

부분 무치악환자에서 Neobiotech 임플란트의 5년 전향적 임상연구

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A 5-year prospective clinical study of Neobiotech implants for partially edentulous patients

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Purpose: The aim of the present prospective clinical study was to assess the cumulative survival rate (CSR) of Neobiotech implants restored with fixed partial prosthesis in relation to its potential risk factors. **Materials and methods:** Thirty six partially edentulous patients received Neobiotech implants and implant supported fixed partial prosthesis at Korea University Guro Hospital Dental Center from November 2009 until November 2011. The observation period was set from the implant placement and the last clinical visit until December 2015. Implant survival rate was determined using the Kaplan-Meier method. The relationship between implant survival rate and the potential risk factors were analysed using the multi Cox proportional analysis ($P < .05$). **Results:** A total of 69 implants were placed in 36 patients after a mean observation period of 45.9 months. Two out of 69 implants failed before loading, yielding a 5-year cumulative survival rate of 97.1%. The maxillary implants have a lesser CSR than the mandibular implants based on log rank test analysis (maxilla=91.3%; mandible=100% $P < .05$). However, the multi Cox proportional analysis showed that implant location has no significant correlation with implant failure ($P > .05$). **Conclusion:** Neobiotech implants showed predictable results with a 5 year cumulative survival rate of 97.1%. (*J Korean Acad Prosthodont 2017;55:272-8*)

Keywords: Dental implants; Survival rate; Risk factors; Maxilla

Introduction

Restoration of fully and partially edentulous patients using dental implants has been a reliable treatment modality option that improves the patients' quality of life.¹⁻³ The advancement in oral rehabilitation initiated the development of commercially available titanium implant systems that can achieve remarkable osseointegration. Since the advent of the dental implants 40 years ago, there has been a constant improvement on implant design, surface characteristics, biocompatibility, biomechanical factors, and surgical techniques through research and development.⁴ Due to an increased demand for implant restorative treatments worldwide, various companies have introduced new systems. A new implant system that is to be

applied clinically, requires meticulous *in vitro* analysis⁵ and long-term clinically proven results.⁶ Many studies have reported a long term predictability of widely used dental implants with implant survival rate of over 90% during a 10 - 15 years follow-up period.^{3,7-11} However, implant systems utilized in these studies were limited to common brands. There were only few long-term clinical studies over a 5-year follow-up regarding several other domestic implant systems in Korea and were only limited to retrospective clinical studies.¹²⁻¹⁴

Despite of numerous papers reporting high implant survival and success rates, implant failures influenced by local and systemic risk factors are still inevitable and showed contradictory results.¹⁵⁻¹⁷ In addition, assessment of Korean ethnic characteristics such as arch form, dietary patterns, bone quality, clench force and other risk fac-

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tors are potential confounding variables which contribute to implant loss.¹⁸⁻²¹ However, studies regarding these aforementioned factors in Korean population are still inadequate.

Therefore, the purpose of this prospective clinical study was to evaluate the 5-year cumulative survival rate of fixed partial implant-supported restorations using Neobiotech implant system in relation to potential risk factors on implant loss as well as its biological complication in Korean population.

Materials and methods

Study design and patient data

All participating patients in this prospective study were recruited consecutively at the implant clinic of the Korea University Guro Hospital Dental Center from November 2009 until November 2011. Eligible patients were assessed by a series of clinical examinations and radiographs. Patients with partially edentulous cases that require implant supported fixed partial restorations were included in this study. On the other hand, patients with chronic systemic diseases and medications that could compromise postoperative healing or the osseointegration process were excluded. Implant placement until the patients' last follow up before December 2015 served as the observation period of this study. This study was approved by the Ethics Committee of Korea university Guro hospital (MD09013).

Treatment intervention

All patients signed an informed consent and received oral hygiene instructions before the implant surgery was performed. Implant placements (CMI, Neobiotech, Seoul, South Korea) were planned based on the pre-surgical cone beam computed tomography (CBCT), radiographic and clinical assessment. All surgical procedures were performed under local anesthesia and aseptic conditions. Implants were placed in compliance with the general surgical principles and protocols defined by the manufacturer. After the healing period, the final restoration was fabricated using conventional prosthodontic procedures. All patients were subjected to supportive therapies, thorough clinical examination (mobility, percussion, screw loosening, discomfort, etc.) every 6 months, and annual radiographic evaluation.

