

Clinical and biological factors related to oral implant failure : a two-year follow-up study

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Summary

Purpose : To evaluate urinary biomarkers of bone formation and resorption as predictive factors, and to contribute to the knowledge of clinical related to oral implant failure.

Methods : Ninety three patients aged between 18 to 85 years, with an indication of oral implant, were eligible in this two-year prospective, open and non-randomized study. Patients who had bone graft before implantation or presented with prosthetic difficulties (implant to crown ratio <1 , and/or unfavorable intermaxillary space) were excluded. All patients received either FRIALIT-2® screwed or cylinder implants with DRS coating or IMZ Twin Plus® cylinder implants, with FRIADENT TRS coating. Serum osteocalcin (OC), and urinary pyridinolines (PYD) and deoxypyridinolines (DPD) were measured, together with bone density at implant location. The primary endpoint was the implant removal (radiographic evidence of peri-implant bone loss and/or pockets). Factors related to implant failure were analyzed using multi-level logistic regression models to take into account within-patient effects.

Results: Of the 93 included patients, 61 % were female and 16 % were current smokers. 266 oral implants were placed and analyzed, with a mean of 3.1 implants by patient. Eleven and 15 % of bone locations scored at D1 and D4, respectively, for the Misch bone density scoring. The majority of implants (72 %) were placed more than three months after tooth extraction, using a FRIALIT-2® implant in 73 % of cases. The mean of OC was $17.3 (\pm 9.4)$ ng/L; those of PYD and DPD were $33.2 (\pm 15.8)$ and $10.2 (\pm 11.9)$ mmol/creatinin mmol, respectively. At one year, the success rate was 95.5 % [92.5-97.5]95%_{o/c}. One year later, no further implant failed. In both uni- and multivariate analysis, OC, PYD and DPD were not significant predictive factors of oral implant failure. In multi-level logistic regression analysis, only tobacco consumption, and single-tooth replacement or removable prosthesis were independent and significant predictive factors of oral implant failure.

Conclusion: Serum osteocalcin, and urinary pyridinolines (PYD) and deoxypyridinolines (DPD) were not predictive of oral implant failure in our study. Our results suggest that oral implants are more likely to fail for posterior single-tooth replacements and removable prosthesis than for complete edentulous fixed bridgeworks or overdentures. Tobacco withdrawal should be highly recommended to patients who undergo oral implants.

Introduction

The introduction of osseointegration principles and improved surgical protocols resulted in an increasing number of oral implants in clinical practice^{1,2}. In spite of few contraindications and high long-term success rates in rehabilitation of fully edentulous³, partially edentulous⁴, and single tooth replacements⁵, there are still cases in which oral implants fail. Risk factors of implant failures can be divided in two main categories. The first one includes factors related to surgical techniques, types and locations of implants, and timing between tooth extraction and implantation. The second group of risk factors includes those related to patients characteristics, such as uncontrolled diabetes⁶, alcohol abuse⁷, and smoking⁸. Several studies suggested that poor quality and quantity bone, and osteoporosis^{9, 10}, are possible risk factors of implant failures. However, this issue is still debated, and as far as we know, no reliable biological predictive factor has been identified.

Until recently, urinary calcium and hydroxyprolines have been the only known markers of bone resorption. Serum alkaline phosphatases have been recognized as markers of bone formation. However it has also been shown that they were neither very sensitive nor specific. Other biomarkers, such as osteocalcin (OC), pyridinolines (PYD), and deoxypyridinolines (DPD) have been identified". During bone formation, newly synthesized OC, a non-collagenous protein found only in bone and dentin, is released into the bloodstream by osteoblasts and is indicative of bone formation rate¹². PYD and DPD are breakdown products of collagen cross-links, released into the blood stream during bone resorption, excreted unmetabolized in urine and unaffected by diet¹³. As far as we know, these biomarkers that have never been studied in the context of oral implants.

The present study aimed to evaluate osteocalcin, and pyridinolines and deoxypyridinolines as predictive factors of oral implant survival, and to contribute to the knowledge of clinical factors related to oral implant failures.

