


Original Research Article

Risk factors for early implant failure: a retrospective-multicentric study of 2323 implants in screw retained fixed full arch rehabilitation

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(Received: 26 December 2022, accepted: 3 June 2023)

Keywords:
Dental implants /
dental prosthesis /
risk factors

Abstract – Objectives: The aim of this retrospective study was to investigate possible risk factors for early implant failure in screw retained fixed full-arch rehabilitation. **Methods:** data of 487 patients (2323 implants) treated with full-arch rehabilitation supported by same implants brand were collected for the time period from 2017 to 2020 and examined to evaluate early implants failure rates. The following data were collected for statistical analysis: sex, age, health disorders (diabetes and hypertension) and bad habit (smoke) of the patient, location of the implant (maxilla or mandible, anterior or posterior site), type of implant's healing and bone regeneration procedures. Chi-squared test, bivariate comparison analysis and univariate mixed model analysis were used to estimate the effect of both patient-related and implant related variables on early implant failure as a potential risk factors. **Results:** 487 patients were included, 218 females (62.3 ± 9.14 of age) and 269 males (62.8 ± 10.11 of age) in 30 private institutions for a total of 2323 implants placed and a total of 526 screw retained fixed full arch rehabilitation. A total of 40 out of 2323 (1.7%) implants failed prematurely within 1 year, 32 in the maxilla 8 in the mandible. Bivariate comparison analysis and univariate mixed model analysis showed that female patient, implant placed in maxilla, age <61 years and submerged healed implants showed a statistically significant higher failure rate among the risk factors considered. **Conclusions:** Implants placed in the upper jaw and their modality of healing seems to be associated with a higher risk of early implant failure.

Introduction

Since Brånemark described implant's osteointegration process in the 1960, the use of titanium implants to support dental prosthesis in edentulous jaws has been widely studied in literature by numerous evidence-based scientific papers. Different longitudinal studies, with a follow-up of more than 10 years, evaluated the behavior of implants used to support full arch prostheses rehabilitation in edentulous patients [1,2]. Various implant protocols have been used with the aim of improving oral function and aesthetics of completely edentulous patients: overdentures, implant-supported, and full-arch fixed implant supported prostheses. Furthermore, fixed restorations provide a feeling of similarity to natural teeth and a sense of psychological well-being, which is a good

reaction in completely edentulous patients. Different modalities and studies have been reported for implant-supported prostheses and subsequent rehabilitation: from 4 to 8 implants in the mandible and from 4 to 12 implants in the maxilla [3]. Nevertheless, despite high implant survival and success rates has been reported, it should be remembered that early failure of implants can also occur. An early failure of an implant results from an inability to establish an intimate bone-to-implant contact. In this case, bone healing after implant insertion is impaired and may be influenced by local and systemic factors [4]. Furthermore, systemic factors influencing the patient's wound healing capability and local inflammation could be associated with an early dental implant failure as well [4–6]. Implant failure has been classified as early and late in retrospective studies according to different cutoff time points, such as at the time of abutment connection, at the time of loading, within several weeks after placement of the final prosthesis, or at the time of first year after loading [7,8].

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The percentage of early implants failure in literature varies from 1% to 6% of implants placed and the incidence can be higher in a specific risk population (es. smoking and the intake of antidepressants were the statistically significant predictors in a retrospective study of 2670 patients) [5,7,9]. Several studies have identified different risk factors as potential causes favoring early implant failure as is the definition of early loss (endpoints, abutment connection, occlusal loading, one year after placement, etc.) [9,10]. Smoke, co-morbidities like periodontitis and metabolic diseases, poor oral hygiene, need for bone augmentation procedures, implant location, type of implant healing, use of short implants are all listed as potential risk factors for early implant [7]. Although many studies have shown the influence of local and systemic factors in the long-term outcome of dental implants [10,11], less studies examined factors affecting the initial phases of osteointegration with the same implant system. Thus, the purpose of this retrospective analytic – multicentric study was to analyze and report clinical data on prevalence of early implant failures (within 1 year) in a large number of implant patients treated in private institutions with fixed full-arch rehabilitations with the same implant system and perform a logistic multivariate data analysis to evaluate possible risk factors with an association to early implant failures. This study followed the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) guidelines.

