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Analysis of the 619 Brånemark System TiUnite Implants: A Retrospective Study

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ABSTRACTS

The purpose of this retrospective study was to determine the outcome of Brånemark System TiUnite® implants (Nobel Biocare/Sweden), and to identify the risk factors associated with implant failure. A total of 151 patients (83 maxillae and 91 mandibles) received 619 implants from July 2003 until May 2010. The patients included 86 males and 65 females, with a median age of 51.6 years and an age range of 16 to 90 years at the time of implant surgery. Seventeen maxillae and 16 mandibles were completely edentulous, and 66 maxillae and 75 mandibles were partially edentulous. All the patients were followed until June 2011. Among the 619 implants, 9 maxillary implants and 8 mandibular implants were unsuccessful. The overall survival rate was 96.82%. A logistic regression analysis identified that a history of steroid treatment, application of a dento-maxillary prosthesis, a lack of mechanical coupling between the implants, and the length of the implants (≤ 8.5 mm) were significant predictors of implant failure.

INTRODUCTION

Direct contact between bone and titanium, that is osseointegration, was demonstrated in the early studies by Brånemark *et al.*¹ and Schroeder *et al.*². Recently, osseointegrated implants have been frequently used to support prosthetic reconstruction for patients with partially or completely edentulous jaws. For successful osseointegration, the surface properties of implants are key factors³. The surface of the TiUnite® implant (Nobel Biocare/Sweden) is highly crystalline, phosphate-enriched titanium oxide characterized by open pores in the low micrometer range⁴, and this surface has repeatedly been proven to elicit a more enhanced bone response in comparison to machined implant surfaces⁵. TiUnite® implants have been commercially available in Japan since December 2000, and we began to utilize this product at Kobe University Hospital in July 2003.

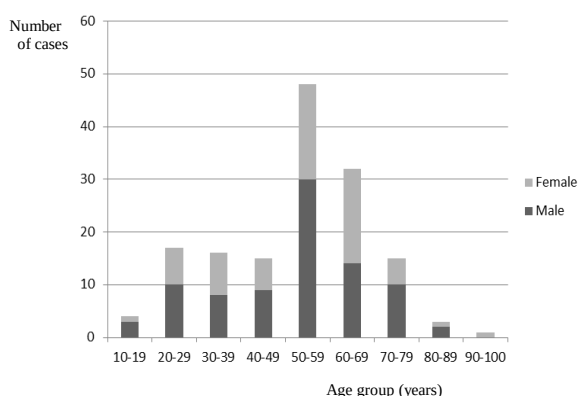
Unsuccessful implant surgery can be characterized by the mobility at the start of the prosthetic phase, the continuing radiolucency around the implant, the peri-implantitis with suppuration, or subjective complaints from the patient. However, specific criteria for

unsuccessful dental implants have not been defined⁶. On the contrary, implant failure is a clinically obvious incident. The inability of tissue to establish or maintain osseointegration is thought to cause implant failures. These failures can be classified into early and late stage failures. In the early failure group, implants are removed before prosthetic restoration, while implants that fail after prosthetic rehabilitation are included in the late failure group. Early failures are characterized by minimal bone loss, and occur predominantly in female and younger patients, while the most common cause of late failures is peri-implantitis, or implant overloading and fracture⁷. The goal of this study was to retrospectively clarify the outcome of TiUnite[®] implants at our hospital, and to investigate the risk factors associated with both early stage and late stage implant failure.

