The concept of immediate implant placement and provisionalization (IIPP) for the replacement of failing maxillary anterior teeth was introduced by Wohrle in 1998.1 Although IIPP procedures have demonstrated high success rates, an average of 1.0 mm of facial gingival recession has been reported following the first year of function.2–5 Recent studies have advocated the use of the subepithelial connective tissue graft (SCTG) to increase the thickness and overall resistance of the implant facial gingiva to recession.5–11 However, studies evaluating the efficacy of SCTG at the time of the IIPP procedure have been limited.5,9,12,13

The purpose of this 1-year randomized controlled prospective study was to compare the facial gingival level (FGL) changes following single IIPP procedures in patients with and without SCTG in the maxillary esthetic zone. The implant success rate and peri-implant tissue response were also evaluated.
MATERIALS AND METHODS

Patient Selection
This study was approved by the Institutional Review Board of Loma Linda University and was conducted in the Center for Implant Dentistry, Loma Linda University School of Dentistry. To be included in this study, all patients had to: (1) be at least 18 years or older with good hygiene, (2) have a single failing maxillary tooth in the esthetic zone (between and including the first premolars) with the presence of adjacent and opposing natural dentition and without active infection, and (3) have sufficient bone volume to accommodate placement of a single implant with minimum dimensions of $3.3 \times 12.0 \text{ mm}$. Any patients (1) with a history of smoking,\textsuperscript{14} head and neck radiation treatment,\textsuperscript{15-17} bruxism,\textsuperscript{18} and/or parafunction; (2) with a lack of stable posterior occlusion; and/or (3) in whom primary implant stability could not be achieved were excluded from this study.

The patients were randomly assigned (QuickCalc software, GraphPad) to two groups: IIPP without SCTG (control) and IIPP with SCTG (test).

Clinical Procedures
All patients underwent standardized diagnostic and treatment planning procedures prior to consenting to treatment (Figs 1 and 2). A provisional restoration was fabricated prior to implant placement surgery.

The failing tooth was removed, and an implant (Bone Level, Straumann USA) was placed 3 mm apical to the predetermined facial gingival margin and at the center of the mesiodistal width of the definitive restoration, with a minimum of 2 mm left between the implant and the roots of the adjacent teeth. From a faciopalatal aspect, the implant was placed along the palatal wall of the extraction socket for primary stability, leaving a gap of at least 1.5 mm between the implant and the facial bone (Fig 3). Primary implant stability was achieved with a minimum insertion torque of 25 Ncm,\textsuperscript{19} and xenograft bone graft material (Bio-Oss, Osteohealth) was used to fill the implant-socket gap (Fig 4).\textsuperscript{20} A prefabricated abutment (NC anatomic abutment, RC anatomic abutment, Straumann USA) was modified and hand-tightened onto the implant. Composite resin (Perma Flo, Ultradent Products) was used to reline the prefabricated provisional shell and
to re-create the emergence profile of the extracted tooth. The provisional restoration was adjusted to clear all centric/eccentric contacts and then cemented (IRM, Dentsply International).

For the test group, an SCTG with a minimum thickness of 1.5 mm was harvested from the palate. Following the IIPP procedure, a full-thickness envelope flap was created between the facial bone plate and the overlying gingiva. The SCTG was inserted into the prepared envelope and secured with resorbable suture material (6-0 chromic gut blue, Ethicon Johnson & Johnson) (Figs 5 and 6). A periapical radiograph was obtained to confirm the fit of the provisional restoration (Fig 7).

Antibiotics and analgesics were prescribed, and patients were instructed to rinse with 0.12% chlorhexidine gluconate solution (Peridex, Zila Pharmaceuticals), twice a day, for 2 weeks. A liquid diet was suggested for 1 week following surgery, with a transition to a soft diet for the next 3 months. The patients were advised to refrain from function at the surgical site.

The final implant-level impression was made (Aquasil Monophase, Dentsply) at 6 months. A customized zirconia abutment (NC CADCAM Abutment, ZrO2 or RC CADCAM Abutment, ZrO2, Straumann) was fabricated and torqued to 35 Ncm according to the manufacturer’s recommendation. The definitive all-ceramic restoration (Vita VM 13, Vita Zahnfabrik) was then cemented (Rely-X Unicem, 3M ESPE) (Figs 8 and 9).

