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A Prospective Clinical Study on Implant Survival at 1-Year Post-Loading of a Bone-Level Tapered Implant in Private Practice: Multicentered Study

Robert A. Levine, DDS; Bradley S. McAllister, DDS, PhD; Robert J. Miller, DMD; Edward Gottesman, DDS; Robert L. Holt, DDS, PhD; Kanyon R. Keeney, DDS; William F. Runyon, DDS; and Philip L. Fava, DMD, MDSc

Abstract: This non-interventional study evaluated the implant survival and success of a new bone-level tapered implant design in seven private dental practices in the United States. One hundred subjects in need of implant(s) were enrolled according to all cleared indications. After implant surgery, subjects were followed for a period of 1-year post-loading. Treatment planning, implant stability, radiographic evaluation of bone levels, soft-tissue characteristics, clinician satisfaction, and adverse events were assessed. A total of 184 implants were placed, of which 172 were evaluable at 1-year follow-up. Of the 172 evaluable implants, 169 survived and were successful at 1-year post-loading. Of 152 implants with radiographs at 1 year, 90% showed no bone remodeling or <1 mm bone loss. Overall clinician satisfaction was high across all centers. Normal soft-tissue profiles were reported around the implants with improvement in color, form, and mucosal attachment at 1 year. In a "real-world" setting this observational study demonstrated high implant survival and success, stable crestal bone levels, high clinician satisfaction, and a low incidence of adverse events.

Tapered (or conical) implants, which have a smaller diameter at the apical end than the crestal end, were developed primarily to provide better adaptation in immediate extraction sockets and avoid anatomical structures, ie, inferior alveolar nerve, mental foramen, nasopalatal foramen, and maxillary sinus.[1] Such implants were designed to engage the socket bone at the apical and palatal portion of the immediate alveolar socket walls and 1 mm apical to the buccal crest at the crestal portion.[2] Hypothetically, the reasoning for this approach was to improve primary stability by engaging more of the socket wall (except the buccal) than an equivalent cylindrical-shaped implant when immediate placement is performed.[3] Additional benefits of a tapered design include converging adjacent roots and buccal bony undercuts.

Only a few studies assess potential differences in stability between tapered and cylindrical implants, but the limited data available generally suggests similar survival rates[4] and no significant differences in implant stability[2,5,6] or marginal bone loss or bone remodeling between the two implant designs.[7-11] Several studies have documented the extent of bone remodeling around tapered implants with immediate and early loading[12-15] and immediate or early placement in extractions sockets.[12,16-19] Comparisons between the studies should be treated with caution, however, due to the heterogeneity of studies in terms of patient populations, implant types, baseline marginal bone levels, indications, and loading protocols.

Since the introduction of a particular bone-level tapered implant (Straumann® Bone Level Tapered Implant [BLT], Straumann, straumann.com), controlled clinical studies have been ongoing to provide further scientific evidence supporting the use of this implant in specific indications; concurrently, observational studies are needed to document the performance and usage of the implant in general clinical practice. Controlled clinical studies have the potential to provide robust evidence of safety and effectiveness of a product; however, these studies may not accurately reflect the situation in a typical dental practice and may result in higher success rates. This is because the subjects included in a clinical study are selected based on strict inclusion and exclusion criteria and may not necessarily reflect the normal patient population found in a dental practice. Furthermore, the investigators participating in clinical studies may be required to follow a treatment plan defined by the protocol, which may not replicate the typical treatment given in a dental practice. For these reasons, it has been argued that the results of clinical studies may not be representative of actual outcomes seen in a general population, thus indicating the need for additional observational studies.[20,21]

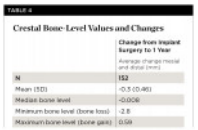
The intention of this non-interventional, observational study was to verify the results of controlled clinical studies through a "real-world" evaluation of the survival and success (as defined below, in "Implant Survival and Success") of Straumann BLT implants placed in seven private practices in the United States, according to all cleared indications and to the standard treatment protocol of each investigator, at 1-year post-loading. The safety and performance of the implants, including treatment planning, implant stability, radiographic evaluation of bone levels, soft-tissue characteristics, clinician satisfaction, and adverse events, were also assessed and analyzed descriptively.

