Immediately Restored, Single-Tapered Implants in the Anterior Maxilla: Prosthodontic and Aesthetic Outcomes After 1 Year

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ABSTRACT

Background: Conventional implant protocols advocate a two-stage technique with a load-free, submerged healing period. Recent studies suggest that immediate restoration of single implants may be a viable treatment option.

Purpose: The purpose of this study was to evaluate prosthodontic and aesthetic peri-implant mucosal outcomes of immediately restored, Southern single-tapered implants in the anterior maxilla after 1 year.

Materials and Methods: Participants (mean age: 43.25 years; range: 23–71 years) satisfying specified inclusion criteria were randomly allocated to conventional two-stage restoration (control group; $n = 14$) and immediate restoration groups (test group; $n = 14$) in a randomized controlled clinical trial. Tapered, roughened-surface Southern implants were placed using a standardized technique, and implant level bone impressions were made. Provisional screw-retained crowns, out of occlusion, were placed at second-stage surgery after 26 weeks for the conventional restoration group, and within 4 hours of implant placement for the immediate restoration group. Both groups had definitive screw-retained metal-ceramic crowns placed in occlusion 8 weeks later. Peri-implant mucosal response and papilla index were recorded 4 weeks after definitive crown placement to allow for mucosal maturation and at 1 year. Prosthodontic and aesthetic outcomes were assessed using established criteria.

Results: There were no significant differences within, or between, the control and test groups for age, gender, bone quality or quantity, implant stability measurements at surgery, or implant length. There were no significant differences in the implant success rate as determined by radiographic bone loss and stability tests after 1 year. There were no significant differences in prosthodontic maintenance, peri-implant mucosal response, and papilla index between the two groups over 1 year.

Conclusions: Tapered, roughened-surface implants immediately restored with single provisional crowns at surgery and definitive crowns 8 weeks later were as prosthodontically and aesthetically successful as conventionally restored two-stage implants during the first year of service. Restoring single implants immediately with screw-retained crowns is an efficient procedure, but the short-term outcome is by no means superior to a conventional two-stage approach.

KEY WORDS: aesthetics, bone impression, immediate restoration, prosthodontic maintenance, single implants

Using a single implant crown is a practical solution for a missing tooth. This treatment modality has had evidence-based success over a 5-year period since 1996.[1] Protocols of prosthodontic procedures for single implant crowns were initially published in the 1980s, although a reference was made to the first single implant crown being placed in 1982.[2] Other pioneer researchers were also simultaneously developing an alternative

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approach to single implant crowns using conventional approaches with another implant system.[3] Clinical research has now focused on reducing the treatment time, achieving optimum hard and soft tissue aesthetics, and improving patient outcomes.[4–7]

The preservation or regeneration of interproximal papillae is critical to the aesthetic success of single-implant-supported crowns.[8,9] Various factors may contribute to the anatomical form of papillae adjacent to single implant crowns, including alveolar crest height at adjacent teeth and maintenance of biologic width.[8–10] Spontaneous papilla regeneration following implant crown restoration using various prosthodontic protocols has been evaluated using an index of papilla contour measurements.[8,9]

A variety of surgical techniques have been advocated to improve the mucosal aesthetic outcome of single implant crowns. These include, albeit controversially, parabolic implant design;[11–13] soft and hard tissue augmentation either prior to, concurrent with, and/or after implant placement;[14–18] and surgical incision techniques that preserve or create papillae.[19,20] Evidence sometimes suggests that these interventions do not improve soft tissue outcomes when compared to simple standardized surgical techniques.[17,18] Prosthodontic techniques to enhance soft tissue contour by using custom abutments and provisional crowns to support the peri-implant mucosa during healing have been described in case reports[14,21,22] and retrospective and prospective cohort studies.[23–25] However, there are a lack of randomized, controlled, clinical trials that report on the aesthetic results of immediate restoration of single implants with crowns, compared to conventional restoration using a simple standardized surgical approach.

The aim of this randomized, controlled, clinical trial was to prospectively compare prosthodontic and aesthetic outcomes of conventional restoration with the outcomes of immediate restoration using roughened-surface, tapered, single implants placed in the anterior maxilla (teeth 15–25) during the first year of service.