Material and methods

Patients

The investigated population was composed of ail patients treated in the Department of Periodontology (Hospital Ambroise Pare, Marseille, France) who gave an informed consent to participate in the study between November 1997 and November 1999. It comprised 57 female and 36 male patients, aged between 18 to 85 years (mean : 60.5 years.). Of the 57 female patients, 49 (86 %) were menopausal of whom nine (23%) had received hormone replacement therapy. Sixteen percent of patients were current smokers.

Prosthetic indications for oral implants were as follows : removable full prosthesis (42%), posterior single-tooth restoration (5 %), with partially or complete edentulous fixed bridgeworks, or overdentures (53%). Patients who had bone graft before implantation or presented with prosthetic difficulties (implant to crown ratio less than one, and/or unfavorable intermaxillary space) were excluded from the study, in order to provide a more homogeneous sample of patients.

Procedures:

Age, sex, information on menopausal status and hormone replacement therapy, and current smoking habits (at least one cigarette per day : yes/no) were obtained at baseline from interview and medical records.

Blood and overnight urine samples were obtained at baseline for ail patients. Ail samples were operated by a central laboratory (Marcel Merieux Institute, France). Radio-immunometric techniques with monoclonal antibodies were used to measure OC (Cis-Bio International Eisa Kit) and DPD (Pyrilinks-D RIA kit, Metra Biosystems, Dade Behring)¹⁴. PYD was assayed using high-pressure liquid chromatography¹⁵. As normal laboratory ranges differ according to sex and age, ail patients were classified as less than lower limit of normal range, within the normal range, and greater than upper limit of normal range.

Screening procedures included a detailed extra- and intra-oral examination, dental, periodontal, and functional examinations, and photographs. Ail patients underwent multi-modal imaging System (Scanora 1.7®, Soredex Finndent Orion Corporation, Helsinki, Finland) to provide reference images, and to determine the residual bone volumes.

Computer tomography with multiplanar reconstruction (Dentascan®, General Electric Medical Systems, Milwaukee, USA) was performed to evaluate residual bone volumes and the density of cortical bone¹⁶.

Clamoxyl (3 g) was orally given one hour before surgery¹⁷. Iodised povidone was used for preoperative decontamination of the oral cavity¹⁸. Ubistesin with adrenaline diluted 1 per 100.000 was used for local anesthesia. Biopsies were obtained with a 2 mm drill from the site of implant. Tissue sections, 3 to 4 microns in thickness, were stained with hematein, eosin and safran, then observed by one trained pathologist using Leitz Labor Lux microscope (Germany).^(#) Implants were placed either within the three months following extraction (immediate implants) or further (delayed implants). The surgical technique for the Tübingen immediate implant FRIALIT-1® first published by Schulte and Heimke¹⁹, was adapted for use with the FRIALIT-2® Implant²⁰. The method described by Worthington and Branemark was used for delayed implants²¹. FRIALIT-2® screwed or cylinder implants with FRIADENT TPS coating and IMZ® Twin Plus, cylinder implants with the same coating, were used in this study (FRIADENT Mannheim, Germany). Length and diameter of implants were determined according to bone evaluation (thickness, height, density) and prosthetics needs. Bone density was scored using visual inspection and dentascan according to the Misch's classification²²

Recall visits were scheduled for suture removal, and reopening surgery. The osseointegration of each implant was clinically assessed, and using Scanora 1.7®, at 12 and 24 months with a tolerance of deviation up to 2 months. All patients were highly educated and motivated for oral hygiene. Oral implants were considered as failed when they had been removed at endpoint (or previously) due to a bone loss evidenced by Scanora 1.7® (more than one third of implant length) and/or probing depths greater or equal to 3 mm.

Statistical analysis

Characteristics of patients and implants were described by counts and percentages. Associations between patients characteristics and implant failure at first year (at least one implant failure for one patient) were tested using the Chi-square statistic or Fisher's exact

