Clinical Outcome and Patient Satisfaction Following Full-Flap Elevation for Early and Delayed Placement of Single-Tooth Implants: A 5-year Randomized Study

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Purpose: *This 5-year follow-up report presents the outcome of early and delayed placement of single-tooth implants.* ***Materials and Methods:*** *An implant was placed on average 10 days after tooth extraction in 23 patients (early) and 3 months after tooth extraction in 22 patients (delayed). All implants were placed in the anterior or premolar regions of the maxilla or mandible. Survival rates, prosthodontic complications, probing pocket depths (PPDs), marginal bone levels measured on radiographs (MBLs), soft tissue appearance (papilla dimensions and clinical crown height), and patient satisfaction were evaluated during an observation period of 5 years. Several patients with prior generalized gingival recession were included in the study, and modification of the papilla scoring was made in these cases.* ***Results:*** *Two implants in the early group and 1 in the delayed group failed before occlusal loading. No further implants were lost during the follow-up period. The mean PPD varied from 3.3 to 4.5 mm in the early group and from 3.6 to 4.4 mm in the delayed group 5 years after implant placement. During the 5-year period, an annual marginal bone loss of less than 0.2 mm was found in both groups. Although the early group performed slightly better than the delayed group as to soft tissue appearance just after seating of the implant restoration, the papilla dimensions and the clinical crown height improved spontaneously over time, and no significant differences between the 2 protocols were seen after 5 years. Furthermore, patients in both groups were highly satisfied with the outcome of their implant treatment.* ***Conclusion:*** *The outcomes of early and delayed placement of single-tooth implants were comparable in terms of high survival rates, few prosthetic complications, acceptable MBLs and PPDs, as well as soft tissue appearance and patient satisfaction during a 5-year follow-up period.* Int J Oral Maxillofac Implants 2008;23:733–743

Key words: *delayed implant placement, early implant placement, patient satisfaction, prosthetic complications, soft tissue appearance*

Single-tooth implant restorations will in many cases be the obvious choice in the treatment of partially edentulous patients. By this treatment modality, involvement of the adjacent teeth can be avoided, and therefore is particularly advantageous if those teeth are intact, have minor fillings, or are restored with cast restorations. Several studies and case reports have demonstrated successful outcomes following single-tooth implant treatment.[1–5] However, only few long-term randomized clinical studies exist.

The concept of immediate or early implant placement after tooth extraction has been adopted to treatment with single-tooth implants.[6–9] Successful results have been reported, but a review of the literature discloses that there is a scarcity of controlled clinical studies on immediate or early placement of implants supporting single-tooth restorations with a follow-up period of 4 years or more.[10,11] To the best of the authors' knowledge only 2 previous prospective long-term (4 years or more) investigations have compared the immediate/early and the delayed/late placement modalities for single-tooth implants.[3,12] In a pilot study, 5-year results of early placement of single implants in 20 patients have been presented.[3] In a study by Gomez-Roman et al,[12] immediate and delayed/late implants were compared, with a mean follow-up period of 4.5 years.

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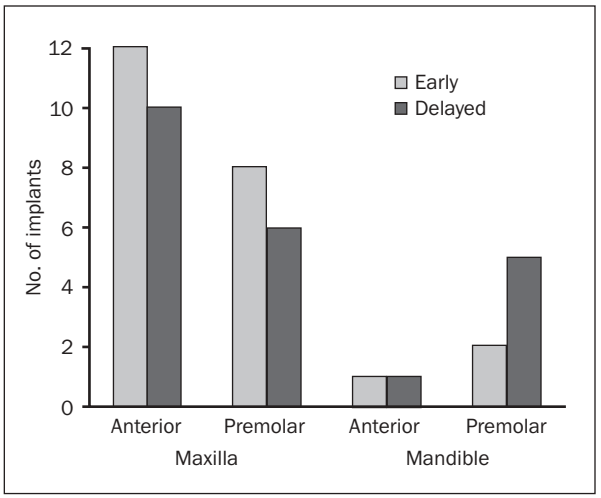

Fig 1 Distribution of implant regions.

