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Early implant failure. Prognostic capacity of Periotest®: retrospective study of a large sample

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Abstract

Objectives: The objectives of this study were to determine the accuracy of Periotest® to monitor primary implant stability at first-stage surgery, to identify by multivariate analysis the variables associated with early implant failure and to compare Periotest® with radiographic study in the diagnosis of implant stability at second-stage surgery (during osseointegration period).

Material and methods: A 10-year retrospective study was conducted on 1084 Brånemark® implants placed in 316 patients. Clinical variables, implant diameter and length, Periotest® values (PTVs) and radiological variables were analyzed in bivariate and multivariate studies in order to determine their influence on early implant failure.

Results: After examination of the sensitivity and specificity values obtained for different PTV cutoff points, a cutoff PTV of -2 was selected (84% sensitivity and 39% specificity). In the bivariate analysis, early failure was significantly related to smoking habits, implant location, bone type, implant features and PTVs (-2 and ≥ -2). In the final multiple logistic model, only age (odds ratio (OR) = 4.53; 95% confidence interval (CI), 1.34–15.27), smoking habits (OR = 2.5; 95% CI, 1.3–4.79), bone type (OR = 1.93; 95% CI, 1.01–3.7) and PTV at first surgery (OR = 3.01; 95% CI, 1.5–6.02) were independently related to early failure.

Conclusions: The Periotest® (with -2 cutoff) at first surgery offers high sensitivity in the prognosis of early implant loss and shows a greater capacity to evaluate stability during the osseointegration period compared with radiographic study.

The earliest possible prediction of implant success remains a challenge. Failure of osseointegration before implant loading, within the first few weeks or months of implantation, is considered early failure, and loss of osseointegration after loading is considered late failure (Albrektsson et al. 1988; Adell et al. 1990; Tonetti 1994). Early failure can be caused by excessive bone injury during the implantation and by bacterial contamination, lack of primary stability or early implant loading (Tonetti 1994).

Osseointegration is a histological event that occurs gradually over a period of time; it is essential for implant stability before and during loading and must be correctly established for successful long-term function (Zarb & Albrektsson 1991). Various techniques and instruments have been proposed to test implant stability, including Periotest®, implant test, percussion test, resonance frequency analysis (Osstell® Integration Diagnostics AB, Sävedalen, Sweden), impulse testing, dynamic modal testing and radiographic study (Dario

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et al. 2002). Although Periotest® was originally designed to measure the damping characteristics of the periodontium around natural teeth, Periotest® (Schulte 1988) and radiographic study (Brägger 1998) are the most widely used assessment procedures in patients with osseointegrated dental implants. Periotest® is a non-invasive diagnostic method for evaluating implant–bone interface stability. Aparicio et al. proposed the use of Periotest® values (PTVs) as initial criteria for implant success after the clinical study of 315 consecutive patients with a total of 1182 Brånemark implants (Aparicio 1997; May et al. 1998). Periotest® can be used at first-stage surgery (implant insertion) for the objective measurement of primary implant stability and at second-stage surgery for complementary assessment during the osseointegration period.

The sensitivity and specificity of diagnostic procedures to determine the degree of implant stability have yet to be elucidated. The objectives of this study were to determine the accuracy of Periotest® to monitor primary implant stability at first-stage surgery, to identify by multivariate analysis the variables associated with early implant failure and to compare Periotest® with radiographic study in the diagnosis of this stability at second-stage surgery (during osseointegration period).

Material and methods

A retrospective study was conducted on 1084 Brånemark® implants (Nobel Biocare Ibérica, Barcelona Spain) placed in 316 consecutive patients at a single periodontal clinic during a 10-year period. The following data were gathered on all patients.

Clinical variables

Data were collected on age, gender and smoking habit at time of surgery (four categories: 0; non-smoking; 1; 1–10 cigarettes/day; 2; 11–20 cigarettes/day; 3; >20 cigarettes/day). Periodontal status before implant insertion was determined by clinical probing and radiographic study, assigning patients to one of three groups (without periodontitis, with periodontitis, edentulous). Patients with periodontitis were treated before implant placement. The degree of periodontitis was defined as previously reported (Arbes et al. 1999) by the percentage of sites with loss of attachment >3 mm (0% = absent; 0–32% = mild; 33–66% = moderate; 67–100% = severe).