The hypotheses were:

1. There would be no significant difference in the prosthodontic maintenance requirements of the provisional or definitive screw-retained implant crowns between the two treatment protocols using accepted criteria.[26]
2. There would be no significant difference in the implant crown mucosal response, including the interdental papillae[8] between the two treatment protocols using established peri-implant parameters.[4,27]

MATERIALS AND METHODS

Participant Selection

This study conformed to the Declaration of Helsinki. Ethical approval was obtained from the New Zealand Lower South Regional Ethics Committee, and all participants provided informed consent before entering the trial. Twenty-eight participants (mean age: 43 years; range: 23–71 years) requiring single implant crowns in the anterior maxilla (teeth 15–25) were recruited. The inclusion criteria included adequate bone volume to accommodate the implant (length: 10–15 mm; diameter: 2.5–4.0 mm), Lekholm and Zarb[28] class I to III bone quality at the implant recipient site by radiographic assessment, a healed recipient site, and adjacent mesial and distal teeth. The exclusion criteria included heavy smoking, severe bruxism or clenching habits, physical and/or mental disabilities that would interfere with the maintenance of the implants, and a previous history of failed implants or untreated periodontitis. Where primary implant stability could not be achieved following implant placement, or where sites required bone grafting or ridge augmentation to accommodate implant prior to surgery, participants were excluded from the trial. Periapical and panoramic radiographs, and cross-sectional tomographs (Scanora®, Soredex, Orion Corporation, Helsinki, Finland) were used to initially evaluate the bone quantity and quality of the implant recipient site and to determine the length of the implant required.[28,29]

Prosthodontic consultations were done prior to randomization. A closed randomization method using sealed envelopes placed 14 participants in the conventional restoration group and another 14 in the immediate restoration group. Surgical consultations were completed after randomization. The clinical trial outline is shown in Figure 1.

Surgical Procedure

A modification of a standardized surgical protocol previously reported for edentulous patients for implant

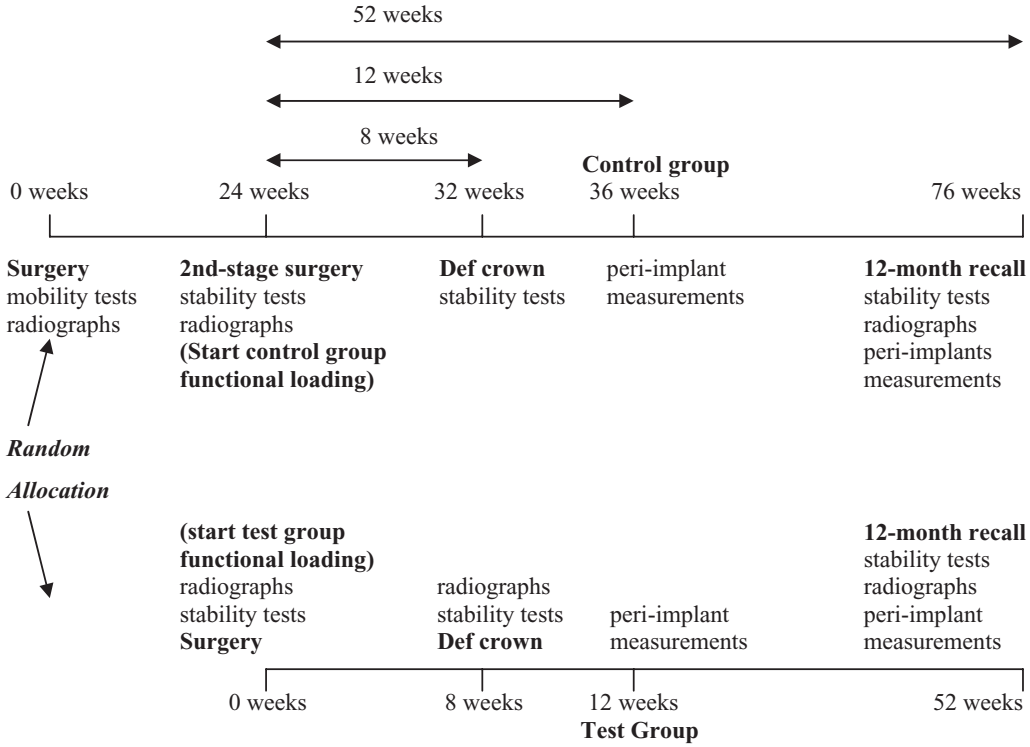

Figure 1 Outline of clinical trial design (Def = definitive).

