Immediate Postextraction Single-Tooth Implants and Provisional Crowns in the Esthetic Area: 2-year Results of a Cohort Prospective Multicenter Study—Patient-Centered Outcomes

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Purpose: A prospective cohort multicenter study was undertaken to identify risk factors for implant survival, complications, and patient-centered outcomes following single-tooth immediate implant placement and loading in esthetic areas. ***Materials and Methods:*** Consecutive immediate implants placed in incisors, canines, and premolar sites were included. Variables recorded as possible risk factors included smoking habit, systemic conditions or therapies, previous assumption of bisphosphonates, inability to take amoxicillin, untreated periodontitis, thin periodontium, parafunctional habits, suppuration, bone dehiscences, and buccal bone fracture during implant insertion. Outcome variables included implant survival, recession, other complications, and patient satisfaction. ***Results:*** Data of 215 implants in 215 patients were collected in 15 centers in 2 years. One implant was seated with a torque < 30 Ncm and was not immediately loaded. It was successfully loaded 10 weeks after placement and was healthy 2 years later. This implant was excluded from subsequent analysis. Potential risk factors were identified in 116 patients (54.21%). There were 11 dropouts after 1 year and 37 after 2 years. Failures were relatively frequent (14.6%) before the delivery of the definitive prosthesis. No significant association was observed between early failures and risk factors. One failure and six recessions were observed after the definitive prosthesis. High satisfaction scores (mean score of 9.47/10 and 9.55/10 for esthetics and function, respectively) were recorded at 2 years. No recession occurred in the no-risk group. Five mucositis cases and one peri-implantitis case were observed in the 2-year follow-up. ***Conclusion:*** Failures were frequent before the definitive restoration and could not be explained by specific risk factors. Tissues appeared stable after the definitive restoration. Patients were very satisfied during the follow-up. *Int J Oral Maxillofac Implants 2020;35:833–840. doi: 10.11607/jomi.7203*

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Single implants in the esthetic zone may be placed immediately after tooth extraction in conjunction with an immediate (within 48 hours) placement of a provisional crown.[1–9] The success of immediate implants is influenced by patient and site characteristics as well as operator training.[10,11] No conclusive evidence is available on peri-implant marginal soft tissue stability, esthetic, and patient-centered outcomes.[9,12,13] Most studies adopt stringent entry criteria to exclude putative risk factors (eg, smoking habit or bone dehiscences), thus reducing failure rates.[1,3,4,9,14,15] Several systemic conditions and local risk factors are suspected to affect postextractive implant survival.[2,16–19] Currently, the most-proposed technique consists of

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flapless extraction, immediate postextractive implant insertion, and immediate provisional crown within 48 hours.[2,4,5,7,8,20–22] The aim of this study was to assess the role of putative risk factors (smoking, systemic conditions and therapies, inability to take amoxicillin, periodontitis, unfavorable anatomical conditions, dental habits) on implant survival, complications, and patient-centered outcomes following single-tooth immediate (postextractive) implant placement and loading in esthetic areas.

MATERIALS AND METHODS

The study design was a multicenter cohort prospective clinical trial and was reported according to the STROBE guidelines.[23] The procedures followed were in accordance with the ethical standards of the national committee on human experimentation and with Helsinki Declaration of 1965, as revised in 2000.[24] Patients were informed that their data would be used for statistical analysis and gave their informed consent to the treatment. No ethical committee approval was sought, since it was not required by any authority when the patient recruitment was initiated (June 2007).

The study involved 15 centers, consisting of private practices in Italy.

Patient Selection

All the consecutive patients treated with single immediate implant placement in the period between June 2007 and July 2009 were enrolled in the study. Putative risk factors were categorized as systemic or local.

Systemic risk factors included smoking habit, diabetes, other systemic conditions, ongoing therapy with anticoagulants or calcium antagonists, previous taking of bisphosphonates, inability to take preoperative amoxicillin, and taking antibiotics and/or steroids in the preoperative week.