Implant-related variables

Brånemark® implants with the same surface configuration (non-threaded titanium) and different diameters (3.3, 3.75, 4, 5 and 5.5 mm) and lengths (7, 8, 8.5, 10, 11.5, 12, 13, 15 and 18 mm) were used. Implant diameter and length were considered as independent continuous variables. The location of the implant was recorded as mandibular ($n = 433$) or maxillary ($n = 651$) and anterior ($n = 507$) or posterior ($n = 577$), and it was noted whether the anchorage was monocortical or bicortical. Bone quality at surgery was classified in one of four categories according to the criteria proposed by Lekholm & Zarb (1985). Finally, it was recorded whether the implant was lost or removed at an early stage (before or at stage-two surgery). Implants were considered to have failed and were removed according to clinical criteria of mobility, pain and gingival inflammation.

PTV and radiographic variables

Periotest® (Siemens AG, Bensheim, Germany) was used to record PTVs (range −8 and +50) at first- and second-stage surgery, following the manufacturer's instructions. A Takara Belmont DK-068 X-ray unit with a 65 KVp 8 mA head was used for the intraoral radiographic study (Belmont House, London, UK). The Digora® system for Windows 2.0 (Orion Corporation Soredex, Finland) was used to capture and manage the intraoral radiographic images; 35 × 45 mm and 466 × 628 pixel image plates were used, and parallelism was assured by use of a positioner (Testset; Kerr Hawe, Kerr Corporation, Orange, CA, USA). Horizontal bone loss (RC) was classified as absence of implant thread without bone (RC1), height loss of 0–20% (RC2) or height loss of >20% (RC3). Vertical bone loss (RS) was categorized as absence of lateral radiolucency (RS1), lateral areas of <30% radiolucency (RS2) or lateral areas of ≥ 30% radiolucency (RS3).

Statistical analysis

To determine the accuracy of Periotest® at first-stage surgery to predict early failure, the area under the ROC curve was calculated using the trapezoid method (non-parametric method) of Hanley & McNeil (1983). Because the comparison of ROC curves was in paired samples, the method of DeLong et al. (1988) was applied. A bivariate analysis was carried out using the Rao & Scott (1981) method to identify the variables associated with early implant failure. Multivariate logistic regression analyses for grouped values were then performed following the methods proposed by Binder (1983) and Kish & Frankel (1974), to determine the independent influence of each variable.

The design, coding and debugging of the database and the statistical analysis were carried out using STATA PC/Windows version 8.0 (StataCorp LP, College Station, TX, USA).

Results

Diagnostic ability

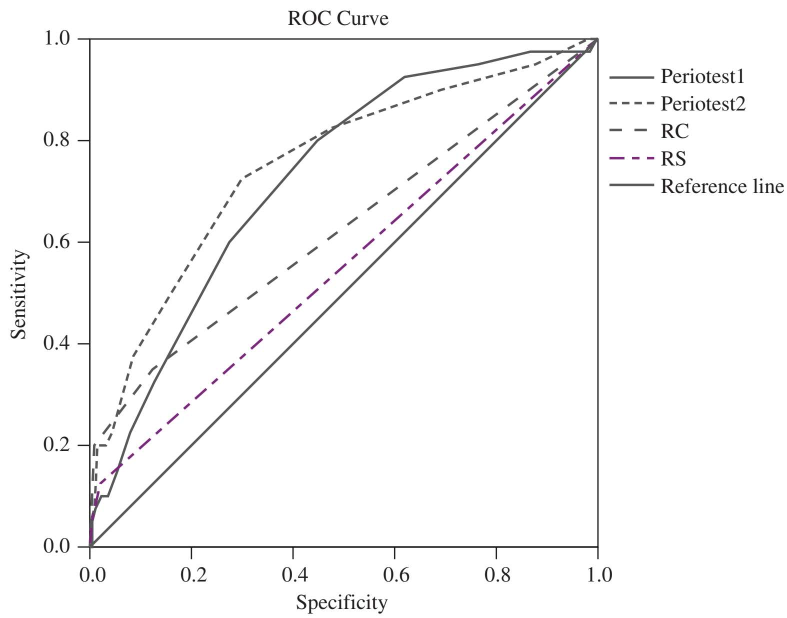
The of the PTVs at first- and second-stage surgery and of the RC and RS radiographic variables as a test of early implant failure is expressed by the ROC curves depicted in Fig. 1, showing the areas under the curve (SD, 95% confidence interval (CI)). In the paired comparison of the four areas, the areas for PTVs at first surgery, PTVs at second surgery and the RC variable significantly differed from the RS area ($P = 0.0015$, 0.0001 and 0.0132, respectively).

