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Marginal bone stability of 1692 tissue-level dental implants over 10 years: Retrospective radiographic observational study

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Directed by Professor Kyoo-Sung Cho

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This certifies that the Doctoral Dissertation
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감사의 글

2014년 9월, 부푼 마음으로 시작한 치주과 대학원 과정이 많은 분들의 도움으로 학위논문의 결실을 맺고 어느덧 막바지에 이르렀습니다. 치주과의 한 일원으로서 많은 것을 배울 수 있었고, 때로는 어렵기도 했던 이 과정을 무사히 마칠 수 있도록 도와주신 모든 분들께 감사의 마음을 전하고자 합니다.

먼저, 부족한 저에게 항상 아버지와 같은 마음으로 격려해주시고 지도해주시며, 인간적, 학문적 가르침을 주신 조규성 지도교수님께 깊은 감사의 말씀을 드립니다. 또한, 항상 따뜻한 마음으로 관심과 격려를 보내주신 채중규 교수님, 창의적인 사고방식을 가질 수 있게 도와주신 최성호 교수님, 연구자의 마음가짐을 잊지 않게 해주신 김창성 교수님, 비판적 시각과 냉철한 안목을 갖게 해주신 정의원 교수님, 가장 가까운 곳에서 이 논문이 완성될 수 있도록 많은 도움을 주신 이중석 교수님, 그리고 바쁘신 와중에도 심사를 맡아주시고 조언을 아끼지 않으신 이근우 교수님께 깊이 감사드립니다. 아울러 대학원 과정 동안 큰 힘이 되어 준 치주과 의국원들과 선후배님들께도 감사의 마음을 전합니다.

마지막으로, 저를 낳아주시고, 길러주시고, 제가 이 자리에 있기까지 아낌없이 지원해주시고 도와주신 사랑하는 부모님께 무한한 감사의 말씀을 드리고, 항상 응원해주는 착한 동생에게도 고마운 마음을 전합니다.

2019년 6월

강 명 훈

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Abstract

Marginal bone stability of 1692 tissue-level dental implants over 10 years: Retrospective radiographic observational study

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Background: Despite accumulating evidence for the longitudinal stability of the marginal bone level around an implant, there is limited evidence of predisposing risk factors for marginal bone loss based on some implants in a relatively large patient population.

Objective: The aim of this study was to retrospectively determine the marginal bone loss around Straumann tissue-level dental implants during follow-up periods among which the maximum lasts up to 10 years, as well as the predisposing risk factors for peri-implant marginal bone loss.

Materials and methods: This study analyzed 1692 Straumann tissue-level dental implants in 881 patients, and relevant data were collected. The peri-implant marginal bone level was measured on periodic radiographs, and the changes in bone level were

analyzed cumulatively from surgery until up to 10 years later. The log-rank test was used to select candidate critical risk factors for marginal bone loss, and multivariate analysis using Cox regression with the shared frailty model was performed.

Results: The overall peri-implant bone loss was 0.07 ± 0.21 mm, 0.09 ± 0.26 mm, 0.14 ± 0.41 mm, and 0.17 ± 0.45 mm at 3, 5, 7, and 9 years, respectively. Only 14 implants showed pathologic marginal bone loss exceeding 2 mm during the follow-up period. While 2 implants were removed with continuous progressive marginal bone loss, 5 of the 14 implants showed early bone loss exceeding 1 mm within the first year but then subsequently tended to show a stable marginal bone level. In the other seven implants, bone loss started after the first year and progressed continuously. Multivariate analysis revealed that diameter of the implant affected the peri-implant marginal bone loss.

Conclusions: Straumann tissue-level dental implants showed only slight peri-implant marginal bone loss, with a very low incidence of pathologic marginal bone loss exceeding 2 mm.