Materials and Methods


Table 1


Table 2


Table 3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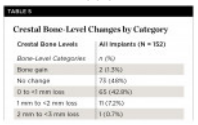
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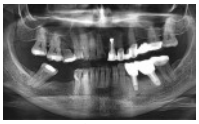


Figure 1

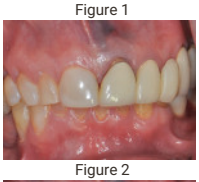
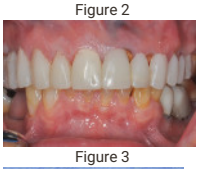


Figure 2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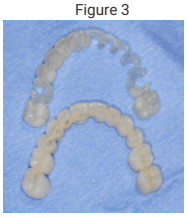
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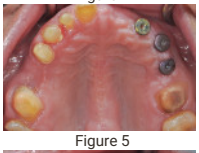


Figure 5

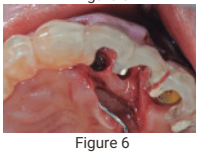


Figure 6

The objective of this multicenter, non-interventional study was to evaluate survival and success of bone-level tapered implants according to the cleared indications in "real-world" situations and according to standard treatment protocols of the investigators. The implants were placed between October 17, 2014, and November 16, 2016. Seven sites participated in the study; 100 patients were recruited. All study centers were private practice offices in the United States, and all investigators were experienced in the placement, care, and maintenance of dental implants.

Patients who presented to the clinics with one or more teeth in need of extraction or that had been lost and who were seeking an implant-supported restoration were eligible for inclusion into the study. The study subjects were the first 100 patients (aged 18 or older) who presented for implant(s), were qualified to be treatment-planned for bone-level implants, and agreed to participate in the study.

After dental implant surgery, the implant restoration was placed according to the desired treatment plan for the subject decided by each investigator. Subjects' participation in the study consisted of four study visits and follow-up for 1 year after implant loading. Demographics, medical and dental history, and risk factors were recorded at baseline. Implant planning and all aspects of implant placement were recorded, including type, size and location of implant, insertion torque, bone quality, any necessary augmentation procedures, drilling sequence, healing, and implant stability. Details surrounding implant loading, final restoration, implant success, and implant survival also were documented. Multiple implants could have been placed in a single subject.

Written informed consent was obtained from all subjects. Institutional Review Board (IRB) (Quorum Review IRB) approval (August 28, 2014) was also obtained at all participating centers prior to enrollment of any subjects. All investigators agreed to conduct and monitor the study at their institution in accordance with national regulations, Good Clinical Practice, and their institution's policies.

The primary parameters evaluated in this study were the implant survival and success rates 1 year after implant loading. Secondary parameters included: (1) documentation of treatment planning and subject selection, (2) documentation of implant placement, (3) implant stability by insertion torque value (ISQ) at surgery and implant loading, (4) radiographic evaluation of vertical implant-to-bone contact levels, (5) assessment of soft-tissue characteristics (form, color, and flexibility), (6) clinician satisfaction, and (7) evaluation of adverse events. All subjects had radiographic and photographic documentation of implant sites throughout the course of the study. Additionally, oral hygiene assessments were captured. The study data was recorded on electronic case report forms in an electronic data capture system (IBM Clinical Development, ibm.com). The Materials and Methods, Results, and Conclusions sections of this article were reviewed and approved by an independent statistician.

Study Population

Because this was a non-interventional study, no formal inclusion/exclusion criteria existed. All subjects were treated according to the cleared indications and contraindications contained in the implant's Instructions for Use (IFU). The investigator should nothave included subjects that met any contraindications, relative contraindications, or local contraindications as outlined in the IFU.

