Retrospective Study of the Survival and Associated Risk Factors of Wedge-Shaped Implants

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Purpose: *To assess the long-term behavior of wedge-shaped implants and evaluate the influence of the associated risk factors on implant survival rates.* ***Materials and Methods:*** *A retrospective review of clinical records of patients treated with wedge-shaped implants between 1992 and 2011 was conducted. Data on patient sex, age, smoking habits, and history of periodontitis; details of implant length, diameter, angle, and location; and data on surgical, reconstructive, and prosthetic procedures, and systemic disease were selected for analysis.* ***Results:*** *A total of 1,169 implants placed in 154 patients (mean age 55.17 ± 11.33 years) were evaluated. Women received 637 implants, and men received 532 implants; 60.4% were placed in patients who were undergoing periodontal maintenance care, 17.9% in smokers, 17.7% in hypertensive patients, 5.7% in diabetic patients, and 4.4% in cardiac patients. The mean overall survival for implants was 194.26 ± 9.91 months. Seventy-three implants were lost: 3 before implant loading and 70 after loading. The cumulative survival rates at 5 and 10 years were 96.6% (confidence interval [CI]: 95.5% to 97.7%) and 91.8% (CI: 90.1% to 94.1%), respectively. Univariate analysis indicated tobacco smoking (P = .014) and implant location (P < .001) as significant risk factors for implant failure. The multivariate analysis showed tobacco smoking (P = .016), location (P = .001), and male sex (P = .038) as significant, and the latter factor was associated with previous periodontal disease.* ***Conclusions:*** *Overall survival of the wedge-shaped implant showed good long-term results. Male sex, tobacco smoking, and posterior maxillary location were associated with a greater risk of implant failure.* Int J Oral Maxillofac Implants 2013;28:875–882. doi: 10.11607/jomi.2821

Key words: *dental implants, observational study, regression analysis, retrospective study, risk factors, survival rate*

In the last few decades, there have been significant advancements in the field of implant dentistry, leading to more predictable treatments for the rehabilitation of fully and partially edentulous patients. Correct macro and micro implant design, extensive understanding of the biologic and biomechanical properties of implants, and selection of a suitable surgical technique for a given patient's bone quantity and quality are major parameters affecting the long-term survival and success of dental implants.

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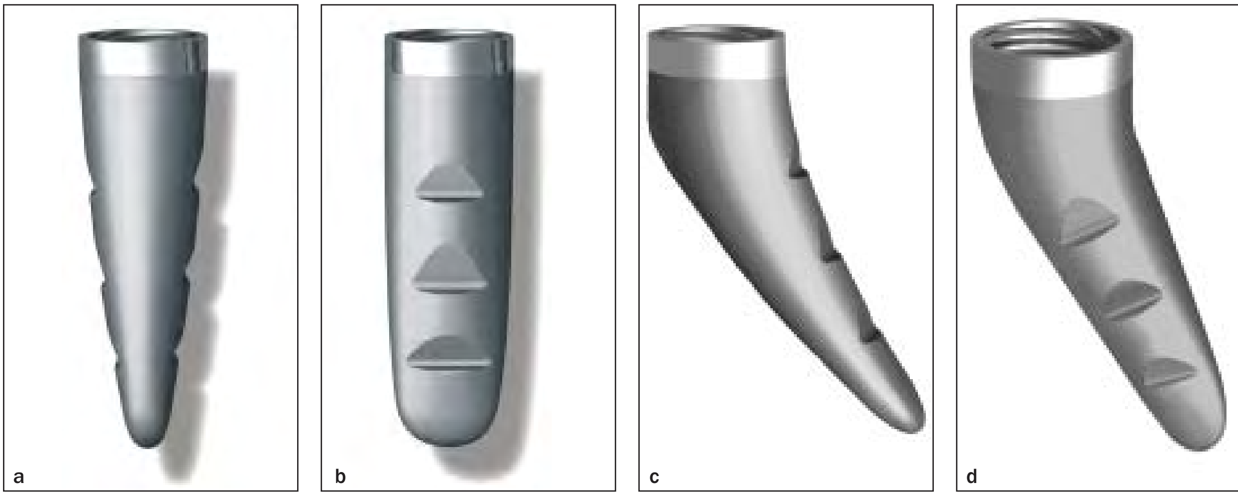

Figs 1a to 1d Wedge-shaped implants. Straight implant, *(a)* lateral view; *(b)* frontal view. Frontal angled implant, *(c)* lateral view; Lateral angled implant, *(d)* frontal view.