Keywords: implant, implant stability, long-term study, marginal bone loss, retrospective

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I. Introduction

Developments in implant dentistry associated with advances in surface characteristics, designs, and surgical techniques have led to its widespread application in dental practice and acceptance as a predictable treatment option for rehabilitating partially or completely edentulous patients thanks to high survival rates of dental implant systems (Jung et al., 2012; Pjetursson et al., 2012). However, survival is a minimum criterion for implant function since surviving dental implants can exhibit varying states of damage, including from no bone loss to a functioning implant with progressive bone loss. Even in cases of severe peri-implant bone loss, implants usually can continue to function without

exhibiting mobility for several years. Peri-implant bone loss may induce a deep peri-implant pocket or gingival recession to produce patient discomfort and implant surface exposure, which acts as a reservoir for plaque accumulation. Therefore, maintaining the peri-implant marginal bone level is a fundamental prerequisite for the long-term success of an implant (Qian et al., 2012).

The Straumann dental implant system has specific design features: a transmucosal machined collar reflecting the implant biologic width (Hermann et al., 2001), and a rigid internal abutment connection. Hermann et al. (2001) demonstrated substantial marginal bone loss due to the presence of a microgap between the implant fixture and abutment, and this was associated with the implant biologic width (Berglundh et al., 1991). In addition, a rigid connection of the abutment into the implant fixture can minimize the stress exerted on the crestal bone around the installed implant (Merz et al., 2000). These features can affect the marginal bone stability, and many previous studies have found high survival and success rates when using this implant system. However, a recent systematic review revealed no significant difference between two types of implants (Vouros et al., 2012). Another concept of implant design called platform switching has also been proposed for decreasing crestal bone loss due to its protective role in preserving the marginal bone (Lazzara and Porter, 2006; Prosper et al., 2009).

Despite accumulating evidence for the longitudinal stability of the marginal bone level around an implant, the reasons for marginal bone loss remain highly controversial. A European workshop found that peri-implantitis shares its disease nature and pathology

with periodontitis, and host responses to oral microbial organisms were considered a critical risk factor for peri-implant bony destruction (Lang et al., 2011). However, Albrektsson et al. (2016) suggested that peri-implant bony destruction can be induced by imbalance between a dental implant and the bone biology (Albrektsson et al., 2016). There is limited evidence of predisposing risk factors for marginal bone loss based on some implants in a relatively large patient population showing unusually excessive and progressive bone loss. Since there is significant diversity among the implants used worldwide and this contributes heterogeneity to study results, the uniformity implicit in a long-term evaluation of a single implant system can be advantageous for evaluating the actual risk factors.

The aim of this study was to retrospectively determine the marginal bone loss around 1692 Straumann tissue-level dental implants in 881 patients during follow-ups lasting for up to 10 years, and to determine the predisposing risk factors for peri-implant marginal bone loss.

II. Materials and Methods

1. Study Design and data collection

The study design and protocols used in this study were reviewed and approved by the Institutional Review Board at Yonsei University Dental Hospital (approval no. 2-2014-0034). This retrospective study included follow-ups of up to 10 years and included all patients who had received dental implants of a single brand and type at the Department of Periodontology, Yonsei University Dental Hospital between 2003 and 2009. The following exclusion criteria were applied for patient selection: (1) psychologic disorder, (2) uncontrolled diabetes mellitus, (3) immune suppression, (4) previous radiotherapy in the head and neck region, and (5) parafunctional oral habits such as clenching and bruxism. The following data on patient characteristics, surgical procedures, prostheses, and clinical and radiographic examinations were collected by searching electronic and paper dental and medical records: patient's age, gender, and health state including information on diabetes mellitus, cardiovascular diseases, and smoking (information related to the patient), implant fixture design and the length and diameter of the implant (information related to the implant), installation site, bone quantity and quality, insertion torque, and history of guided bone regeneration or sinus augmentation (information related to the surgical site), and healing periods before loading the prosthesis and the type of prosthesis (information related to the prosthesis).

