Evaluation of the Treatment of Partially Edentulous Patients With Bone Level Tapered Implants: 24-Month Clinical and Radiographic Follow-Up

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The aim of this case series was to assess, over a period of 24 months, the clinical and radiographic outcomes in partially edentulous patients receiving bone-level tapered implants. In total, 33 partially edentulous patients and 50 implants were evaluated. Patients received single or multiple implants in the posterior maxilla. Clinical and radiographic measurements of vertical bone levels were assessed at surgery, at loading, and 6, 12, and 24 months after surgery. The success and survival rates of the implants were also evaluated. Within the 24-month follow-up, only 1 implant failed (2.0%). Other biological or technical complications were not observed. The mean insertion torque was 34 $\pm$ 5.3 Ncm. Bone-level changes of 0.35 $\pm$ 0.23 mm were found between surgery and 12 months after surgery, and changes of 0.03 $\pm$ 0.05 mm were found between 12 months and 24 months after surgery. The overall change from surgery to 24 months after implant placement was 0.38 $\pm$ 0.24 mm. Most of the bone loss occurred between surgery and 3 months (0.28 $\pm$ 0.19 mm; $P < .001$); thereafter, the loss was minimal and statistically nonsignificant. Bone-level tapered implants yielded a high survival and success rate with minimal bone-level changes. Tapered implants could be considered as a predictable treatment option for partially edentulous patients with different types of bone qualities and loading protocols.

Key Words: dental implants, bone level tapered, bone loss, partially edentulous

INTRODUCTION

Over the past decades, the treatment of partially and totally edentulous patients with dental implants has become a routine procedure. Although high predictability and long-term success of this approach have been shown, different surgical and prosthetic techniques, as as well implant designs, are still being developed to ensure successful results.[1–3]

Primary stability, defined as the absence of clinically detectable implant mobility in the implant bed after implant insertion,[4] is commonly determined by resonance frequency analysis (RFA) and insertion torque value. Primary stability is a fundamental prerequisite for osseointegration.[5,6] RFA was developed as a noninvasive method that yields a parameter called "implant stability quotient," which ranges between 1 (low stability) to 100 (high stability).[7] Moreover, insertion torque value is a mechanical parameter that measures the resistance of bone during implant placement.[8]

Different factors can affect primary stability, including bone quality and quantity, surgical and prosthetic techniques, implant surface, and macro-design.[9–12] The latter has been shown to play an important role in the management of challenging clinical scenarios, such as the presence of soft bone, or in postextraction procedures.[13–16] Therefore, several manufacturers have been focused on the creation of novel designs that can be used in these situations.

One of these innovations is the tapered implant. These implants mimic a dental root shape, as they have a smaller diameter at the apical part than at the neck of the implant. The claimed benefits of this design include enhancement of the primary stability by the pressure of the cortical bone on regions with poor bone quality as well as the reduced risk of bone perforation due to its macrotopography.[17,18]

Few long-term investigations have evaluated the performance of tapered implants in these particular clinical situations and are commonly described as implant survival and success studies. A 5-year retrospective study of 56 patients treated with tapered implants immediately placed and loaded reported a cumulative implant survival rate of 100% and a mean bone level of –2.45 mm.[19] Moreover, a 6-year retrospective clinical study evaluated 96 sites with sinus augmentation procedures

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and 31 sites with alveolar ridge augmentations. The implant survival was 97.9% and 93.5%, respectively, and a low peri-implant bone resorption was shown.[14]

Furthermore, scientific literature regarding the tapered design has mainly shown its benefits compared with the cylindrical design in compromised clinical scenarios.[13,15,16] When carefully analyzing the current literature, the documentation of clinical and radiographic assessments of bone-level tapered (BLT) implants with a follow-up longer than 18 months is scarce. Therefore, the aim of this study was to evaluate the clinical and radiographic outcomes in partially edentulous patients treated with BLT implants over a 24-month period.

