Comparison of Implant and Provisional Placement Protocols in Sinus-Augmented Bone: A Preliminary Report

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Purpose: To evaluate preliminary data on clinical outcomes associated with timing of placement of single implant–supported provisional crowns and implants in augmented bone. Materials and Methods: Twenty patients underwent sinus elevation bone grafting followed by a 6-month healing period before implant placement and immediate placement of a provisional crown (group [G] 1); 20 patients received sinus elevation bone grafting at the time of implant placement and immediate placement of a provisional crown (G2); 20 patients required no bone augmentation before implant placement and immediate placement of a provisional crown (G3); and 20 patients received sinus elevation bone grafting followed by a 6-month healing period before implant placement followed by a 6-month healing period before restoration (G4). The height of the crestal bone was measured and recorded to determine mean bone changes, and success rates were determined.

Results: Mean bone level comparisons were made between G2 and G3, G2 and G4, and G3 and G4. No statistically significant differences were found between the groups (P < .05). G1 was discontinued based on the initial results: two implants did not meet the 35-Ncm insertion test, and one implant failed within 1 month after implant placement. The 1-year implant survival rates were 86% (n = 12/14), 95% (n = 19/20), and 100% (n = 16/16) for G2, G3, and G4, respectively. Differences in survival rates between the groups were not statistically significant (P < .05). Conclusion: Implant survival is affected by the timing of sinus augmentation and implant placement in relation to the timing of crown placement. Implants that were restored immediately regardless of the timing of bone augmentation showed greater failure rates than implants in augmented bone with delayed restoration protocols or those that were restored immediately in sites without bone augmentation. Neither the timing of loading nor timing of implant placement in relation to bone augmentation surgery affected mean bone loss. Int J Oral Maxillofac Implants 2015;30:648–656. doi: 10.11607/jomi.3863

Key words: bone augmentation, bone loss, clinical outcomes, immediate implant placement, immediate provisionalization

Successful implant therapy is dependent on achieving and maintaining osseointegration.1 Early experiences with implant treatment relied on the surgical placement of implants followed by a healing period of 3 to 6 months during which the implants were protected from externally applied forces.2–5 Clinical studies for single-implant restorations indicate high success rates.6–9 With the development of new implant types, surface technology, and advanced knowledge about the physiology of osseointegration, the requirement for delayed restoration of dental implants has been challenged.6,10–12 Interest has surfaced with regard to placing a dental restoration on the day of surgical implant placement to foster early esthetic improvement, guide appropriate healing of the peri-implant soft tissues, increase patient comfort, and decrease treatment time. Immediate loading of dental implants using different types of restorations has been accomplished.
successfully in animal models\textsuperscript{13,14} and then in humans.\textsuperscript{15–19} The restoration of single missing teeth with implant-supported crowns has been performed routinely by clinicians.\textsuperscript{20,21} Although clinical studies presenting short-term outcomes of immediately loaded implants supporting single crowns are available,\textsuperscript{22–24} only a few studies exist showing long-term results (≥ 5 years) of immediately loaded implants supporting single crowns.\textsuperscript{25–27}

Many studies prior to 2005 reported a higher failure rate for short implants.\textsuperscript{28–30} Winkler et al\textsuperscript{30} found that short implants failed significantly more often after loading than longer implants. A logistic regression analysis found that implant length was a significant factor for survival. Weng et al\textsuperscript{29} and Goodacre et al\textsuperscript{31} reported that implants ≤ 10 mm had a significantly lower cumulative success rate. Van Steenbergh et al\textsuperscript{28} found that shorter implants in patients with poorer quality of bone were more at risk for implant failure or nonintegration. However, others\textsuperscript{32–34} have documented similar success rates for short as well as longer implants.