The included implants were categorized according to their diameter (≥4 mm or <4 mm), length (≥10 mm or <10 mm), and design (standard, standard plus, or tapered effect). The installation site was defined as the maxilla/mandible and anterior/posterior areas, and bone quality was classified according to Lekholm and Zarb (1985). The prosthesis type was classified into single fixed partial dentures, hemilateral fixed partial dentures, bilateral fixed partial dentures, and removable dentures.

2. Radiographic measurements

The peri-implant marginal bone level was measured utilizing all periodic radiographs that were taken at follow-up visits after implant placement. Both panoramic and periapical radiographs were used in this study, although with a focus on periapical ones (De Bruyn et al., 2013). Since the present study involved a retrospective analysis, radiographs were not always taken at fixed time of visits; a time interval of 6 months was used to input only single measured value in a single time interval. Missing values in the time interval were imputed using the last-observation-carried-forward method. After calibration based on the known distance between the threads, the border between the polished surface and rough surface was determined as a reference point, and the distance between this reference point and the most-coronal bone-to-implant contact point was measured on both the mesial and distal sides of the implants using Adobe Photoshop (version CS6, San Jose, CA, USA). The marginal bone level was calculated by averaging two measurement values. All measurements were performed by one examiner (M.H.K.)

after confirming a good interclass correlation with an experienced researcher (J.S.L.) by a coefficient of 0.902 ($P < 0.01$). The intraclass correlation coefficient for the repeated measurement made 2 weeks later was 0.934 ($P < 0.01$).

3. Statistical analysis

After using the log-rank test to select candidate critical risk factors for marginal bone loss ($P < 0.05$), these candidates were entered into a multivariate analysis. Cox regression with the shared frailty model was performed (SPSS version 23, SPSS, Chicago, IL; and R version 3.3.2, http://www.r-project.org), and the exponential value of the coefficient was used as the hazard ratio of selected study variables.

III. Results

1. Data demographics

In total, 1692 implants were placed in 881 patients with a mean age of 52.2 years (range 17~90 years), and the follow-up period was 5.3±2.7 years (mean±SD). The longest follow-up period was 10.7 years, and 1013 of the placed implants had a follow-up of at least 5 years. The cumulative implant survival rate was 98.2%, with 21 implants being removed: 13 implants before prosthetic treatment due to failure of osseointegration, and 8 after prosthetic treatment with or without marginal bone loss. The demographics data of the patients, surgeries, and prostheses are described in Table 1. Most of the cases were treated using implants with a diameter of ≥4 mm (98.3%), a length of ≥10 mm (86.6%), and a standard design (74.9%). Implants were placed mostly in the mandibular posterior area (58.0%) and maxillary posterior area (39.7%). Guided bone regeneration and the sinus graft procedure were performed in 7.7% and 6.7% of the cases, respectively. Diabetes mellitus and cardiovascular diseases were present in 7.7% and 19.0% of the patients, respectively.

2. Peri-implant marginal bone loss

Figure 1 shows a spaghetti plot of all data for the bone loss pattern in the 1692 implants. Most of the implants showed only slight peri-implant marginal bone loss, with a

very low incidence of pathologic marginal bone loss exceeding 2 mm. As described in Figure 2, only 14 implants showed pathologic marginal bone loss exceeding 2 mm during the follow-up. While 2 implants were removed with continuously progressive marginal bone loss at 5.5 and 7.5 years after the surgery, 5 of these 14 implants showed early bone loss exceeding 1 mm during the first year, but subsequently showed a tendency of a stable marginal bone level. In the seven other implants, the bone loss started during the first year and then progressed continuously. The overall peri-implant bone loss was 0.07 0.21 mm, 0.09 0.26 mm, 0.14 0.41 mm, and 0.17 0.45 mm at 3, 5, 7, and 9 years, respectively, when there were 1356, 1106, 675, and 198 implants (Table 2).