Different sensitivity and specificity values were obtained for Periotest® at different cutoff points, and a cutoff PTV of −2 was considered to offer the optimal results (84% sensitivity and 39% specificity) (Table 1).

Model for early failure

Bivariate analysis

First, a bivariate model to predict early implant failure was constructed including all variables of possible interest. Table 2 shows the significant association found between early implant failure and the following variables: age, smoking habits, implant location (maxillary or mandibular), location area, bone type, implant features (diameter and length) and PTV (cutoff of −2).



Areas under the ROC curve of the different variables for early failure prognosis

Parameters	Area	SD	[95%CI]	
Periotest-first-stage surgery	0.7049	0.0374	0.63150	0.77828
Periotest-second-stage surgery	0.7259	0.0370	0.65336	0.79839
RC	0.6583	0.0365	0.58675	0.72980
RS	0.5655	0.0251	0.51619	0.61477

SD = standard deviation; RC = horizontal radiolucency; RS = vertical radiolucency

Fig. 1. Areas under the ROC curve of the different variables for early failure prognosis.

Table 1. **Sensitivity and specificity of Periotest® at first surgery using different cutoff points**

PTV	Failure		Total implant	Cutoff point	
	No	Yes		Spec.	Sens.
−8	2	0	2	0	100
−7	14	1	15	0.19	100
−6	38	1	39	1.55	98.18
−5	84	2	86	5.25	96.36
−4	108	1	109	13.41	92.73
−3	152	4	156	23.91	90.91
−2	177	5	182	38.68	83.64
−1	176	9	185	55.88	74.55
0	149	14	163	72.98	58.18
1	48	5	53	87.46	32.73
2	25	4	29	92.13	23.64
3	19	3	22	94.56	16.36
4	14	1	15	96.4	10.91
5	12	1	13	97.76	9.09
6	6	2	8	98.93	7.27
7	0	1	1	99.51	3.64
8	0	1	1	99.51	1.82
9	1	0	1	99.51	0
10	2	0	2	99.61	0
15	1	0	1	99.81	0
20	1	0	1	99.9	0
Total	1029	55	1084		

PTV, Periotest® value; Spec., specificity, Sens., sensitivity.

Multivariate analysis

Second, a multivariate logistic regression model was constructed using the variables that provided information on and showed independent influence on early implant failure (Table 3). For this analysis, age and smoking variables were each collapsed into two categories. The periodontal status variable, also considered in two categories (edentulous/non-periodontal and periodontal), was not significant (5%) but was retained in the model because it had a non-negligible effect (odds ratio (OR) 2.36, 95% CI 0.9–6.21). A three-category variable was created for implant diameter and length (see Discussion). The first category (≥ 15 mm length) was associated with a lower risk of early failure compared with the other two (<15 mm length and <4 mm diameter; <15 mm length and ≥ 4 mm diameter). The final model showed that this variable had a significant influence ($P=0.0428$), although the comparisons of the first category with the other two categories were not significant (Table 3). The PTV (cutoff of −2) at first-stage surgery showed a significant independent influence on early failure (OR 3.01; 95% CI 1.5–6.02).

Discussion

The aim of this study of 1084 non-threaded titanium implants was to evaluate the effectiveness of various methods for the prediction and diagnosis (sensitivity/specificity) of early implant failure.

The results obtained show that the PTV at first-stage surgery is a good predictor of early failure (area of 0.7049 under the ROC curve) and has a greater discriminative capacity compared with radiographic data obtained at second-stage surgery after completion of osseointegration, again showing a larger area under the ROC curve (0.7259). Our findings confirm previous reports that Periotest® values are more favorable (i.e., more negative) with longer wound-healing time (Morris et al. 2000; Engel et al. 2001; Deporter et al. 2002) although no statistically significant differences were found between PTVs at first- and second-stage surgery.