Some investigators have reported a positive correlation between an increased crown-to-implant ratio and a higher risk for marginal bone loss,\textsuperscript{35} whereas others\textsuperscript{36} failed to show such a correlation. At a consensus conference\textsuperscript{37,38} in 2004, the panel was not able to develop definitive statements with regard to crown-to-implant ratio. However, guidelines regarding crown height space (CHS) were developed because of the belief that the crown height is a vertical cantilever. In fixed prosthetic restorations, an excessive or limited CHS results in increased mechanical (prosthetic) complications. An acceptable range for CHS of 8 to 12 mm emerged.\textsuperscript{38}

Several authors have suggested that it is the combination of short implants and low bone density that is responsible for higher failure rates rather than length alone.\textsuperscript{39–42} A significant difference was shown among implant failures associated with bone quality and implant length.\textsuperscript{42} Herrmann et al\textsuperscript{42} reported that type 4 quality of bone demonstrated the highest failure rates. With regard to implant length, when the implants were divided by short and long implants, a post hoc analysis found a correlation between shorter implants and failure rates.\textsuperscript{42} Therefore, it has been recommended that a minimum bone height of 10 mm is required in the posterior maxilla to place implants without augmentation.\textsuperscript{43}

The edentulous areas for single and multiple missing teeth were classified by Garber\textsuperscript{44} based on the residual osseous tissue and the need for supplemental grafting. The maxillary sinus is frequently pneumatized in the edentulous or partially edentulous maxilla. Inadequate available bone can result, which precludes dental implant placement without the need for bone grafting. Similar clinical scenarios require autogenous, alloplastic, or allogeneic sinus bone grafting for successful implant placement in the posterior maxillary edentulous regions.

Standard maxillary sinus bone grafting techniques entail surgical exposure of the lateral wall of the maxillary sinus, lateral wall osteotomy, elevation of the sinus membrane, and bone grafting. The bone graft is typically left in situ to consolidate for 6 months before reevaluation and implant placement. After surgical implant placement, most patients are left to heal another 4 to 6 months before surgical exposure and dental provisionalization of the implant. Therefore, patients may wait up to 1 year before receiving a prosthetic component for their implant. Published reports regarding bone augmentation and simultaneous implant placement have shown no statistically significant difference in marginal bone loss\textsuperscript{45} as compared to delayed implant placement. Herzberg et al\textsuperscript{45} suggested that simultaneous implant placement may be implemented safely when primary implant stability can be obtained regardless of the amount of preoperative residual bone. Studies evaluating survival rates have shown comparable results between delayed and simultaneous sinus floor elevation surgery.\textsuperscript{46–48} Five-year implant survival rates of simultaneous vs delayed implant placement in augmented bone showed no statistically significant differences, 95.7% and 90.4%, respectively.\textsuperscript{47}

No reports have been published on the immediate loading of dental implants placed in allograft bone. Because many patients seeking dental care require some type of bone augmentation surgery to be candidates for surgical placement of dental implants, the question arises regarding success and complications of immediately loading single tooth restorations in patients receiving bone grafts. The findings on when to place an implant after bone grafting and/or when to provisionalize—immediately vs after 6 months of healing—are anecdotal. To date there is no published clinical research that suggests one treatment protocol is more successful than another.

The purpose of this report is to present the preliminary data on the clinical outcomes associated with the timing of (1) implants placed in augmented bone and (2) single implant–supported provisional crowns. The null hypothesis was that there is no difference between the expected success rates and radiographic bone levels for immediate restoration of single dental implants with provisional crowns in native bone and a treatment regimen involving immediate placement of provisional restorations at the time of the sinus augmentation plus implant placement.
MATERIALS AND METHODS

This was a prospective, controlled, nonrandomized, clinical study that evaluated patients who received one dental implant. Patients were enrolled in this study from 2005 to 2012. The patients were assigned to one of four groups (G1, G2, G3, and G4). Table 1 provides a description of the groups’ treatment protocols.

Subjects were selected on the basis of a comprehensive evaluation. A complete medical history, dental history, and comprehensive diagnostic workup were conducted by the investigators to ascertain the subjects’ current state of health, and to identify any contraindications to participation in the study. Inclusion and exclusion criteria were the medical and clinical findings that could negatively affect the outcomes of the study. Table 2 lists the inclusion and exclusion criteria. General health requirements consisted of patients free of any condition that would have a negative impact on healing. Patients with malignancies or dysplastic oral and head and neck lesions were also excluded from participation.

Patients were included in the study if they had an intact dentition except for a single missing tooth from the maxilla with stable occlusion and restorative space of ≥ 5 mm for a satisfactory implant restoration and adequate bone volume to accommodate a 3.7 to 4.7-mm-diameter implant.