Material and methods

Informed consent was obtained from all participants at the time of surgery. The present observational multi-center retrospective study followed the STROBE checklist guidelines for observational studies. The study design was analytical, correlational and retrospective based on 487 patients who received 2323 implants by 58 surgeons with different experience and were then treated with implant supported fixed screw-retained full-arch rehabilitation (Toronto bridge) between 2017 and 2020 in 30 different clinics (Dentalpro clinics, Italy) but same implant system with an acid-etched sandblasted machined surface (Avenir srl, Rimini, Italy) for a total of 526 prostheses.

Definitions

An implant was considered as a failure if presenting signs/symptoms such as to require their removal within 1 year of their insertion. In this study, implant failure is considered to be an implant removed.

Participants and data collecting

The eligibility criteria were the following: (i) patients that received a Toronto bridge for a final fixed oral rehabilitation in the maxilla and/or the mandible (Figs. 1 and 2); (ii) the Toronto bridge had to be fabricated with a metal or zirconia framework.

The following exclusion criteria were applied: (i) insufficient information to comply with the record data included in the study; (ii) patient death. Smoking, diabetes and bruxism were not considered as contraindications for treatment. General health and behavioral history were collected from the patient's anamnesis file. Patients' treatments were performed at thirty Italian DentalPro clinics. Socio-demographic (age in years, gender, smoking) and medical issues (diabetes, hypertension, hypercholesterolemia) were recorded in the database (patient-related risk factors). For the variables smoking and diabetes, only their presence or absence was noted and used in statistical analysis (each considered as yes/no). More detailed data (number of cigarettes smoked or glycemic values) were not available. The following data were also documented for each implant (implant-related factors): implant site (anterior placement between 13–23 or 33–43 or posterior placement), implant jaw location (maxilla or mandible), need for bone augmentation procedures and mode of healing (closed: implant submerged with cover screw below the mucous membrane, re-exposure of implants needed after healing period and open: immediate loading with provisional installed within 24–48 h of surgery). Patients whose implant healing modalities was submerged used a removable provisional total prosthesis during the months of implant healing. The following information were collected from the database files of each patient (St-order, Rimini, Italy).

Statistical analysis

Only patients in which target variables were complete were included in this retrospective analysis. A database was created for data collection and statistical purpose. Mean, percentages and standard deviation were presented as a descriptive statistic. Logistic regression models were used both for implant and patient related variables. Consecutive numbers were chosen for each patient and implant placed. The primary outcome, successful osteointegration of the implant, was considered dichotomously (0 = yes; 1 = no). Patients-related target variables considered in this study were the age, dichotomized by using the median as the cut-off ($0 \leq 61$ y; $1 \geq 61$ y), gender (F/M), smoke (yes/no), diabetes (yes/no) and hypertension (yes/no). Chi-squared tests were performed for bivariate comparison analysis of correlation between successful osteointegration and the target variables. For each possible target variable of the primary outcome osteointegration, a univariate linear mixed model including the patient as a random factor was also adopted to consider the group structure of the data. The criterion for statistical significance was set at $P < 0.05$. Odds ratios with 95% confidence intervals were estimated from all models, with respective P -values and 95% confidence intervals (CI). Statistical analysis was performed by use of Python software.

Results

The total number of patients included in the study was 487 with an average of 16.2 patients per clinic, the group was composed of 218 females (44.8%, 62.3 mean age) and 269



Fig. 1. Multi-unit abutment of full arch rehabilitation.

males (55.2%, 62.8 mean age) with a total of 2323 of implants placed during the year 2017–2020 for a total of 526 fixed screw retained full arch rehabilitation. Overall, 40 of the 2323 implants failed (1.7%) in 24 patients (4.9%) within one year to their installation. Smokers were 151 (31%) of which 59 female and 92 males, patients with diabetes were 30 (6.2%) and 43 with hypertension (8.8%). The mean age was approximately 62% with a range between 98 and 32 years old. Regarding the implant-related predictive variables, it was found that the position of the implants was as follows: 1002 in the lower arch, 1321 in the upper arch, 1114 implants placed in anterior site between 13–23 in the maxilla and 33–43 in the mandible, 1209 placed in posterior sites. Furthermore, regarding the modality of healing of the implants, 1793 (77.2%) of implants were immediate loaded, 530 submerged (22.8%). A total of 258 implants (11.1%) were placed in previously augmented sites.