Local risk factors included inadequate oral hygiene, history of past or adjacent endodontic care, untreated periodontitis, thin phenotype, parafunctional and other bad dental habits, suppuration, bone dehiscences, and fracture of the facial plate during implant insertion. Periodontitis was defined by the presence of proximal clinical attachment loss ≥ 3 mm (not ascribed to non–periodontitis-related causes) in at least two nonadjacent teeth and clinical pocket depth ≥ 3 mm associated with local bleeding on probing.[25]

Refusal of the patient to undergo the treatment of periodontitis, when indicated, was an exclusion criterion. Implants with insertion torque lower than 35 Ncm were treated with a standard healing abutment to allow for secondary stability.[26]

Surgical and Prosthetic Protocol

The extractions were performed, trying to preserve the facial cortex. Fracture of the facial cortex was considered a local risk factor and not an exclusion criterion. The implants were inserted immediately after tooth extraction without flap elevation. The facial and lingual bone surfaces were located by palpation. A needle was used to locate the palatal bone surface after anesthesia. The Gelb probe was used after extraction to assess the contour of the socket and the presence of fenestrations or dehiscences.

Tapered implants (NanoTite Certain Tapered Implants, Biomet 3i) were selected in order to increase primary stability after undersized osteotomy.

The site was prepared with the following objectives: placement of the facial surface of the implant at least 1 mm from the facial wall of the socket; placement of the implant platform 3 to 4 mm apical to the level of the facial gingival margin; achievement of primary stability (insertion torque ≥ 35 Ncm). Spongious granules of bovine demineralized denatured bone (Bio-Oss, Geistlich) or bone chips harvested from the surgical site were inserted between the implant and residual alveolar wall when the gap exceeded 1 mm.

Provisional screw-retained crowns, tightened at 20 Ncm, were seated within 48 hours after surgery, taking care to provide the soft tissues with adequate support. Any occlusal contact was eliminated.

Definitive restorations were scheduled 3 months after implant placement.

Data were gathered before surgery and during surgery, immediately after provisionalization, at the seventh postoperative day, and at 3 months after surgery. Subsequent follow-up visits were scheduled at 1 and 2 years after implant placement.

The following variables were recorded for each patient:

- Before surgery: sex, age, extraction site, indications for extraction, and putative risk factors.
- During surgery: duration of the extraction, U/V-shaped bone dehiscence, bone fenestration, distance of crestal bone from the gingival margin on the facial aspect, diameter and length of the implant, insertion torque, fracture of the facial bone plate, position of the implant platform relative to the bone crest (apical, coronal, same level), facial gap between the bone and implant, biomaterial inserted into the gap, suture to close the gingiva over the bone gap, and duration of implant surgery.
- During the provisional prosthetic phase: time elapsed between the end of surgery and provisional crown, platform switching or not, presence of contact point with adjacent teeth.

Outcome Measures

Outcome measures were recorded at each follow-up visit.

Implant failure was the primary outcome. The removal of any implant for any reason.

Gingival Recession. Facial recession was recorded on the basis of the visual examination at the midfacial aspect of the tooth.

Esthetic Outcomes. The Pink Esthetic Score (PES) was retrospectively evaluated on clinical pictures when available at each phase, from preoperative to follow-up.[27]

Marginal Bone Levels. Radiographic bone levels were measured at the mesial and distal sites of each implant on the available intraoral films taken using a long-cone parallel technique with a Rinn-type film holder at each time point. The distance from the implant platform to the interproximal bone crest and the distance from the implant platform to the most coronal bone-to-implant contact were measured parallel to the implant axis. The measurements were made on enlarged pictures, using the distance between the implant threads as a unit and then converting the obtained figures into millimeters. The interthread distance was rounded to the closest second decimal digit.

PES and radiographic measurements were carried out by two independent examiners (C.C. and N.M.S.). Discordances were solved by discussion.

Mechanical complications were also recorded.

Patient-Centered Outcomes. Intraoperative and postoperative pain was assessed using a numeric ascending scale in 11 scores (0 to 10).[28,29] A similar scale was used to grade the satisfaction of esthetics[30] and functional aspects, where 0 meant that they could not be more dissatisfied, while 10 meant that they could not be more satisfied. Patient satisfaction was investigated at each follow-up visit. The satisfaction of function was recorded only at 1 and 2 years, because the patients had been asked not to chew on the provisional crown.

Centers unable to provide the required data at the 3-month interval were excluded from the study before statistical analysis.