Study Device

Straumann BLT implants were utilized in this study. The implants available had an endosteal diameter of 3.3 mm, 4.1 mm, or 4.8 mm and lengths of 8 mm, 10 mm, 12 mm, 14 mm, and 16 mm, and were designed to be placed at bone level in healed sites.[2] However, many dental surgeons believe that, in immediate-placement sites, the placement must be 1 mm below the intact buccal crest to allow for natural vertical bone remodeling with resorption, which is seen post-extraction, with the buccal wall and its predominance of bundle bone.[2,12]

The implants were made of a titanium-zirconium alloy (Roxolid®, Straumann) and had a hydrophilic surface (SLA-ctive®, Straumann), which comprises a large-grit sandblasted and acid-etched surface in a chemically activated state. Each clinician selected the appropriate restorative components for the case from among those available from the manufacturer for the BLT implants.

Surgical and Implant Loading Procedures

General surgical procedures were used in the study as described by the manufacturer's approved labeling. Clinicians in this non-interventional study were free to treat subjects according to their standard practice as it related to implant placement, healing time, loading procedures, restoration types, or implant positions. The categorization of implant loading followed the International Team for Implantology consensus statement[22] where: (1) immediate loading was considered to be less than 1 week after implant placement, (2) early loading was taken to mean between 1 week and 2 months after implant placement, and (3) conventional loading was considered to include loading times longer than 2 months after implant placement.

Implant Survival and Success

The primary parameters of the study were implant survival and success at 1-year post-loading. Implant survival was defined as an implant that was in place at the time of follow-up. Implant success was defined as an implant that met the following criteria[23]: (1) absence of persistent subjective complaints, such as pain, foreign-body sensation, and/or dysesthesia; (2) absence of a recurrent peri-implant infection with suppuration; (3) absence of mobility; and (4) absence of a continuous radiolucency around the implant. Furthermore, non-surviving implants were counted as unsuccessful implants.

Radiographic Bone-Level Change

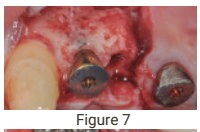
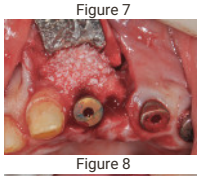


Figure 7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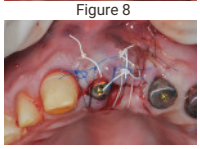
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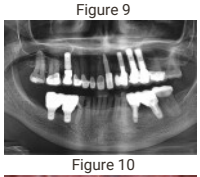
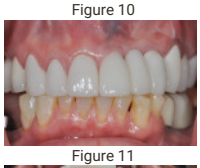


Figure 10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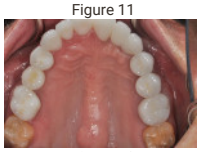
Figure 12

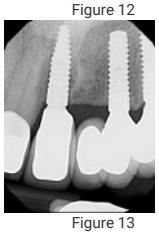
Figure 13

and at the 1-year follow-up. Occasionally, in some cases panoramic radiographs were also used to check whether a patient was ready to proceed with his or her final case. The periapical radiographs from implant placement and the 1-year follow-up were evaluated for bone-level changes. Radiographs were sent to a common, central, independent reviewer for evaluation and bone-level measurements to minimize bias. If a radiograph was missing or unreadable from either the surgical visit or the 1-year follow-up, the subject was not included in the analysis; no imputation was performed for subjects with missing data.

The independent reviewer measured the bone levels from the implant shoulder to the first bone-to-implant contact on the mesial and distal aspects of the implant. Only bone-level remodeling along the implant surface was taken into account. Any bone that was above the implant shoulder (ie, implant placed deeply in bone) was not measured and was given a bone-level value of 0 mm. A negative value indicated a bone loss, and a positive value indicated bone gain.