overdentures was used.[30] An intra-sulcular incision was made including the interdental papilla of the adjacent teeth through the mid-crest of the edentulous space. Vertical relieving incision was made from the distal papilla. Labial mucoperiosteal flap was elevated to expose the alveolar bone. A surgical guide stent was used to position each implant (Southern Implants Ltd, Irene, South Africa). The tapered implant (2.5–4.0 mm) had an external hexagon and a roughened surface S_a of 1.43 μm giving a developed surface area of 50%. Threads were 1-mm apart with a pitch of 10 degrees. It was made from grade 4 commercially pure titanium. An osteotomy was performed using a round bur, 2-mm pilot drill, and a tapered final drill. Bone quality and quantity were evaluated during surgery of each participant.[28] One experienced surgeon (R. K.) placed 15 implants (nine conventional restoration group, six immediate restoration group) and supervised an inexperienced graduate student in periodontology who placed 13 implants (five conventional restoration group, eight immediate restoration group). After the implant was placed, an implant head bone mill was routinely used for the immediate restoration group to ensure unhindered access for prosthodontic components, before a temporary healing abutment was placed. Buccal fenestrations and dehiscences were covered with autogenous bone graft recovered from the osteotomy and the immediate surgical site. No membranes were used. The mucoperiosteal flaps were then carefully adapted around the healing abutments and sutured. Closure was with size 4/0 suture material (Vicryl Rapide®, Ethicon, Inc., Somerville, NJ, USA).

Cover screws were placed on the control group (conventional restoration) implants and the mucoperiosteal flaps sutured with the same suture material. Postoperatively, the participants were instructed to mouth rinse with 0.2% chlorhexidine for 2 weeks and to begin soft brushing the provisional crowns and/or surgical sites as soon as pain subsided. The participants in the immediate restoration group were asked to refrain from chewing on the implant crown for 12 weeks.

Prosthodontic Procedures

To ensure consistency, all prosthodontic clinical procedures were completed by one clinician (J. H.) and technical work by one technician (B. T.). Study models, tooth shades, clinical digital photographs, diagnostic wax-ups, light-cured custom trays (Megatray®, Megadenta Den-

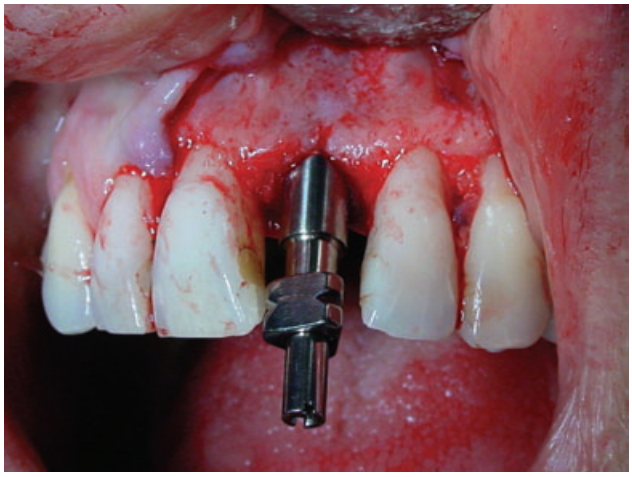

Figure 2 Impression coping on implant at surgery.

Figure 4 Immediate restoration provisional crown.

talprodukte GmbH, Radeberg, Germany), and clear self-curing methylmethacrylate resin surgical stents (Orthocryl®, Dentaurum, Ispringen, Germany) were made. Surgical stents had 3-mm-diameter guide holes for cingulum or occlusal prosthodontic screw access and clearly defined planned cervical emergence profiles to facilitate correct implant head depth 3 to 4 mm from the expected labial mucosa emergence, depending on tissue biotype.[10] An implant/bone level, vinyl polysiloxane impression (Exahiflex regular®, GC Corp., Tokyo, Japan) was made using the open-tray technique prior to each surgical closure (Figures 2 and 3).

For the conventional restoration group, second-stage surgery was performed at 26 weeks. The implant was exposed using a 5.2-mm tissue punch and palatal relieving incisions where necessary. An implant bone mill was used to ensure unhindered access for prosthoclontic components before a screw-retained provisional crown was fitted. The immediate restoration group had a similar provisional crown fitted within 4 hours of the implant placement surgery (Figure 4). The occlusion was verified free of contact in maximum intercuspation and excursions for all provisional crowns, using 200 µm articulating paper (Bausch, Köln, Germany). All provisional crowns had proximal contacts except where a diastema was required for aesthetic reasons.