The proportions of implants with different amounts of bone loss at selected time intervals are presented in Table 3. More than 99% of the implants showed less than 1 mm of bone loss during a 3-year follow-up, and thereafter 1.9% of the implants showed bone loss exceeding 1 mm. Implants with more than 3 mm of bone loss were found only for follow-up period exceeding 5 years after the surgery. Two representative cases are demonstrated in Figure 3: (1) one that showed minimal bone loss and maintained its stable marginal bone level during a 6.5-year follow-up, and (2) one accompanying a crestal approach sinus graft procedure that showed an initial bone loss of ≥1 mm within 1 year followed by a stable marginal bone level during a 7-year follow-up. In the latter case, screw loosening of the prosthesis was detected after 3 years, but there were no signs of inflammation. Implants that exhibited pathologic marginal bone loss exceeding 2 mm during follow-up periods of up to 10 years are summarized in Table 4.

3. Multivariate analysis using Cox regression with shared frailty for peri-implant bone loss

Applying the log-rank test to all study variables revealed three statistically significant factors (diameter ≥4 mm or <4 mm, P = 0.000; installation site, P = 0.000; prosthesis type, P = 0.006), and these were entered into the multivariate analysis. Cox regression with the shared frailty model revealed that the peri-implant marginal bone loss was affected by the implant diameter: implants with diameter of ≥4 mm showed a hazard ratio of 0.09 (P = 0.018, Table 5).

IV. Discussion

This study retrospectively analyzed 1692 implants using a single implant system that were placed by periodontal and prosthodontic specialists at a single center. It was found that most of the implants showed only slight bone loss (close to 0 mm), with a very low incidence of pathologic marginal bone loss exceeding 2 mm. However, a multivariate Cox regression analysis suggested that the implant diameter can affect the marginal bone loss around this implant system. Therefore, while the Straumann dental implant system can provide highly predictable long-term results, a protocol for selecting the implant diameter needs to be developed in order to ensure the most favorable outcomes.

The observed overall peri-implant bone loss was 0.07±0.21 mm, 0.09±0.26 mm, 0.14±0.41 mm, and 0.17±0.45 mm at 3, 5, 7, and 9 years, respectively, when there were 1356, 1106, 675, and 198 implants. These values are much lower than those of other studies that have investigated implant survival and changes in the marginal bone level of Straumann dental implants [e.g., 1.2 mm at 5 years (Behneke et al., 2000) and 0.9 mm at 5 years (Meijer et al., 2004)], but they are consistent with a prospective cohort study finding that 99 of 100 implants exhibited a mean change in bone level of 0.15 mm between 3 months and 5 years after the day of abutment connection (Bornstein et al., 2005). Derks et al. (2016) investigated national social insurance agency data for randomly selected patients, and found that the bone loss was 0.72±1.15 mm at about 9 years after the prosthetic treatment (Derks et al., 2016). However, that study used various implant

systems, and the prosthetic treatments were performed by general practitioners in 74% of patients. In contrast, in our study only a single implant system was applied in all cases and all of the surgical and prosthetic treatments were performed by periodontal and prosthodontic specialists at a single center.

The available numbers of implants decreased as the follow-up period increased in this study, and so proportions of implants with different amounts of bone loss in selected time intervals were calculated (Table 3). The proportion of implants with pathologic marginal bone loss exceeding 2 mm increased over time, but it remained very low (0.8%; 14 of 1692 implants). This is a much lower proportion than in a 5-year retrospective study of a single implant system, which found that 14.8% and 5.2% of implants showed bone losses exceeding 2 and 3 mm, respectively (Pettersson and Sennerby, 2015), and in another retrospective study that found that 18.6% of implants showed bone loss exceeding 2.1 mm (Dierens et al., 2012).