Table I showed all data collected of implant failure, target variables and bivariate comparison analysis. Bivariate evaluation of patients-related target variables showed significantly more failures for female patients than male patients

($P=0.004$). Regarding implant-related levels, bivariate analysis observed a statistically significant value for implant location jaw with more failures for implants placed in maxilla than in mandible ($P=0.004$) and a submerged mode of implant healing than open healing ($P=0.005$). Bivariate analysis showed no statistical significance value among the target value age ($P=0.05$), smoke ($P=0.99$), diabetes ($P=0.265$) and the other variables. Results of univariate, mixed model analysis are presented in Table II and revealed a significant 2.4 greater risk of failure (95% CI 1.1–5.4) for implants placed in maxilla. Greater risk was also found for female patients (OD 0.4), closed implants healing (OD 0.3) and patients <61 years old (OD 0.4).

Discussion

This study was focused on implant failure only in the early phase of healing (within the first year) in which literature report higher incidence of failures than the late phase [12,13] and evaluated both patient and implant level variables. The prevalence of early failure observed in this study (1.7%) is

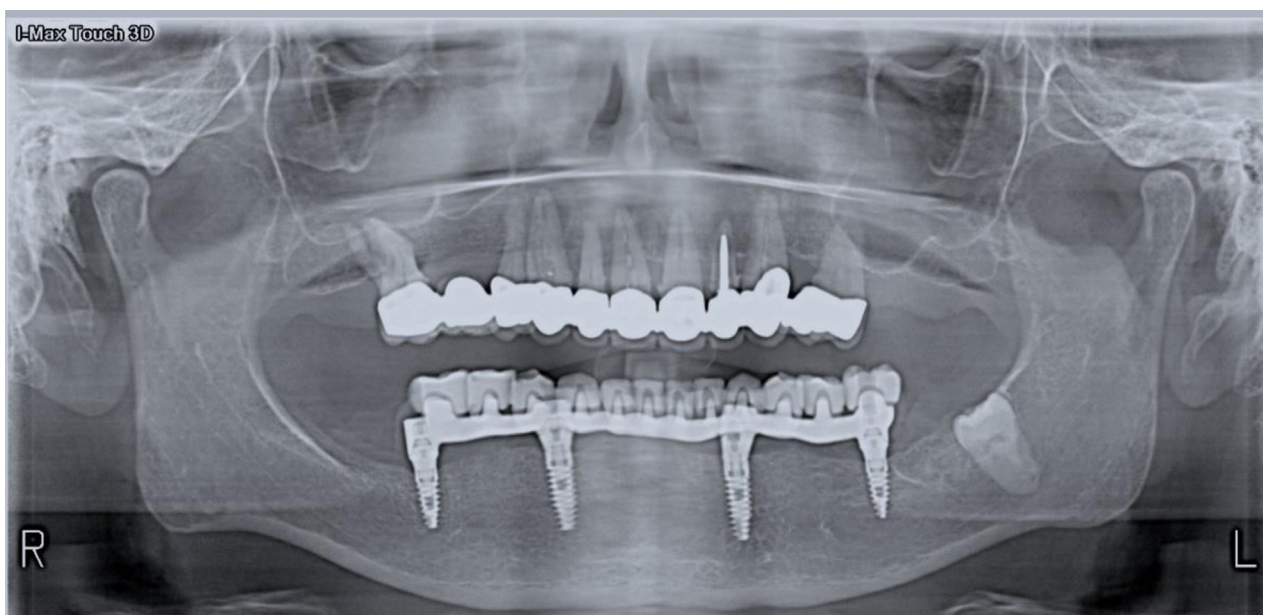


Fig. 2. Lower full arch screw-retained implant supported rehabilitation.