Clinician Satisfaction

Clinician satisfaction was measured on a scale of 1 to 6, with 1 being "not satisfied/confident/suitable at all" to 6 being "highly satisfied." This measurement was taken at various timepoints throughout the study (primary stability, time required to prepare implant bed and place implant, confidence placing another bone-level tapered implant, suitability of a bone-level tapered implant for the case, and overall satisfaction).

Statistical Analysis and Safety Analysis

Descriptive statistics were used to analyze the primary parameters, including 95% confidence intervals for survival and success rates, and secondary parameters, which comprised implant stability, bone loss, and soft-tissue assessment. Statistical software (SAS® version 9.4, SAS, sas.com) was used for these calculations. All safety aspects of the implant treatment were documented and analyzed.

All subjects were monitored for the occurrence of adverse events throughout the study. All adverse events, whether or not they were related to the study device or procedure, were documented with regard to seriousness, severity, and relationship to the device or procedure. Any device deficiencies that led to an adverse event, or could have led to an adverse event, were also recorded.

Results

The first subject was enrolled on October 17, 2014; the last subject follow-up was completed on November 16, 2016. The lengthy enrollment period was due primarily to the fact that the training and implementation process in each of the participating offices throughout the country varied substantially. A total of 100 subjects were enrolled. The mean age was 56.5 years with just over half of the subjects (56%) being female. Eighty-seven percent of the subjects were white. Seven percent of the subjects were current smokers (including both light smokers, ie, one to 10 cigarettes per day, and heavy smokers, ie, >10 cigarettes per day). Twenty-one percent of subjects had a history of periodontitis. Nine percent of subjects were enrolled despite other risk factors, including parafunctional habits, poor compliance, and systemic diseases such as scleroderma, cancer, and diabetes.

Reasons for tooth loss varied among subjects with most (72%) being due to fractured teeth and caries. The majority of subjects (65%) had no existing implants at baseline; 35% of subjects had from one to 10 existing implants at baseline. The study population represented a typical private practice distribution of missing dentition, from zero to fully edentulous. Selection criteria for treatment planning with the BLT implant are outlined in Table 1.

A total of 184 implants were placed in the 100 subjects enrolled. Of the 184 implants placed, 177 were evaluable at loading, 176 were evaluable at final restoration, and 172 were evaluable at 1-year follow-up. The decline in evaluable implants was due to early withdrawals, subjects lost to follow-up, and implant failures. Eighty-nine subjects completed 1-year follow-up evaluations. Eight subjects were lost to follow-up prior to the 1-year follow-up and could not be contacted, while three subjects withdrew early. Of 172 evaluable implants, 169 (98.3%) survived and were successful at 1-year post-loading. Twelve of the original 184 implants placed were lost to follow-up, leaving a verifiable survival rate of 92% (169/184).

Surgical Protocol and Implant Loading

The majority of implants (54.9%) were immediately placed (type 1 placement) with 9.6% of the immediately placed group immediately loaded. Table 2outlines details surrounding these parameters. Sixty-four implants were placed in the premolar region, 60 incisor, 43 molar, and 17 cuspid, representing a broad distribution of implant placement. Table 3details loading categories and corresponding restoration types.

Implant Survival and Success Rates

Implant survival and success rates were 98.3% in a total of 172 evaluable implants with a 95% confidence interval of 95%-99.6%. Three implants failed, with 169 surviving/successful. One subject received four implants (Nos. 5, 7, 10, and 13) and presented approximately 2 weeks later with complaints of discomfort in the area of Nos. 7 through 10. The immediate full-arch provisional hybrid restoration was removed and impression material was found subgingivally and removed from under the tissues in the area of Nos. 7 through 10; however, No. 5 did not osseointegrate. In one subject who received three implants (Nos. 7, 10, and 11), No. 10 was removed for failure to osseointegrate approximately 16 weeks after implantation. It was noted that the subject was a heavy smoker (>10 cigarettes per day). Radiographs on one subject who received two implants (Nos. 19 and 20) demonstrated progressive bone loss at site No. 20, and the implant failed to osseointegrate. The implant was removed with no further sequelae approximately 16 weeks later.