Pathologic marginal bone loss exceeding 2 mm was found in 14 of the implants in the present study, of which 5 implants showed early bone loss exceeding 1 mm during the first year combined with a tendency of maintaining a stable marginal bone level thereafter. However, the bone loss that started during the first year in the other seven implants subsequently progressed continuously. The biologic width around natural teeth differs between both individual patients and installation sites, and the peri-implant biologic width or marginal bone level can also differ. Therefore, considering that 5 of the 14 implants were regarded as having a certain distance between the implant shoulder and

bone crest, the progressive bone loss that occurred in the other 7 implants should be regarded as surpassing the physiologic defensive mechanism, and hence needing careful supervision.

The multivariate analysis showed that the implant diameter affected the pathologic marginal bone loss (Table 5). However, the proportion of implants showing pathologic marginal bone loss differed significantly between implants with diameter of <4 mm and ≥4 mm: 2 of 28 (7.14%) vs 12 of 1469 (0.82%). The two cases involving implants with diameter of <4 mm showed very narrow ridges: one case had a 5-mm buccal dehiscence defect, and showed an early marginal bone loss of 1.08 mm during the first year that then slowly progressed to 2.35 mm at 3 years, and maintained a stable bone level thereafter; the other case had a buccal dehiscence defect spanning 1~2 threads of the fixture, and an autogenous bone graft procedure without using membrane was performed, and it showed a relatively stable marginal bone level up to 3 years with bone loss of <1 mm, but then suddenly showed 3.31 mm of bone loss at the 4-year follow-up. These observations suggest that in addition to the implant diameter, the presence of a bone defect around the fixture due to a significantly narrow alveolar ridge and the bone graft procedure performed in the latter case negatively influenced the stability of the peri-implant marginal bone.

The very low occurrence rate of significant pathologic marginal bone loss in this study means that the reported results should be interpreted conservatively. This study is based on retrospective analysis, which used large samples of data without having

precisely controlled follow-up visits. This may lead to employing substitution of missing values occasionally. Therefore, to confirm a prevalence of pathologic marginal bone loss and to identify its risk factors, prospective study with large samples and long term observational period should be needed.

V. Conclusion

This retrospective study has demonstrated that Straumann tissue-level dental implants can show minimal changes in the marginal bone level during follow-up periods among which the maximum lasts up to 10 years.

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Figure Legends

Figure 1. Spaghetti plot showing marginal bone loss pattern of 1692 implants; if marginal bone loss progressed to 10mm depth, the implant failed.

Figure 2. 14 implants showed marginal bone loss ≥ 2mm up to 10 years of follow-up periods; if marginal bone loss progressed to 10mm depth, the implant failed.

Figure 3. Representative cases. Implants on #36,37 showed stable marginal bone level through 6.5 years of follow-up period. The radiograph 6.5 years after the surgery showed no bone resorption. (a)~(e) Implant on #16 showed initial crestal bone resorption thereafter stable marginal bone level. The 7-year follow-up radiograph showed reduced but stable marginal bone level. There was screw loosening of prosthesis once 3 years after the prosthesis without any inflammation signs (f)~(j).

Tables

Table 1. Variables investigated at the implant and patient levels (DM, diabetes mellitus; GBR, guided bone regeneration).

Implant		Patient	
Diameter		Gender	
≥ 4 mm	1664	Male	496
< 4 mm	28	Female	385
Length		DM	
≥ 10 mm	1469	Yes	68
< 10 mm	223	No	813
Implant design		Cardiovascular diseases	
Standard	1268	Yes	167
Standard plus	92	No	714
Tapered effect	332	Smoking	
Site		Yes	56
Mandibular anterior	26	No	185
Mandibular posterior	981	(no record)	640
Maxillary anterior	14		
Maxillary posterior	671		
Bone quality			
D1	18		

D2	510
D3	563
D4	189
(no record)	412
Insertion torque	
< 20 N	10
20~29 N	256
30~39 N	371
40~49 N	282
≥ 50N	419
(no record)	354
GBR	
Yes	131
No	1561
Lateral sinus graft	
Yes	113
No	1579
Prosthetic type	
Single fixed partial denture	524
Hemilateral fixed partial denture	1112
Bilateral fixed partial denture	13
Removable denture	13

Table 2. Average bone loss and standard deviation at the selected time interval.