Over time the macro design of implants has gradually changed and evolved, becoming more efficient and attaining higher levels of applicability.[1,2]

The wedge-shaped implant, both straight and angled,[4,6–8] is a possibility that could enhance the applicability of implants and reduce the quantity and morbidity of reconstructive procedures before implantation (Figs 1a to 1d). This implant design, in which the characteristics change from circular in the platform to wedge-shaped in the body, is the main factor that allows implant-induced bone expansion,[3] so that the implant can separate the bone blades and fit into the osteotomy site properly. Its applicability index reached levels of 95.1%[5] because of the possibility of placing this type of implant in atrophic alveolar ridges without any previous or additional procedure. Its biomechanical behavior has been tested in different studies,[3–8] and the results have been shown to be favorable. The surgical technique used for placement can be performed by a professional who is well-trained in any dental implant technique. The osteotomy is performed using a conical drill, with the operator following the shape of the straight or angled implant. This preparation is made in the same manner as in a dental cavity preparation. After the implant layer has been tested with the implant analog, the implant is introduced by percussion. In cases of bone expansion, the crest is divided using a circular saw in the cortex and a 0.5-mm cylindrical drill in the medulla. Then, as the implant is introduced by percussion, it expands the bone crest due to its wedge-shaped design.

A large number of observational longitudinal studies have evaluated the prognosis and long-term functionality of different types of dental implants, reporting survival rates of around 90% to 96% over periods of 5 to 10 years.[9–20]

These studies have generated evidences that guarantee the safe clinical application of the technique. Overall survival is an important measure of dental implant success and the associated risk factors.[21,22] Several methods are used to estimate survival, including four-field table analysis, descriptive statistics, hypothesis tests such as the *t* test or chi-squared tests, life-table analyses, Kaplan-Meier analysis, and Cox multivariate proportional-hazards regression analysis.[18,22–24]

The purpose of this study was to retrospectively analyze of a group of patients who had wedge-shaped implants placed, to evaluate the medium- to long-term survival and the associated risk factors.

MATERIALS AND METHODS

With approval from the institutional review board of the Federal University of Juiz de Fora (CEP-UFJF-2245.305.2010 no. 341/2010), a retrospective review was conducted of clinical records of patients treated with wedge-shaped implants. This review included all patients treated with dental implants between mid-1992 and mid-2011 at the Clinest - Clinical Center of Research in Stomatology. Clinical histories were reviewed, and clinical and radiographic examination data were gathered. Only the reviewers had access to the records and to the database so that patients' identities were protected.

Only information related to wedge-shaped implants (Bioform, BiomacMed) was included in this research. Patients and implants that did not fulfill the following criteria were excluded:

- Records without a signed informed consent form allowing use of the data on research and case reports

- Missing information about any variable
- Information that was inconsistent, confusing, or subject to double interpretation
- Any written condition (physical or mental), informed by the patient, a companion, or in the dentist's notes, which could affect the patient's ability to maintain oral hygiene
- Records of patients with pathologies that were not included as variables but could seriously affect results, such as oral cancer and osteoradionecrosis

The implant data forms were originally filled out in a digital format. The forms were synchronized with a database (Excel, Microsoft), which was then synchronized with the statistical program (SPSS 15.0, IBM), eliminating the risk of changes in data during transfers.

The dependent variable was implant failure, defined as complete removal of the implant for any reason. The survival duration was calculated from the date of implant placement to the date of the last follow-up, which in the case of failures was implant removal.

The independent variables included the patient's age at the time of implant surgery; sex; smoking habit; systemic disease; periodontitis history; implant location; length; diameter; angle of the implants; and surgical and prosthetic procedures.[25–36]

Data on periodontal disease were retrieved from the clinical records. A history of periodontal disease (yes/no) of patients was considered when a diagnosis of previous periodontitis was recorded in the clinical history by the periodontist or the clinician. Patients whose records identified them as a current tobacco user were classified as smokers. Subjects who had never smoked or those who had stopped smoking at least 1 year before implant treatment were classified as nonsmokers.

