.[24] The limited bone loss for the Straumann Bone Level implant may be related to its platform switch, which has been corroborated by preclinical studies comparing this design for both submerged and transmucosal healing approaches.[15,18]

Due to the large number of enrolled patients and implants, this noninterventional study may also serve as a survey, eg to assess potential reasons why patients lose teeth and subsequently request implant treatment. From the 852 enrolled patients, more than 56% of the recorded tooth losses were due to periodontitis or caries (Table 1). These values were similar to the reasons for tooth loss reported previously.[25] In contrast, tooth fracture or trauma was the reason for slightly more than 16% of the cases, suggesting that noncompliance with oral hygiene was a far more frequent factor for tooth loss in this study. Similarly, the distribution of bone quality among the patients seeking implant treatment was assessed for the 1,355 sites where implants were placed. This revealed that the majority of implants were placed in bone quality type 2 or 3 (86.6%, Table 2). Bone quality type 1 or 4 was rarely documented, which is in accordance with other assessments of the bone quality distribution.[26] These values reflect the general situation in patients seeking implant treatment, thereby confirming that the current noninterventional study represents the real-world scenario of daily dental practice.

The current study is one of only a few such noninterventional studies in dental implantology. In contrast, controlled clinical trials have strictly defined patient inclusion and exclusion criteria and are often performed under highly controlled conditions, which can increase the likelihood of more favorable outcomes. Larger trials tend to be in the form of cohort studies, which can be prospective or retrospective. These usually involve patients who share a common dental situation (eg, requiring implants to replace hopeless teeth,[27] patients receiving a similar prosthesis,[28,29] requiring vertical augmentation,[30] receiving short implants in posterior jaws,[31] periodontally compromised patients,[32,33] edentulous mandible,[34,35] and sinus augmentation[36]). The advantage of a noninterventional study is that the performance of a product, technique, or treatment can be investigated under conditions that mirror those typically seen in private practice settings.

One drawback of such large prospective longitudinal studies, however, is that the patient attrition rate may be much higher than with controlled clinical trials.[37] Most of this is due to patients being lost to follow-up, eg due to factors such as patients moving away or changing their dentist, not attending scheduled visits, not being contactable by the clinician, referrals to other clinicians (eg, for prosthetic work), or for other reasons. In other cases, there may be data missing despite the patient attending for the scheduled visit, due to inconsistent/incomplete data entry; this is known to be

more common for secondary parameters, as the focus is often on the primary outcome.[38] The rate of attrition in the present study was just over 30%. It has been suggested that attrition of 20% or greater may raise concerns about the possibility of bias in randomized controlled trials,[38] especially if there is a high rate of loss to follow-up in a particular group of patients; however, due to the large number of patients and the greater heterogeneity of patients and indications in a large noninterventional trial such as this, it seems likely that the risk of bias introduced by patient attrition may be substantially reduced. Therefore, although many variables in such a study are not controlled, the predictability of the implant treatment was unlikely to be affected.

CONCLUSION

This prospective, multicenter, noninterventional clinical study demonstrated very successful outcomes with Straumann Bone Level SLActive dental implants. In a daily dental practice situation without strict inclusion or exclusion criteria and no contraindicated medical conditions or surgical procedures, a cumulative survival rate of 98.5% and success rate of 96.0% were achieved by a large number of independent dental practitioners. The crestal bone level remained unchanged for the majority of implants and a bone loss of greater than 1 mm was observed for fewer than 5% of implants. Thus, the results reported here were consistent with those that had been reported in selected patients under more controlled conditions.

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