test, in case of cells with less than five observations. Our data formed a hierarchical structure of implants nested within patients, and explanatory variables were measured at each of these two levels (e.g. age was measured at patient level, implant diameter was measured at implant level). The utility of multilevel, or hierarchical, models is well documented, and the methods have been applied in a variety of health settings²³. Liang and Zeger formalized an approach to this problem using Generalized Estimating Equations (GEEs) to extend Generalized Linear Models to a regression setting with correlated observations within subjects²⁴. The method is based on the principal that implants are naturally grouped into patients, and that characteristics of a given patient may influence the outcome of oral implants. In other words, as implants are not statistically independent, modeling the risk of oral implant failures must include patients effects. Logistic regression was used to model the binary outcome (oral implant failure), and parameters were obtained fitting GEEs regression models. Each implant characteristic was first tested separately. A saturated model including all characteristic with a p-value less than or equal to 0.20 was then constructed. The final model was obtained through a backward stepwise procedure. First-order statistical interactions were tested in the final model. All statistical computations were performed using SAS® software 8.1 (SAS Institute Inc., Cary). Fitting GEE regression models was performed using Stata® software 5.0 (Stata Corporation, Texas, USA).

Results

Table 1 shows the main results for patients characteristics, according to oral implant survival at first year. The mean number of implants was 3.1 per patient, ranging from one to 12 implants. Seven of 93 patients (7.5 %) experienced at least one oral implant failure at first year of follow-up. At second year, no further implant failed. Survival of oral implant at first year was not significantly related to age, sex, and menopausal status (for women). Smoking was significantly related to oral implant failure. The baseline mean of serum osteocalcin was 17.3 ng/L ; those of urinary pyridinolines, and deoxypyridinolines were 33.2 and 10.2 mmol/creatinin mmol, respectively.

When patients values were classified according to age and sex, 15%, 29%, and 14% of patients had values less than lower values of normal range for OC, PYR, and DPD respectively. Patients whose implants survived did not differ for OC, PYR, and DPD from patients whose implants did not survive. A total of 266 oral implants were placed and covered during the study period (Table 2). The majority of implants were placed more than three months after extraction, using a FRIALIT-2® model, and a screwed form in most of cases. Implants were mainly located in the mandible; 11% and 15% of bone locations scored at D1 (low density/quality) and D4 (high density/quality), respectively, for the Misch scoring of bone density/quality. After one year, 95.5 % [92.5-97.5]_{95%o/c} of oral implants survived. After two years, no further implant failed among the 452 that were followed up. The results of the univariate analysis are presented in Table 2. This analysis showed that implant survival was more likely to be reported with complete edentulous fixed bridgeworks or overdentures than in other prostheses or bridgeworks, and when implant diameter was greater or equal than 3.8 mm. Multi-level logistic regression models (including the within -patient effect) did not show any significant relationship between OC, PYR, and DPD (p values ranging from 0.29 and 0.96). Table 3 displays the results of the final multi-level logistic regression model of the risk of oral implant failure at first year, adjusting for patient and type of implant (FRIALIT-2® or IMZ Twin Plus). Implants were more likely to fail among smokers (relative risk (RR) multiplied by 14.4), and patients who received posterior single-tooth replacement or removable prosthesis (RR multiplied by 9.2). Biomarkers of bone modeling, together with other study variables, were not retained in the final multi-level logistic regression model.

DISCUSSION

Our study showed that serum osteocalcin, urinary pyridinolines, and deoxypyridinolines were not reliable predictors of oral implant survival. Other factors related to patients (smoking) and indications of implants (posterior single-tooth replacement and removable prostheses) were more likely to explain oral implant failures at the first year.

Both design and analysis of our study strengthen the reliability in our results. First, our sample is comparable for several characteristics to others reported in previous studies, in particular for mean age of patients²⁰. On the other hand, our sample was different regarding the position of implant. For example, Gomez-Roman et al. placed most of their implants in the anterior region of the maxilla while in our study they were placed mostly in the anterior region of the mandible. Our study included a high number of patients and implants fitting generalized estimating equations (GEEs) logistic regression models has been shown very useful in health research²³. Using that technique allows to obtain more powerful analyses, and, in the end, more reliable estimates of risk²⁵. In the future, these techniques should be more often employed in research on oral implants, in order to take account the potential confounders and the hierarchical structure of data with implant nested within patients²⁶.