PATIENTS AND METHODS

We identified a total of 151 patients who received TiUnite[®] implants between July 2003 and May 2010 in the Department of Oral and Maxillofacial Surgery of Kobe University Hospital. This study is exempt by the Medical Ethics Committee of Kobe University because of the retrospective method. All of the patients visited our hospital for the replacement of single or multiple teeth by osseointegrated implants. Of the 151 patients, 86 were male and 65 were female. Their median age was 51.6 years, with a range of 16 to 90 years at the time of implant surgery. The 50-59 age group was the most populous for the males, and both the 50-59 and the 60-69 age groups were the most populous for the females (**Figure 1**). The implantation was performed as a two-stage surgical procedure. There were 31 cases of completely edentulous jaws (17 maxillae and 16 mandibles), and 120 partially edentulous jaws (66 maxillae and 75 mandibles). Alveolar availability at the edentulous sites was evaluated by panoramic radiography and CT scans. These imaging studies provided the most anatomically accurate depiction of the patient's arches in terms of not only the vertical height, but also the bucco-lingual width and alveolar shape. A single implant was placed in only 14 maxillae and 14 mandibles, while the other cases received multiple implants. Removable prostheses were mounted on 13 maxillae and 15 mandibles, and the other cases were treated with fixed prostheses. After implant surgery, all the patients were followed until June 2011, and implant survival rate was calculated using the Kaplan-Meier method.

Fig.1. Distribution of age and sex



To determine the factors related to implant failure, a logistic regression analysis was performed (SPSS v.19, IBM, USA). The predictive variables were the patient's age, sex, smoking habits, general health (history of steroid treatment, diabetes, osteoporosis), history of radiation therapy, application of a dento-maxillary prosthesis, type of prosthesis (fixed/removable), employment of alveolar bone augmentation, area where the implant was placed (anterior/posterior), mechanical

coupling between implants, Eichner index⁸, and the length and diameter of implants. The outcome variable was the failure of an implant.

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At first, a bivariate statistic using a logistic regression analysis was performed and the predictive variables with probabilities > 0.25 were excluded. Second, a pair of the remaining predictive variables was analyzed by a logistic regression analysis, and it was confirmed that the partial regression coefficient of one predictive variable did not fluctuate owing to the other predictive variable. Finally, a forward stepwise multivariate logistic regression analysis (entry P value =0.05 and retention P value =0.10) was performed with the remaining predictive variables.

RESULTS

A total of 174 jaws from 151 patients (83 maxillae and 91 mandibles) had 619 implants placed from July 2003 through May 2010 in our hospital. Among the study subjects, 75 patients (49.7%) directly visited our hospital, 41 patients (27.2%) were referred from private dental offices, 23 (15.2%) were referred from other hospital's dentistry departments, and 12 (7.9%) were referred from medical clinics. The reasons for the missing teeth included periodontitis or dental caries (86 cases/57.0%), trauma (30 cases/19.9%), tumors (19 cases/12.6%), loss of previous implants (6 cases/4.0%), tooth root fracture (4 cases/2.6%), congenital absence of teeth (3 cases/2.0%) and cyst formation (2 cases/1.3%) (**Figure 2**).