**Data Collection and Analysis**

All examinations and corresponding data collection were performed by one examiner (SY). The data, when indicated, were collected and compared between each follow-up time interval: before surgery (T0), immediately after implant placement (T1), and at 3 months (T2), 6 months (T3), and 12 months (T4) after surgery. The implant success/failure and marginal bone level (MBL) changes were evaluated and compared at T1, T2, T3, and T4; facial gingival level changes were measured at T0, T2, T3, and T4; implant stability (via resonance frequency analysis [RFA]) was assessed at T1 and T3;...
modified Plaque Index and modified Bleeding Index were recorded at T2, T3, and T4; and Papilla Index was recorded at T1, T2, T3, and T4.

- **Gingival biotype**: The gingival biotype of each failing tooth was evaluated during bone sounding at the midfacial aspect of the failing tooth (T0). The gingival biotype was categorized as thin or thick according to the visibility of an underlying periodontal probe (SE Probe SD12 Yellow, American Eagle Instruments) through the gingival tissue (visible = thin; not visible = thick).

- **Implant success rate**: The implants were evaluated according to the criteria proposed by Smith and Zarb where applicable.

- **Marginal bone level**: The MBLs were measured on the mesial and distal aspects of each implant with the use of sequential periapical radiographs and the long-cone paralleling technique with a commercial Rinn XCP holder (XCP post bite blocks 54-0862, Dentsply). An occlusal jig made of vinyl siloxane (Exabite II, GC America) was used to standardize the position and angulation of the film to the x-ray beam. The implant platform was used as the reference line (RL) (Fig 10). The distance between the RL and the first bone-implant contact was measured. A measured value of zero was given when the MBL was coronal to the RL. A negative value was given when the MBL was apical to the RL. The overall MBL of each implant was the average value of mesial and distal measurements. The overall MBLs were compared between each follow-up time interval (T1, T2, T3, T4) and the changes in MBL calculated. The intraexaminer reliability of the measurements was determined through duplicate assessments of MBL measured 3 months apart by one examiner and expressed as the intraclass correlation coefficient (ICC).

- **Facial gingival level**: Impressions were made (Jeltrate, Dentsply International) at different time intervals (T0, T2, T3, T4). These casts were used to evaluate the changes in FGL. A customized template fabricated from the preoperative cast was used to standardize the measurement points and the direction of the measuring device (15 UNC Color-Coded Probe, Hu-Friedy). A perpendicular slot was created at the most apical part of the midfacial gingival level, and the lower border of the customized template was used as a reference line. The FGL was evaluated at each time interval using a periodontal probe (15 UNC Color-Coded Probe, Hu-Friedy) and the FGL change calculated. All measurements were made to the nearest 0.5 mm. The intraexaminer reliability of the measurements was determined with duplicate assessments of FGL measured 3 months apart by one examiner and expressed as the ICC.

- **Implant mobility**: An RFA instrument (Ostell) was used to evaluate implant stability at T1 and T3. Measurements were registered and recorded as implant stability quotients (ISQs).

- **Plaque and bleeding indices**: The presence of plaque and the incidence of bleeding were assessed at the mesiolabial, labial, distolabial, mesiolingual, lingual, and distolingual surfaces of the implant provisional and definitive restorations according to the modified Plaque Index (mPI) and modified Bleeding Index (mBI) at T2, T3, and T4. Only the highest score for each implant was used for statistical analyses.

- **Papilla Index Score**: The interproximal soft tissue was evaluated using the Papilla Index Score (PIS). Mesial and distal PIS were analyzed individually.

- **Surgical complications**: Surgical complications were documented and included but were not limited to dehiscence, connective tissue graft necrosis, infection, and/or inability to establish adequate primary stability.

- **Prosthetic complications**: Prosthetic complications were documented as any repairs or modifications of the provisional restoration or definitive prosthesis. These included but were not limited to debonding/fracture of the provisional restoration, and/or abutment screw loosening.

The data were analyzed using Friedman, Wilcoxon signed-rank, and Mann-Whitney U tests at a significance level of $\alpha = .05$.