Although not required, in some centers implant stability was assessed using the ISQ at the time of surgery and implant loading. Of the 105 implants with reported measurements at implant placement, 49 had an ISQ value of ≥70, 37 had an ISQ value of 60-69, and 19 had an ISQ value <60. Of the 45 implants with reported measurements at implant loading, 40 had an ISQ value of ≥70, four had an ISQ value of 60-69, and one had an ISQ value <60. (ISQ values were obtained only once for immediate-load implants [63 implants], and these values were included at implant surgery. Loading data was not recorded for seven implants due to early study discontinuation. Also, ISQ was not recorded for one implant at loading because the subject received five other implants that were immediate load.)

Radiographic Evaluation of Bone Levels

Radiographs were available for 152 implants. The average change from implant surgery to 1-year follow-up was -0.3 mm ± 0.46 mm. No significant differences were seen between the mesial and distal aspects, so they were combined in Table 4, which provides a summary of crestal bone-level values and changes.

Subjects were categorized into groups based on the change in bone level from implant surgery to 1-year follow-up. Most of the subjects (>90%) showed either no bone remodeling or less than 1 mm bone loss. Two subjects (1.3%) had bone gain.Crestal bone-level changes by category are presented in Table 5.

Assessment of Soft-Tissue Characteristics

Investigators were asked to document soft-tissue characteristics at the time of final restoration and 1-year follow-up in terms of color, form, and mucosal attachment. Normal soft-tissue profiles were reported around the implants with improvement in all three of these parameters at the 1-year follow-up visit.

Clinician Satisfaction Scores

Overall satisfaction, confidence, and suitability were high across all centers. Satisfaction scores of 5 or 6 ranged from 89% to 99% across all categories. Of note, considering the number of immediate implants, 93% of investigators reported satisfaction scores of 5 or 6 related to achievement of primary stability.

Adverse Events

Three non-device, non-procedure-related events were reported (stroke, mild mouth pain post-sinus lift, and infection). No study device or procedure-related events were reported other than the three implant failures summarized above. None of the events resulted in permanent injury or disability. No device deficiencies were recorded.

Case Sample

A sample case report from this study is presented in Figure 1 through Figure 13.

Discussion

This non-interventional, observational study evaluated the use of bone-level tapered implants in "real-world" clinical practice, eliminating strict inclusion/exclusion criteria and protocol-defined treatment plans, which are typically part of controlled clinical trials. All investigators were surgical specialists with years of experience in dental implant insertion, maintenance, and follow-up. Additionally, they all recruited and treated subjects from their private practice and used their existing practice treatment protocols when treating subjects, again reflecting a "real-world" scenario.

Based on the cases treated in the study, the SAC (Straightforward, Advanced, Complex) category[24] was predominately Complex as the majority of the implants (54.9%) placed were immediately placed after extraction (type 1 placement) with 9.6% of these being immediately loaded.[25] The percentage of implants placed in the esthetic zone (site Nos. 4 through 13) was 50.4%. The success rate and maintenance of marginal bone levels was excellent even with this challenging profile of patients. The primary endpoint measures were implant survival and success rates 1 year following implant loading.

Three implants failed over the course of the study, yielding an implant survival rate of 98.3% of the 172 evaluable implants. Likewise, implant success, defined as the absence of subjective complaints, peri-implant infection with suppuration, mobility, and continuous radiolucency around the implant, was also found to be 98.3%. All three failed implants did not osseointegrate during early healing. In one of these cases impression material was found under the anterior soft tissues and the corresponding full-arch provisional was removed during the critical healing period, between 7 and 21 days, to retrieve the material. In another case, the subject was a heavy smoker. The third failed implant demonstrated a progressive loss of bone at the implant site. None of the subjects with failed implants suffered any long-term or permanent effects.