Materials and Methods

Study design

This investigation was designed as a retrospective case series. After approval from the local institutional review board (Comité d'evaluation d'ethique de recherche biomedicale, Paris, France; register number IRB00006477), patients who fulfilled the inclusion and exclusion criteria were involved in the study. All information was anonymized according to recommendations for the protection of individuals by the Commission Nationale de l'Informatique et des Libertés, Paris, France. As described under the inclusion and exclusion criteria, the study met the current WMA Helsinki Declaration of ethical principles for medical research involving human patients.

Patient population

Based on the usual protocol of the Department of Prosthodontics and Implant Dentistry, University Hospital Louis-Mourier, Colombes, France; patients requesting a tooth replacement were screened consecutively, and the pretreatment examination included the following procedures:

- Cone-beam computerized tomography to determine bone availability for dental implants using a 3-dimensional software (coDiagnostiX, Dental Wings GmbH, Chemnitz, Germany)
- Clinical examination and medical history to evaluate the patient inclusion and exclusion criteria.
- Fabrication of clinical casts

Patients were selected based on the following inclusion criteria:

- Man or woman $\geq$18 years old
- Absence of 1 or more teeth in the maxilla
- Adequate bone quality and quantity at the implant site to allow the insertion of Straumann Roxolid BLT SLA implants (Institut Straumann AG, Basel, Switzerland) of diameters 3.3 mm, 4.1 mm, or 4.8 mm and lengths of 8 mm, 10 mm, or 12 mm.
- Physically and psychologically able to undergo surgical and restorative procedures (American Society of Anesthesiologist class I or II).

Each patient was contacted, informed of the study procedures, and asked to give permission for the use of relevant personal and clinical information. A written consent was signed.

In addition to the general contraindication for dental implants, the exclusion criteria were the following:

- Medical conditions that require prolonged use of steroids and/or medications that can interfere with bone metabolism
- Metabolic bone disorders such as osteoporosis
- Use of any experimental drug or device within the 30-day period immediately before implant surgery on study day 0
- Smoking $>$10 cigarettes per day or cigar equivalents
- Any bone augmentation procedure on the implant site with a healing period $<$6 months
- Persistent intraoral infection
- Mucosal diseases such as erosive lichen planus
- History of neoplastic disease requiring the use of radiation or chemotherapy within the previous 5 years
- Unhealed extraction sites ($<$3 months pafter extraction of teeth in intended sites)

Surgical procedures

Implant procedures were performed by 2 experienced surgeons (K.D. and L.P.). The surgical phase was done between September 2014 and May 2015, according to the standard protocol of the manufacturer. All patients received antibiotic prophylaxis (2 g Amoxiciline, Mylan Pharmaceuticals, Canonsburg, Pa) 1 hour before surgery, and this treatment continued for 6 days (1 g Amoxiciline twice per day) after implant placement. Before surgery, all patients rinsed with 0,2% chlorhexidine (Pierre Fabre Oral Care, Paris, France) for one minute and local anaesthesia was induced by 4% articaine solution with epinephrine 1:100 000 (3M ESPE, St Paul, Minn).

Mucoperiosteal flaps were raised by means of midcrestal and intrasulcular incisions. Mesiodistally, these were at least 1.5 mm from the adjacent natural tooth, or there was at least a distance of 3.0 mm between 2 implants.

Bone density was assessed during the drilling phase following the Lekholm and Zarb classification and according to surgeon experience. Each drill was used under copious irrigation, and the tip was always brought back and forward to avoid overheating. A cortical drill was used in all cases to avoid excessive compression of cortical bone to the implant collar. Insertion torque values were measured and recorded using a surgical unit (Implantmed, (W&H, Berlin, Germany) during the implant placement.

After the surgery, all patients received oral and written recommendations about medication, oral hygiene maintenance, and diet. Patients were instructed to brush the treated area with minimal trauma and to rinse twice a day with 0.15 mL 0.2% chlorhexidine for 1 minute until sutures were removed (7 to 10 days after surgery). Anti-inflammatory treatment was prescribed: ibuprofen 400 mg (Sanofi, Paris, France) every 6 hours for 2 days or longer if required.

