치의과학석사학위논문

Clinical phenomena of bone responses depending on implant-abutment connection structures

임플란트-지대주 연결 구조에 따른 골반응의 임상적 현상

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-ABSTRACT-

Clinical phenomena of bone responses depending on implant-abutment connection structures

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1. Purpose

This study aimed to evaluate the effect of two different implant–abutment connection structures with identical implant design on peri-implant bone level.

2. Materials and Methods

This clinical study was a randomized controlled trial following the CONSORT 2010 checklists. Implants with internal friction connection were compared to implants

with external hex connection. Eleven external hex and eleven internal friction implants were analyzed in this study. These implants had the same design except the connection structure. One implant for each patient was installed, replacing the second molar in the maxilla or mandible. Cement-retained crowns were delivered at four months after implant insertion. Standardized periapical radiographs were taken at prosthesis delivery (baseline), and one year after delivery. On the radiographs, distance from implant shoulder to first bone-to-implant contact (DIB) and peri-implant area (PA) were measured. These measurements were compared between two connections using the independent t-test, which was evaluated at 0.05 significance level. Also, this study measured strain around the implant–abutment joint area at an *in vitro* bone model setting under 100,000 cyclic loading

3. Results

Mean changes of DIB from baseline to 1-year loading were 0.59 ± 0.95 mm for the external, and 0.01 ± 0.68 mm for the internal connection. Although no significant differences were found between two groups in the change of PA and DIB, medium effect size was found in DIB between the connections (Cohen's d=0.67). The internal friction connection displayed higher values of strain than the external hex connection. Internal friction connection's strain was measured 993 μm/m and external connection registered 904 μm/m.

4. Conclusions

Within the limitation of this study, the results of this one-year comparative clinical trial suggested the possibility of internal friction connection in more effective preservation of marginal bone despite of no significant differences in the bone level between the implant-abutment connection structures, considering the effect size in the vertical bone level change.

Keywords: Clinical trials; Bone implant interactions; Periodontology; Implant–abutment connection; Marginal bone level

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CONTENTS

INTRODUCTION

The stability of hard and soft tissues around dental implants is one of the most decisive factors for long-term implant prognosis.[1,2] Marginal bone loss is a major factor in implant success or failure.[3] Peri-implant infection plays a role in the marginal bone resorption around a dental implant.[4]

A previous study has suggested several factors that cause the marginal bone loss, including surgical trauma, reformation of biologic width, implant-abutment connection structure, history of periodontitis, and occlusal overloading.[5,6] Some studies have assessed the effects of implant-abutment connection structure on the marginal bone level change.[7-10] The implant-abutment connection structure is an important etiologic factor for peri-implant bone remodeling and crestal bone loss, as the highest number of inflammatory cells is infiltrated and the bacteria causing periodontitis are colonized at the microgap of implant-abutment connection.[11,12]

Biomechanical bone responses depending on implant-abutment connection structure are also considered to affect marginal bone level at peri-implant sites. Compared to the external hex connection, the internal friction connection structure has been shown to be mechanically more stable and advantageous in force distribution.[13,14] Some studies have reported high stress and marginal bone loss around the external hex connection structure compared with the internal friction.[15-17] Also, some authors have reported higher strain around internal friction connection than external hex connection.[18] In contrast, other studies have

reported that marginal bone loss between two different connection structures is not statistically significant.[19,20] Inconsistent results might stem from uncontrolled confounding factors of implant design, such as microthread, platform switching, and surface texture.

An occlusal overload could affect peri-implant marginal bone loss.[21] Because of the biomechanics of the lever system of the mandible and jaw elevator muscles, the occlusal force is greater on the posterior than on the anterior region. Hence, relative distribution of occlusal bite force in the posterior region is higher than that in the anterior region.[22] Therefore, it is necessary to limit implant sites to exclude the difference of occlusal force.

To the best of our knowledge, a direct comparison between two different implant–abutment connection structures (external hex and internal friction connections) with identical implant design in the posterior region has not been investigated. The current study aimed to evaluate the effect of implant–abutment connection structure with identical implant design in the posterior second molar region on the peri-implant bone level. Also, this study measured strain around the implant–abutment joint area at an *in vitro* bone model setting under cyclic loading.

MATERIALS AND METHODS

This blinded, randomized, parallel, controlled clinical trial was performed according to the principles of the Declaration of Helsinki and was approved by the

Institutional Review Board (IRB #CMP13001), Seoul National University Dental Hospital, Seoul, Korea. The CONSORT 2010 checklists for clinical trials were followed.[23] Two different connection structures of the implants were compared: external hex connection structure (the control group) and internal friction connection structure (the test group). The study was performed between March 2013 and July 2015 at Seoul National University Dental Hospital, Korea. The flowchart of this study is presented in Fig 1.