Evaluation of survival rate

In this study, the evaluation of the survival rate followed the criteria proposed by Albrektsson and Zarb.²² Implant failure was defined as implant loss or removal, implant mobility and sleeping

implant. The assessment of the implant survival rate was conducted from implant placement until the last follow up or when the implant had failed.

Related risk factors

The potential risk factors in the cumulative survival rate were classified in the following order; patients' age (≥ 65 vs. < 65), gender (male vs. female), presence of chronic systematic disease, implant size (length, diameter), implant arch location (maxilla vs. mandible), implant position (anterior vs. posterior), additional surgery (GBR, sinus augmentation), prosthetic design (non-splinted vs. splinted) and abutment type (ready-made vs. customized).

Measurement of marginal bone level

The standardized intraoral periapical radiographs were evaluated for peri-implant radiolucency and marginal bone level. The radiographic evaluations were performed at baseline, 1 year, 3 years and 5 years after loading. The junction between the implant collar and the rough/treated surface of the implant was used as the reference point from which two perpendicular lines were drawn on the mesial and distal side of the implants at the bone-to-implant contact. The actual implant inter-thread (0.8 mm) distance was chosen as an internal reference to calibrate the degree of radiographic distortion (Fig. 1).

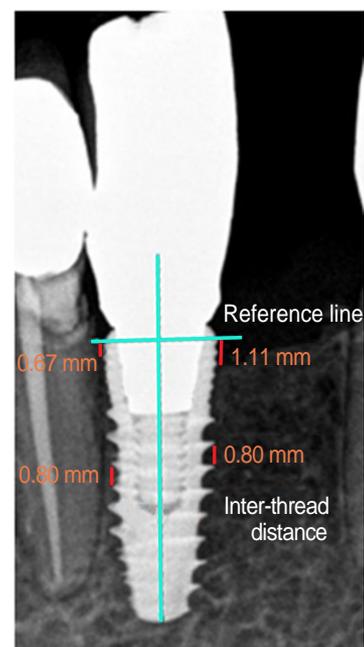


Fig. 1. Measurement of marginal bone level.

Statistical analysis

Cumulative survival rate (CSR) was analyzed using Kaplan-Meier survival analysis method and the potential risk factors on CSR were assessed using log-rank test (Mantel Cox) ($P < .05$). The risk factors that showed at least a statistically borderline significant ($P < .20$) were re-assessed using the multiple Cox proportional hazard regression analysis. All statistical analysis, were performed using SPSS software ver. 22.0 (SPSS Inc., Chicago, IL, USA).

Results

From a total of 41 initially screened subjects, finally 36 patients (26 males and 43 females) received 69 implants with a mean follow up period of 45.9 months. Patients' age ranged from 20 to 74 with

the mean age of 56 years. The implant distributions in relation to risk factors are summarized in Table 1.

Descriptive implant survival rate and risk factor analysis

During the observation period, 2 out of 69 implants failed before loading. According to Kaplan-Meier survival analysis (Fig. 2), the cumulative survival rate (CSR) at 5-year follow up was 97.1%. Implant arch location has a significant association with implant failure based on log rank test analysis ($P = .047$). Implant placed in the maxilla (91.3%) showed lower CSR than in mandible (100%). However, multiple Cox proportional analysis of the relevant risk factor revealed that, implant arch location has no significant association with implant failure (Table 2, $P < .05$).