Implant location was classified as anterior and posterior maxilla and anterior and posterior mandible. Implant variables included length: short (9 mm), regular (11 to 13 mm), and long (15 to 17 mm); diameter: narrow (3.3 mm), regular (4 mm), and wide (5 to 6 mm); and design: straight or angled (frontal or lateral angled). Surgical variables included sinus elevation technique, guided tissue regeneration with nonabsorbable membranes, bone substitutes, bone grafts, and bone expansion.

Cumulative proportion survival analysis was performed using life tables (actuarial). Kaplan-Meier methods were used to identify the survival rates and the risk that each variable represents. Cox proportional-hazards regression analysis modified for correlated dependent observations was also used, with the implant as the unit of analysis. Significance was set at $P < .05$ ($\alpha = .05$).

This study report was structured following the STROBE statement for observational studies.[34]

Table 1 Variables for Descriptive Statistics

Variable	No. (%) of implants	No. of failed implants
Implant status		
Failed	73 (6.24)	–
Survived	1,096 (93.76)	–
Demographic variables		
Age (y)		
< 45	221 (18.9)	16
45–65	745 (63.7)	44
> 65	203 (17.4)	13
Sex		
Female	637 (54.5)	33
Male	532 (45.5)	40
Smoking habit		
Nonsmokers	960 (82.1)	53
Smokers	209 (17.9)	20
Systemic disease		
Diabetes	67 (5.7)	2
Hypertension	207 (17.7)	7
Cardiac disease	51 (4.4)	0
Periodontitis history		
Yes	706 (60.4)	54
No	463 (39.6)	19
Anatomical variable		
Implant location		
Anterior maxilla	256 (21.9)	16
Anterior mandible	83 (7.1)	0
Posterior maxilla	385 (32.9)	41
Posterior mandible	445 (38.1)	16
Implant variable		
Length		
Short: 9 mm	5 (0.4)	1
Regular: 11–13 mm	82 (7.0)	9
Long: 15–17 mm	1,082 (92.6)	63
Diameter		
Narrow: 3.3 mm	467 (39.9)	17
Regular: 4 mm	584 (50.0)	39
Wide: 5-6 mm	118 (10.1)	17
Angle		
Straight	764 (65.4)	50
Angled	405 (34.6)	23
Operative variables		
Surgical procedures		
Sinus elevation	44 (3.8)	3
Nonabsorbable membrane	425 (36.4)	27
Bone substitute	278 (23.8)	17
Bone graft	13 (1.1)	2
Bone expansion	29 (2.5)	1
Prosthetic procedures		
Single crowns	203 (17.4)	14
Fixed partial prosthesis	874 (74.8)	57
Fixed complete prosthesis	92 (7.9)	2

Table 2 Actuarial Life Table for Wedge-Shaped Implants (n = 1,169)

Time (y)	No. of Implants: At beginning of interval	Censored	Failed	Cumulative proportion surviving at beginning of interval	Confidence interval: Lower 95%	Upper 95%	Standard error
0 – < 1	1,169	63	21	1.000	1.000	1.000	0.000
1 – < 2	1,085	104	10	0.982	0.973	0.988	0.004
2 – < 3	971	128	3	0.972	0.962	0.981	0.005
3 – < 4	840	108	2	0.969	0.958	0.976	0.005
4 – < 5	730	112	6	0.966	0.955	0.977	0.005
5 – < 6	612	124	10	0.958	0.946	0.970	0.006
6 – < 7	478	99	4	0.940	0.927	0.958	0.008
7 – < 8	375	64	5	0.932	0.917	0.951	0.009
8 – < 9	306	89	0	0.918	0.901	0.941	0.010
9 – < 10	217	50	3	0.918	0.901	0.941	0.010
10 – < 11	164	73	3	0.904	0.883	0.932	0.013
11 – < 12	88	38	1	0.882	0.859	0.921	0.016
12 – < 13	49	8	0	0.870	0.842	0.915	0.018
13 – < 14	41	18	0	0.870	0.842	0.915	0.018
14 – < 15	23	2	2	0.870	0.842	0.915	0.018

Table 3 Univariate and Multivariate Analysis of Factors Related to Implant Survival (n = 1,169)