When a Periotest® cutoff value of −2 was considered, 84% of eventually failed implants were correctly identified (sensi-

Table 2. **Bivariate analysis**

Variable	Categories	Non-failure	Failure	F_{EXP}	P
Age	<40 years	112 (95.7%)	5 (4.3%)	3.27	0.022
	41–50 years	325 (93.7%)	22 (6.3%)		
	51–60 years	332 (93%)	25 (7%)		
	>60 years	260 (98.9%)	3 (1.1%)		
Smoking habits	Non-smoking	499 (95.8%)	22 (4.2%)	4.6296	0.0033
	<10 cigarettes/day	177 (96.2%)	7 (3.8%)		
	10–20 cigarettes/day	163 (98.2%)	3 (1.8%)		
	>20 cigarettes/day	187 (89%)	55 (11%)		
Location	Maxillary	611 (93.9%)	40 (6.1%)	2.7812	0.0964
	Mandibular	418 (96.5%)	15 (3.5%)		
Area	Anterosuperior	299 (94.3%)	18 (5.7%)	2.25	0.0825
	Posterosuperior	312 (93.4%)	22 (6.6%)		
	Anteroinferior	188 (98.9%)	2 (1.1%)		
	Posteroinferior	230 (94.7%)	13 (5.3%)	7.7935	0.0056*
Bone type	Type I	54 (93.1%)	4 (6.9%)	2.106	0.1103
	Type II	436 (97.1%)	13 (2.9%)	8.1643	0.0046†
	Type III	462 (93.7%)	31 (6.3%)		
	Type IV	72 (91.1%)	7 (8.9%)		
Diameter	<4 mm	756 (96.1%)	31 (3.9%)	5.6794	0.0178
	≥ 4 mm	273 (91.9%)	24 (8.1%)		
Length	<15 mm	549 (93.2%)	40 (6.8%)	6.7791	0.0097
	≥ 15 mm	480 (97%)	15 (3%)		
Periotest®	≤ −2	575 (97.6%)	14 (2.4%)	16.6063	0.0001
First-stage surgery	> −2	454 (91.7%)	41 (8.3%)		

*Because of the significances obtained, the probability of implant failure in the anteroinferior region vs. other regions was analyzed.
†Because of the significances obtained, the probability of implant failure on Type II bones vs. other bone types was analyzed.
The gender, menopause, and periodontal status variables were clearly non-significant.

Table 3. **Final multivariate model with variables that independently discriminated early implant failure**

Variables	Reference category	Risk category	Odds ratio	95% confidence interval
Age	>60	≤ 60	4.53	1.34–15.27
Smoking habits	≤ 20 cigarettes/day	>20 cigarettes/day	2.5	1.3–4.79
Oral status	Edentulous + non-periodontal	Periodontal	2.36	0.9–6.21
Bone	Type II	rest	1.93	1.01–3.7
Length (*L*), Diameter (*D*)	≥ 15 mm (*L*)	<15 mm (*L*) and <4 mm (*D*)	1.44	0.66–3.15
		<15 mm (*L*) and ≥ 4 mm (*D*)	1.96	0.97–3.95
Periotest® (first-stage surgery)	≤ −2	> −2	3.01	1.5–6.02

tivity) at first-stage surgery; only 39% of successful implants were identified (specificity), although this has less clinical relevance. At first-stage surgery, 515 implants presented a PTV of ≤ −2, and 14 of these were removed. Out of the 55 implants removed in the present study, 45 showed vertical and/or horizontal radiolucency compatible with normality on X-rays. Therefore, although several authors recently advocated the use of radiography to test implant success (Gröndahl & Lekholm 1997), our findings support those who have questioned its role in the diagnosis of osseointegration (Sewerin 1990; Albrektsson et al. 1994). The role of radiographic study to determine bone loss around implants has been challenged because of its limitations for vestibular and lingual surfaces and because of technical errors (Sewerin 1990; Bauman et al. 1992). The subjectivity of radiographic studies has been confirmed by the demonstration of a wide inter-examiner variability in the diagnosis (Sunden et al. 1995). Osseointegration cannot be guaranteed by radiographic methods because the maximum X-ray resolution under optimal conditions is 0.1 mm, 10 times the size of a soft tissue cell (Albrektsson et al. 1994).

According to the present results, Periotest® performs better than radiography as a prognostic method (at first-stage surgery) and it assesses implant stability as a complementary diagnostic technique for osseointegration (at second-stage surgery), given that sub-clinical implant mobility appears before signs of inflammation are detected by radiographic means (Gröndahl & Lekholm 1997). The present study was not designed to compare PTVs with osseointegration because of the lack of histological data and of PTVs during the implant loading.