Time (Years)	1	2	3	4	5	6	7	8	9	10
Average bone loss (mm)	0.05	0.06	0.07	0.08	0.09	0.11	0.14	0.17	0.17	0.13
Standard deviation (mm)	0.17	0.19	0.21	0.23	0.26	0.31	0.41	0.33	0.45	0.17
Number of implants	1585	1444	1356	1252	1106	931	675	410	198	25

Table 3. Percentage of implants showing a range of bone loss at the selected time intervals.

	Bone loss < 1mm	1mm ≤ Bone loss < 2mm	2mm ≤ Bone loss < 3mm	Bone loss ≥ 3mm
<1 year	99.5%	0.4%	0.1%	0.0%
1-3 years	99.1%	0.5%	0.3%	0.0%
3-5 years	98.1%	1.4%	0.5%	0.0%
>5 years	96.6%	2.5%	0.5%	0.4%

Table 4. Details of bone loss ≥ 2mm cases (NR, no record; GBR, guided bone regeneration).

Position	Age	Gender	Diameter (mm)	Length (mm)	System	Bone quality	Insertion torque (Ncm)	Follow-up (Years)	Bone loss (mm)	Note
25	43	M	4.8	12	S	D2	55	7.5	5.445	Implant removal
16	36	F	4.8	10	TE	D2	30	5.5	3.005	Implant removal
36	48	F	4.1	12	S	D2	50	9	5.403	-
27	68	M	4.8	12	TE	D3	20	7	3.715	GBR
46	44	F	4.8	10	S	D3	50	7.5	3.675	-
35	48	M	3.3	12	S	D2	55	9.5	3.310	GBR
47	47	M	4.8	10	S	NR	30	8.5	2.755	-
16	48	F	4.8	10	TE	D3	30	7	2.705	-
23	50	M	4.1	10	S	D3	40	7	2.670	-
42	53	M	3.3	10	SP	D2	50	8	2.655	Penicillin allergy
47	22	F	4.8	10	TE	NR	50	3.5	2.655	-
48	62	M	4.1	8	S	D2	50	7	2.310	-
11	54	F	4.1	12	S	D4	NR	2.5	2.220	-
47	82	M	4.8	10	S	D3	35	4	2.040	-

Table 5. Multivariate cox regression with shared frailty.

Variables	Hazard ratio	P value	95% Confidence interval
Diameter ≥ 4mm (reference: < 4mm)	**0.09**	**0.018**	**0.01 – 0.67**
Site (reference: Mn. Anterior)			
Mn. Posterior	1.19	0.920	0.04 – 31.79
Mx. Anterior	22.94	0.078	0.71 – 744.34
Mx. Posterior	1.01	1.000	0.03 – 29.60
Prosthetic type (reference: Bilateral fixed partial denture)			
Single fixed partial denture	0.66	0.780	0.03 – 12.70
Hemilateral fixed partial denture	0.39	0.530	0.02 – 7.55