Statistical Analysis

The analysis unit was the patient since only one implant was placed in each patient.

Descriptive statistics with means, standard deviations, and percentages were calculated for the participant characteristics at baseline, for intervention data, and for outcomes at different time points of follow-up. Fisher exact test was used to assess differences in the prevalence of outcome variables among patients exposed to different risk factors and treated by surgeons with different experience at different time points.

Table 1 Life Table Statistics Used to Determine Survival at Different Time Points, Censoring Data for Dropouts

Interval	Total	Failures	Dropouts	Survival	95% CI
T0–T1	214	5	1	0.977	0.945–0.990
T1–T2	209	25	7	0.878	0.804–0.899
T2–T3	179	0	6	0.858	0.804–0.899
T3–T4	173	1	26	0.849	0.792–0.889

Each patient had received only one implant.
T0 = baseline; T1 = 1 week after surgery; T2 = 3 months after surgery; T3 = 1 year after surgery; T4 = 2 years after surgery.

Life table statistics were used to determine survival at different time points, censoring data for dropouts. Single and multiple logistic regression models were used to assess any influence on implant failure, recession, pain, and satisfaction of the collected variables. Regression models were conducted considering clustering of patients by center/surgeon. All tests were two-tailed, and all statistical comparisons were conducted at .05 level of significance. Analyses were performed by an independent operator (K.Z.) using Stata version 13 (Stata Statistical Software, release 13.0, StataCorp).

RESULTS

A total of 215 implants were inserted from June 2007 to July 2009 in 15 centers. One implant was seated with a torque < 30 Ncm and was not immediately loaded. It was successfully loaded 10 weeks after placement and was healthy 2 years later. This implant was excluded from subsequent analysis. The data on the remaining 214 implants inserted in 214 patients were gathered from 15 centers/operators. Survival rates are summarized in Table 1.

Baseline and Surgery (T0)

Out of 214 patients, 92 (43%) were men and 122 (57%) were women, with an overall mean age of 48.3 years, ranging from 17 to 84 years.

Absence of potential risk factors was observed in only 46 patients (22%); 24 (9%) smoked more than 10 cigarettes per day, and 4 (2%) could be labeled as heavy smokers (more than 20 per day). Preoperative amoxicillin was administered to 196 patients (92%).

Gingival phenotype was judged as thin in 19 patients (9%), medium in 120 patients (56%), and thick in 75 patients (35%). V-shaped and U-shaped dehiscences were found in 14 sites (6.54%) and in 37 sites (17.3%), respectively. The majority of implants were inserted in the maxilla (179/214; 84%) and more than half on the site of maxillary premolars (104/214; 58%). Only 35 implants were placed in the mandible (16.3%). Implants were mostly 13-mm (112/214, 52.3%) or 15-mm length

(69/214, 32.2%); the most-used diameter was 5 mm (129/214, 60.3%). No filling material was used to fill the gap between the implant and bone in 110/214 (51%) cases. Bone chips were inserted in 51 (24%) cases, bovine bone granules in 38 (18%), and a mixture thereof in 15 (7%). The average duration of surgery (extraction+implant surgery) was 32.9 minutes (standard deviation [SD] 20.64; range: 23 to 105 minutes).

Mean intraoperative pain was only 0.79/10 (SD: 1.60), with 70% of patients reporting no pain. A regression model indicated that intraoperative pain was associated with three predictive variables: younger age (OR: 0.96, 95% CI: 0.946 to 0.99, $P = .005$), higher surgical intervention duration (OR = 1.03, 95% CI: 1.02 to 1.05, $P = .007$), and the maxilla (mandible vs maxilla, OR = 0.18, 95% CI: 0.05 to 0.62, $P = .006$). The provisional crown was delivered in less than 24 hours in 157/214 instances (73.5%) and the rest (57/214, 26.5%) within 48 hours.

Follow-up

1 week (T1). Two hundred eight patients with surviving implants were seen at the end of the first postoperative week. Implant failure was observed in five patients.