Factor	Univariate analysis	Multivariate analysis
Age	.458	.080
Sex	.161	.038*
Smoking habit	.014*	.016*
Systemic disease		
Diabetes	.311	.438
Hypertension	.102	.309
Cardiac disease	.107	.136
Periodontitis history	.095	.619
Implant location	.000*	.001*
Length	.472	.497
Diameter	.177	.187
Angle	.849†	.946
Surgical procedures		
Sinus elevation	.520	.907
Nonabsorbable membrane	.652	.860
Bone substitute	.876†	.991
Bone expansion	.650	.699
Bone graft	.119	.477
Prosthetic procedures	.153	.084

In univariate analysis, the *P* value was calculated using the Kaplan-Meier method ($P \leq .005$); in multivariate analysis, the *P* value was calculated using the Cox regression model. ($P \leq .005$).
*Statistically significant values.
†Variables that were not included in the multivariate analysis to avoid possible effects of colinearity.

RESULTS

This study was conducted to evaluate the records of 154 patients, with a mean age of 55.17 ± 11.33 years (range, 20 to 87 years) who received 1,169 implants. The mean number of implants per patient was found to be 7.59 because the majority of the patients who were selected to receive this implant were completely edentulous. These patients received 10 to 12 implants in each arch. Patients who were partially edentulous received 1 implant per tooth lost.

Of the implants evaluated, 637 were placed in women and 532 in men; 60.4% (706 implants) were placed in patients who were undergoing periodontal maintenance care; 17.9% in smokers; 17.7% in hypertensive patients; 5.7% in diabetic patients; and 4.4% in cardiac patients. The majority of implants were placed in the posterior mandible (445 implants, 38.1%); 385 were placed in the posterior maxilla (32.9%), 256 in the anterior maxilla (21.9%), and 83 in the anterior mandible (7.1%). All patients were treated by one experienced oral surgeon and two experienced prosthodontists. Table 1 shows the distribution of the variables studied.

The mean overall survival for implants was 194.26 ± 9.91 months. A total of 73 implants were lost: 3 before implant loading (early loss) and 70 after loading (late loss). The cumulative survival rates at 5 and 10 years were 96.6% (confidence interval [CI]: 95.5% to 97.7%) and 91.8% (CI: 90.1% to 94.1%) respectively (Table 2).

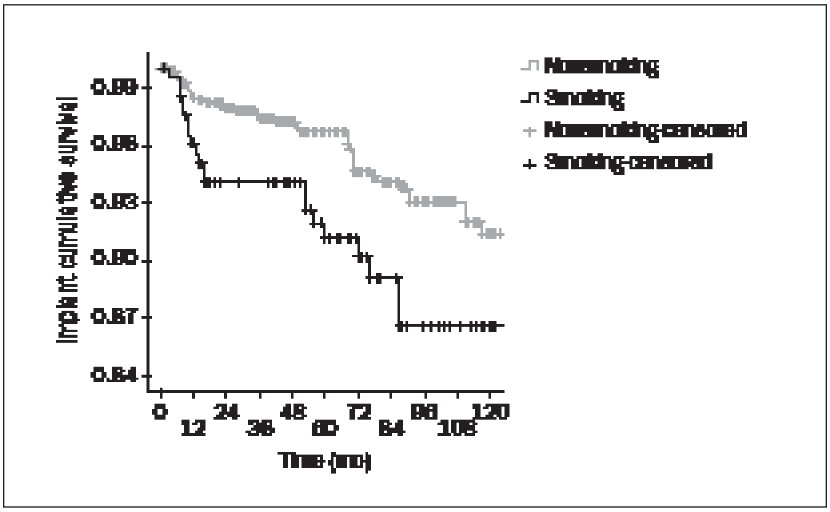

Fig 2 Kaplan-Meier survival analysis considering smoking habit (nonsmoking mean = 195.73 ± 10.13; smoking mean = 126.236 ± 5.281; log-rank test = 6.101; *df* = 1; *P* = .014).