Fig. 2. The cause of missing dental articulation

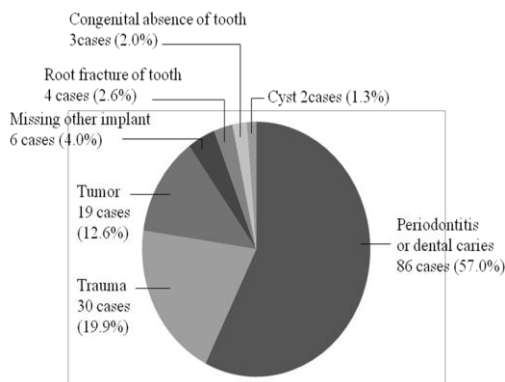


Fig. 3. Distribution of the fixture implanted

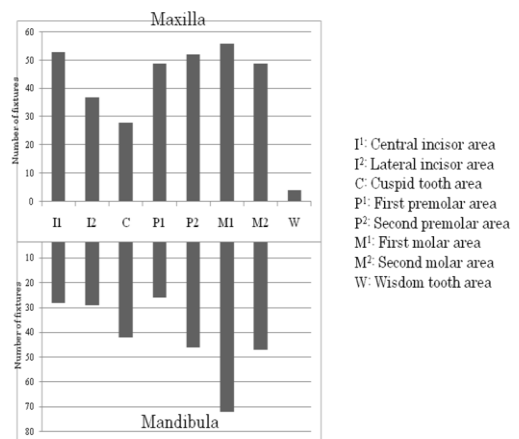


Table I. The kinds of alveolar bone augmentation

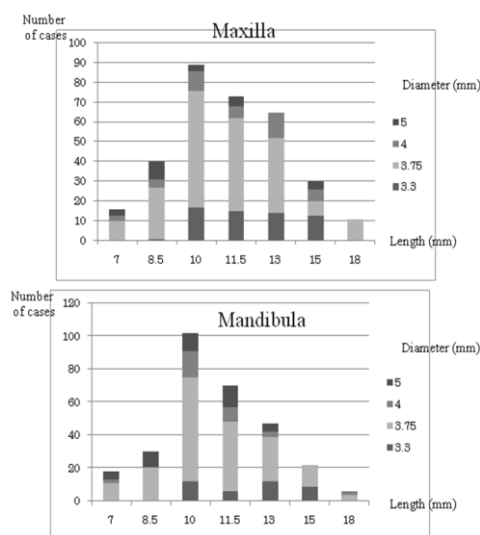
Mandibula/27 cases		Maxilla/57 cases	
Vertical distraction osteogenesis	7 cases	Maxillary sinus lifting	33 cases /46 sides
Guided bone regeneration	6 cases	Veneer bone grafting	16 cases
Veneer bone grafting	5 cases	Guided bone regeneration	13 cases
Onlay bone grafting	3 cases	Osteotome sinus floor elevation	4 cases /5 sides
Split crest	2 cases	Others	5 cases
Others	9 cases		

Some methods overlap in the same case.

The distributions of the implant sites are shown in **Figure 3**. The majority of the fixtures were placed in the first molar region of the maxillae and the mandibles.

For dental implant preparation, various methods of alveolar bone augmentation were performed in 57 maxillae and 27 mandibles (**Table I**). Among the maxillae, 33 cases (46 sides) underwent maxillary sinus

Fig. 4. Distribution of the fixture size



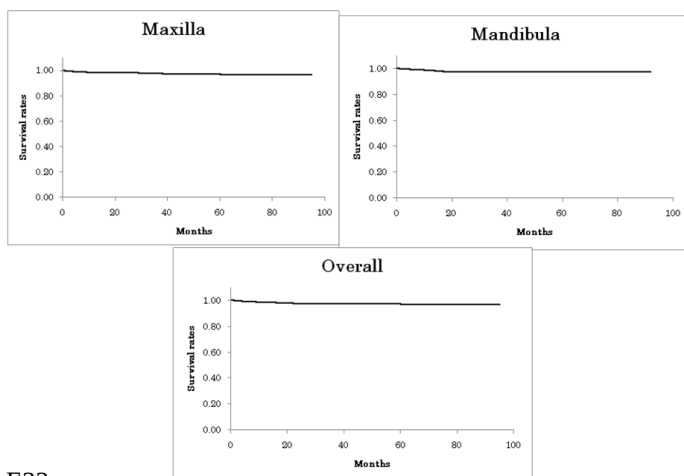
frequently used size was 3.75 mm in diameter/11.5 mm in length on the maxilla and the mandibles.

Table II. Risk factors of implant

Risk factor	No. of cases /no. of implants
Smoking	57 cases/276 implants
Steroid	3 cases/8 implants
Diabetes	6 cases/19 implants
Radiation therapy	3 cases/18 implants
Metal allergy	3 cases/4 implants
Osteoporosis	2 case/9 implants

Seventeen implants were completely lost, and the overall survival rate was 96.82% in this study (Figure 5). The details of the failed cases are presented in Table III.