Three implants out of 179 (1.6%) failed in the maxillary arch (a central and a lateral incisor and a canine) and 2/35 (5.7%) in the mandibular arch (a lateral incisor and a second premolar). One patient did not attend the 7-day visit, but came to a later appointment and is accounted for in a subsequent paragraph. Local risk factors ($P = .42$) or systemic risk factors ($P = .06$) were not correlated with failures. The overall 1-week survival rate was 0.977 (95% CI = 0.945 to 0.990). Fisher's exact test indicated no significant difference between maxillary and mandibular implants ($P = .611$). Regression analysis indicated no important influence of experience level (1 vs 0, $P = .209$; 2 vs 0, $P = .108$).

Sixteen complications were observed: one mechanical (loosening of a provisional crown) and 15 minor biologic complications consisting mainly of superficial infections (mucositis) and transient disturbances of local sensitivity.

More than half of the patients (109) did not take any analgesic on the first week following the operation. Similarly, 116 patients (55%) reported 0 pain, whereas the overall numeric mean score was 1.31/10 (SD: 2.01). The mean score on esthetic satisfaction with immediate provisional restoration was 8.62/10 (SD: 1.82). No specific variable seemed to be associated with patients' satisfaction at this stage.

3 months (T2). At the time scheduled for the definitive restoration (3 months), patients were recalled even if they chose to delay the substitution of the provisional crown.

Seven patients dropped out by the third month, and 25 additional implants were lost, resulting in an overall survival rate of 0.878 (95% CI = 0.804 to 0.899). Different reasons were alleged for the seven dropouts: one had moved to another city; one did not come to the follow-up visits, but stated that everything was going well with the implant and did not want to spend money for a permanent crown; the remaining five could no longer be contacted by the centers. Two of these patients were recorded as dropouts at 3 months but attended the 1-year follow-up visit. One failure was observed in the patient who had missed the previous visit.

No significant association of local risk factors ($P = .10$) was observed with implant failure, whereas presence of more than one systemic risk factor compared with no risk factor seemed to increase implant failure (OR = 3.14; 95% CI: 1.10 to 8.96; $P = .032$).

The regression model showed some evidence that implant failure might be associated with shallower gingiva (moderate vs thin OR = 0.32; 95% CI: 0.11 to 0.98; $P = .047$; thick vs thin OR = 0.25; 95% CI: 0.07 to 0.84; $P = .025$).

Nevertheless, bone grafting ($P = .90$) and type of bone grafting ($P = .471$) did not seem to have any influence on implant survival. Similarly, other factors such as implant length, insertion torque, arch, distance between platform and gingival margin, platform switching, and contact point were not associated with implant failure. The logistic regression model suggested a potential weak association between the narrowest implant diameter and implant failure (4 mm vs 3.25 mm, OR = 0.22; 95% CI: 0.42 to 1.13; $P = .06$; 5 mm vs 3.25 mm, OR = 0.21; 95% CI: 0.42 to 1.00; $P = .05$). Five failures occurred in the 18 patients unable to take amoxicillin and 20 in the 196 patients who had taken amoxicillin. The difference was statistically significant (Fisher exact test: $P < .05$). Finally, 30 failures were recorded 3 months after surgery: 20/156 (12.8%) occurred when provisional crowns had been seated within 24 hours from implant surgery, while 10/58 (17.2%) were in cases with more than 24 hours of delay. Regression analysis indicated no association between implant failure and time of provisional prosthetic loading (more than 6 hours vs less than 6 hours, $P = .314$; more than 24 hours vs less than 6 hours, $P = .507$).

The individual failure rate varied from 0 to 6/22 (27%) among individual centers, but no association was observed between implant failure and surgeon experience.

No gingival recession was observed at this stage in any patient.

Mechanical complications were observed in 10 patients (8 provisional crowns fractured and 2 loosened).

Overall mean esthetic satisfaction score was 9.5 (SD: 0.83).

1 year (T3). No additional implants were lost. Six patients dropped out in the period between T2 and T3, whereas two patients who had been recorded as dropouts at 3 months presented at 1 year. One patient did not show up at the 1-year follow-up visit because of a car accident but came regularly to the following 2-year visit. The other five dropouts included a death, a myocardial infarction, two patients who moved, and a patient who could not be contacted any longer. The overall survival rate was 0.858 (95% CI = 0.804 to 0.899).