Placement of implants in nonhealed extraction sockets often implies that the coronal part of the implant will not be integrated in bone immediately after surgery. Since this fact could be a matter of concern with regard to the implant prognosis, attempts have been made to ensure bone formation in peri-implant bone defects. Bone-reconstructive methods, such as guided bone regeneration (GBR) and grafting have shown promising results.[13] However, these additional treatment procedures may increase the expense, treatment time, number of visits, and risk of complications. Thus, reliance on spontaneous bone formation in the gaps occurring between implant and bone could be preferable. Data from animal and human studies indicate that bone defects of a moderate size heal spontaneously without use of grafting or membranes in relation to immediate implant placement.[14–16] It is imperative to determine what influence peri-implant bone defects in cases of implant placement into extraction sockets may have on long-term outcomes. Whether treatment with implant-supported restorations is successful depends on several factors, such as implant survival; peri-implant conditions, including radiographically assessed marginal bone level; soft tissue contours; and technical complications. Furthermore, the patient's subjective satisfaction with the overall treatment, esthetics, chewing function, and cleaning ability is also of utmost importance.

The aim of this follow-up report was to evaluate survival rates, peri-implant conditions and technical complications, soft tissue appearance, and patient satisfaction following early or delayed placement of single-tooth implants over a 5-year period.

MATERIALS AND METHODS

Study Population and Implant Treatment Procedures

This article presents the 5-year results of a previously published randomized, clinical study initiated in 1999.[16] The study sample was recruited among patients referred to the School of Dentistry, University of Aarhus, Denmark for treatment with single-tooth implants. Forty-five patients (24 women and 21 men) with a mean age of 48 years (range, 20 to 74 years) were treated with an Osseotite implant (Biomet/3i, Palm Beach Gardens, FL) in the maxillary or mandibular anterior or premolar region. The distribution of implant sites is presented in Fig 1. The patients were randomly allocated to an "early" group or a "delayed" group at the initial examination. The implants in the early group were placed an average of 10 days after tooth extraction, with a range of 3 to 15 days. In the delayed group, the extraction sockets were allowed to heal for approximately 3 months (range, 65 to 138 days) before placement of the implants.

A gentle extraction technique was used for removal of the teeth. No soft tissue closure was performed, except in 2 "early" cases where flap elevation was required for removal of a fractured root. When the implants were placed, a full-thickness flap was elevated (according to standard surgical protocol in 1999), and the implant was placed with the top of the cover screw even with the bone ridge. No membranes for GBR were applied in either of the groups, and grafting of infrabony defects (defined as a defect with an intact bone plate facing the implant surface) was not carried out. However, grafting of dehiscences or fenestrations was performed in cases of exposed implant surfaces at implant surgery or abutment surgery in the delayed group. No grafting was used at implant placement in the early group, but in cases of dehiscences or fenestrations at abutment surgery exposed implant threads were covered with autogenous bone grafts.

Three months after implant placement, a mucoperiosteal flap was elevated to expose the implant. To allow guided soft tissue healing, a 1-piece or 2-piece EP healing abutment (Biomet 3i) was connected to the implant and tightened by hand. After 4 to 6 weeks, 42 patients were treated with an implant-supported ceramometal crown made on STA or UCLA abutments (Biomet 3i). The final abutments were connected with Gold-Tite square uniscrews (Biomet 3i) and tightened with a torque driver (32 Ncm). Forty restorations were cemented with either a zinc phosphate cement (Dentsply, DeTrey, Konstanz, Germany) or a temporary cement (TempBond, Kerr, Orange, CA), and 2 crowns replacing mandibular incisors were screw-retained.

Details on the surgical treatment procedures have been described in a previous article.[16]

Clinical and Radiographic Examination

Clinical examination was performed 1 week after seating of the implant crown (baseline) and at follow-up visits 2 years and 5 years after implant placement. Probing pocket depths (PPDs) were measured at the buccal, mesial, distal, and lingual aspects of the implant by the same examiner. Biological and technical complications, including implant failure or mobility, purulence, fistulae, loosening of the crown or abutment, porcelain fractures, exposure of metal margins, extensive wear of the crown, and supra-occlusal contacts, were recorded. Marginal bone levels (MBLs) mesial and distal to the implants were determined on standardized, digitized intraoral radiographs at healing abutment connection and at 2-year and 5-year follow-ups. The reference point was set at the implant shoulder. Furthermore, the implant dimensions were measured to calculate the image magnification, and the bone level measurements were adjusted accordingly. The radiographic measurements were repeated to estimate the reproducibility of the method. High agreement between the first and second recordings of the bone levels as well as the implant dimensions was found by Wilcoxon matched-pairs signed rank test ($P > .32$; for details on radiographic assessment, see Schropp et al.[16])