Restorative procedures

For immediate loading, implants were immediately restored with provisional screw-retained prosthesis using Titan alloy temporary copings and polymethyl methacrylate material. All implants were restored with definitive CAD/CAM restorations with Straumann CARES Ti abutments and ceramic crowns

during the 3-month follow-up visit. Additional visits were scheduled to take place 6, 12, and 24 months after implant placement.

Outcome variables

Radiographic Assessment

An experienced radiologist (D.P.) evaluated the changes in interproximal bone levels by measuring the distance from the implant shoulder to the first visible bone- to- implant contact. Standardization of the radiographs was achieved using a long-cone parallel technique, an image plate, and a film holder (VistaScan system, Dürr Dental, Bietigheim-Bissingen, Germany).

Before the radiographic analysis, the examiner was trained for DBSWin5.9.1 measurements. Intraexaminer reproducibility was set following a calibration phase showing a repeatability frequency of 9 of 10 repeating measures on 5 different radiographs.

To eliminate image distortions and determine the exact magnification, all images were calibrated using the known distance of 2 implant threads and the diameter and length of the implants. Mesial and distal measurements were averaged to calculate the mean bone level around the implant at time of implant placement and 3, 6, 12, and 24 months after surgery.

Implant Success and Survival Rate

Implant success and survival were assessed at every visit. A surviving implant was defined as an implant in place at the time of follow-up. Furthermore, an implant was deemed a success if all of the following criteria applied:

- Absence of persisting subjective discomfort, such as pain, foreign body perception and or dysesthesia (painful sensation)
- Absence of a recurrent peri-implant infection with suppuration; an infection was deemed recurrent if it was observed at 2 or more follow-up visits after treatment with systemic antibiotics
- Absence of implant mobility on manual palpation.
- Absence of any continuous peri-implant radiolucency

Complications

Complications were classified as biological (eg, bone fracture, peri-implant pathology) and mechanical (eg, fracture of devices such as implant, crown or abutment).

Statistical analysis

Personal, clinical, and technical information was extracted from the patients' clinical records. Patient and implant categorical characteristics were summarized as counts and proportions. Continuous characteristics were presented as means, standard deviations, medians, and ranges.

Interproximal bone-level change was considered the primary outcome. The mean of the measurements at the mesial and distal sites was used for the calculations. The secondary outcomes were implant success, implant survival rate, and complications (mechanical and biological). Although the nature of the study design yielded descriptive results, the association between the primary outcome at different time points and each of the potential risk factors (patient's gender, smoking status, loading protocol, implant length, tooth type, and bone density type) was examined using linear mixed regression models. The factor identifying individuals was included as a random effect and each of the risk factors as a fixed effect.

The statistical analysis was assessed by an independent statistician (L.G.). The SAS software (version 9.4, 2002–2012, SAS Institute Inc, Cary, NC) was used for the analysis. The alpha level for significance was set at 0.05.

Results

Study population

Surgeries were performed between September 2014 and May 2015. In total, 33 patients were included in this study and 50 implants were used in the surgeries. One patient receiving 1 implant was lost due to a failure in osseointegration before loading; therefore, 32 patients and 49 implants were included in the longitudinal analysis.

Demographic data and general health status

The study sample included 17 (51.5%) men and 16 (48.5%) women. Mean age was 46.5 $\pm$ 11.4 years. Nine (27.3%) patients had a history of chronic periodontitis, and 8 (24.2%) were current smokers ($\leq$10 cigarettes/day). Most patients (63.6%) received only 1 implant, eight patients received 2 implants, 3 patients received 3 implants and 1 patient received 4r. The majority of the patients (84.8%) receiving 38 implants chose immediate loading and the rest conventional 2-stage restoration (Table 1). Reasons for tooth loss included tooth fracture (n = 17, 34.0%), endodontics (n = 21, 42.0%), periodontal disease (n = 7, 14.0%), and unknown (n = 6, 12.0%) (Table 2).