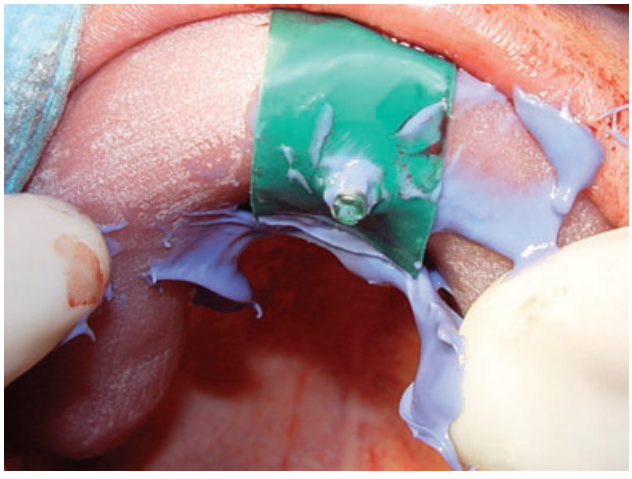

Figure 3 Vinyl polysiloxane bone level impression at surgery.

An innovative technique was developed for the fabrication of the provisional crowns. The acrylic denture tooth facing, that had been previously used in the diagnostic wax-up, was bonded using light-cured composite (Sinfony®, 3M ESPE AG, Seefeld, Germany) to a silanated (Rocatec Plus™, 3M ESPE AG) hexed titanium cylinder (Southern Implants, Ltd). The denture tooth facing was positioned on the cast made from the surgical impression, using a silicone index made on the diagnostic wax-up.

A subsequent implant level impression using vinyl polysiloxane was made after 6 weeks of provisionalization and was used to make the definitive crowns in both conventional and immediate restoration groups. For both groups, the provisional crowns (Figure 5) were subsequently replaced by definitive screw-retained metal-ceramic crowns on hexed gold cylinders (Imagine Reflex® veneering ceramic on Porta SMK 82 alloy, Wieland Dental+Technik GmbH, Pforzheim, Germany). Definitive crowns were fitted, in occlusion, after 8 weeks of provisionalization (Figure 6).

Figure 5 Immediate restoration provisional crown at 8 weeks.

Figure 7 Circumferential reference line incorporated in definitive crowns.

Data Collection

Implant success according to established criteria[31] as part of this randomized controlled clinical trial has been reported elsewhere.[32] This was done using standardized radiographs and implant stability tests at the time of surgery, at definitive crown placement, and at 1 year. The method of obtaining standardized radiographs was a modification of established techniques.[33,34] Radiographs were digitally photographed and electronically measured to detect changes in bone height.[31] The mesial and distal crestal bone levels were measured and the mean bone levels were then measured. The method of determining implant stability was resonance frequency analysis (Osstell®, Integration Diagnostics, Göteborg, Sweden).

Figure 6 Immediate restoration definitive crown at 1 year.

Prosthodontic maintenance was recorded over the first year of service. Separate analyses were performed for the prosthodontic outcomes of the provisional crowns after 8 weeks and the definitive crowns after 1 year. The participants were assigned to six-field tables for prosthodontic outcome for implant-supported fixed prostheses.[26] Prosthodontic "success" was defined as "review of patient records during the study period reveals no evidence of re-treatment except for accepted maintenance." "Survival" was defined as "patient cannot be examined directly, but the patient or another clinician confirms no evidence of re-treatment except that defined for a successful outcome." The remaining categories—"unknown/lost to follow up," "dead," "re-treatment–repair," and "re-treatment–replace"—are self-explanatory.

Soft-tissue parameters for aesthetic assessment[4,27] and papilla index[8] were recorded 4 weeks after definitive crown placement (to allow for mucosal maturation) and at 1 year. A periodontal probe with Williams markings (Hu-Friedy, Chicago, IL, USA) was used and a circumferential reference line was incorporated into all definitive crowns at the gingival margin to facilitate accurate mucosal measurements (Figure 7). The soft-tissue parameters measured at six sites per implant crown were recession and probing depth, modified plaque index and gingival index, and width of keratinized tissue at mid-buccal site, as described in studies on mandibular implant overdentures.[30] The recession and width of keratinized tissue were measured at the mid-buccal of each crown. The periodontal probe was inserted into the peri-implant crevice with light force and run circum-

ferentially around the implant crown to assess bleeding. Peri-implant mucosal inflammation was then categorized as absent, mild, moderate, or severe and given a score of 0–3, according to the criteria described for the gingival index and modified for use with implants.[35] Peri-implant interdental spaces were photographed and delineated as a triangular area extending coronally from a baseline connecting the reference line on the implant-borne crown and the cementoenamel junction of the adjacent tooth, and terminating at the implant crown-to-tooth contact point. The degree to which the papillae filled this space was then scored from 0 to 4 using a modification of a documented papilla index,[8] as follows:

Diastema	No score – no contact point (at the request of participant)
Score 0	No papilla; flat interproximal contour
Score 1	Papilla fills >0 and <50% of interdental space.
Score 2	Papilla fills ≥50, but <100% of interdental space.
Score 3	Papilla fills 100% of interdental space.
Score 4	Papilla fills >100% of interdental space (hyperplasia).