Soft Tissue Contour Evaluation

Clinical photographs of the implant restorations were obtained 1 week after seating of the crown (baseline) and at 2-year follow-up and 5-year follow-up. An experienced prosthodontist made a blinded evaluation of the clinical crown height and the interproximal papillae at the mesial and distal aspect of the implant restoration. Photographs from the 3 examinations were all evaluated the same day. Three scores for clinical crown height assessments were used: 1 = too long; 2 = too short; 3 = appropriate. The score index for papilla assessments was as follows: 0 = no papilla or a negative papilla; 1 = less than half of the height of the proximal area occupied by soft tissue; 2 = at least half of the height of the proximal area occupied by soft tissue; 3 = interproximal area completely occupied by soft tissue.[17] In case of generalized gingival recession and also at the neighboring teeth, completely filled interproximal spaces of the implant restoration cannot be expected. Therefore, the level of the interproximal soft tissue distal to the adjacent teeth was used as a reference line when evaluating the papilla height. This means that a papilla occupying, for example, only 70% of the interproximal space should have a score of 3 if the soft tissue level corresponds to that of the adjacent papillae.

1. Were you satisfied with the crown after insertion?
Very unsatisfied ——— Very satisfied

2. When did you get accustomed to the new crown?
Never ——— Immediately

3. Are you in general satisfied with the appearance of the crown?
Very unsatisfied ——— Very satisfied

4. How do you find the shape of the crown?
Ugly-looking ——— Fine

5. How do you find the color of the crown?
Ugly-looking ——— Fine

6. How do you chew after insertion of the crown?
Badly ——— Well (normally)

7. How is cleaning around the tooth?
Difficult ——— Easy

8. How was your experience of the overall treatment?
Very unsatisfied ——— Very satisfied

Fig 2 Questionnaire translated from Danish.

In conjunction with a 2-year follow-up study,[18] photographs from baseline and 2-year follow-up was evaluated twice to determine the intraobserver reproducibility within 6 weeks. In this 5-year study, evaluation of the photographs from the 5-year examination was repeated after 3 months, and the percentage agreement between the scores from the first and second recordings was calculated. Furthermore, the photographs from baseline and at the 2-year follow-up were re-evaluated at the 5-year follow-up to determine the intraobserver reproducibility within 3 years.

Patient Evaluation

A questionnaire survey was conducted to measure the patients' satisfaction with the implant-supported single crown in terms of appearance, chewing comfort, cleaning ability, adaptation, and satisfaction with the overall implant treatment. The questions were scored on a 100-mm visual analog scale (VAS), with the most negative expression at the zero point and the most positive at 100 (Fig 2). Patient evaluations were carried out at the 2-year and 5-year follow-up examination (for more details on patient evaluation, see Schropp et al.[19])

Table 1a Probing Pocket Depths (mm) at Implant Sites in the Early and Delayed Groups at Baseline (1 Week After Mounting of the Implant Crown), 2 Years, and 5 Years After Implant Placement

	Early			Delayed			Early vs Delayed (*P*)
	Mean	SD	Median	Mean	SD	Median	
Buccal							
Baseline	4.4	1.3	4.0	4.3	1.3	4.0	.89
2-year	3.6	1.5	3.0	4.0	1.2	3.5	.27
5-year	3.3	1.3	3.0	3.8	0.8	4.0	.12
Proximal							
Baseline	5.0	1.5	5.0	4.5	0.9	4.5	.27
2-year	4.3	1.0	4.3	4.5	1.0	4.8	.48
5-year	4.5	1.2	4.5	4.4	1.0	4.5	.94
Lingual							
Baseline	4.9	1.5	5.0	4.3	1.2	4.0	.17
2-year	3.4	0.9	3.0	3.8	1.0	4.0	.20
5-year	3.4	0.8	3.0	3.6	1.0	4.0	.29

Table 1b *P* Values for Probing Pocket Depths (mm) at Implant Sites in the Early and Delayed Groups at Baseline (1 Week After Mounting of the Implant Crown), 2 Years, and 5 Years After Implant Placement

	Early	Delayed
Buccal		
Baseline vs 5-year	.001	.14
2-year vs 5-year	.29	.21
Proximal		
Baseline vs 5-year	.09	.92
2-year vs 5-year	.40	.69
Lingual		
Baseline vs 5-year	.001	.03
2-year vs 5-year	.81	.27

Data Analysis

Data from 34 of the 45 subjects (20 women, 14 men) originally included in the study entered the 5-year follow-up analysis. The patients, with a mean age of 47 years (range, 20 to 69 years) at the beginning of the treatment, were about evenly distributed in the early (n = 18) and delayed (n = 16) groups. Age distribution was tested by the Student *t* test, while χ^2 tests were applied for testing gender and implant region distributions.