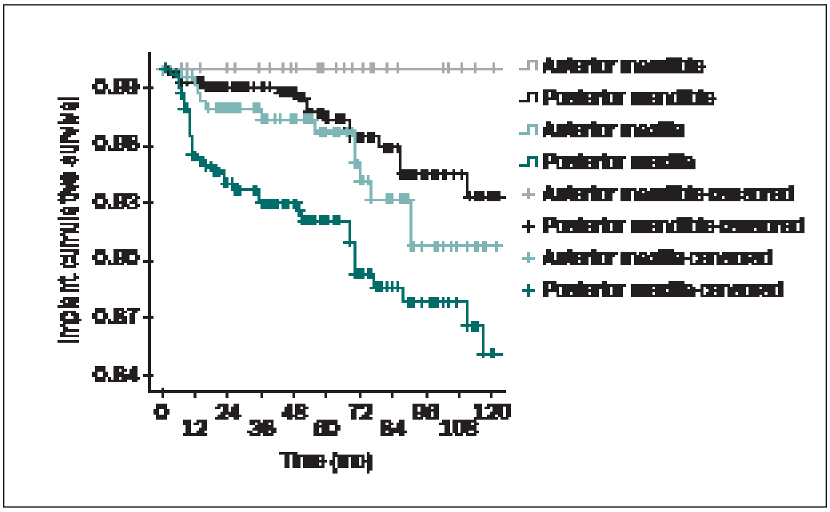

Fig 3 Kaplan-Meier survival analysis considering implant location of all implants included (log-rank test = 23.813 *df* = 3; *P* < .001).

By means of univariate analysis, implant loss was found to be associated with the smoking habit (*P* = .014) (Fig 2) and implant location (*P* < .001) (Fig 3). and the multivariate analysis showed the same variables (*P* = .016 and *P* = .001, respectively) in addition to sex (*P* = .038) (Table 3).

Implants placed in women had a 40% less chance of being lost than those in men. In the cases of patients who smoked, the odds ratio indicated that the risk of losing an implant was almost double. Implants placed in the posterior maxilla were twice as likely to be lost compared with those placed in the anterior maxilla. Implants placed in the posterior mandible were 70% less likely to be lost than those placed in the posterior maxilla. Implants placed in the anterior maxilla were 50% less likely to be lost than implants placed in the posterior maxilla (Table 4).

Table 4 Risk Factors for Wedge-Shaped Implant Loss

Variable	Hazard Ratio	95% Confidence interval	*P* value
Sex			.038*
Male	1.0		
Female	0.6	0.382–0.973	
Smoking habit			.016*
Smokers	1.92	1.131–3.259	
Nonsmokers	1.0		
Implant location			.001*
Anterior maxilla	0.5	0.295–0.942	
Anterior mandible	0.0	0.000–0.000	
Posterior maxilla	1.0		
Posterior mandible	0.3	0.184–0.587	

*Significant association (*P* < .05).

DISCUSSION

The purpose of this investigation was to evaluate the clinical outcome of wedge-shaped implants and analyze their survival rates and the factors associated with failure. The study covered a period of almost 20 years, enrolled 1,169 implants, and found a cumulative survival index of 96.6% at 5 years and 91.8% at 10 years.

The patients included were treated by professionals experienced in oral surgery and prosthodontics, a factor that might have contributed to these rates. All implants were placed in accordance with the general guidelines for implant placement. Surgical procedures and patient follow-up were similar for all individuals. There was uniformity in the study sample since the implants were placed within the same parameters of diagnosis, planning, and surgical conditions, and the procedures were performed in the same operating room. However, this might have produced some bias, and multicentric studies should be conducted to eliminate this uniformity.

Among the major limitations of this study were the retrospective design, the lack of suitable controls, lack of an independent assessment of the outcomes, and the lack of an objective evaluation of implant success. Although retrospective uncontrolled studies are not the ideal study design to evaluate the efficacy of an intervention, they are able to provide some information on whether a certain implant design can work.

To provide more objective and real information on the clinical behavior of a specific dental implant, one outstanding consideration is to evaluate a large number of implants placed using different surgical approaches, in different locations, with different bone quality and quantity. In this study, a positive point was that the implants were placed under different conditions: two-stage surgeries, immediately postextraction, and with sinus elevation, guided tissue regeneration, and implant-induced bone expansion. Moreover, they were placed in different anatomical positions and using different implant diameters and lengths and types of prostheses.

To identify risk factors associated with implant loss in a statistically appropriate and valid manner, it is important to consider as much information as possible for univariate and multivariate statistical analysis. This information is necessary for calculating survival rates over long time intervals with extensive collection of information, including recently placed implants, otherwise the loss of these data may lead to significant loss of statistical information. The information collected in this study about each implant studied included not only the survival time but factors inherent to each individual, which may have been involved during the time the implant remained in the mouth.