Interventions

Table 2 shows the distribution of implant diameter and lengths. A total of 29 (58.0%) implants were placed in molar sites and 21 (42.0%) in premolar sites. In terms of bone density, 18 (36.7%) implants were inserted in bone density type 2, 26 (53.1%) in type 3, and 5 (10.2%) in type 4. None were inserted in bone density type 1.

The average insertion torque was 34.0 Ncm (standard deviation = 5.3); the highest was 45 Ncm (8.0%) and the lowest 25 Ncm (20.0%). Regarding the fixation of the restorations, 16 (32.7%) were cement retained and 33 (67.3%) screw retained.

Follow-up

None of the patients experienced implant or prosthetic mechanical complications. One patient receiving 1 implant (2.0% of all implants) had a biological complication (failure in osseointegration) 3 months after surgery. This patient/implant was excluded from the analysis. The overall implant survival and success rate was therefore 98.0%. Figure 1 shows an example of the clinical results of the procedure 24 months after the intervention.

TABLE 1

Patients' demographic, general health, and clinical characteristics (n = 33)*

Characteristic	n (%)
Gender	
Female	16 (48.5)
Male	17 (51.5)
Age (y)	
Mean ± SD	46.5 ± 11.4
Median (IQR)	47 (37 to 53)
Smoking status	
Current smoker	8 (24.2)
Ex-smoker	4 (12.1)
Nonsmoker	21 (63.6)
History of chronic periodontitis	
Yes	9 (27.3)
No	24 (72.7)
Periodontal therapy before implant placement	
Hygiene instructions	25 (75.8)
Nonsurgical	8 (24.2)
Healing	
Conventional, 1 stage	28 (84.8)
Conventional, 2 stages	5 (15.2)
No. of implants received	
1	21 (63.6)
2	8 (24.2)
3	3 (9.1)
4	1 (3.0)

*IQR indicates interquartile range (from first to third quartile); SD, standard deviation.

TABLE 2

Characteristics of the implants and implant sites (n = 50)

Characteristic	n (%)
Implant diameter (mm)	
3.3	10 (20.0)
4.1	19 (38.0)
4.8	21 (42.0)
Implant length (mm)	
8.0	18 (36.0)
10.0	20 (40.0)
12.0	12 (24.0)
Implant site*	
2	2 (4.00)
3	11 (22.0)
4	2 (4.0)
5	7 (14.0)
12	8 (16.0)
13	4 (8.0)
14	14 (28.0)
15	2 (4.0)
Tooth type	
Premolar	21 (42.0)
Molar	29 (58.0)
Reason for tooth loss	
Root fracture	16 (32.0)
Enodontics	21 (42.0)
Periodontics	7 (14.0)
Other/unknown	6 (12.0)
Bone density	
Type 1	0 (0.0)
Type 2	18 (36.7)
Type 3	26 (53.1)
Type 4	5 (10.2)

*American Dental Association's current dental terminology, 2011–2012.

Radiographic assessment

Figure 2 shows the periapical radiographs just after surgery and at the 24-month follow-up visit for the same patient as in Figure 1. The analysis included 32 patients and 49 implants. The mean distance between the reference point and the marginal bone level was 1.24 ± 0.50 mm the day of the surgery, 1.53 ± 0.52 mm after 3 months, 1.59 ± 0.52 mm after 6 months, 1.60 ± 0.51 mm after 12 months, and 1.62 ± 0.52 mm after 24 months. Figure 3 shows, for the same outcome and time points, the resulting means and 95% confidence intervals adjusted for the effect of the patients. A statistically significant difference in adjusted mean distance was observed only between intervention and the 3-month follow-up. This parameter remained quite stable after this time point.

The mean marginal bone losses and respective standard deviations between the surgery and the 3-month visit was 0.28 ± 0.19 mm, 0.34 ± 0.26 mm between surgery and 6 months, and 0.35 ± 0.23 mm between surgery and 12 months. The overall change from surgery to 24 months after implant placement was 0.38 ± 0.24 mm.