Mean values, standard deviations, and medians were calculated for PPD and MBL. An average for each implant of the recordings at the mesial and distal sites was used for the statistical analyses. Changes over time from baseline to 5-year follow-up and from 2-year follow-up to 5-year follow-up were analyzed by Wilcoxon matched-pairs signed rank test for the early and delayed groups. Differences between the 2 groups at baseline and at the 2-year and 5-year follow-ups were tested using Mann-Whitney test.

Frequencies for the papilla and clinical crown height scores were calculated. The data for crown height were dichotomized into 2 groups: *(1)* "too long or too short" (scores of 1 or 2) and *(2)* "appropriate" (scores of 3). Differences between the early and delayed groups were tested by the Mann-Whitney test for papilla scores and by χ^2 tests for clinical crown height scores. Changes over time were tested by Wilcoxon matched-pairs signed rank test for the papilla scores and by McNemar's test for the clinical crown height scores. An average of papilla scores at the mesial and distal sites per implant was used for the statistical analyses.

Differences in VAS scores between the early and delayed groups were tested by Mann-Whitney test. Wilcoxon matched-pairs signed rank test was used to compare patient satisfaction evaluated at 2-year and 5-year follow-up examinations. In addition, statistical analyses were performed to determine the impact of patient age (age dichotomized into patients younger than and patients older or equal to the mean age of the study group), gender, and implant region (anterior versus posterior) on patient satisfaction with single-tooth implant treatment.

The level of statistical significance was set at $P < 5\%$.

RESULTS

The age distribution, gender distribution, and distribution of implant sites in the maxilla and mandible or the anterior and posterior regions were not statistically significantly different for the early and delayed groups.

Two implants in the early group and one in the delayed group were removed at abutment surgery because of failed osseointegration. All had been placed in the maxilla. No further implants were lost within the 5-year observation period. At the 2-year follow-up, 2 patients had withdrawn from the study. Before the 5-year follow-up, 2 implant crowns were remade and in 1 case, the implant was later used to support a removable prosthesis. Since crown remake might affect the condition of the soft tissue, as well as the position of the proximal contact point that was used as a reference point in assessment of the papilla height, it was decided to exclude all 3 patients from the data analysis. Three of the remaining patients did

Table 2a Marginal Bone Levels (mm) in the Early and Delayed Groups at Baseline (Radiographs Obtained at Healing Abutment Connection) 2 Years, and 5 Years After Implant Placement

	Early			Delayed			Early vs
Proximal	Mean	SD	Median	Mean	SD	Median	Delayed (*P*)
Baseline	0.6	0.5	0.6	0.7	0.8	0.7	.86
2-year	1.3	0.6	1.2	1.5	0.5	1.5	.06
5-year	1.2	0.5	1.2	1.5	0.7	1.4	.08

Table 2b *P* Values for Marginal Bone Levels (mm) in the Early and Delayed Groups at Baseline (Radiographs Obtained at Healing Abutment Connection, 2 Years, and 5 Years After Implant Placement

Proximal	Early	Delayed
Baseline vs 2-year	.003	.001
2-year vs 5-year	.98	.23

not attend the 5-year follow-up visit but confirmed in a telephone interview that their implant restoration was still in place and did not cause any inconvenience.

Clinical and Radiographic Findings

Except for the remake of 2 implant restorations, no major prosthetic complications arose among the patients included in this study. In 1 of these cases, it was decided to make a new abutment and crown after the crown had lost retention several times. The other crown was remade because of poor fit between the abutment and the implant, which had resulted in fistula formation and pronounced crestal bone loss. Three more crowns initially fixed with a temporary cement lost retention and were subsequently cemented with a zinc phosphate cement. In another patient where the crown had a large height, several decementations occurred during the study period.

The metal margin of the implant restoration was exposed in 1 patient at the 5-year follow-up. This exposure occurred between the 2-year and 5-year follow-ups and was associated with lack of attached mucosa buccally to an implant crown replacing a mandibular incisor. Exposed metal was seen after 2 years in 1 more patient, who did not attend the 5-year follow-up visit. Three crowns with visible metal margins at seating and/or at 2-year follow-up became covered spontaneously with soft tissue during the observation period.

No fractures of implant components or porcelain were observed, and none of the restorations were associated with loosening of the abutment retention screw. There was no need for correction of the occlusion, and no excessive wear of the porcelain was found.