Table I. Results from bivariate analysis of implant and target variables. *P*-value was obtained with Chi-squared test. Significant *P*-value are marked in bold.

	Number of healed implants (%)	Number of failed implants (%)	p-values
		Age (years)	0.05
age < 61	936 (97.6)	23 (2.4)	
age ≥ 61	1347 (98.8)	17 (1.2)	
		Gender	0.004
Female	997 (97.4)	27 (2.6)	
Male	1286 (99)	13 (1)	
		Smoking	0.99
No	1572 (98.3)	27 (1.7)	
Yes	711 (98.2)	13 (1.8)	
		Diabetes	0.265
No	2165 (98.2)	40 (1.8)	
Yes	118 (100)	0 (0)	
		Arterios Hypertension	0.424
No	2105 (98.4)	35 (1.6)	
Yes	178 (97.3)	5 (2.8)	
		Anterior Posterior	0.919
Anterior	1094 (98.2)	20 (1.8)	
Posterior	1189 (98.3)	20 (1.7)	
		Maxilla Mandible	0.004
Maxilla	1289 (97.6)	32 (2.4)	
Mandible	994 (99.6)	8 (2.4)	
		Open Closed	0.005
Open	1770 (98.7)	23 (1.3)	
Closed	513 (96.8)	17 (3.2)	
		GBR	1.0
No	2029 (98.3)	36 (1.7)	
Yes	254 (98.4)	4 (1.6)	

within the range already reported in the literature (0.7–6.3%) [7,14,15]. In the present study, we included only patients treated with the same implant system and same rehabilitation with screwed fixed full-arch prostheses. The reason was to standardize as much as possible the type of rehabilitation and the consequent healing modality of the implants (submerged with a provisional removable prosthesis during the healing phase of the implants or immediately loaded). Regarding to patient lifestyle, smoking is considered as the most important

risk factor both for early and late failure of osteointegration [7,16]. Impaired blood circulation in the areas just adjacent to the implant placement can jeopardize a correct osteogenesis and angiogenesis with subsequent important consequence on healing tissue [17]. A recent meta-analysis analyzing more than 100 studies has shown that failures of implants placed in smoker patients are 2.23 times more likely to happen than failures of implants inserted into nonsmokers [16]. This correlation was not found in our study, conversely confirmed

Table II. Result from univariate, mixed model analysis with dependent variable osteointegration (yes/no) participants as random factor and target variables as fixed factor. Significant *P*-value marked in bold.

Names	Effect	95% Exp(B) Confidence Interval			p-values
		odd ratio	Lower	Upper	
Age	ETA>=61 - ETA<61	0.472	0.244	0.914	0.026
Anterior Posterior	Posterior - Anterior	0.875	0.464	1.648	0.679
Maxilla Mandible	Maxilla - Mandible	2.447	1.102	5.433	0.028
Open closed	Open - Closed	0.392	0.201	0.765	0.006
Gender	M - F	0.406	0.205	0.803	0.010
Smoking	SI - NO	1.042	0.522	2.080	0.907
Diabetes	Yes - No	2.03e-7	3.77e-68	1.09e+54	0.829
Arterial Hypertension	Yes - No	2.448	0.914	6.555	0.075
GBR	SI - NO	0.478	0.163	1.402	0.179

what reported in other recent studies that failed to identify smoke as affecting early or late implant failure [10,18]. It might also be scrutinized that the number of cigarettes smoked is correlated with bone healing, as reported in previous study [6], but this detail was not including in our study. In addition to smoking, other disorders such as diabetes mellitus is associated to early failure in osteointegration [19]. Diabetes is a metabolic chronic disease that occurs when pancreas does not produce enough insulin or when the body can't use the insulin that it produces. Hyperglycemia affect different aspects of tissues healing and in general leads to a greater predisposition to infection of the wound that can alter the osteointegration process [20]. In this study, however, no association was observed between the presence of diabetes and osteointegration. One reason should be that participants were compliant with anti-diabetic medication and diabetes was well controlled. This result agrees with the meta-analysis of Chrcanovic in which was not found a significant statistically difference in implant failure rates placed in diabetic and non-diabetic patients [21]. Also, the role of age in implant failure is controversial. Reduced bone quality associated with an increase of systemic disorders and intaking medicines could affect the healing of the wound. Moy reported higher failure rate in patients aged >60 years [22], otherwise Park et al. found that elderly patients (>65 years) reported significant