The insertion of the implant in an "optimal three-dimensional position"[36] was described using a combination of clinical and radiographic analyses, and the effect of alveolar bone levels on aesthetic outcome was assessed according to previously described criteria.[4,10] The presence of coronal dehiscences and fenestrations at initial surgery that might impact the aesthetic outcome was recorded. Standardized radiographs of the implants taken immediately before definitive crown placement and at the 1-year recall appointment were digitized into a personal computer (Apple eMac, Apple Computer, Inc., Cupertino, CA, USA) and the following measurements were made using an image analysis program (NIH-Image, Scion Corp., Frederick, MD, USA):

1. vertical distance from cementoenamel junction to bone crest at each of the adjacent teeth (bone–cej);
2. vertical distance from the mid-buccal of the implant shoulder to a horizontal line connecting the mid-buccal point of the cementoenamel junction of the two adjacent teeth (implant–cej);
3. horizontal distance from implant shoulder to the root surface of the adjacent tooth (implant–tooth).

Repeat measurements were made on a subgroup of the radiographic measurements (mesial bone–cej and implant–cej for the control group) and intra-examiner reliability estimated using Pearson's correlation.

The mean results were established at mesial and distal surfaces for each group of implants. The degree of correlation between these measurements and the classification of the mesial and distal papillae using the papilla index[8] were tested statistically. Additionally, implants were classified as being within the aesthetic danger area if one or more measurements exceeded the recommended dimensions for horizontal proximity to adjacent teeth, bone loss at adjacent teeth, or apico-coronal relationship of the implant platform to the cementoenamel junctions of adjacent teeth.[4,10,36,37] It is acknowledged that the level of the interproximal papillae is independent of the proximal bone next to the implant, but is related to the interproximal bone level next to the adjacent teeth.[37]

Statistical Analysis

Quantitative statistical analysis was done using statistical software (SPSS version 13, SPSS, Inc., Chicago, IL, USA). The groups were compared using paired and independent sample *t*-tests. The former was used to test the statistical significance of within-group changes over time, and the latter was used for cross-sectional comparisons. Nonparametric tests were used where appropriate (eg, Mann–Whitney U). Categorical measures were compared using the chi-square test. The correlation between radiographic measures and the papilla index was tested using Pearson's correlation. Significance for statistical analyses was set at $p < .05$.

RESULTS

Clinical Results

Twenty-eight implants in 28 participants were included in this randomized controlled clinical trial. The mean participant age was 43.3 years (range: 21–71 years). Six control participants and three test participants were smokers. There were no statistically significant differences between the two groups by age, gender, or smoking status. Surgical outcomes have been reported.[32] Implant lengths were mainly 15 mm (control: 8 of 14; test: 10 of 14). During surgical placement, four implants in the conventional restoration group had buccal feneS-

trations with three to seven threads exposed and one implant had a dehiscence. In the immediate restoration group, five implants had buccal fenestrations with one to nine threads exposed and two implants had buccal dehiscence.

There were no significant differences within, or between, the conventional and immediate restoration groups for age, gender, bone quality or quantity, or implant length (range: 10–15 mm). Lekholm and Zarb[28] bone quantity B was recorded for 79% of sites and quality 3 was recorded for 89% of sites. There were no significant differences between the conventional and immediate restoration groups. The implant stability test mean values showed no significant change within or between groups from surgical placement to 1 year. The implant stability quotient range was from a minimum of 68.67 (±4.85) to a maximum of 72.92 (±4.76). The mean marginal bone loss from definitive crown placement to 1 year was 0.78 mm (SD 1.01 mm) for the conventional restoration group and 0.63 mm (SD 1.00 mm) for the immediate restoration group. This was within established criteria for success.[31] There was no significant difference between the groups for bone loss.[32]

Prosthodontic Outcomes

Tables 1 and 2 detail the six-field classification for prosthodontic outcomes related to the provisional crowns at 8 weeks and the definitive crowns after 1 year using established criteria for prosthodontic success.[26] Two control participants failed to return for the first-year recall and were assigned to the "unknown" field in the outcome tables. One test participant did not return for the 1-year recall but when contacted, confirmed that the implant was still in function; this participant was assigned to the "survival" field. One test participant was excluded from prosthodontic maintenance when the implant failed and was removed at 10 weeks postsurgery.