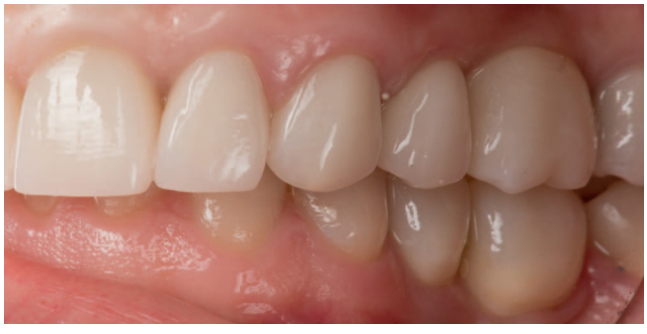

FIGURE 1. Implant (No. 26, 1 of 4 implants received by a nonsmoking female patient for a molar in position 15) after 24 months.

Effect of different factors on the change of marginal bone level

Since the largest marginal bone loss was observed in the period from surgery to the 3-month visit, the association of this change and each of the probable risk factors was examined. The factors that could probably influence the change in this period of time would be the length and diameter of the implant, the loading protocol, current smoking status, and bone density type. Although the amount of marginal bone loss was higher for the expected levels of these factors, the differences were not statistically significant (Table 3). Similar results were observed for the period from surgery to the 24-month visit (results not shown).

DISCUSSION

Tapered implants are suggested for 1-stage procedures and where primary stability might not be optimal.[20] It has been described that primary stability depends on bone quality, surgical technique, and implant design and is a factor for the success of

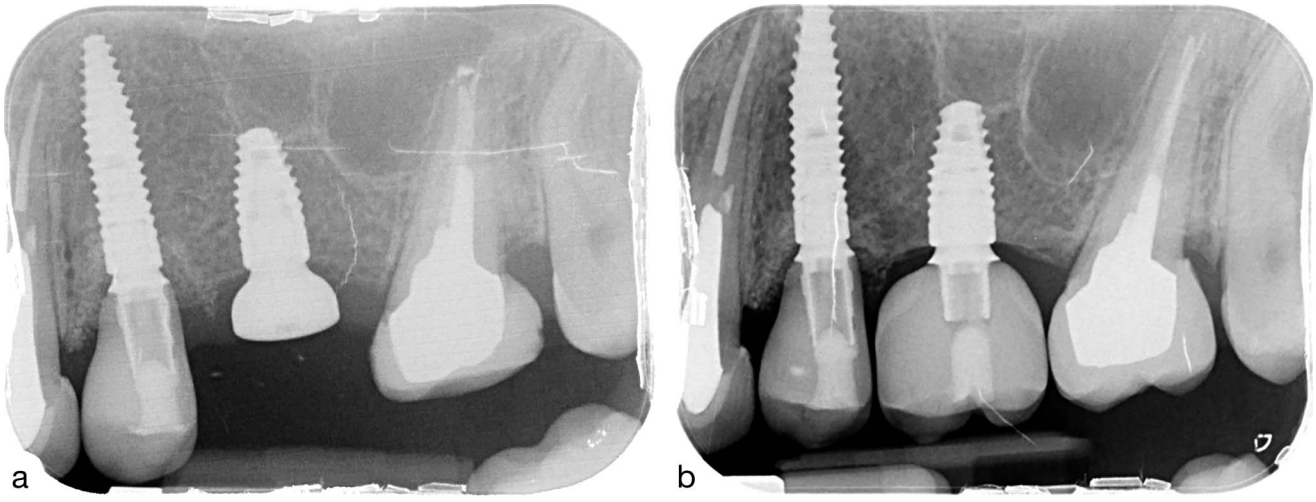

Figure 2. Periapical radiograph (implant No. 26): (a) after surgery, (b) at the 24-month follow-up.

dental implant treatment. However, it is important to consider not only this outcome but also the long-term behavior of crestal bone maintenance and biological complications that could occur.[21]

The follow-up time of the present study was 24 months. More than half of the implants (76%) were restored with immediate loading and presented type III and IV bone quality (63.3%). In a systematic review comparing 1-stage versus 2-stage procedures, no statistically significant difference was found between the procedures. However, a trend toward a 2-stage approach was found to be more favorable in fully edentulous patients, whereas the authors indicated that the 1-stage approach could be indicated in partially edentulous patients or when optimal primary stability was not achieved.[22] Therefore, the surgical technique in the present investigation was chosen according to the achieved primary stability and patients' demands.