Recessions were noticed in three cases only. No recession occurred among patients without any risk indicator. Two crown fractures and two mucositis cases were observed. Both esthetic and functional satisfaction recorded a mean score of 9.5/10 (SD: 0.74 and 0.77, respectively).

Two years (T4). The number of dropouts reached 37 at the end of the second year of follow-up. One of the centers did not provide follow-up data at this stage (15 patients). Some of the other 22 can be accounted for: these included two deaths, one severe systemic disease, and two patients who moved.

One additional implant was lost, resulting in an overall survival rate of 0.849 (95% CI = 0.804 to 0.899).

Complications occurred in 4/146 patients (6.85%): 3 cases of mucositis and one of peri-implantitis. No mechanical complication was observed.

Three new recessions (2.10%) occurred during the second year of follow-up. No recession occurred in the no-risk group.

For satisfaction scores, a score of 10 was assigned to the esthetics of the permanent rehabilitation by 97/146 patients (66.44%; 95% CI = 58.16% to 74.03%). The mean score was 9.49.

A satisfaction score of 10 was assigned to the functional performance of the permanent rehabilitation by 102/146 patients (69.86%; 95% CI = 61.72% to 77.17%). The mean score was 9.57.

Most patients were satisfied (rating ≥ 7) with both esthetics and function of their permanent crowns (95% CI = 97.50% to 100%).

Table 2 Bone Level Change on the Mesial/Distal Aspects of Implants Between T0 (Surgery) and T4 (2-year Follow-up): Most Coronal Bone-Implant (or Bone to Abutment) Contact Levels Relative to the Implant Platform (BIC), Crestal Bone Levels (Crest), and Vertical Distance Between BIC and Crest (Distance)

	BIC (gain)	Crest (loss)	Distance (reduction)
Mesial bone level differences			
Mean	0.47*	−0.40*	−0.87*
SD	1.18	0.89	1.33
95% CI	0.208 to 0.732	−0.598 to −0.202	−1.23 to −0.515
Distal bone level differences			
Mean	0.75*	−0.60*	−1.35*
SD	0.94	0.76	1.64
95% CI	0.541 to 0.959	−0.769 to −0.431	−1.64 to −1.06

N = 78 (sites with available radiograph at the time points of interest). BIC measurements led to record a significant net gain. Crest peak height decreased significantly. Mean vertical distance between crestal bone levels and BIC decreased significantly as a consequence.
*Significant difference ($P < .05$).

Pink Esthetic Score[27] was used to evaluate the esthetic results in terms of marginal soft tissue on clinical images when available. The average score at 2 years was 13.16 (95% CI = 12.9 to 13.5). No significant difference was observed in PES from T1 to T4.

Bone levels were measured at the same sites mesial and distal to 78 implants at surgery and at the final visit: the measurements at surgery and 2 years later document a substantial stability, with a mean gain of supporting bone of 0.47 mm on the mesial aspect (95% CI = 0.208 to 0.732) and 0.75 mm on the distal aspect (95% CI = 0.541 to 0.959), and a correspondent mean loss of crestal bone (mesial −0.40 mm; 95% CI = −0.598 to −0.202; distal −0.60 mm; 95% CI = −0.769 to −0.431). The average distance between the crest and the most coronal bone-to-implant contact decreased accordingly, leading to a flattening of the bone profile (Table 2).

DISCUSSION

A multicenter prospective cohort study was considered adequate for pragmatic research on the frequency of implant, prosthetic, and esthetic failures of immediate prostheses on single-tooth postextractive implants. The explorative nature of the study guided the choice of the experimental design: possible sources of bias were accepted if it was the price to gain an insight about the mechanisms of failures. Broad inclusion criteria permitted the evaluation of several putative risk factors. Systemic and local conditions are usually employed as exclusion criteria in the current literature, thus preventing obtaining information about their actual role in determining failures. As a result, many of the commonly excluded cases were included in this work.[1,9,11,31] The main purpose was the identification of possible risk factors and not the definition of clinical recommendations.[32] Moreover, the subjective evaluation of the indication for immediate tooth replacement imposes caution in the interpretation of the present results.