Patient selection

Patients who met all of the following criteria were eligible for inclusion.

1) Patients aged 20–66 years who could undergo surgical treatment
2) Patients who needed to restore a single posterior second molar due to the tooth loss
3) Patients with sufficient healing time of at least 3 months following tooth extraction
4) Patients who agreed to take the test and sign the informed consent form
5) Patients with at least 9 mm width and 9 mm height of alveolar bone in cone beam computed tomography analysis.

The exclusion criteria were as follows:

1) Untreated periodontal disease
2) Acute abscess with pain

3) Heavy smokers (>10 cigarettes per day)

4) Parafunctional habit (bruxism, clenching)

5) General contraindications to surgery

6) Participation in other clinical trials that may interfere with the present protocol

Randomization sequence was created using the randomization program on http://www.randomization.com by an examiner who did not performed the treatment. In total, 24 subjects were randomized into six blocks. The allocation was concealed by sealing it in an opaque envelope, and the envelope was opened immediately after the final drilling procedure performed at implant surgery.

Patients were recruited and treated by two different periodontists and one prosthodontist. The treatment was performed using a standardized protocol, and the surgery was conducted by two periodontists on 24 patients (12 in each group). Detailed explanations were given to all recruited patients and a written informed consent form was obtained before enrolling in the clinical trial.

Clinical procedures

After local anesthesia using 2% lidocaine solution with epinephrine 1:100,000 (Huons, Seongnam, Gyeonggi, Korea), a flap was reflected and dental implants (diameter 5.0 mm; length 8.5, 10, or 11.5 mm; Shinhung, Seoul, Korea) were placed at the buccal bone crest level at maxillary or mandibular second molar region according to the manufacturer's recommendation using a non-submerged protocol,

and a healing abutment was immediately connected. At implant placement, patients were allocated either to control group (external hex connection type; Sola, Shinhung, Seoul, Korea) or test group (internal friction connection type; Luna, Shinhung, Seoul, Korea) following the implant drilling procedure (Fig 2). No bone augmentation procedure was conducted around the implant placement site. Instructions not to brush the surgical area and to rinse with 0.1% chlorhexidine (BUKWANG PHARM.CO., LTD., Seoul, Korea) until suture removal were given to the patients, and the suture was removed 7–10 days after surgery. Antibiotics (Augmentin 625 mg) and analgesics (acetaminophen 650 mg) were also prescribed every 8 hour for 5 days. The prosthetic procedure was performed at 4 months following implant surgery.

A standardized periapical radiograph (Kodak Ektaspeed Plus film, 1512 × 1134 pixels, 40 × 30 mm, 256 grayscale, Eastman Kodak Co., Rochester, NY, USA) was taken using the paralleling technique (60 kV, 10 mA, 0.250 s) with RINN XCP positioners (Dentsply Sirona, York, PA, USA) at implant placement, prosthesis delivery (baseline, 4 months after implant placement), and 1 year postloading. The standardized radiographs were obtained with customized polyvinyl siloxane (Blu-Mousse, Parkell, Edgewood, NY, USA) radiograph templates according to a previous study.[24] Radiographic images were stored in tiff format (INFINITT PACS, Infinitt, Seoul, Korea).

An examiner conducted repeated measurements of the radiographic

parameters using an image analysis program (ImageJ 1.60, NIH, Bethesda, MD, USA). Radiographs were assessed on a 24-inch liquid crystal display monitor (Samsung, Seoul, Korea) under standardized conditions (ISO 12646:2015). Parameters in the radiograph were calibrated with the known width and length of the implants. After training 10 samples, a high intra-examiner reliability was achieved. The intra-class correlation coefficients for the radiographic parameters were 0.918 and 0.924, respectively.

Strain gauge analysis

An examiner conducted the experiment using a strain gauge. It was a comparison for strain between the external hex and internal friction connections. One external hex and one internal friction implant were analyzed. Two strain gauges were attached to the surface of each wood block imitating bone with cyanoacrylate glue. Strain gauge 1 and strain gauge 2 were placed to 90 degrees adjacent to the implant (Fig 3a). Each gauge was wired separately. Two strain gauges were arranged in series to form a Wheatstone bridge. A computer was interfaced with the bridge amplifier to register the output signal of the surface wood block. A data acquisition software (CatmanAP, HBM, Darmstadt, Germany) was used to accumulated the data. All strain gauges were set to 0. Initial strain measurement was performed at abutment screw retightening before axial cyclic loading. Final strain was recorded after 100,000 cyclic loading. The abutment screw was tightened with

a hand-operated screwdriver (Torque Driver, Shinhung, Seoul, Korea), and with a torque of 30 Ncm according to the manufacturer's instruction. The specimens (control group: external hex connection, test group: internal friction connection) were placed and axial compressive loading was applied to the specimens (Fig 3b). The load was applied with a chewing simulator (Dual-Axis Chewing simulator CS-4.8, SD Mechatronik GmbH, Germany) at a rate of 1.19 Hz for 100,000 cycles. After 60-N vertical loading for 100,000 cycles, final strain was measured.