The oral implant survival rate in our study was similar to that reported by other authors^{8,17}. Henry reported success rates approaching 100 % with implants located in mandibles, and 73 to 97 % with implant located in maxillae; the results being slightly better for single-tooth replacement and fixed bridgeworks than for overdentures²¹. In our experience, such as Gomez-Roman et al¹⁷, we did not observe any significant difference between the maxilla and mandible, even after adjustment for potential confounding factors. Henry emphasized the importance to present results according to the type of prostheses and bridgeworks that cover implants. In our case, after adjustment for the other potential confounding factors, implant failure was more frequent among implants placed in patients who had either posterior single-tooth replacement or removable denture. Explanation for this result remains unclear. The issue of timing between implant and prosthetic rehabilitation is still debated. Gomez-Roman et al suggested that most losses occurred in delayed implants, mainly because of

inadequate techniques²⁰. In our study, we did not observe, both in univariate and multivariate analyses, any relationship between delay tooth extraction and implant. Our results suggest that implants should be not delayed after tooth extraction. Moreover Friberg et al. reported that the shortest implants had the highest failure rate both in the maxillae and mandibles²². In our series, we observed a significant relationship between survival and diameter of implants. However, after adjusting for smoking and indication of implants in a multivariate analysis, we did not observe any significant impact of implant diameter.

Smith et al. suggested that increasing the number of implants per area contributes to an increased complication rate⁶. On the other hand, Branemark et al concluded that four implants do as well as six to support fixed full prostheses in edentulous jaws²⁹, and Henry stated that the tendency of some clinicians to place as many implants as possible should be seriously questioned. Actually, in our experience, there was no significant relationship between the number of implants and implant failure. The remaining question for survival analysis of oral implant is : Do we have to consider implant failure or restoration (prosthesis or bridgework) failure? If we consider the treatment success, it is likely that a higher number of implants could provide more chance of success. Further comparative studies should be carried out to answer this issue.

There is still a controversy about the impact of osteoporosis on implant failure^{9,30}. In our study, biomarkers of bone remodeling, such as osteocalcin that is indicative of bone formation rate, and pyridinoline and deoxypyridinoline that are released during bone resorption, were not associated with implant failure. In the same way, the bone density/quality scored according to the Misch's classification was not related to oral implant survival. However, it is noteworthy that 15-30% of patients in our sample had values lower than normal ranges for these biomarkers of bone modeling. Further investigation is necessary to study these markers in periodontal diseases. As others authors^{6 31 32}, we did not find any relationship between implant failure, age and gender. However, we also observed a strong relationship with smoking habits. In our experience, smoking was the most contributing risk factor, multiplying the risk of implant failure by 14. Duyck and Naert reminded several explanations, such as the role of tobacco on the microflora, the inflammatory response, and the neutrophilic function, together with

inadequate techniques²⁰. In our study, we did not observe, both in univariate and multivariate analyses, any relationship between delay tooth extraction and implant. Our results suggest that implants should be not delayed after tooth extraction. Moreover Friberg et al. reported that the shortest implants had the highest failure rate both in the maxillae and mandibles²². In our series, we observed a significant relationship between survival and diameter of implants. However, after adjusting for smoking and indication of implants in a multivariate analysis, we did not observe any significant impact of implant diameter.

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of patients.

Further prospective, large-sized and long-term studies should be carried out to identify other predictive factors of failure implants, especially according to the choice of prostheses and techniques, the number of implants and local conditions, and to clarify the role of bone quality/density and osteoporosis. However more data should not be awaited any longer to prompt tobacco prevention among patients who undergo oral implant surgery.

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Table 1 : Main characteristics of patients according to oral implant survival at first year (univariate analysis; n=93)

	Total* (n=93)	Survival (n=86)	Failure (n=7)	P
Age (years)*	60.5 (12.3)	60.6 (12.2)	59.3 (13.9)	0.79
Sex				0.99
<i>Female</i>	57 (61%)	53(93%)	4(7%)	
<i>Mâle</i>	36 (39%)	33 (92%)	3(8%)	
Menopausal women				0.70
<i>No</i>	8 (14%)	8(100%)	0	
<i>Yes</i>	36 (63%)	33 (92%)	3 (8%)	
<i>Yes, with hormonal replacement therapy</i>	13 (23%)	12 (92%)	1 (8%)	
Tobacco				0.01**
<i>Smoker</i>	15 (16%)	11 (73%)	4 (27%)	
<i>Non-smoker</i>	78 (84%)	75 (96%)	3(4%)	
Osteocalcin (ng/L)*	17.3 (9.4)	18.0(9.6;	14.1 (7.2)	0.30
Osteocalcin lower than the normal range	14 (15%)	12 (86%)	2 (14%)	0.28
Urinary pyridinolines (nmol/creatinin mmol)*	33.2 (15.8)	33.0(16.1)	35.6(11.1)	0.72
Urinary pyridinolines lower than the normal range	27 (29%)	25 (93%)	2 (7%)	0.99
Urinary deoxypyridinolines (nmol/creatinin mmol) *	10.2(11.9)	10.2 (12.2)	10.0(6.9)	0.95
Urinary deoxypyridinolines lower than the normal range	13 (14%)	11 (85%)	2 (15%)	0.25
Number of implants*	3.1 (2)	3.1 (1.9)	3.6(3.4)	0.76