The association between individual risk factors and failures did not reach the threshold of statistical significance. The failure rate

was significantly higher only in patients unable to take amoxicillin. This observation is in agreement with the conclusions of other studies; the inability to take preoperative amoxicillin was recently identified as a risk factor[10] and might be even more harmful in challenging situations such as postextractive implants, as suggested by the study of Wagenberg and Froum (2006).[16]

The time distribution of implant failures (most of them in the first 3 months) suggests an overwhelming role of the initial conditions in determining the success or the failure, even if a strong correlation with any of the investigated putative risk factors could not be substantiated by the data. Postponing the seating of provisional crowns after 24 hours did not appear to jeopardize the success of implants.

Based on the data of this study, 15% of early failures may be expected, but only prior to the definitive restoration. On the other hand, some months of patient discomfort and significant chair time were saved in the other 85% of cases while improving the quality of life remarkably. Only one implant was lost among the 176 at 3 months and followed up to 2 years. Less than 0.6% of failures in the first 2 years after definitive restoration and full occlusal loading is an encouraging figure.

Immediate implant placement in the anterior maxilla is an attractive option, but several articles warn against the risk of unpredictable tissue healing after immediate postextractive implants, reporting mean retraction of the soft tissues of 0.5 to 1 mm.[2,3,18,33] Experimental studies suggest that a flapless approach to tooth extractions and immediate implant placement results in better preservation of the soft tissue contour.[34,35] Nevertheless, the flapless approach entails some inconveniences, including the difficulties in appraising the size and shape of the crest and the soft tissue thickness; the clinician must rely on indirect evaluation by means of probing and palpation. Flapless atraumatic extraction, immediate implant insertion in the fresh socket, and immediate incorporation of a provisional crown are associated with minimal facial recessions (0.45 ± 0.25 mm) 1 year after implant insertion.[5] A significant association was found between U-shaped dehiscences and higher incidence of facial recessions in a previous study.[36] The exclusion of site fenestrations and dehiscences is consistent through the clinical literature on immediate implants. The present multicenter study did not exclude such bone defects and showed a minimal incidence of facial recession in the two postoperative years (6/176). These data do not confirm or disprove the hypothesis of a correlation between recessions and phenotype or dehiscences, mainly due to the low frequency of recessions. It is, however, remarkable that no recession was observed in the patients without any risk factor and only one recession occurred in the 37 sites with U-shaped bone dehiscences.

Recessions were also minimal in other clinical studies employing immediate provisional crowns,[11,37] even in a randomized clinical trial.[4] The outcomes of this approach appear to be better than alternative techniques involving elevation of the flap and even GBR.[15,38]

A very interesting point is the incidence and amount of marginal tissue recessions after conventional implant insertion in healed sites; the average values are quite comparable to the recession after immediate postextractive implants inserted according to the principles of the trimodal approach.[8,39–43] The observed stability of the peri-implant soft tissues irrespective of phenotype and bone defects might be explained by the role of the immediate insertion of a provisional crown, according to the hypothesis of Restorative Tissue Inhibition (RTI).[44,45]

It is interesting to note that despite the dentists' recorded recessions, patients scored 10 for the esthetic satisfaction in 3/6 cases and 8 and 7 in one and two cases, respectively. The discrepancy between dentists and laymen in appreciating esthetic defects is well documented.[46] The upper lip covered the gingival margin in three cases and left it exposed in the other three when patients smiled. The analysis of patient-centered outcome (esthetics and function) demonstrates that this treatment option is really welcome by the patients even when the dentist may observe minor defects. It is noteworthy that the average PES score improved over time.

Radiographic measurements of bone levels mesial and distal to implants at surgery and 2 years later document substantial stability. The distance between the crest and the most coronal bone-to-implant contact remained almost unchanged.

CONCLUSIONS

Immediate provisionalization with nonfunctional loading is a viable option for immediate implants. Early failures (before the definitive restoration) were more frequent than those reported in the conventional approach, and loss of implants after occlusal loading was a rare event in the first 2 postoperative years, even in cases with putative risk factors.

The implant failure rate varied greatly among operators, independently from surgeon experience.

Little or no discomfort and few trivial complications have to be expected; in particular, very few and shallow recessions may be observed by the dentists, but they appeared negligible to the patients. Good levels of patient satisfaction may be expected in association with the surviving implants.

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