Tables 1a and 1b present PPD at implant sites for the early and delayed groups. PPDs were reduced in both groups during the 5-year observation period. The mean PPD reduction for the 4 measurement points was 0.9 mm in the early group and 0.3 mm in the delayed group. At the lingual site in both groups and at the buccal site in the early group, this reduction was statistically significant ($P < .04$). The greater part of the PPD reduction took place from baseline to the 2-year follow-up. The mean PPD varied from 3.3 mm (buccal site) to 4.5 mm (proximal sites) 5 years after implant placement in the early group and from 3.6 mm (lingual site) to 4.4 mm (proximal sites) in the delayed group. No significant differences between the groups were found ($P > .12$). Overall for the groups, 56% of the PPDs were ≤ 3 mm at the buccal and lingual sites, while 78% of the PPDs were > 3 mm at the proximal aspects of the implants. At 97% of the buccal or lingual sites and 84% of the proximal sites, the PPD was < 6 mm.

MBL at implant sites evaluated on radiographs is presented in Tables 2a and 2b. Peri-implant bone loss was observed proximally in both groups from healing abutment connection to 5-year follow-up. The bone level changes were statistically significant in the early group (from 0.6 to 1.2 mm), and in the delayed group (from 0.7 to 1.5 mm). This corresponds to an annual bone loss of < 0.2 mm in both groups. The loss was > 2 mm at 4 sites out of 68. Almost no changes in MBL were seen between 2-year follow-up and 5-year follow-up. MBL in the early and delayed groups did not differ significantly 5 years after implant placement and was located 1.2 mm apically to the implant shoulder in the early group and 1.5 mm in the delayed group ($P = .08$).

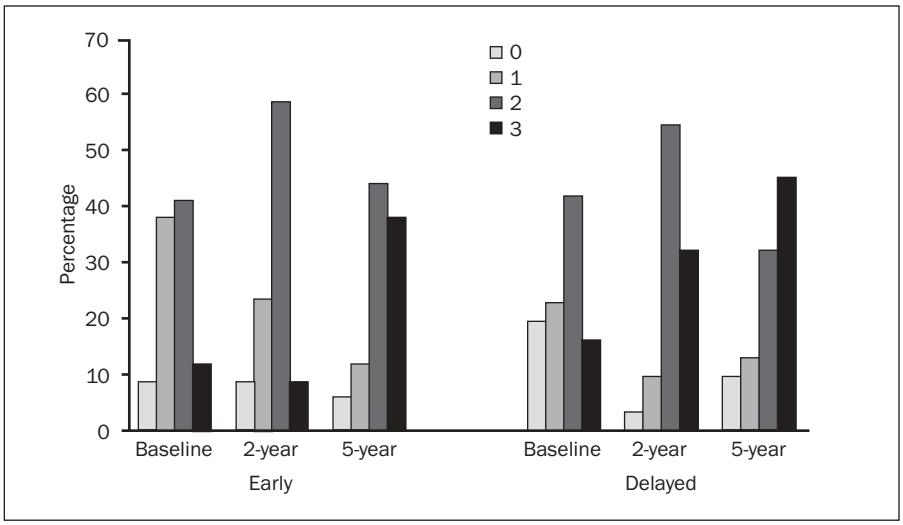

Fig 3 Papilla scores at baseline, 2-year follow-up, and 5-year follow-up for the early and delayed groups (total for the mesial and distal papillae). Score 0 = no papilla or a negative papilla; score 1 = less than half of the height of the proximal area occupied by soft tissue; score 2 = at least half of the height of the proximal area occupied by soft tissue; score 3 = interproximal area completely occupied by soft tissue.

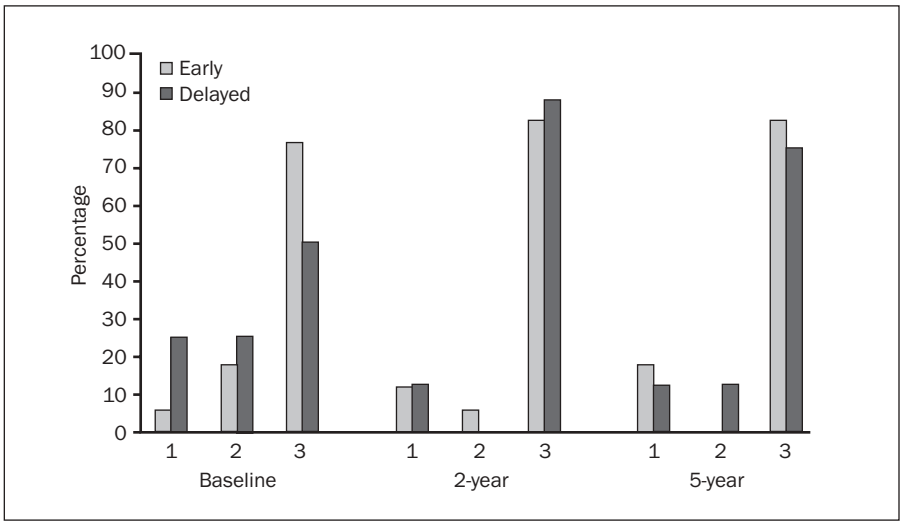

Fig 4 Clinical crown height scores for the early and delayed groups at baseline, 2-year follow-up, and 5-year follow-up. Score 1 = too long; score 2 = too short; score 3 = appropriate.