Figures

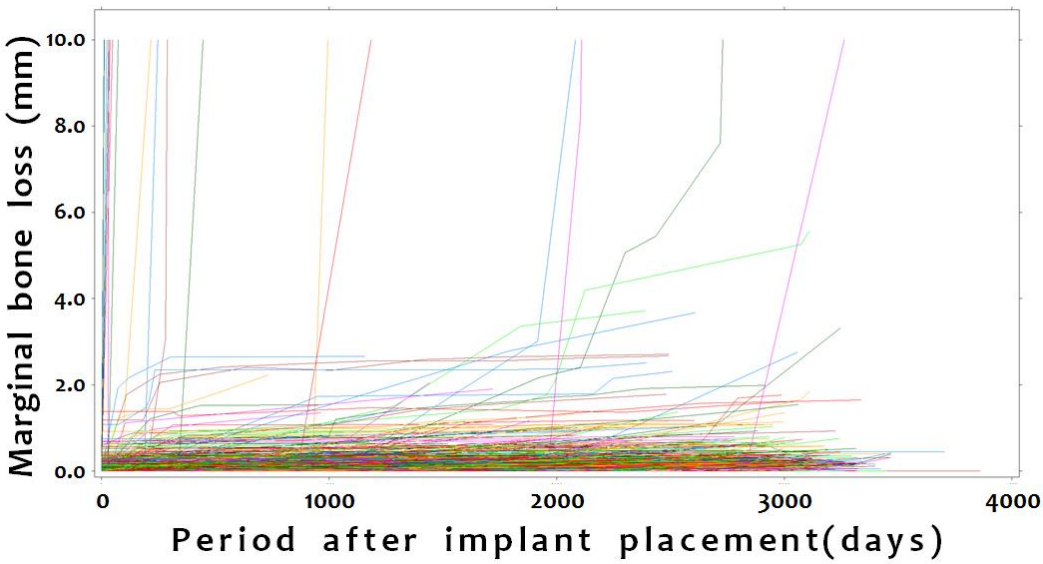

Figure 1

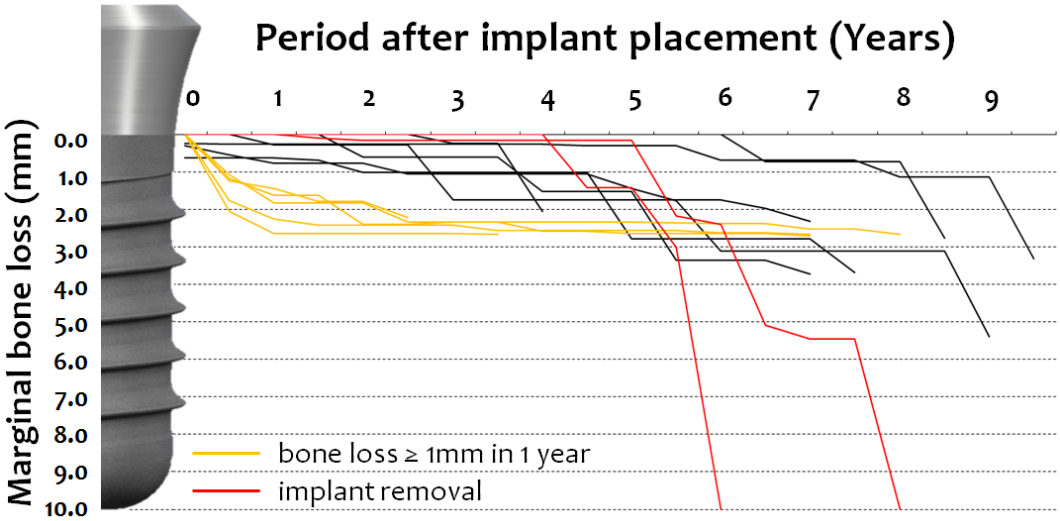

Figure 2

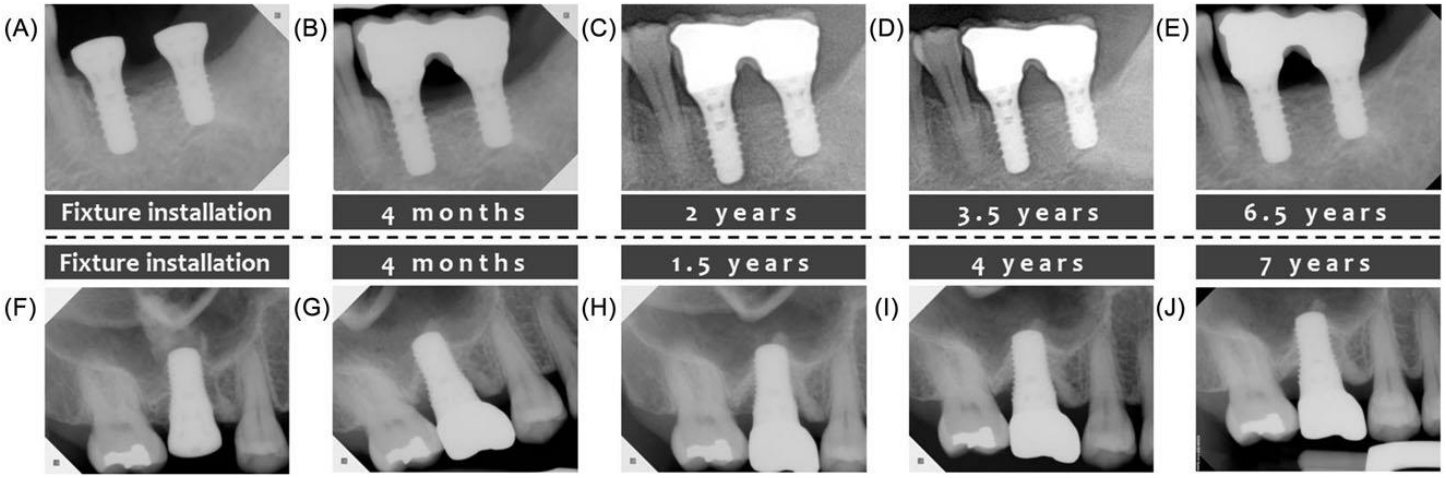

Figure 3

국문요약

1692 개 티슈 레벨 임플란트 주위 변연골 안정성에 대한 10 년간의 후향적 방사선학적 연구

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임플란트 식립은 높은 성공률 및 예지성 있는 치료결과를 보이지만, 임플란트 성공률과 주위 변연골 흡수에 대한 다수의 환자에서 10 년까지의 추적 임상 데이터를 기반으로 하는 장기간 연구는 그리 많지 않은 실정이다. 이 연구는 연세대학교 치주과에서 스트라우만 티슈 레벨 임플란트를 식립을 시행한 환자들에게서 환자와 임플란트 관련 여러 요소들과 임플란트 주위 변연골 흡수량 사이의 관계를 조사하고 분석하는데 목적을 둔다.

총 1692 개의 임플란트가 881 명 환자에 식립되었고, 관련 자료가 수집되었다. 임플란트 변연골 높이가 방사선 사진 계측을 통해 평가되었고, 10 년까지의 변화가 추적되었다. Log-rank test 로 후보 위험 요소들이 선택되었고, Cox regression with shared frailty model 을 이용한 다변수 분석이 이루어졌다.