The terms "survival rate" and "success rate" are often used incorrectly. Survival is defined as a dental implant and fixed prosthesis placed, independent of the mechanical or biological complications over a follow-up period, and success as the presence of the dental implant and the absence of these complications.[23] In our investigation, survival and success rates

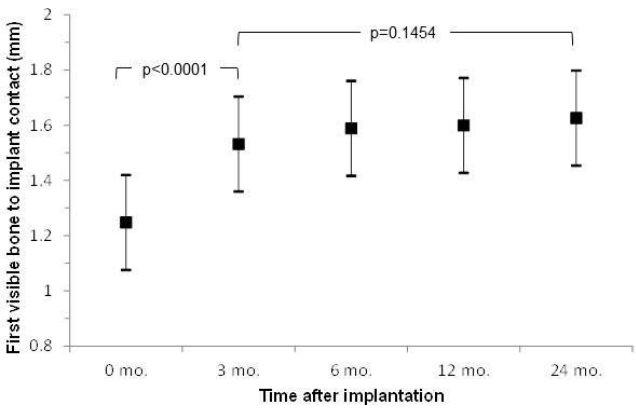

Figure 3. First bone to implant contact at the different time points. The squares represent the mean values and the whiskers their 95% confidence intervals, calculated taking into account the random effect of the patients. Linear mixed regression models were used.

were very high after 24 months of follow-up, and these findings were in agreement with previous studies.[24–26] A randomized controlled trial showed that tapered implants could provide optimal primary stability for both immediate and early loading. No implant loss was found within a period of 5 years' follow-up.[27] It has been demonstrated that smoking and history of periodontal diseases are potential risk factors for peri-implantitis.[28,29] In this study, 50.5% of the patients had at least 1 of these risk factors. However, only 1 patient presented an early failure in osseointegration. These results may be attributed to the good plaque control of the patients and the lower amount of cigarettes per day by smoking patients ($\leq$10 cigarettes).

Crestal bone maintenance is an important factor in treatment success with dental implants. In our study, the overall marginal bone loss from surgery to 24 months after implant placement was 0.38 $\pm$ 0.24 mm. The assessment was performed by an experienced dental radiologist. All images were calibrated using the known distance of 2 implant threads and the diameter and length of the implants.

Currently, there is no consensus regarding the influence of the implant macrodesign and peri-implant bone loss.[30–32] In an animal study with mini-pigs, no statistically significant differences were found between tapered and nontapered designs.[33] However, some human studies have shown better clinical performance with tapered implants in than cylindrical implants.[34,35] In a similar study with a 24-month follow-up, the change in bone levels was 0.28 mm for tapered implants and 0.48 mm for cylindrical implants, almost twice the amount of bone loss for nontapered implants.[34] Furthermore, with 12 months of follow-up, another study showed bone loss of 0.61 $\pm$ 0.34 mm for tapered implants and 0.88 $\pm$ 0.43 mm for cylindrical implants.[36] The results obtained in this investigation were similar to those described in the literature.