To eliminate any variables associated with long clinical crowns that might influence prosthetic complications that could affect the clinical outcomes, presurgical evaluation required convincing evidence that the final implant-supported restoration would demonstrate a crown-to-implant ratio of approximately 1:2. It was determined that to eliminate implant length as a variable, all patients would receive a 13-mm-long implant. This would allow for examination of the outcomes as a percentage of native bone to augmented bone for G1 (< 50%: > 50%), G2 (> 50%: < 50%), G3 (100%:0%), and G4 (< 50%: > 50%). Patients assigned to groups G1, G2, and G4 had to have a bone height that required bone augmentation with sinus elevation to place a 13-mm implant. Patients were recruited in this study by solicitation through advertisements and review of dental records currently on file in the University of Texas Health Science Center San Antonio Dental School. All recruited patients signed a consent form designed specifically for this study and approved by the university’s institutional review board.

### Table 1 Description of Study Groups by Treatment Protocol

<table>
<thead>
<tr>
<th>Group</th>
<th>Treatment protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>G1</td>
<td>Sinus elevation bone grafting followed by a 6-month healing period before implant placement and immediate placement of a provisional crown</td>
</tr>
<tr>
<td>G2</td>
<td>Sinus elevation bone grafting at the time of implant placement and immediate placement of a provisional crown</td>
</tr>
<tr>
<td>G3</td>
<td>Control group that required no bone augmentation for implant placement and immediate placement of a provisional crown</td>
</tr>
<tr>
<td>G4</td>
<td>Control group that received a sinus elevation bone grafting followed by a 6-month healing period before implant placement followed by a 6-month healing period before restoration</td>
</tr>
</tbody>
</table>

### Table 2 Inclusion/Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 18 years of age and able to give informed consent</td>
<td>Patient unable to give informed consent</td>
</tr>
<tr>
<td>General health requirements: free of uncontrollable diabetes, existing malignancy, and not receiving immune suppressive therapy</td>
<td>Advanced cardiovascular disease, pulmonary disease, renal disease, liver disease, or significant alcohol ingestion</td>
</tr>
<tr>
<td>An intact dentition with stable occlusion except for a single missing tooth from the maxilla</td>
<td>Patients with malignancies or dysplastic oral and head and neck lesions</td>
</tr>
<tr>
<td>Sufficient restorative space (≥ 5 mm) in the edentulous area for satisfactory implant restorative procedures</td>
<td>Dentition with unstable occlusion and more than one missing tooth</td>
</tr>
<tr>
<td>A crown-to-implant ratio of approximately 1:2</td>
<td>Insufficient restorative space (&lt; 5 mm) for an implant restoration in the edentulous area</td>
</tr>
<tr>
<td>Patients were caries free or amenable to caries control and appropriate restoration</td>
<td>Patients with unfavorable and excessive occlusal forces</td>
</tr>
<tr>
<td>Free of active periodontal disease</td>
<td>Patients with poor oral hygiene (PI ≥ 1)</td>
</tr>
<tr>
<td>Any tooth mobility had to be physiologically acceptable</td>
<td>Poor periodontal condition (MGI ≥ 1)</td>
</tr>
<tr>
<td>Proposed implant site presented clinically with at least 2 mm of attached, keratinized tissue</td>
<td>Pregnant women</td>
</tr>
<tr>
<td></td>
<td>Smokers with a habit of ≥ 20 cigarettes per day</td>
</tr>
<tr>
<td></td>
<td>Patients with malignancies or dysplastic oral, head, and neck lesions</td>
</tr>
</tbody>
</table>

Plaque Index; MGI = Modified Gingival Index.
A diagnostic wax-up of the proposed coronal restoration was used to construct: (1) a surgical template to provide positional guidance during implant site preparation, (2) an occlusal matrix for use in transferring the implant position to the diagnostic cast after the implant placement; and (3) a pressure-formed matrix to aid in fabrication of the provisional crown.

Patients were assigned to groups based on the amount of available bone. Before surgery, patients were assigned to groups based on digital radiographic findings. Patients requiring sinus elevation were examined using a metal crown caliper to directly measure the thickness of the native bone at the time of augmentation surgery (Fig 1). Patients with 6 mm or less native bone were assigned to G1 and G4, and required a 6-month healing period after sinus lift bone grafting before implant placement and provisionalization.