Table 1. Distribution of implants and cumulative survival rate in relation to investigated risk factors

Risk factors	Characteristics	Number of implant	CSR %	P value
Age	Younger (< 65)	47	95.7	.331
	Advanced (≥ 65)	22	100	
Gender	Male	26	92.3	.066
	Female	43	100	
Systemic condition	Healthy	47	97.9	.588
	Chronic disease	22	95.5	
Width	Small	8	100	.552
	Regular	18	100	
	Wide	43	95.3	
Length	Short	11	100	.542
	Long	58	96.5	
Implant arch location	Maxilla	23	91.3	.047*
	Mandible	46	100	
Tooth position	Ant	8	100	.602
	Post	61	96.6	
Other Surgery	No	50	98.0	.441
	Yes	19	94.7	
Splinting	Splint	26	100	-
	Non-splint	41	100	
Abutment	Ready made	32	100	-
	Customized	35	100	

Systemic disease included diabetes mellitus and/or cardiovascular disease; Other surgery includes guided bone regeneration (GBR) and/or sinus augmentation;

*significant difference (log-rank test, $P < .05$).

Table 2. Multivariate associations with cumulative survival rate of implants

	B	P value	Exp (B)	Exp (B) 95.0% CI	
				Lower	Upper
Implant arch location (Maxilla vs Mandible)	5.371	.427	215.110	.000	123185820.51
Gender (Male vs Female)	5.041	.423	154.601	.001	35065013.208

Only the risk factors that showed a statistically borderline significant in the log-rank test ($P < .20$) were included in the multivariate model.

The included risk factors showed no significant correlation with implant failure ($P > .05$).

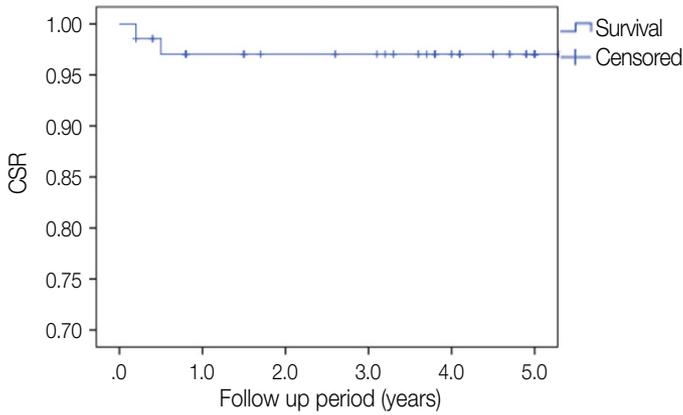


Fig. 2. 5-year cumulative survival rate (CSR) of Neobiotech implants by Kaplan-Meier method.

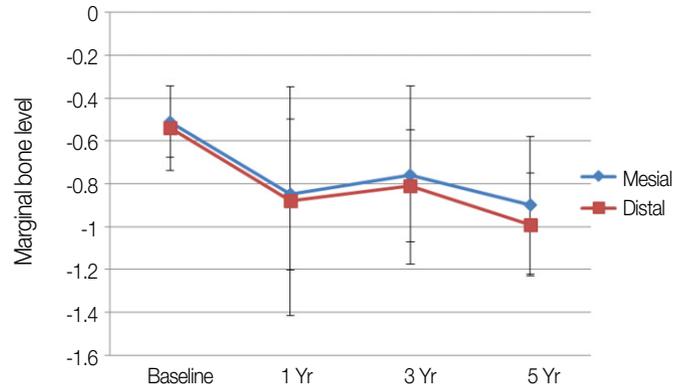


Fig. 3. Mean marginal bone level from the reference point.

Marginal bone level

Evaluation of radiographs showed that the mean marginal bone level on the mesial and distal side were -0.52 ± 0.17 mm and -0.54 ± 0.20 mm at baseline, and after 5-year loading -0.91 ± 0.32 mm and -0.99 ± 0.24 mm respectively from the reference point (Fig. 3).

Discussion

CMI implant (Neobiotech, Seoul, South Korea) that was introduced and FDA approved in 2009 is one of the popular brands in South Korea. It uses a resorbable blast media (RBM) surface and is considered as an internal bone level implant. In this study, 69 Neobiotech implants were placed in 36 patients. The cumulative survival rate (CSR) at the implant level was 97.1% at 5-year follow up period. A total of 2 implants failed due to lack or absence of osseointegration before loading. All failed implants underwent re-implantation with patients' consent. This result is comparable with CSR results of previous studies of widely used titanium implants in Korean population with survival rate ranges from 95.4 - 98.9% and follow up period from 5 to 9 years.^{12,14,23-25} Furthermore, 5 and 10-year retrospective clinical study of Implantium implants system (Dentium, Seoul, South Korea) and 7 years of Osstem implants (Osstem Implant Co., Ltd., Busan, Korea) reported a CSR of 97.27%, 97.9% and 95.37% respectively.¹²⁻¹⁴