Soft Tissue Appearance

Figure 3 presents the percentage distribution of the papilla scores obtained at baseline and at the 2-year and 5-year follow-ups. No significant differences between the early and delayed groups were observed 1 week after seating of the crown (baseline; $P = .80$). However, 19% of the papillae in the delayed group were negative or lacking (score 0) versus 9% in the early group. A continuous improvement of the papilla height occurred within the 5-year observation period, and no differences between the groups were found at 5 years after implant placement.

The score distribution of clinical crown height is shown in Fig 4. Seventy-seven percent of the implant crowns in the early group were assessed to have an appropriate clinical height 1 week after seating (baseline) versus 50% in the delayed group. At the 2-year or 5-year examinations, the percentage of crowns having a score of 3 was almost the same for the early group (82% at both time points) and the delayed group (88% and 75%, respectively). The improvement for the delayed group during the observation period was not statistically significant. All of the crowns determined to have an inappropriate height in the early group were too long at 5 years, whereas in the delayed group an equal number of crowns were assessed to be too long as too short.

Intraobserver reproducibility of 59% and 60% was found for papilla assessment when re-evaluating soft tissue appearance, with an interval of 3 months or 3 years, respectively. Interobserver reproducibility was 73% and 77% for clinical crown height assessment.

Patient Satisfaction

The response rate for the questionnaire was 100%. Tables 3a and 3b show that the patients were highly satisfied with their implant restorations and the course of treatment assessed 2 and 5 years after

Table 3a VAS Scores

	All			Early			Delayed			Early vs Delayed (*P*)
	Median	25th	75th	Median	25th	75th	Median	25th	75th	
Q1										
2-year	95	93	98	96.5	95	99	92	88	95	.004
5-year	96	91	100	96.5	91	99	96	90	100	.70
Q2										
2-year	91	85	96	95	88	98	87	80	94.5	.05
5-year	89	78	100	93.5	78	100	84	79	97.5	.54
Q3										
2-year	95	93	98	96.5	95	99	93	90	95	.008
5-year	95	82	100	96	84	100	93	79	99	.41
Q4										
2-year	95	83	96	96	89	98	92	82	95	.12
5-year	95	84	100	95.5	79	100	93	84.5	99.5	.86
Q5										
2-year	94	88	97	96	89	97	91	86.5	95.5	.20
5-year	95	84	100	95	80	100	94	86.5	100	.96
Q6										
2-year	97	94	99	97	96	99	97	92	97.5	.30
5-year	96	95	100	96	93	100	99	96	100	.10
Q7										
2-year	94	87	96	94.5	88	96	89	74	95	.33
5-year	89	75	99	87	70	100	92	77.5	98	.69
Q8										
2-year	95	90	97	96.5	95	98	92	88.5	95	.02
5-year	95	92	98	95.5	93	100	95	89.5	95.5	.52

0 = most negative; 100 = most positive. 25th and 75th refer to percentiles.

implant placement. For some of the parameters, the scores were significantly higher in the early group than in the delayed group when evaluated at the 2-year follow-up visit. Three years later, the patients in the delayed group expressed an increased satisfaction in general, and no significant differences between the groups were found. At the 5-year follow-up, the mean VAS scores for all patients ranged from 89 to 96. The lowest ratings were recorded regarding adaptation and cleaning ability.

To see whether patient age had an impact on satisfaction with treatment outcome, the scores of patients younger than the mean age of the study group and of those greater than or equal to the mean age were compared. At the 5-year evaluation, it was revealed that older patients accustomed themselves to their implant restoration significantly sooner than the younger patients (98 versus 82; $P = .01$). Furthermore, the older patients were significantly more satisfied with the general appearance of the crown (96 versus 89; $P = .02$) and found it easier to clean around the crown (96 versus 79; $P = .03$) compared with the younger patients. No significant differences between men and women were observed for any of the questions in the survey at either follow-up. Likewise, the location of the implant (anterior vesus posterior sites) had no influence on patient satisfaction.