임플란트 변연골 소실량은 각 3, 5, 7, 9 년에 0.07 ± 0.21 mm, 0.09 ± 0.26 mm, 0.14 ± 0.41 mm, 0.17 ± 0.45 mm 로 측정되었고, 이는 스트라우만 티슈 레벨 임플란트가 10 년까지 유지 기간 동안 매우 안정적인 변연골 수준을 유지할 수 있음을 보여준다. 오직 14 개의 임플란트에서 2mm 를 초과하는 변연골 소실량을 보였고, 다변수 분석 결과 임플란트의 직경이 변연골 소실에 영향을 주는 것으로 나타났다. 하지만 임플란트 직경에 따른, 2mm 를 초과하는 변연골 소실을 보이는 임플란트의 상대적 비율에 유의미한 차이가 있었고, 직경 4mm 이하의 임플란트에서 변연골 소실이 2mm 를 초과하는 두 증례에서 협측 치조골 열개가 있었다는 점, 후향적 연구라는 점에 비추어볼 때 이번 연구 결과는 해석에 주의가 필요하며, 더 정확한 분석을 위해서는 더 많은 표본을 통한 더 긴 기간 동안의 전향적 연구가 필요할 것으로 사료된다.

핵심되는 말 : 임플란트, 임플란트 안정성, 장기간 연구, 변연골 소실, 후향적