One participant in the conventional restoration group fractured the provisional crown and a new provisional crown was placed within 24 hours. This subject was recorded as a re-treatment (failure). Two participants in the conventional restoration group had incorrect angulation of the implant, necessitating a labial screw access hole that was restored with composite. Another participant in the conventional group was restored with a ridge-lap crown because of palatal placement. Five implants (three conventional and two immediate restoration) were restored with crowns with a subgingivally receding buccal profile toward a palatally positioned implant. Another participant in the conventional group had incisal porcelain chipping that was smoothed to her satisfaction. No other prosthodontic maintenance events occurred. At 1 year, there were no significant differences between the two groups for prosthodontic outcome or maintenance requirements (see Table 2). All participants expressed satisfaction with their implant crowns.

TABLE 1 Provisional Crown Outcome After 8 Weeks*

Provisional Crowns	Conventional Restoration *n* = 14	Immediate Restoration *n* = 14
Success	13	14
Survival		
Unknown		
Dead		
Re-treatment (repair)		
Re-treatment (failure)	1	

*According to Walton.[26]
n = number of participants.

TABLE 2 Definitive Crown Outcome After 1 Year*

PFM Definitive Crowns	Conventional Restoration *n* = 14	Immediate Restoration *n* = 13
Success	12	12
Survival		1
Unknown	2	
Dead		
Re-treatment (repair)		
Re-treatment (failure)		

*According to Walton.[26]
n = number of participants; PFM = porcelain-fused-metal crown.

Aesthetic Outcomes

There were no statistically significant differences in either the peri-implant mucosal response (Table 3) or the papilla index within or between the two groups at 1 year. Analysis of the papillae indices for both groups combined showed that all mesial and distal sites either remained unchanged (28.5%) or improved (63%)

TABLE 3 Peri-Implant Mucosal Response Over 1 Year

Mucosal Response	Conventional Restoration Baseline to 1-Year Mean Change (SD)	Immediate Restoration Baseline to 1-Year Mean Change (SD)
Peripheral recession	–0.18 mm (0.26)	–0.35 mm (0.21)
Mid-buccal recession	–0.33 mm (0.78)	–0.67 mm (0.49)
Probing depth	+0.28 mm (0.38)	+0.14 mm (0.37)
Width of keratinized tissue	–0.83 mm (1.59)	–1.08 mm (1.31)
Modified plaque index	–0.26 (0.43)	–0.14 (0.17)
Gingival index	–0.50 (0.39)	–0.26 (0.34)

(Table 4). No implant crown had a deterioration of the papilla index over the 1-year period in either treatment group.

During placement, four implants in the conventional restoration group had buccal fenestrations with three to seven threads exposed and one implant had a dehiscence. In the immediate restoration group, five implants had buccal fenestrations with one to nine threads exposed, two implants had buccal dehiscence, and one had an apical dehiscence that did not affect aesthetics. There were no statistically significant differences in the presence of fenestrations or dehiscences between the two groups ($p > .05$).

The alveolar bone levels at adjacent teeth and the two-dimensional spatial relationship of the implant within the site are shown in Table 5. Intra-examiner reliability appeared to be acceptable ($R = 0.93$; $p = .01$). A comparison of mesial and distal measurements showed no statistically significant differences for bone/cementoenamel junction among the control implants at baseline ($p = .2$), whereas the distal implant-tooth distances were significantly lower than the mesial ($p = .007$). Test implants had no significant differences between mesial and distal measurements at baseline.

A comparison of the mean values for control versus test groups at both baseline and at 1-year recall showed no statistically significant differences for any measurements. There were minor changes for all measurements over time, but there were no statistically significant differences when baseline and 1-year recall means were compared within each group. Likewise, there were no statistically significant differences in the size of change over the first year when the test and control groups were compared.