Table 3b *P* Values for VAS Scores

2-year vs 5-year	All	Early	Delayed
Q1	.97	.16	.31
Q2	.48	.97	.28
Q3	.09	.13	.44
Q4	.54	.41	.08
Q5	.85	.45	.58
Q6	.45	.29	.04
Q7	.54	.11	.36
Q8	.48	.61	.18

DISCUSSION

The present 5-year randomized prospective clinical study demonstrated that single-tooth restorations supported by implants placed an average of 10 days after tooth extraction are a valid treatment alternative to delayed placement of single implants. The implant survival rates were 91% for the early group and 95% for the delayed group. Even if the implants that could not be accounted for at the 5-year examination were considered implant failures, the average overall survival rate for the groups was 89%. These results are comparable with previous investigations.[10,11,20,21] The 3 lost implants failed before occlusal loading. Only a

few failures of the implant restoration were observed in the study. One crown in each group was remade because of technical complications. Loosening of abutment screws and fractures of implant components or porcelain have been reported in previous implant studies.[2,22–24] None of these complications arose in this study. Gold alloy–coated screws (Gold Tite, Biomet 3i) and a torque controller system were used for the retention of the abutments and may be one explanation for avoidance of problems with screw loosening.[25]

A maximum mean PPD of 4.5 mm was found for early placed implants 5 years after placement. The PPD was greater at the proximal sites as compared to the buccal and lingual sites. During the observation period, a reduction in PPD was found in both groups. Even though this reduction was more pronounced for the early group than the delayed group, the difference of approximately 0.5 mm was not considered clinically significant, and furthermore it was within the measurement error of the method. It is noteworthy that PPD was stable from the 2-year follow-up to the 5-year follow-up in both groups. Even though no relationship between increased pocket depths and a decreased implant prognosis has been proven, it may be assumed that PPDs as small as possible are preferable. The findings in this study were considered acceptable, and it was demonstrated that neither of the 2 treatment protocols was superior to the other 5 years after implant placement. It has been stated that peri-implant probing is associated with shortcomings, since the measurements are influenced by, for instance, tissue composition, peri-implant mucosal health, force applied, and possible obstructions from implant threads or crown contours.[26–29] However, PPD has been accepted as one of the indicators for peri-implant health status.[30] The same examiner performed all probing measurements in this study to improve the uniformity of force application.

A marginal bone loss was observed on radiographs at implants in both groups within the first 2 years of the follow-up period. However, it should be noted that the marginal bone levels were stable from 2 years postplacement to 5-year follow-up and that alteration in the bone level during the 5 years of observation therefore is well within the success criteria of less than 0.2 mm bone resorption per year proposed by Albrektsson et al.[31] The results are in agreement with those of a recent study that demonstrated similar rates of bone loss adjacent to implants placed either in native bone or in extraction sockets.[32]

Achievement of favorable contours of the peri-implant soft tissue is essential in single-tooth implant treatment. To fulfill the high demands on the esthetic outcome from the patient and to ensure the ability of self-performed plaque control, it is important to end up with well-dimensioned interproximal papillae and a clinical crown height of the implant restoration that is in harmony with the adjacent teeth. The present study demonstrated that the early placement protocol performed as well as the delayed protocol in terms of soft tissue appearance. No significant difference between the groups was found for papilla dimension at the 5-year follow-up. The papilla scores were a little lower than the results of a study by Jemt,[17] who found that at least half of the height of the papilla was present in 88% of the interproximal spaces adjacent to single-tooth implant crowns 1 to 3 years after insertion of the restoration. Moreover, in the present study, the criteria for complete fill was modified since a papilla height similar to the neighboring teeth was considered as complete fill even if it did not occupy the interproximal space completely. Since many of the patients in the present study had generalized gingival recession, this modification of the papilla scores was necessary to get realistic results. However, there might be a major problem when analyzing papilla dimensions in a pool of patients with generalized recession, since the underlying bony architecture differs from the norm in these patients. However, the study material was considered to be too small to analyze data separately for patients with pre-existing papillae and those with varying degrees of generalized gingival recession.

A striking observation of the present study was that twice as many papillae were negative or lacking in the delayed group one week after insertion of the implant restoration compared with the early group. However, a considerable spontaneous improvement of the papilla height took place in both groups during the observation period. This finding is in agreement with previous studies.[17,33]

Five years after implant placement, at least 75% of the crowns were determined to have an appropriate clinical height irrespective of the time of implant placement. The early protocol performed better than the delayed protocol just after seating of the crown, since almost 80% in the former group had an appropriate crown height, versus 50% in the latter group.