Our results show that advanced age and menopause, which both produce loss of body bone mass, do not contraindicate implant treatment. The age variable, categorized into ages <60 years and ages ≥ 60 years, was an independent predictor of early implant failure (adjusted OR of 4.53). This effect may be caused by a selection bias, as over 60-year-olds would only be treated with implants under 'ideal' conditions or might, as past users of removable prostheses, value and take greater care of their new fixed prostheses.

Smoking showed a significant and independent influence on the bivariate and adjusted comparisons, in agreement with other findings in prospective studies of peri-implant marginal bone loss in smokers and the correlation between this loss and the number of cigarettes/day (De Bruyn & Collaert 1994; Lindquist et al. 1996, 1997). We considered >20 cigarettes/day as the cutoff point for our model, although a study with more early failures would probably have a lower cutoff point.

Esposito et al. (1998) published a review of 73 follow-up studies of Brånemark implants and reported more failures (early and late) in edentulous patients. We did not find this difference, although late failures were not recorded because our study finished at the second-stage surgery.

Although the periodontal status variable (edentulous/non-periodontal vs. periodontal) did not reach significance in our final adjusted model, we did not consider its effect to be negligible (see Table 3). In our study, all patients with periodontitis were previously treated before inserting the implants, and although our results do not contraindicate implant technique in this group of patients, the tendency of the effect suggests that they require periodontal treatment and especially close monitoring to ensure successful osseointegration.

In agreement with the majority of published studies (Quirynen et al. 1992; Hutton et al. 1995), implants not placed on type II bone had a 1.93-fold higher likelihood of early failure. In this context, Esposito et al. (1998) described surgical trauma, bone volume and bone quality as the most important factors in early implant failure.

Implants with the same surface configuration and variable size were used, from 3.3 to 5.5 mm in diameter and from 6 to 18 mm in length. The least risk of failure was shown by implants longer than 15 mm, followed by those less than 15 mm in length and less than 4 mm in diameter. The greatest failure risk was shown by 15-mm-long implants with a diameter larger than 4 mm, which were twice as likely to undergo early failure. These results support the conclusion by Friberg et al. (1991) that length is the implant dimension most related to early failure. The use of implants with a larger diameter has been recommended for increasing the surface area of bone–implant contact, for cases of inadequate bone height or poor bone quality, and for the immediate replacement of fractured or non-integrated implants (Langer et al. 1993; Jemt & Lekholm 1995). In the present study, however, implants of larger diameter did not show a higher success rate, at least up to the time of second-stage surgery.

The Periotest® (cutoff PTV $= -2$) offers high sensitivity in the prognosis of early implant failure and a greater capacity to assess stability during the osseointegration period compared with the data obtained by radiographic study.

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要約

目的：本研究の目的は、一次手術時のインプラント初期安定性をモニターする **Periotest®** の精度を測定し、多変量解析によりインプラントの初期の失敗に関連する変数を特定し、二次手術時（骨性結合期間）のインプラント安定性の診断において **Periotest®**とレントゲン像分析を比較することであった。

材料と方法：患者３１６名に埋入された合計１０８４本の **Branemark ®**インプラントについて１０年間の後ろ向き研究を行った。臨床的変数、インプラントの直径と長さ、**Periotest®**の値（**PTV**）及びレントゲン像の変数を二変量及び多変量解析によって評価し、これらがインプラントの早期失敗に影響を及ぼすかどうかを検討した。

結果：異なる **PTV** のカットオフ値で求められた感受性と特異性の試験後に、**PTV**－２をカットオフ値として選択した（感受性８４％、特異性３９％）。二変量解析では、早期の失敗は喫煙癖、インプラント部位、骨のタイプ、インプラントの特性と **PTV**（－２と≧―２）に有意に相関していた。最終の多重ロジスティック・モデルでは、年齢（オズ比［ＯＲ］＝４．５３；９５％ＣＩ、１．３４－１５・２７）と喫煙癖（ＯＲ＝２．５０；９５％ＣＩ、１．３０－４．７９）、骨のタイプ（ＯＲ＝１．９３；９５％ＣＩ、１．０１－３．７０）と一次手術時の **PTV** のみが、各々独立して早期の失敗に相関していた。

結論：一次手術時の **Periotest®**（カットオフ値－２）はインプラントの早期喪失の予後を高い感受性で示し、骨性結合期間の安定性を評価する上でレントゲン像の分析よりも優れた能力を示した。

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