Patients with native bone that was greater than 6 mm but less than 11 mm were assigned to G2, which was designated to have simultaneous sinus lift bone grafting, implant placement, and immediate provisionalization. Patients with sufficient bone to support a 13-mm implant comprised G3, which did not receive bone augmentation, and received a provisional crown on the day of implant placement. Table 3 lists the location and bone height for the implants in the groups that had sinus elevation bone augmentation surgery.

All surgical procedures were performed by a board-certified oral and maxillofacial surgeon. Local anesthesia with or without sedation was administered. Bone grafting surgery was performed using (60:40 ratio) Puros cancellous/cortical particulate graft (Zimmer Dental). Sinus elevation augmentations were performed through lateral osseous windows using

*Universal tooth numbering system.*
standard sinus lift techniques. All patients receiving sinus bone augmentation were placed on a 1-week course of penicillin V potassium every 6 hours.

For patients assigned to G1 and G4, after placing the bone graft material, a 6-month healing period occurred before implant placement surgery. For patients assigned to G2, the implant surgery was performed after placing the bone graft material.

Standard surgical protocols were followed with a nonrestricted surgical guide. The implant site was prepared using the surgical template to guide the 2.3-mm pilot drill. Additional site preparation was accomplished in the absence of the surgical template; the surgical guide was used only for verification of implant position. After the osteotomy was completed, the implant (Tapered Screw-Vent implant, Zimmer Dental) was placed, and the site was sutured for primary closure. The selection of implant diameter was based on dimensional analysis of the available bone site. The patients assigned to G1, G2, and G3 received a provisional crown on the day their implant was surgically placed, whereas those assigned to G4 did not receive a provisional crown on the day of implant placement, but instead had a 6-month healing period before placement of their restoration. A periapical radiograph was made using a radiographic positioning template immediately after the surgical procedure.

The implant was evaluated for primary stability regardless of the group to which the patient was assigned. An implant was judged to be stable if the insertion torque was greater than or equal to 35 Ncm. If the insertion torque of the implant did not meet the 35-Ncm test at the time of implant surgery, a provisional crown was not placed because of the possibility of implant loss. If this occurred, the patient was withdrawn from the study and not included in the data analysis.

For the implants receiving immediate provisional crowns (G1, G2, and G3), when the implant was judged to be mechanically stable, the fixture mount was used as a direct transfer impression post. The occlusal matrix was positioned on the teeth adjacent to the implant site. A light-activated resin was used to attach the fixture mount to the occlusal matrix. When the resin was cured, the matrix was removed and became an index used for laboratory fabrication of the provisional crown.

A provisional crown (Integrity, Dentsply Caulk) was constructed using a plastic temporary abutment (Hexlox, Zimmer Dental) and the pressure-formed matrix. Occlusal contacts were adjusted so that in the maximum intercuspal position an occlusal contact drag of shim stock (Almore International) at the 12-μm level was created. All eccentric contacts were eliminated. The access channel was obturated with a temporary filling material (Fermit, Ivoclar Vivadent). After a 6-month healing period, a final impression was made to fabricate the definitive restoration following standard protocol with a closed-tray impression technique. Definitive screw-retained metal-ceramic crowns were fabricated using standard laboratory procedures. Occlusal contacts were adjusted so that light occlusal contacts were present in the maximum intercuspal position—shim stock drag through the occlusal contact. The shim stock held with maximum occlusal force. All eccentric contacts were eliminated. Mutually protected occlusion was generally considered optimal. When appropriately adjusted for fit, form, and function, the final crown was fastened with a screw to the implant. After the definitive restoration was placed, a periapical radiograph was made to ensure complete seating of the crown. A temporary restorative material was placed in the screw access channel.

Each patient was examined and experimental data collected by the investigators at baseline (the time of implant insertion), 3 months, 6 months, and 1-year time points. Criteria for implant success were evaluated following those published by Albrektsson et al.49 Patient examination and study data collected, including (1) measurement of implant mobility, (2) presence or absence of the peri-implant infection or pain, and (3) radiolucency were assessed beginning at the 3-month recall visit after placement of the definitive restoration and at 1-year follow-up. An implant was considered a failure if it was removed and no longer in function.