The limitations of this study include those inherent to the nature of the study design (retrospective case series): observational, lack of comparison group, incomplete data collection, and susceptibility to selection and measurement bias. In this study, all data were gathered in a standardized way as the private practice follows the same protocol for all patients treated with dental implants, and surgeries are performed by 2

TABLE 3

Association* between marginal bone loss from implantation to 3-month follow-up and each of probable risk factors (n = 49 implants)†

Risk Factor	Regression Coefficient	Standard Error	*df*	F	*P* (overall effect)	Mean (95% CI)	*P*‡ (for comparison)
Sex							
Male	0.005	0.054	17	0.01	.9297	0.286 (0.211–0.360)	.9297
Female	0					0.281 (0.195–0.367)	Ref
Age							
1 year increase	–0.001	0.002			.8380		
Loading protocol							
1 stage	–0.044	0.062	17	0.50	.4895	0.273 (0.208–0.338)	.4895
2 stages	0					0.317 (0.203–0.430)	Ref
Current smoking							
No	–0.033	0.059	17	0.31	.5849	0.274 (0.208–0.341)	.5849
Yes	0					0.307 (0.202–0.412)	Ref
History of chronic periodontitis							
No	0.053	0.058	17	0.86	.3666	0.300 (0.233–0.367)	Ref
Yes	0					0.247 (0.146–0.348)	.3666
Therapy							
Hygiene instructions	0.026	0.064	17	0.17	.6894	0.289 (0.2255–0.354)	Ref
Nonsurgical	0					0.263 (0.144–0.383)	.6894
Reason for tooth loss							
Fracture	0.133	0.089	14	1.13	.3702	0.333 (0.231–0.435)	Ref
Endodontics	0.095	0.085				0.295 (0.209–0.382)	.8858
Periodontics	0.014	0.103				0.214 (0.065–0.364)	.4049
Other/unknown	0					0.200 (0.038–0.362)	.3591
Tooth type							
Premolar	0.012	0.054	16	0.05	.8283	0.291 (0.204–0.377)	.8283
Molar	0					0.279 (0.204–0.354)	Ref
Implant diameter							
3.3 mm–	–0.011	0.072	15	0.84	.4504	0.249 (0.123–0.374)	.9829
4.1 mm	0.066	0.060				0.327 (0.235–0.418)	.4582
4.8 mm	0					0.260 (0.171–0.349)	Ref
Implant length							
8 mm	–0.049	0.069	15	1.93	.1794	0.222 (0.127–0.318)	Ref
10 mm	0.069	0.066				0.340 (0.253–0.427)	.1244
12 mm	0					0.271 (0.158–0.384)	.7115
Bone density							
Type 2	–0.072	0.104	14	0.32	.7288	0.278 (0.183–0.372)	Ref
Type 3	–0.081	0.10				0.269 (0.191–0.348)	.9852
Type 4	0					0.350 (0.149–0.551)	.7296

*Calculated using mixed linear regression models where the effect of the patient was included as a random effect and the risk factor was included as a fixed effect.

†CI indicates confidence interval; df, degrees of freedom; Ref, reference level for comparison.

‡Adjustment for multiple comparisons was done using the Dunnett-Hsu method.

experienced surgeons. With the exception of 1 patient with a failing implant, there was no missing follow-up information. Selection bias cannot be excluded, and measurement bias was probably limited as surgeries were performed by 2 experienced surgeons and outcomes were evaluated by 1 experienced radiologist. The outcomes were evaluated within 24 months after implant placement, which cannot be considered a long follow-up, but nevertheless it is longer than the average published in the literature.

This retrospective case series was conducted in a private practice environment, which ensures real-world treatment and outcomes assessment approaches. Results and observations from this study shall be helpful for planning future studies where tapered implants or different surgical and loading procedures will be tested.

Conclusions

Within the limitations of this study, BLT implants presented high survival and success rates without mechanical or biological complications after loading. The marginal bone loss was minimal within the study time. These outcomes and other presented observations indicate that tapered implants seem to be suitable for different clinical scenarios.

Abbreviations

BLT: bone level tapered

CAD/CAM: computer aided design/ computer aided manufacturing

RFA: resonance frequency analysis

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Note

Susy Linder and Michel Dard are employees of Institut Straumann AG. The other authors are employees or owners of a private practice in Paris, France. Institut Straumann AG provided implants installed as part of the study. The results of the study were not influenced by the aforementioned facts.

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