When the radiographic measurements of implant positioning with respect to the adjacent tooth were compared with the papilla index for the matching papilla, the correlation was poor, ranging from $R = –0.22$ to 0.353 (p values ranged from .09 to .96). Four of the control implants and one test implant were positioned either ≥4 or ≤1 mm below the cementoenamel junctions of the adjacent teeth, but this difference between the groups was not statistically significant ($p = .13$). The combined data for the two groups showed no discernible relationship between apico-coronal position and mid-buccal recession after 1 year of loading ($R = –0.01$, $p = .96$). Overall, 81.8% of control implants had one or more measurements that fell outside the recom-

TABLE 4 Papilla Index Change Over 1 Year for Both Groups Combined*

Papilla Index for Combined Groups	Diastema	0	1	2	3	4
Mesial papilla of both groups						
Placement	4		6	10	4	
1 Year	4		3	10	7	
Distal papilla of both groups						
Placement	5		8	8	3	
1 Year	5		4	10	5	

*According to Jemt.[8]
n = number of participants.

TABLE 5 Spatial Relationships Between Alveolar Bone, Implant, and Adjacent Teeth Over 1 Year

X-ray Measurement (mm)	Test (SD)	Control (SD)
Bone–cej		
Mesial baseline	2.6 ± 1.45	1.98 ± 0.84
Mesial 1-year recall	2.38 ± 1.4	2.19 ± 1.06
Distal baseline	2.41 ± 0.75	2.32 ± 0.75
Distal 1-year recall	2.33 ± 1.16	2.49 ± 0.9
1-Year change – mesial	−0.18 ± 0.96	0.21 ± 0.36
1-Year change – distal	−0.15 ± 0.62	0.18 ± 0.62
Implant–cej		
Baseline	2.91 ± 1.14	2.81 ± 0.91
1-Year recall	2.83 ± 1.21	2.84 ± 0.99
1-Year change	−0.03 ± 0.22	0.03 ± 0.26
Implant–tooth		
Mesial baseline	2.27 ± 0.96	2.82 ± 0.99
Mesial 1-year recall	2.4 ± 0.96	2.69 ± 1.09
Distal baseline	1.98 ± 0.62	1.96 ± 0.45
Distal 1-year recall	2.0 ± 0.59	1.95 ± 0.51
1-Year change – mesial	0.1 ± 0.35	−0.02 ± 0.45
1-Year change – distal	−0.13 ± 0.32	−0.01 ± 0.19

mended guidelines for optimal implant positioning, compared with only 33.3% of test implants; this difference was statistically significant ($p = .02$).

DISCUSSION

In this randomized controlled clinical trial, prosthodontic and aesthetic outcomes of immediately restored tapered single implants did not differ over 1 year, when compared with implants restored using a conventional two-stage protocol. It is acknowledged that the follow-up period of 1 year is short and the sample size may have contributed to a type-2 statistical error.

In this randomized controlled clinical trial, the surgical protocol was designed to allow screw-retained implant crowns, with cingulum or occlusal access.[38] This excluded the possibility of cement contamination of the healing peri-crown mucosa and allowed the researchers easy access for crown removal to document data related to radiographs and stability. It has been suggested that the retention mechanism (screw vs cement) does not affect the long-term position of peri-implant marginal bone or soft tissue and can be selected as the clinician prefers.[39]

The use of a surgical stent directing implant position and the planned emergence profile, as dictated by the diagnostic wax-up, aided in the correct three-dimensional position for the prosthetic platform.[10] However, the screw access sometimes created complications for the dental technician. There is a balance between having adequate metal support for the incisal porcelain and compromising porcelain aesthetics. Small angulation changes of the implant became significant with the screw-retained technique, but would have been insignificant with a cemented restoration or transverse screw system. Basic metal-ceramic build-up technique requires a 1.5-mm labial depth consisting of 0.3 mm of metal and 1.2 mm of porcelain layers.[40] Our experience was that the technician requires 3-mm thickness from the access hole to the labial porcelain to allow 1 mm of metal for strength and support of the incisal porcelain and 2 mm for aesthetic porcelain buildup.