Investigators examined the subjects’ radiographs for normal healing and no radiographic evidence of intraosseous abnormalities. Radiographic technique and bone loss measurements were standardized by using an XCP technique with a film holder for each subject (XPC Film Holding Instrumentation, Dentsply/Rinn), whereby the device was used to hold the film perpendicular to the central radiographic beam. Digital periapical radiographs were made (Eastman Kodak) using standard current and voltage settings for each implant study site.

The height of the crestal bone relative to the collar of the implant was measured and recorded. One blinded investigator performed the periapical radiographic evaluations. Radiographs were made at implant placement and at 3-month follow-up intervals through 12 months. The diameter of the implant was used to calibrate the computer software for measurement. Bone loss measurements were recorded at the mesial and distal areas for each implant.

Paired and unpaired t tests were used to determine if there were significant differences in bone level change (loss or gain) related to implant surface (mesial vs distal) between groups. An unpaired t test and analysis of variance (ANOVA) were computed to determine if there were differences in the amount of bone change between the groups. A chi-square analysis was
completed to determine if there were any differences in survival rates between the groups.

**RESULTS**

This study evaluated the 1-year preliminary data on the clinical outcomes associated with timing of placement of single implant–supported provisional crowns in implants placed in augmented bone. The first patient in G1 withdrew from the study after the sinus bone augmentation surgery, but before the implant placement surgery. Sequentially for the next three patients in group G1, two implants did not meet the 35-Ncm insertion test, were judged to lack primary stability at the time of placement, and were withdrawn from the data analysis part of the study; the third implant failed within 1 month after implant placement. Based on the initial results, it was determined by the investigators to terminate this arm of the study. The survival rate of this group was 0% (Table 4).

Nineteen patients were enrolled in group G2. One patient withdrew before sinus augmentation–implant surgery; two patients withdrew after implant placement but before the first recall; and one patient was dismissed from the study by the investigators because of noncompliance with recall appointments. One patient experienced an undisclosed sinus infection, which she reported days after the implant surgery. The patient indicated that she thought she had been “coming down with a cold several days prior to the surgery.” This patient was excluded from the analysis because of the fact that disclosure of a possible sinus infection on the day of surgery would have led to postponement of the surgery. Of the remaining 14 patients, two experienced implant failure. All implant failures were reported at the 3-month recall. The survival rate of this group was 86% (Table 4).

Nineteen patients comprised group G3 (no bone augmentation required). This control group had one failure that was identified at the 3-month recall. The survival rate for this protocol was 95% (Table 4). At the 1-year recall appointment, two patients were unavailable for examination, and were noncompliant with this appointment. However, they were available for subsequent recall follow-up, so they were included in the overall survival data but excluded from the bone loss data.

Group G4 served as a negative control group. Patients in this group received bone augmentation with delayed implant placement and delayed restoration. Nineteen patients were enrolled in this group, of whom three patients withdrew before implant placement. Of the remaining 16 implants, none failed. The survival rate for this group was 100% (Table 4).

The survival rates of the four groups were analyzed using chi-square analysis (Table 4). All implants that failed in sinus-augmented groups were in the molar region. However, it should be noted that there were only three premolars in G2 and G4. G1 showed a statistically significant difference compared with all other groups. There was no significant difference between G2 and G3, between G2 and G4, and between G3 and G4.

Changes in bone height around the implants were evaluated to determine if there was a difference in the amount of bone changes on the mesial and distal side of the implant for each group evaluated. Paired and unpaired t tests were used to determine if differences were significant at \( P < .05 \). Table 5 shows the results of this analysis. There was no statistically significant difference between the changes in bone levels on the mesial or distal surface. Therefore, the data for each group were pooled.

The combined bone level data were then compared across groups. Comparisons were made between G2 and G3, G2 and G4, and G3 and G4. The data were analyzed using unpaired t tests and ANOVA, and significance was set at \( P < .05 \). Table 6 reports the statistical analyses. There was no statistically significant difference between the groups.

**DISCUSSION**

The study evaluated the midterm clinical outcomes of sinus elevation surgery, implant placement, and provisional restoration of single implant-supported crowns in relation to healing time. The differences in bone levels were compared across groups using an unpaired t test. Changes in bone level over the course of 1 year were
not significantly different for patients who received a simultaneous bone augmentation, implant placement surgery, and an immediate provisional crown (G2) compared with those who did not receive bone augmentation and received an immediate provisional crown at the time of implant placement surgery (G3). Similarly, G2 changes in bone level showed no statistically significant difference compared with those who received bone augmentation surgery, 6-month delayed implant placement surgery, and 6-month delayed restoration (G4).