Fig. 5. Survival rates



lifting, 16 cases received veneer bone grafts, 13 cases underwent guided bone regeneration (GBR), and 4 cases (5 sides) had osteotome sinus floor elevation. In the mandibles, vertical distraction osteogenesis was performed in 7 cases, GBR was employed in 6 cases, veneer bone grafting was performed in 5 cases, onlay bone grafting was applied in 3 cases, and a split crest was used in 2 cases. The fixture sizes are shown in Figure 4. The fixture with a 3.75 mm diameter and 10 mm length was the most frequently employed in both the maxilla (18.2%) and the mandibles (21.4%). The other most

The risk factors associated with the implant success are shown in Table II. There were 57 smokers (276 implants), 3 patients receiving steroid treatment (8 implants), 6 patients with diabetes (19 implants), 3 patients undergoing radiation therapy (18 implants), 3 patients with a metal allergy (4 implants), and 2 patients with osteoporosis (9 implants).

Of the 619 implants, only 9 maxillary implants and 8 mandibular implants were unsuccessful (survival rates: 96.39% and 97.23%, respectively). There were 7 smokers, 2 patients undergoing radiation therapy, 1 patient with 2 implants receiving steroid treatment, and 1 patient with diabetes who experienced implant failure; however, there were no unsuccessful implants in patients affected by a metal allergy or osteoporosis. There were 9 implants in 2 patients with osteoporosis, and oral bisphosphonates (risedronate sodium hydrate) had been

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administrated to one case. In this case, the use of oral bisphosphonates was interrupted before implant surgery, and the four implants have functioned successfully for 18 months as a retaining appliance for a maxillofacial prosthesis.

Table III. Details of failure cases

Case No.	Sex /age	Jaw	Risk factors	Local incidents	Type of prosthesis	Failure implants	
						Survival months	Diameter (mm) /length (mm)
1	F/34	Maxilla	Steroid, Smoking	Implantation with beta-TCP, Overload	Fixed prosthesis	29 38	3.3/13 3.75/11.5
2	M/59	Maxilla	Radiation, Smoking	Overload, MSL with autogenous bone	Removable MP	9	3.75/10
3	F/65	Maxilla	Smoking	Overload, MSL with autogenous bone	Fixed prosthesis	60	5/8.5
4	M/70	Maxilla	Diabetes	Overload	Fixed prosthesis	22	5/8.5
5	F/72	Maxilla	None	GBR	Before loading	1	3.3/10
6	M/79	Maxilla	None	Overload	Removable MP	4 4	3.75/13 3.75/7
7	F/83	Maxilla	None	Recurrence of oral cancer	Removable MP	3	3.75/8.5
8	F/36	Mandibula	None	HBTI of drilling	Before loading	10	4/18
9	M/43	Mandibula	Smoking	Implantation with beta-TCP	Before loading	14 17	3.75/11.5 5/11.5
10	M/51	Mandibula	Radiation, Smoking	None	Before loading	16	3.75/7
11	M/56	Mandibula	Smoking	HBTI of drilling	Before loading	5	3.75/10
12	F/56	Mandibula	None	Overload	Fixed prosthesis	22	3.75/8.5
13	F/62	Mandibula	Smoking	HBTI of drilling	Before loading	9	4/10
14	M/71	Mandibula	None	HBTI of drilling	Before loading	1	5/10

MSL: Maxillary sinus lifting HBTI: Heat-induced bone tissue injury TCP: Tricalcium phosphate MP: maxillofacial prosthesis