* mean (std)

** Fisher exact test

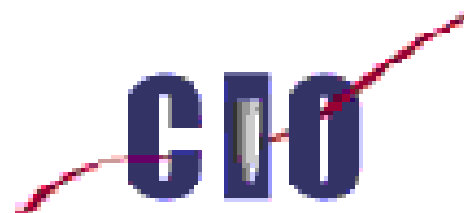
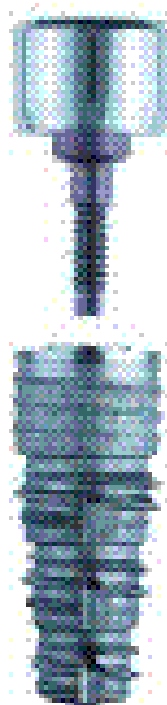
Table 2: Main characteristics of implants according to oral implant survival at first year (univariate analysis; n=266)

	Total* (n=266)	Survival At one year (n=254)	Failure year (n=12)	p
Indication of implant				
<i>Removable prosthesis</i>	111 (42)	101 (91)	10 (9.0)	0.006
<i>Single-tooth replacement</i>	14 (5.3)	13 (93)	1 (7.7)	
<i>Partially/Complete edentulous fixed bridge works or overdenture</i>	141 (53)	140 (99)	1 (0.7)	
Delay between tooth extraction and implant				
< 3 months	74 (28 %)	12 (97%)	2 (2.7%)	0.52
> 3 months	192 (72%)	182 (95%)	10 (5.2%)	
Type				
F2	194 (73%)	187 (96%)	7 (1.6%)	0.32
IMZ	12 (27%)	67 (93%)	5 (6.9%)	
Form				
<i>Screwed</i>	147 (55%)	140 (95%)	7 (4.8 %)	0.99
<i>Impacted</i>	119 (45%)	114 (96%)	5 (4.2 %)	
Site				
<i>Ant. Mandibule</i>	95 (36%)	90 (95%)	5 (5.3 %)	0.90
<i>Lat. Mandibule</i>	60 (23%)	58 (97%)	2 (3.3 %)	
<i>Ant. Maxillaire</i>	11 (29%)	73 (95%)	4 (5.2 %)	
<i>Lat. Maxillaire</i>	34 (13%)	33 (97%)	1 (2.9%)	
Bone quality/density at scanner (Misch scoring)				
D1	29 (11%)	26 (90%)	3 (10%)	0.25
D2-D3	196 (74%)	188 (96%)	8 (4.7 %)	
D4	41 (15%)	40 (95%)	1 (2.4 %)	
Diameter (mm)				
3.3	31 (11%)	26 (54%)	5 (76%)	0.004
3.8-4.5	197 (74%)	191 (97%)	6 (3.7%)	
5.5-6.5	38 (14%)	37 (97%)	1 (2.6%)	
Length (mm)				
8	11 (4.7 %)	11 (100%)	0	0.72
10-11	74 (28%)	70 (95%)	4 (5.4%)	
13-15	181 (65%)	173 (96%)	8 (4.4 %)	

* Column percentage

**Table 3: Multilevel logistic regression model of the risk of oral implant failure at first year
(number of implants = 266; number of patients = 93)**

Variable	<i>Référence</i>	Relative risk of oral implant failure	
Smoker	<i>(Non smoker)</i>	14.4	0.0001
Removable prosthesis or single-tooth replacement	<i>(Other indications)</i>	9.2	0.04
<u>IMZ implant</u>	<u><i>(Frialit F2 implant)</i></u>	0.99	0.99



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