The differences in mean bone loss on the mesial and distal surfaces of the implants were compared at the 1-year measurement interval. Results showed no statistically significant difference between changes in bone levels on the mesial or distal surface of the implant in each study group. This is in agreement with the findings of Kan et al.\(^6\) who also demonstrated no statistically significant difference between marginal bone loss on the mesial or distal surface of the implant. The mean changes in bone level on the mesial and distal surfaces of the implants in the present study for G3 (similar protocol to the Kan et al study\(^6\)) were \(-0.53 \pm 0.53\) mm and \(-0.50 \pm 0.53\) mm, respectively. The marginal bone losses in the present study were more favorable than those reported by Kan et al.\(^6\) (0.72 mm and 0.62 mm, mesial and distal surfaces, respectively).

The mean bone loss around implants placed at the time of the sinus elevation surgery in G2 was less than the mean bone loss in G4, the delayed implant placement group, but the difference was not statistically different (\(P = .90\)). These findings are similar to those of Herzberg et al.\(^{45}\) who discovered an association between delayed implantation and mean bone loss > 0.2 mm per year; the findings were not statistically significant. However, unlike the present study, in patients treated after the delayed implant placement protocol and with \(\leq 4\) mm of residual bone, mean bone loss > 0.2 mm per year was found to be statistically different than the group with simultaneous placements (\(P < .018\)).\(^{45}\) The findings of this study would suggest that the timing of loading did not affect the mean bone loss, nor did the timing of implant placement in relation to the bone augmentation surgery.

The findings of G4 in the current study are in agreement with the findings of Urban and Lozada,\(^{48}\) and Bornstein et al.\(^{16}\) that implants placed in sinus-augmented bone, using the classic approach of delayed implant placement and loading, had similar success rates as implants placed in native bone.

Kan et al.\(^6\) evaluated 35 patients clinically and radiographically at presurgical examination, immediately after implant placement and provisionalization. They reported a survival rate of 100%, after a mean follow-up time of 4 years (range, 2 to 8.2 years). Koo et al.\(^7\) found the 1- to 5-year cumulative survival rate (CSR) for single-tooth implants placed in the second molar region to be 95.1%. In both studies,\(^5,7\) implants were immediately loaded in bone that did not require augmentation procedures. These study protocols were similar to G3 with similar success rates.

In a systematic review, Del Fabbro et al.\(^{50}\) examined the timing of implant placement. Simultaneous sinus floor elevation followed by implant placement revealed similar outcomes regardless of whether the implants were in use \(\leq 36\) months or \(\geq 36\) months. The overall implant survival rate was 94.59%, and 94.26% for delayed and simultaneous implant placement, respectively. This review\(^{50}\) found that implant survival was not dependent on the use of a delayed or simultaneous placement technique, but instead on whether primary implant stability could be obtained at the time of the sinus floor elevation. These survival rates are comparable to those of implants placed in native bone not requiring bone augmentation surgery. There was no indication that the implants in the Del Fabbro et al.\(^{50}\) review were immediately loaded.

In contrast to the Del Fabbro et al.\(^{50}\) study, in the present study,

### Table 5 Results of Bone Loss and Comparisons Within Groups*

<table>
<thead>
<tr>
<th>Surface</th>
<th>G2 (n = 12)</th>
<th>G3 (n = 17)</th>
<th>G4 (n = 16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesial</td>
<td>Mean ± SD bone loss (mm)</td>
<td>Mean ± SD bone loss (mm)</td>
<td>Mean ± SD bone loss (mm)</td>
</tr>
<tr>
<td>Distal</td>
<td>0.35 ± 0.29 (P = .29)</td>
<td>0.53 ± 0.53 (P = .80)</td>
<td>0.45 ± 0.32 (P = .34)</td>
</tr>
<tr>
<td>Mesial + distal</td>
<td>0.39 ± 0.34</td>
<td>0.51 ± 0.52</td>
<td>0.41 ± 0.32</td>
</tr>
</tbody>
</table>

*The differences were examined using unpaired t test and paired t test. \(P < .05\) was considered statistically significant.