**RESULTS**

A total of 7 men and 13 women between the ages of 27 and 87 years (mean age, 52.6 years) participated in this study. Ten patients underwent IIPP procedures with SCTG (test group) and 10 patients received IIPP without SCTG (control group). Of the 20 implants placed, 13 were located in the maxillary central incisor region,
The mean MBL changes from T1 to T4 were –0.01 ± 0.27 mm for the test group and –0.14 ± 0.53 mm for the control group (Table 2). There were no significant differences in MBL and MBL change at or between any time intervals between the test and control groups (P > .05; Tables 1 and 2).

The ICC for MBL measurements was 0.99. Statistical values for the changes in FGL are presented in Table 3. The mean FGL change from T0 to T4 was statistically significantly greater in the control group (–0.7 ± 0.48 mm) than in the test group (–0.25 ± 0.35 mm) (P = .049; Table 3).

After 1 year in function, all implants in the test (10/10) and the control (10/10) groups were stable and osseointegrated, which corresponded to an overall implant success rate of 100%.

**Clinical Indices**

The ICC for MBL measurements was 0.99. In the test group, 19 of 20 sites (95%) showed a MBL at or coronal to the RL (MBL = 0 mm) at T1; at T4, this was seen at 17 of 20 sites (85%). In the control group, 15 of 20 sites (75%) showed MBL at or coronal to RL (MBL = 0) at T1; at T4 this had fallen to 12 of 20 sites (60%). The overall MBL and MBL changes for each implant at different time intervals are presented in Tables 1 and 2. The mean MBL changes from T1 to T4 were –0.01 ± 0.27 mm for the test group and –0.14 ± 0.53 mm for the control group (Table 2). There were no significant differences in MBL and MBL change at or between any time intervals between the test and control groups (P > .05; Tables 1 and 2).

The ICC for FGL measurements was 0.99. Statistical values for the changes in FGL are presented in Table 3. The mean FGL change from T0 to T4 was statistically significantly greater in the control group (–0.7 ± 0.48 mm) than in the test group (–0.25 ± 0.35 mm) (P = .049; Table 3).

The mean ISQs at T3 were statistically significantly higher than those at T1 for both the test (75.2 ± 6.1 vs 61.7 ± 2.8; P = .005) and control (76.6 ± 4.9 vs 65.6 ± 5.6; P = .005) groups. No statistically significant difference was observed between the test and control groups (P > .05; Table 4).

With the exception of one test group site with an mPI score of 2 recorded at T2, mPI scores of 0 and 1 were consistently recorded throughout the study in both groups (Table 5). Statistically significant differences in mPI scores were observed among different time intervals in both test and control groups (P < .05; Table 5). There were no statistically significant differences in the mPI scores at any time intervals between the test and control groups (P > .05; Table 5).
With the exception of two sites with an mBI score of 2 recorded at T2, mBI scores of 0 and 1 were consistently recorded throughout the study (Table 6). There were no statistically significant differences in the mBI scores among the different time intervals and between the test and control groups ($P > .05$; Table 6).

The PIS ranged from 0 to 3 at all time intervals in this study (Tables 7 and 8). No statistically significant differences were noted for either mesial or distal papilla levels among the different time intervals and between the test and control groups ($P > .05$; Tables 7 and 8). At T4, more than 50% papilla fill (PIS 2 to 4) was observed in 75% of the test sites and 80% of the control sites.

**Surgical and Prosthetic Complications**

Rotational instability was observed with one implant at the time of placement for the test group and was resolved by placing a larger-diameter implant. An episode of provisional restoration debonding was observed at 3 and 6 months for one implant. This appeared to be a result of inadequate resistance and retention form of the provisional abutment. One provisional restoration fractured near the cervical aspect during removal at the time of final impression making. A fistula tract was noted at 3 months during the provisional phase, 2 mm apical to the facial gingival margin of one implant, as a result of the residual flowable composite resin. After the composite resin was removed, the fistula healed uneventfully. Exudate was noted around the gingival margin of one implant at 6 months. Because both clinical and radiographic evaluations were within normal limits, the area was simply irrigated with 0.12% chlorhexidine gluconate.