In this study, full flap elevation was performed in conjunction with implant placement. The reason for using flap elevation was the ability to achieve better visual inspection of the implant site and in turn make the control of drill direction easier. This technique was considered the standard procedure when this trial was initiated in 1999. It is likely that this surgical approach may have had an impact on the soft tissue appearance. Minimally invasive procedures, such as flapless implant surgery, have been suggested to improve the esthetic results.[34] Recent studies have shown success-

ful results following this technique in cases of immediate or delayed implant placement.[35,36]

The test for intraobserver reproducibility indicates that comparison of soft tissue appearance at different time points in the same patient might be difficult. The exact agreement between the scores recorded with an interval of either 3 months or 3 years was moderate (less than 80% for clinical crown height and 60% for papilla dimension). A more favorable reproducibility (88% for the clinical crown height and 84% for the papilla dimension) has been observed previously when the scores were re-evaluated within 6 weeks.[18] The score index used in this study is subjective by nature. Therefore, the authors suggest that comparison of peri-implant soft tissue appearance at different time points ideally should be made within a few days, aiming at as high uniformity in the evaluation as possible. For that purpose clinical photographs are very useful.

Previous investigations have mainly focused on implant survival and clinical outcomes in the evaluation of success of implant treatment. However, it may be reasonable to include patient satisfaction in the assessment of whether a new treatment procedure performs equally well as a gold standard method. This study demonstrated a high patient satisfaction with early placement of implants restored with single-tooth crowns in the anterior and premolar regions. The results corroborate data from a number of other studies evaluating satisfaction with esthetics by patients treated with single-implant restorations.[37–40] It was revealed that the patients in the early group 2 years after implant placement were significantly more satisfied than those in the delayed group concerning satisfaction with the restoration in general, the appearance of the crown, and the experience of the overall treatment. However, after 3 more years, the patients in the delayed group had become more satisfied with the outcome for most of the parameters assessed, although no significant differences between the groups were found. These findings could be explained by the fact that an improvement of the soft tissue conditions in the delayed group occurred between 2-year and 5-year follow-ups in terms of papilla regeneration and by the presence of more crowns with an appropriate clinical height. Older patients accustomed themselves sooner to the implant restoration and found it easier to clean around the crown than younger patients, and they were more satisfied with the general appearance. Based on the prosthodontist's assessment of the peri-implant soft tissue, which showed more favorable conditions in younger patients, it is more likely that the lower satisfaction among younger patients is an expression of possible higher expectations of the implant treatment than older patients. It is important to analyze the implant site carefully before treatment regarding the possibility to achieve a natural appearance of the peri-implant soft tissue and to discuss whether the expected outcome matches the patient's conceptions of an esthetically acceptable result.

Occurrence of peri-implant bone defects has been one of the concerns about placement of implants in extraction sockets. In the present study, 65% of the implant sites in the early group were associated with a bone defect just after implant placement.[16] The performance of bone augmentation of such defects has been advocated; however, in this study it was decided to rely on spontaneous healing. Thus, the results suggest that bone reconstructive procedures with bone grafts and/or membranes are not absolutely indicated in case of bone defects around implants.

Placement of the implants in the early group was deferred 3 to 15 days after tooth extraction to reduce the risk of complications caused by infection. Currently, there is no evidence as regards the effect of local infection on the success of immediate implants.[10] However, Lindeboom et al[41] reported in a recent prospective, randomized trial a higher failure rate for immediately placed implants in periapical infected sites compared with placement in non-infected sites.

Other studies have demonstrated that good results can be achieved for either the submerged or the nonsubmerged healing protocol in conjunction with immediately placed implants.[10,42] Recently, encouraging data have likewise been published on immediate restoration or loading of implants placed in fresh extraction sockets.[43,44] However, long-term clinical investigations are needed to confirm that this strategy could be used as a standard implant treatment procedure.

CONCLUSION

This randomized, clinical study demonstrated that early placement of acid-etched titanium implants supporting single-tooth restorations in the anterior or premolar regions can be a successful treatment. After 5 years, the outcomes of this method and delayed placement of implants were comparable, with high survival rates, few prosthetic complications, acceptable marginal bone levels and probing pocket depths, and acceptable soft tissue appearance and patient satisfaction. In comparison with other studies, it should be emphasized that patients with generalized gingival recession prior to implant treatment were included in the present study. This

fact was taking into account by a modification of the scoring when evaluating the papilla dimensions. Furthermore, the reproducibility of the papilla scores was low, which indicates that the method used may not be suitable in a study population with a history of marginal periodontitis. Consequently, the outcome as to soft tissue appearance must be interpreted with caution.

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