Among the 17 failed implants, 8 implants failed prior to loading, and 9 implants failed after loading. For the before loading failure cases, the patients had diverse clinical backgrounds. Case No. 5 was placed on the guided bone regeneration (GBR) region. Case No. 9 was a smoker whose fixture was placed on the bone augmented region with beta-tricalcium phosphate as a bone substitute after tooth extraction. In this case, the first implant was removed 14 months after placement, and the replaced implant was also removed at the 17th month, while the third implant has functioned successfully for 18 months as a retaining appliance for a fixed prosthesis. Case No. 10 was a smoker undergoing radiation therapy whose implant failed 16 months after the stage I surgery. The other 4 patients (Case Nos. 8, 11, 13 and 14) of the before loading failures seemed to be affected by heat-induced bone tissue injury (HBTI). All of these cases involved the mandible, and they failed within 10 months after fixture placement. On the other hand, among the after loading cases, only 1 implant (Case No. 7) was removed surgically because oral cancer recurred near the fixture. The other 8 implants seemed to have been overloaded by various pressures, in combination with various other negative factors. Case No. 1 was a smoker undergoing steroid treatment whose implant failed because of absorption of the beta-tricalcium phosphate around the fixture. Case No. 2 had a large maxillofacial prosthesis after total maxillectomy. This patient was a smoker whose implant was placed in the maxillary sinus lifting region within the radiation field, and the implant failed 9 months after the stage I surgery. Case No. 3 was a smoker who received a long-span fixed bridge (not the cantilever type) in which the rearmost fixture failed 60 months after the stage I surgery. Case No. 4 had diabetes, and the free end implant with a single crown failed 22 months after the stage I surgery. Case No. 6 had a large maxillofacial prosthesis after total maxillectomy without other risk factors, and 2 implants were lost during the 4th month after the stage I surgery. Case No. 12 had no risk factors, but an implant placed obliquely against the occlusal plane was lost 22 months after the placement.

There were only 2 cases receiving radiation therapy in this study, and one failed after loading and another was lost before loading. Case No. 2 had maxillary cancer complicated with non-Hodgkin's lymphoma in the bilateral orbital region. The patient was irradiated with a total dose of 80 Gy and lost one implant after loading. Case No. 10 had tongue cancer and was irradiated at a total dose of 60 Gy, and this patient's implant failed before loading.

The median duration of implant survival in the failure cases was 15.5 months, with a range of 1 to 60 months, and the diameter and length of the failed fixtures varied.

Statistical analysis

At first, the bivariate statistical evaluation using a logistic regression analysis was performed to exclude the predictive variables with probabilities > 0.25, which led to six predictive variables being omitted, including the patient's age, sex, smoking habits, history of diabetes or osteoporosis, and employment of alveolar bone augmentation (**Table IV**).

Table IV. Preprocedural clinical variables and outcomes

* ; $p < 0.05$, ** ; $p < 0.01$ CI, confidence interval

Predictors		Number of Implants		Odds ratio	95%CI	p
		Failed	Non-failed			
Age	≤40	3	124			
	41-50	2	70	1.181	0.193~7.238	0.857
	51-60	4	213	0.776	0.171~3.525	0.743
	≥ 61	8	195	1.696	0.441~6.514	0.442
Sex	Female	6	240			
	Male	11	362	1.215	0.444~3.331	0.704
Smoking	No	8	321			
	Yes	9	264	1.368	0.521~3.595	0.525
Steroid treatment	Absent	15	595			**
	Present	2	7	11.333	2.170~59.184	0.004
Diabetes	Absent	16	590			
	Present	1	12	3.073	0.376~ 25.083	0.295
Osteoporosis	Absent	17	593			
	Present	0	9	0.000	0.000~ .	0.999
Radiation therapy	Not performed	15	581			
	Performed	2	21	3.689	0.792~17.178	0.096
Dento-maxillary prosthesis	Not applied	7	525			*
	Applied	3	53	4.245	1.066~16.903	0.040
Type of prosthesis	Fixed	5	473			*
	Removable	5	106	4.462	1.269~15.690	0.020
Alveolar bone augmentation	Not employed	11	324			
	Employed	6	278	0.636	0.232~1.741	0.378
Placement	Anterior	3	216			
	Posterior	14	386	2.611	0.742~9.188	0.135
Mechanical coupling between implants	Coupled	4	493			**
	Separated	6	86	8.599	2.377~31.104	0.001
Eichner index	≤b1	2	175			
	≥b2	8	405	1.728	0.363~8.222	0.492
Length of implants	≥ 10 (mm)	11	504			*
	≤8.5	6	98	2.805	1.014~7.764	0.047
Diameter of implants	3.3 (mm)	2	97			
	3.75 /4.00	11	442	1.207	0.263~5.533	0.809
	5.0	4	63	3.079	0.548~17.313	0.202