**DISCUSSION**

The cumulative implant success rates for single IIPP procedures with and without SCTG in this study were 100% (10/10) and 100% (10/10), respectively, after a follow-up period of 1 year. This is comparable to implant success rates reported with single IIPP procedures (90% to 100%).

The implant-abutment junction of the implant used in this study featured a conical “platformSwitched” interface, which could be beneficial in maintaining peri-implant MBL biologically and mechanically. Studies evaluating IIPP procedures using “platform-switched” implants reported MBL changes ranging from +1.30 to −0.85 mm. This response is less negative compared to the peri-implant MBL changes reported for IIPP procedures using non–platform-switched implants (−0.22 to −1.02 mm). In this study, comparable peri-implant MBL changes after 12 months were noted in both the test group (−0.01 ± 0.27 mm) and in the control group.
group (−0.14 ± 0.53 mm) (P = .76; Table 2). Furthermore, high percentages of proximal sites where the MBL remained at or coronal to the implant platform were observed in both the test (17/20 = 85%) and control (15/20 = 75%) groups at T4, indicating that the peri-implant bone response of platform-switched implants is favorable. The absence of statistically significant differences in MBL and MBL changes at all time intervals between the test and control groups (P > .05; Tables 1 and 2) suggests that adding an SCTG to IIPP does not adversely affect the peri-implant marginal bone response.

FGL tissue changes of –0.3 to –1.1 mm have been reported following IIPP procedures.2–4,12,13,35,52 Because a thin gingival biotype has been associated with gingival recession following surgical procedures,53 Kan et al demonstrated the potential benefit of tissue biotype conversion by incorporating the SCTG during IIPP procedures.8 Minimal FGL change after IIPP procedures with SCTG has since been reported.5,9,12,13 In this study, the FGL changes observed in the control group (–0.70 mm) were more pronounced than those seen in the test group (–0.25 mm). This suggests that, with proper 3-dimensional implant positioning and bone grafting of the socket gap between implant and facial bone, SCTG in conjunction with IIPP procedures in the esthetic zone might minimize facial recession.

The use of RFA to assess implant stability has been advocated because of its accuracy and noninvasive nature.26 An ISQ > 60 has been suggested to be an objective parameter for implants prior to immediate loading.54,55 The mean ISQs at T1 with and without SCTG were 61.7 ± 2.8 and 65.6 ± 5.6 (range, 60 to 68) in this study, indicating that implants in both groups were sufficiently stable for IIPP procedures. The increase in mean ISQ seen at 6 months in the test (75.2 ± 6.1) and control (76.6 ± 4.9) groups indicated that osseointegration is an ongoing process from immediate implant placement to 6 months.4,38 Barone et al38 and Palattella et al4 also reported similar ISQ values of 74.0 ± 6.0 at 12 months and 72.0 ± 3.0 at the time of definitive restoration placement, respectively, with IIPP procedures.

While plaque accumulation can potentially induce a negative mucosal response,2 the relationship between compromised oral hygiene and implant failure remains controversial.56–61 Most of the mPI and mBI scores recorded throughout the duration of this study were either 0 or 1, implying that patients had been able to maintain a good level of oral hygiene (Tables 5 and 6). Statistically significant differences in mPI scores
were observed among different time intervals in both test and control groups ($P < .05$; Table 5), also indicating an improvement in the patients' oral hygiene at the end of the study.

The PIS in the present study ranged from 0 to 3 at all time intervals. There were no statistically significant differences in the PIS among different time intervals and between the test and control groups ($P > .05$; Tables 7 and 8). This confirms that, while the implant papilla level is dictated by the proximal bone level of the adjacent teeth, it can be maintained by providing immediate papilla support after tooth removal.

**CONCLUSIONS**

Within the limitations of this 1-year randomized controlled prospective study, it appears that immediate implant placement and provisionalization and bone graft in the socket can be considered to be a valuable treatment option for the failing tooth in the esthetic area. Subjects who underwent immediate implant placement and provisionalization with a subepithelial connective tissue graft experienced less facial gingival level change than those who did not receive a subepithelial connective tissue graft. Although favorable results were achieved in this short-term follow-up, further studies are needed to properly evaluate the long-term efficacy of such procedures.

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**REFERENCES**