### Table 6 Combined Results of Bone Loss and Comparisons Between Groups

<table>
<thead>
<tr>
<th>Group</th>
<th>No.</th>
<th>Mean ± SD bone loss (mm)</th>
<th>(P^*)</th>
<th>Unpaired t test</th>
<th>G2 vs G3</th>
<th>G2 vs G4</th>
<th>G3 vs G4</th>
<th>ANOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined mesial-distal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G2</td>
<td>12</td>
<td>0.39 ± 0.34</td>
<td>.49</td>
<td>.90</td>
<td></td>
<td></td>
<td></td>
<td>.69</td>
</tr>
<tr>
<td>G3</td>
<td>17</td>
<td>0.51 ± 0.52</td>
<td>.90</td>
<td>.51</td>
<td></td>
<td></td>
<td></td>
<td>.69</td>
</tr>
<tr>
<td>G4</td>
<td>16</td>
<td>0.41 ± 0.32</td>
<td>.51</td>
<td>.69</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ANOVA = analysis of variance.

\(P^*\) < .05 was considered statistically significant.
primary stability was not an indication of implant survival when implants were restored on the day of surgical placement at the time of bone augmentation. In the present study, implants (G2) that were placed and restored simultaneously on the day of the sinus floor elevation surgery, had ≥ 6 mm of native bone, and were perceived to have achieved primary stability had a success rate of 86%. The lower survival rate would suggest that timing of sinus floor elevation and implant placement in relation to implant survival is affected by the timing of implant loading. Implants that were immediately loaded regardless of the timing of the sinus augmentation showed greater failure rates than implants in augmented bone that received a delayed loading protocol or those that were loaded immediately in sites that did not require a bone augmentation procedure. However, although implants placed during the sinus augmentation surgery and immediately restored (G2) had a lower success rate, the success rate of these implants were statistically similar to those implants with delayed placement and delayed restoration (G4) and those immediately restored implants placed in native bone (G3).

In the group in which less than 50% of the implant was placed in native bone (G1), the arm of the study had to be terminated because the implants either did not achieve primary stability or, despite achieving 35-Ncm insertion torque, failed 1 month after immediate provisionalization. This suggests that the immature grafted bone does not provide stability to the implant, and that bone height greater than 50% of the length of an implant may be necessary to immediately provisionalize with a crown. Further evidence supporting this finding is that in G4, which also had less than 50% of the implant placed in native bone but which had the delayed restoration, there were no failures.

It should be noted that in the groups that had implant failures, all failures occurred within the first 3 months after implant placement. No implant failed after 3 months of healing regardless of the treatment protocol. The fact that all failures were early failures rather than late-stage failures suggests that additional factors may be influencing clinical outcomes.

A limitation of this study was that the masticatory function was not taken into account. The clinical examination did not note whether the patient’s dominant side for mastication was on the ipsilateral or contralateral side of the implant. It would be interesting to know whether the failures were on the side of the patient’s dominant side of mastication. If that were true, then the crown would be in function during masticatory episodes, which may account for the failures. This could be considered a contraindication for immediate provisionalization or loading in augmented bone. Future studies in this area should collect data measuring masticatory functional preference (the dominant side for mastication).

The null hypothesis was that there is no difference between the expected success rates for immediate restoration of single dental implants with provisional crowns in native bone and a treatment regimen involving immediate placement of provisional restorations in grafted bone; this hypothesis, however, was rejected. The second null hypothesis proposed was accepted: there is no difference between radiographic bone levels for immediate restoration of single dental implants with provisional crowns in native bone and a treatment regimen involving immediate placement of provisional restorations in grafted bone.

CONCLUSIONS

Within the limitations of this study, it may be concluded that (1) the timing of neither loading nor implant placement in relation to bone augmentation surgery affected mean bone loss; (2) immediate placement of a provisional crown at the time of implant placement surgery in augmented bone in which native bone is less than 50% of the implant length is not recommended; (3) delayed implant placement and delayed restoration in augmented bone is a viable treatment protocol; and (4) the treatment protocol of simultaneous placement of a dental implant at the time of bone augmentation surgery followed by immediate placement of a provisional crown must be viewed cautiously because the potential for implant failure is greater.

ACKNOWLEDGMENTS

This project was funded by a research grant from Zimmer Dental. The authors reported no conflicts of interest related to this study.

REFERENCES