The survival and success rates of the present study compare well with other non-interventional studies. For example, Filippi et al found that of 759 patients who received 1,355 bone-level implants, the 1-year cumulative survival and success rates were 98.5% and 96%, respectively, with less than 5% of implants having more than 1 mm of bone loss.[21] Wallkamm et al followed a subset of patients enrolled in the study reported by Filippi wherein 233 patients with 342 implants, followed over 3 years, were found to have survival and success rates of 97.5% and 93.5%, respectively.[26] In another non-interventional study of tapered implants in 436 patients, Wilson et al demonstrated a 1-year survival rate of 98.3% with a cumulative 97.7% survival from 2 to 5 years.[27] Minimal or no bone loss was seen in that study. Other studies have shown similar rates of survival and bone loss.[12,15,16,27-34]

typical cases in which tapered implants are implemented, the ease of use of these implants according to the practitioners, and additional outcomes of tapered implant placement in private practice. Soft-tissue profiles were evaluated in each center and were reported as normal around the implants with respect to improvement in color, form, and mucosal attachment at 1 year, and this evaluation is in line with other reports on tapered implants.[9,15,20] Of the 152 implants with radiographs at 1 year, more than 90% showed no bone remodeling or <1 mm bone loss, thus demonstrating that bone remodeling is not a significant issue when placing tapered implants in private practice; this, too, is in agreement with other studies.[12,20,35]

Although patient satisfaction is often reported in randomized clinical trials, in private practice only general patient satisfaction may be assessed; therefore, in this multicenter study, clinical satisfaction was assessed to better understand how practitioners experienced surgical and prosthetic outcomes related to primary stability, their confidence in placing implants, the time required for the procedure, and the suitability of the implant. Overall satisfaction was found to be high across all centers, with scores of 5 or 6 out of 6 from 89% to 99% of practitioners across all categories. Of particular interest, given the high number of complex cases treated in this study, 93% of investigators reported satisfaction scores of 5 or 6 related to achievement of primary stability. The overall incidence of adverse events in this study was low; three adverse events (implant failures) were related to the device and/or procedure. Only three events occurred that were unrelated to the device or procedure. All events resolved without sequelae. This study demonstrated the safety of the device when used in a real-world clinical setting.

Conclusion

This non-interventional, observational study of a bone-level tapered implant demonstrated high reliability and clinician satisfaction in typical private practice situations, including complex SAC cases such as immediate placement and immediate loading. Implant survival and success rates were high, and bone-level changes over the 1-year follow-up period were found to be limited, with both findings being consistent with other studies evaluating non-tapered bone-level implants. This study also demonstrated that the implants were safe as evidenced by an overall low incidence of device- and procedure-related adverse events.

Limitations of this study include the short duration of follow-up (1 year), the inherent variability in practice across the different centers, and the use of only descriptive statistics, as this was an observational study. Future work will benefit from a randomized control trial with extended follow-up to establish treatment efficacy of bone-level tapered implants when used for immediate placement.

Disclosure

All study participants, including the authors, received a research project payment from Straumann® USA.

About the Authors

Robert A. Levine, DDS
Private Practice limited to Periodontics and Implant Dentistry, Philadelphia, Pennsylvania

Bradley S. McAllister, DDS, PhD
Private Practice limited to Periodontics, Tualatin, Oregon

Robert J. Miller, DMD
Private Practice limited to Periodontics and Implant Dentistry, Plantation, Florida

Edward Gottesman, DDS
Private Practice limited to Periodontics and Implant Dentistry, New York, New York

Robert L. Holt, DDS, PhD
Private Practice limited to Periodontics and Implant Dentistry, West Palm Beach, Florida

Kanyon R. Keeney, DDS
Private Practice limited to Dental Implant Surgery, Mechanicsville, Virginia

William F. Runyon, DDS
Private Practice limited to Oral and Maxillofacial Surgery, Fort Worth, Texas

Philip L. Fava, DMD, MDSc
Private Practice limited to Periodontics and Implant Dentistry, Philadelphia, Pennsylvania

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