The 5-year study of Implantium implants system showed that implant failure may be associated with systemic disease, smoking, reasons of tooth loss, arch, the edentulous site and prosthodontic design, while the 10-year study did not evaluate the potential risk factors.^{12,13} On the other hand, 7-year clinical study of Osstem implants

revealed that implant survival rate was influenced with increased implant diameter, reduced prosthetic loading period and performance of bone graft.¹⁴ In this study, age, gender, systemic condition, implant size, additional surgery, and splinting had no significant effect on implant failure. Only implant arch location has significant association with implant failure based on log-rank test analysis. Although some studies reported contradictory results that implant survival rate has no correlation with the anatomic location of the implant,^{17,26,27} there are various studies that reported favorable results in mandibular implants than that of the maxillary implants.^{16,28-30} A recent meta-analysis that includes 54 clinical studies of no less than 3 year follow up period were evaluated, and resulted to an annual implant failure rate that is significantly higher in that of the maxilla than the mandible.³¹ Oral rehabilitation with osseointegration can be successful and predictable in patients with favorable bone quality and quantity. However, dental implant placed in the maxilla can be associated with poor bone quality and loading condition especially on the posterior region resulting to increased number of implant failures.^{32,33} Sufficient cortical bone at the alveolar bone level is essential to achieve a satisfactory stabilization, but the maxilla has thinner cortical bone and less dense trabecular bone in comparison with the mandible.³⁴ The presence of anatomic structure such as the maxillary sinus may also limit the amount of available bone.

Although log rank test analysis showed maxillary implants has a lower CSR than mandibular implants, multi Cox proportional regression analysis revealed that implant location has no significant association with implant failure in this study ($P < .05$). These conflicting results may be due to low number of sample size which reduces the capability for further analysis. Therefore, related factors influencing the implant survival rate should be interpreted with caution and meticulous attention.

Conclusion

Within the limitation of this study, Neobiotech implants showed predictable results with a 5-year cumulative survival rate of 97.1%. However, long-term follow-up period is needed to assess the implant predictability.

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부분 무치악환자에서 Neobiotech 임플란트의 5년 전향적 임상연구

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목적: 본 전향적 임상 연구의 목적은 고정성 보철물로 수복된 Neobiotech 임플란트의 누적생존율 및 임플란트 실패의 위험 인자를 평가하는 것이다.

재료 및 방법: 본 연구는 고려대학교 구로병원 치과 센터에서 2009년 11월부터 2011년 11월까지 Neobiotech 임플란트와 임플란트 지지 고정성 보철치료를 받은 부분 무치악 환자 36명을 대상으로 시행하였다. 관찰 기간은 임플란트 식립일에서 2015년 12월 이전 마지막 방문일까지로 설정하였다. 임플란트 생존율은 Kaplan-Meier 방법을 이용하였으며, 임플란트 실패에 대한 위험 인자 평가는 다중 콕스 비례 분석을 이용하여 분석하였다 ($P < .05$).

결과: 36명의 환자에게 총 69개의 임플란트가 식립되었으며, 평균 관찰 기간은 45.9개월이었다. 총 69개의 식립된 임플란트 중에 2개의 임플란트가 하중을 가하기 전에 실패하여 97.1%의 5년간 누적 생존율을 보였다. 로그 랭크 테스트 분석 결과 상악에 식립된 임플란트는 하악에 식립된 임플란트보다 낮은 임플란트 생존율을 나타내었다 (상악=91.3%, 하악=100%, $P < .05$). 하지만 다중 콕스 비례 분석 결과 임플란트 위치와 임플란트 실패는 유의한 상관 관계가 나타나지 않았다 ($P > .05$).

결론: Neobiotech 임플란트의 5년간의 누적 생존율은 97.1%를 나타내었다. (*대한치과보철학회지* 2017;55:272-8)

주요단어: 임플란트; 생존율; 위험인자; 상악

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