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Second, a pair of the remaining predictive variables was analyzed by a logistic regression analysis, and it was confirmed that there were no predictive variables whose partial regression coefficients fluctuated owing to the other predictive variable. Finally, a forward stepwise multivariate logistic regression analysis (entry P value =0.05 and retention P value =0.10) was performed with the remaining predictive variables, and it was identified that a history of steroid treatment, application of a dento-maxillary prosthesis, a lack of mechanical coupling between the implants, and the length of implants (≤ 8.5 mm) were significant predictors of implant failure (**Table V**).

Table V. Factors associated with implant failure

*, $p < 0.05$; **, $p < 0.01$

B, partial regression coefficient; s.e., standard error; CI, confidence interval

Predictors		B	s.e.	Wald	p	Odds ratio	95%CI
Steroid treatment	Absent				**		
	Present	3.823	1.178	10.531	0.001	45.722	4.544~460.021
Dento-maxillary prosthesis	Not applied				*		
	Applied	1.996	0.796	6.281	0.012	7.356	1.545~35.029
Mechanical coupling between implants	Coupled				**		
	Separated	2.225	0.712	9.767	0.002	9.254	2.293~37.355
Length of implant	≥ 10				**		
	≤ 8.5 (mm)	1.918	0.733	6.839	0.009	6.809	1.617~28.670

DISCUSSION

In the first clinical studies reporting the success of osseointegrated implants, the survival rates of Brånemark implants (Nobel Biocare/Sweden) were 86% in the mandible and 78% in the maxilla after 15 years of function in completely edentulous arches⁹. However, the survival rates of this implant system have increased in recent years. Recently, the surface of the Brånemark implant system was changed from a machined-surface to the TiUnite[®] surface. This surface is characterized by many open pores in the low micrometer range⁴, which are thought to improve the bone-to-titanium surface contact. The survival rate for the TiUnite[®] surface implants was shown to be higher (98.6%) than that for the Brånemark implants with machined surfaces (92.1%)⁶. The overall survival rate of 96.82% of the TiUnite[®] implants in this study compares favorably with the previous reports.

There are no clear criteria that define the success of dental implants⁶, whereas implant failure is a distinct incident for a clinician. Implant failures can be classified into early stage (failed prior to loading) and late stage (failed after loading). Among the 17 failed implants of this study, eight were during the early stage and 9 were during the late stage. In the early stage group, four implants seemed to be damaged by the drilling heat. The drilling procedures used for implants can cause mechanical damage to the bone, which is regarded to be heat-induced bone tissue injury (HBTI)¹⁰. It was previously demonstrated that when the test implants were heated to a temperature above 47°C for 1 minute, bone regeneration was significantly impaired¹¹.

HBTI sometimes occurs during drilling for implant placement, and early bone absorption around the fixtures usually occurs before loading. In the present study, HBTI was diagnosed by the X-ray findings of bone absorption around the fixtures before the stage II

surgery, and the median implant duration of 6.3 months of the HBTI cases was shorter than the median 15.5 months of the overall failed cases. Appropriate irrigation during drilling restricts the maximum temperature to 33.8°C for 5 seconds¹². The conventional irrigation method utilizes the external irrigation drilling system employed by the Brånemark system, whereas an internal irrigation system has recently been adopted by other dental implant systems. Although the internal irrigation system is thought to improve the delivery of coolant to the bone-drill interface, Benington *et al.* have demonstrated that there was no significant difference between internal and external irrigation systems with regard to the temperature generated via the drilling procedure¹³. However, delivering coolant to the tip of a long length drill is difficult using the external irrigation system.