higher survival rates [23]. According to the retrospective study of Kang bivariate analysis didn't find significance age-related differences in early implant failure [24]. However, it is possible that biologic age might be more relevant than chronological age. On the other hand, authors found that female gender was significantly correlated with early failure than male patients, as opposed to what was reported by Sverzut who found a 1.2 higher risk in male for early implant failure [25]. Regarding the implant-level variables, among the most discussed topic in the literature about early failure risk factors there are the location of implant placement and their healing modalities. Several studies showed how bone quality and quantity can influence the correct osteointegration process. Implants installed in maxilla were found to have a 2.4 higher risk of early failure in this study, in agreement with the literature. This result is consistent with a recent meta-analysis of Manzano who revealed that the maxilla location was a significant risk factor (odds ratio 1.27) for early failure of dental implants [26]. According to Noda et al., this result can be explained for the different bone quality between maxilla and mandible and for the need in a full arch rehabilitation to place implants in the upper posterior sites where the bone quality has a lower level of corticalization [27]. On the contrary, bivariate analysis showed no significance difference ($P=0.9$) between implants placed in anterior or posterior sites, with the same number of failures

[18]. This result is inconsistent with several studies [7,24]. However, other studies report contradictory results and there is no consensus to consider the implant placement in maxilla or in posterior areas as potential risk factor [27,28]. When implant healing modalities have been evaluated several studies showed opposite results [3,18]. Bivariate analysis and univariate mixed model analysis revealed a significant correlation between submerged implants healing than open healing (immediate loading). One explanation may be due to the fact that provisional total prosthesis generates trauma on the implant wound during the post surgical healing. Controversial results existed also for the influence of bone augmentation procedures as a potential risk factor for early implant failure. Several studies observed a negative influence of bone augmentation both on early and late failures of implants [29,30] whereas others showed no correlation [7]. In the present study, authors identify no association between implants placed in augmented sites and early implant failure. The biggest limitation of this research was that is a retrospective study and consequently a lack of specific information. This gap of information characterizes mainly the patient's systemic condition such as the real glycate value in diabetic patients that play a key role factor in tissue healing and patient's bad habit such as the number of cigarettes per day in smoker patients. Another gap in the study is the partial lack of data relating to some potential risk factors such as the condition of the dentition in the opposite arch or the registration of the implant insertion torque. The authors agree that one of the major strengths of the study is represented by the fact that a relatively large sample of patients were treated in the same clinics (but different surgeons with different professional experience) and with the same implant system (Avenir srl, Rimini Italy) which allows a homogenization of the sample.

Conclusions

Implant supported fixed full arch restoration can be considered as a good treatment option for patients with edentulous jaws. This study identified female gender, upper arch implant location and submerged implant healing as potential risk factors for early implant failure. Other research with larger samples and more homogeneous variables will have to be done to confirm these associations. Furthermore, other variables can affect the early implant failure such as implant's length and diameter, torque insertion value and bisphosphonate intake but we didn't find enough information in clinical patient's file.

Conflicts of interest

There was no conflict of interest in this manuscript.

Funding

The full cost of the study was paid by the authors.

Ethical Approval

This study followed the STROBE (STrengthening the Reporting of OBServational studies in Epidemiology) guidelines, approval from an ethical committee was not required.

Informed consent

All participants of this study signed informed consent forms and their data kept confidential.

Author's contribution

Matteo Di Lorenzo participated to Concept/Design, Data analysis/interpretation, Article writing, Approval of article. Andrea Torsanii participated to Concept/Design, Patient recruitment, Clinical management, Critical revision of the article, Approval of the article. Paolo Tonveronachi participated Concept/Design, Critical revision of the article, Approval of article. Samuele Baruch participated to the statistical evaluations, reporting data in text and tables, and Approval of the article.

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