The study of survival is a useful statistical methodology in the analysis of multiple variables affecting the success of implant treatment. It provides reliable information for a sample with the characteristics of the one studied.

In this study, premature loss of an implant (ie, before loading) was 0.2% (three implants). This value was below that reported by a multicenter study of implants with the same surface characteristics, which found a premature loss rate of 0.8%.[20] This difference can be explained by the strict patient selection criteria and the clinical protocol used for their treatment. The late loss rate was 5.99%, a value that lies between the limits of 2.1% and 11.3% of late loss rate reported in a systematic review of longitudinal studies of over 5 years.[15]

Smokers represented 17.9% of patients, a finding consistent with other reports.[27,32] In this study, the risk of losing an implant in a patient who smokes was 1.92 times higher when compared with patients who do not. This finding corroborates the value of 2.4 times given in a meta-analysis study.[31] Smoking has often been associated with periodontal disease, and in particular, with the incidence of peri-implantitis.[17] However, in this sample, previous periodontal disease had no statistical significance ($P = .619$). Smoking showed statistical significance in both univariate ($P = .014$) and multivariate analyses ($P = .016$). A similar study that included analysis of 4,680 implants studied for 21 years also reported the statistical significance of smoking, with a 1.56-times higher probability of losing an implant in the smokers.[29]

In the univariate analysis, there was very strong significance for the variable implant location ($P < .001$), and this was maintained even in the multivariate analysis ($P = .001$).

Implants placed in the posterior maxilla showed the most likelihood of being lost. In comparison, implants in the anterior maxilla and posterior mandible were 50% and 70% less likely to be lost, respectively. The most favorable region was the anterior mandible. This same order of probability of loss was observed in the study conducted by Moy et al.[29] The greatest loss of implants in the posterior maxilla has frequently been reported in the literature. The results of this study were also consistent with reports showing higher rates for risk of implant loss in the maxilla compared with the mandible[9,11] and with reports indicating that implant loss was less likely to occur in the anterior mandible.

The differences in success rates between regions were associated with the different types of bone found in these areas. Jaffin and Berman[10] reported 35% loss of Brånemark implants placed in the posterior maxilla where type 4 bone is found, compared with 3% loss in other types of bone. Other studies have reported that implants in the posterior maxilla present inadequate primary stability, which generates micro-movements and loss of implants. The biomechanical and hygienic conditions of the posterior region must also be considered.

The third statistically significant variable in the multivariate analysis was the patient's sex ($P = .038$). The results indicate that the probability of an implant being lost in a woman was 40% lower than that in a man. Initially, in the univariate analysis, this variable showed no statistical significance ($P = .161$). This change in the multivariate model indicated the existence of an interaction between variables.To locate a possible explanation for this effect, association analysis was performed using the Pearson chi-squared statistical test, which revealed that previous periodontal disease was much more common in men ($P < .001$). Although other factors may play a role, this finding is very important to help explain the increased likelihood of implant loss in men.

A meta-analysis that applied surveys to over 50,000 subjects concluded that men had a higher prevalence of destructive periodontal disease than women.[36] Similar studies based on public health surveys provided important comparative data on men and women in which the former show higher prevalence of gingival bleeding and greater probing depth, gingival recession, dental calculus, and periodontal attachment loss.[25]

The contribution of more specific data would be recommended for further prospective study, such as patient's occupation, stress levels, hygiene quality, extent of periodontal disease, and severity index, which measures the periodontal clinical attachment level and probing depth.

This study provided valuable information on survival and factors that represent risk for the survival of an implant system. However, future studies such as randomized controlled trials with suitable controls and prospective case series could be designed to confirm these results.

CONCLUSIONS

The results of this retrospective study showed that the overall survival of the wedge-shaped dental implants was good and that this implant design is feasible to use in long-term treatment. Failure rates were significantly associated with men, tobacco smoking, and posterior maxilla location. Men also showed a greater association with previous periodontal disease. Factors such as age, systemic disease, length and angulation of the implant, use of reconstructive procedures, and type of prosthesis were not contributory factors to implant loss.

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