We chose not to use the implant level impression technique of an impression coping attached with resin to a modified surgical stent[41–43] for several reasons. The vinyl polysiloxane bone level impressions taken at surgery[14,44] had no adverse effects and allowed accurate model construction. The hydrophobic properties of this material minimized contact with exposed tissues within the surgical site. Although the wet conditions made it more difficult to record surface details, the dimensional accuracy of this material under such conditions is still within the American Dental Association standards.[45,46] The custom tray was designed with a rim lock, which eliminated the need for adhesive and helped contain the flow of the material. The tray was spaced 3 mm, covered the full arch but not the palate, and used a double layer of light-cured material for rigidity. The disposable mixing tip for impression dispensing was autoclaved prior to use and the tray was cold sterilized. The simple impression procedure took less than 5 minutes. The bone impressions taken at surgery had the advantage that they showed the alveolar bone height at adjacent teeth and the distance from the implant shoulder to tooth. The technician could be precise in constructing a contact point within 5 mm of the alveolar bone, a position proven to be ideal for papilla fill between natural teeth.[47] However, the adjacent or contralateral crowns often dictated the shape of the final restoration, and hence, the contact point. We believe the shape of the final restoration is more important than complete papilla infill for aesthetics. Therefore, contact points

were placed with regard to the tooth shape and not arbitrarily modified to fill in the spaces of potential soft tissue voids.[9] Hence, no attempt was made to correlate the distance between bone-to-contact point with papilla infill. Instead, the technician created ideal definitive emergence profiles for the provisional crowns and replicated this with the definitive crowns to support the healing peri-crown mucosa.[14,17,21–24]

In this study, a single diameter of implant was used for all participants. In some cases, there was insufficient buccal bone to accommodate the implant without dehiscences and exposure of buccal threads, a situation that is said to compromise the aesthetic result.[4,36] Bone quantity B[28] was encountered for 79% of sites at implant placement. Peri-implant deficiencies in alveolar bone were found around 35% of the conventional restoration (control) group and 50% of the immediate restoration (test) group. All cases were treated with autogenous bone graft recovered from the primary osteotomy site, without membrane stabilization. This standardized protocol did not permit the use of membranes for guided tissue regeneration or connective tissue grafting to augment soft-tissue defects, both recommended techniques for the optimization of compromised aesthetics.[4,36]

The standardized surgical protocol we used differs from the protocol of implant-site bone development prior to placement and is associated with the risk of soft tissue recession or implant failure.[4,36] One study reported the use of guided bone regeneration and connective tissue grafting to achieve optimal aesthetics with single implant crowns and early placement (8 weeks) after extraction.[15] The study reported that the visible length of the crown measured at the mid-buccal point, increased by 0.6 mm over 1 year. In our study, the visible length at the mid-buccal point of the conventional group increased by 0.33 mm (SD 0.78 mm) and of the immediate restoration group by 0.67 mm (SD 0.49 mm). A lack of association between buccal dehiscences and adverse aesthetic outcome has been presented in two recent studies.[18,48] Our study supports the preliminary evidence that once immediately restored implants integrate, they appear to have longitudinal bone and soft-tissue stability comparable to those of conventionally restored implants.[49,50]

We used an established papilla index[8] to objectively assess papilla infill. There was no change in the classification after 1 year for 28.5% of the papillae. The present study showed an improvement in 63% of sites. This result is consistent with, but less than, the 80–84% improvement reported in two similar studies, albeit after longer recall periods.[8,9] After 1 year, only one adverse soft-tissue response was recorded, a mid-buccal recession of 2 mm in the conventional restoration group associated with a buccal bone dehiscence. Two other participants had one papilla that received a poorer papilla index rating. The relationship of the papilla to implant bone height appears nonlinear when considering the general improvement or stability of the papilla during a period of concurrent peri-implant bone loss. The lack of statistical difference in peri-implant mucosa or papilla measurements between the immediately restored and conventionally restored groups suggests that the loading strategy may have little or no clinical effect on soft tissue remodeling for this implant system.[51] However, we do acknowledge that there is a further limitation in this randomized controlled clinical trial in that it did not classify the periodontium of the participants of this study into thick or thin peri-implant biotypes.[37,52,53] The aesthetic concerns to avoid dark, triangular spaces (black triangle) are increased when patients have an alveolar morphotype leading to a pronounced scalloped profile of the hard and soft tissues.[13,54–56] This is also further complicated with a high smile line.[56]

No advantage was found with the use of a provisional crown—prior to definitive crown—for restoration of the conventionally restored implants. Therefore, it may be possible to exclude the provisional crown stage and construct definitive crowns from an impression taken at surgery.[14] This would save costs/time, reduce the appointments (a second impression appointment is not required), and reduce time pressures on the dental technician and the prosthodontist.

CONCLUSIONS

During the first year of service, there was no difference in prosthodontic maintenance or implant crown mucosal response, including the interdental papillae between immediate restoration and conventional restoration of screw-retained crowns on tapered, roughened-surface external hexed single implants.

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