In this study, the median implant length of HBTI cases was 12.0 mm, while the failed implants in the mean length of after loading cases was 9.8 mm. In addition, all of the HBTI cases occurred in the mandible. The bone quality of the mandible is generally assessed to be harder in comparison to the maxilla¹⁴. The dense quality of the mandible is advantageous for the mechanical success of implants in osseointegration, therefore dental implants in the mandible usually have higher success rates than those in the maxilla¹⁵. However, high frictional heat can be produced during the drilling procedures, especially in dense bone, which is thought to be the reason why the HBTI cases occurred predominantly in the mandible. In the other 4 implants that failed during the early stage, no X-ray findings of bone absorption relevant to HBTI were found. Three of these failed implants were placed into the bone augmentation area by GBR or with beta-TCP, therefore it was thought that immature bone regeneration likely caused the implant failure. The remaining case was a short implant of 7 mm. Many studies have shown that a short length is associated with implant failure¹⁶. Misch *et al.* observed a low success rate (85.3%) for implants less than 10 mm in length¹⁷. Olate *et al.* concluded that there was a significant relationship between early implant failure and a short length implant (6-9 mm)¹⁸. Short implants may be unsuitable in terms of their primary stability because the total surface in contact with the bone tissue is restricted.

In the late failure implant group, only one implant was accidentally displaced by recurrent oral cancer. The other 6 patients (8 implants), who had good oral hygiene without any suppurative inflammatory lesions, were considered to be overloaded cases in this study. Previous clinical studies have indicated that excessive loading in a lateral direction is a common reason for implant failure¹⁹. Among the late failed implants in this study, 2 patients (3 implants) were edentulous with an extensive maxillary defect after total maxillectomy, and the heavy maxillofacial prosthesis may have resulted in excessive lateral pressure on the implants. Among the other overloaded cases, one implant was placed in the mandible obliquely from the occlusal plane and received intense lateral pressure. To reduce the local excessive stress being placed on an implant, the mechanical coupling between plural implants is one of the methods that should be considered.

There are many types of alveolar bone augmentation used in preparation for dental implants. Aghaloo *et al.* reported that the implant success rate was 95.5% for GBR, 94.7% for distraction osteogenesis, 90.4% for onlay/veneer grafting, and 83.3% for combinations of onlay, veneer, and interpositional inlay grafting²⁰. In our 14 failed cases, 5 cases underwent alveolar bone augmentation, in which 2 cases were involved in maxillary sinus lifting with autogenous bone.

A complication of maxillary sinus lifting is perforation of the Schneiderian membrane. One study showed that the implant success rate in maxillary sinus lifting procedures with an intact membrane was higher (98%) than in those with a perforation (88.6%)²¹, although other

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reports have shown no statistically significant difference between patients with and without a perforation²². Perforation of the Schneiderian membrane occurs in 10%-35% of procedures²¹. In this study, 11 of 46 (23.9%) maxillary sinuses had a perforation, while the implants in those cases did not fail. It was noteworthy that 4 of the 5 failed implants with alveolar bone augmentation were observed in smokers. It was previously demonstrated that there were statistically significant differences in the success rates for implants between smokers and nonsmokers²³, although there were no statistically significant differences in the present study. Klokkevold *et al.* showed no difference in the implant success rate between patients with and without diabetes²³, and it was suggested by other studies that osteoporosis is not a risk factor for the failure of dental implants²⁴. In contrast, high implant failure rates have been demonstrated in irradiated cancer patients²⁵.

In our study, there were no statistically significant differences between patients with and without diabetes, osteoporosis or between those undergoing radiation treatment and those without. On the other hand, our study showed that the factors involved in implant failure were a history of steroid treatment, application of a dento-maxillary prosthesis, a lack of mechanical coupling between implants, and the length of implants ($\leq 8.5\text{mm}$). It is known that the patients who are treated with corticosteroids for a prolonged period become immunocompromised and develop osteoporosis, both of which may impact the success of dental implants. However, the number of subjects in the present study was too small to draw any definitive conclusions about the associations with the risk of implant failure.

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