Outcome measures

The parameters were calculated as follows (Fig 4):

DIB: distance from implant shoulder to first bone-to-implant contact

PA: peri-implant area

The average calculated value of the mesial and distal parts was obtained for each implant. The measurement was progressed to the nearest 0.01 mm.

Statistical analysis

To calculate the appropriate sample size, we assumed the mean difference of changes in marginal bone level between internal and external connection types as 0.6, and its standard deviation as 0.5, based on results of a previous study.[16] The sample size of 12 per group was calculated by setting the effective size as 1.2, required minimum power level as 0.8, and alpha error level as 0.05. The actual

power was 0.80 with the sample size using the G*Power 3.1.[25]

Most outcome variables for data normalization were accepted using the Shapiro–Wilk test ($P > 0.05$). Descriptive statistics were displayed using mean and standard deviation. To assess the difference in DIB and PA values between groups and their changes within the groups, parametric independent *t* test and paired *t* test were applied, respectively. An effect size of Cohen's d was calculated to assess the actual difference in changes of DIB and PA as following formula:[26]

$$\text{Cohen's d} = \frac{\text{Mean}_1 - \text{Mean}_2}{\sqrt{\frac{n_1 {SD_1}^2 + n_2 {SD_2}^2}{n_1 + n_2 - 2}}}$$

The statistical software IBM SPSS Statistics Version 22 (IBM Corp., Armonk, NY, USA) was used for the analysis. Statistical significance was set at $P < 0.05$.

RESULTS

Patient data

A total of 24 subjects were recruited and 22 received treatment. One patient in the control group did not receive the allocated intervention due to the participant's decision to change, and one patient in the test group did not return to the treatment program. Eleven implants in 11 patients were assigned to control group (the external connection) and test group (the internal connection).

Patient characteristics related to sex, age, smoking, systemic disease, history of periodontitis, reason for extraction, presence of the adjacent third molar, implant length (data not shown), gingival thickness, and bone quality are presented in Table 1. No statistically significant differences were found between the two groups.

Clinical results

Insertion torque was between 25 and 40 Ncm in all implants. No remarkable complications were reported throughout the study. Implants success rate was 100%, according to the criteria proposed by the International Congress of Oral Implantologists Consensus Conference.[3] Prosthetic screw loosening was observed once in one subject and two times in one subject (two patients were in the control group). All loose screws were replaced according to the manufacturer's recommendation.

Radiographic analysis

The means of DIB and PA at implant prosthesis delivery (baseline) and at 1 year postloading are shown in Table 2. There were no statistically significant differences between the control and test groups at baseline. The mean changes of DIB from baseline to 1 year were 0.59 ± 0.95 mm and 0.01 ± 0.68 mm for external and internal connection structure, respectively. No significance was found in the DIB

change between the two groups (P = 0.116). However, the effect size of average change between two group was observed to medium (Cohen's d = 0.67). Average changes in PA between baseline and 1-year post loading were 0.10 ± 0.46 mm and 0.09 ± 0.51 mm in the control and test groups, respectively, and there was no significant difference between the two groups (P = 0.923). The effect size of average change between two group in PA was small (Cohen's d=0.02).

Strain-gauge analysis

The internal friction connection displayed higher values of strain than the external hex connection. After 10^5 cyclic loading, internal friction connection's strain was measured 993 μm/m and external connection registered 904 μm/m (Table 3, Fig 5).

DISCUSSION

The present clinical study aimed to evaluate the crestal bone response to implant–abutment connection structures. To date, no published randomized controlled trial has evaluated the effect of implant–abutment connection on single implant-supported crowns replacing only the missing second molar. Previous studies that have estimated marginal bone level change have focused on diverse factors, especially with respect to implant location, implant–abutment junction, surgical approach (submerged or non-submerged), implant surface, presence of adjacent

tooth, and history of periodontitis.[6,13,16,17] However, to preclude aforementioned factors as a variable, the present study had to adhere to strict inclusion criteria, with the only difference being the implant–abutment connection, same implant thread design and texture, second molar position, two-stage protocol, implant diameter (5 mm), and length falling within the ranges of 8.5 – 11.5 mm, respectively. Fortunately, in our recruited subjects, there were no differences between two groups for reasons for extraction (P = 0.678) and history of periodontitis (P = 0.361). Therefore, the authors of this study considered the effect of localized and/or generalized periodontitis was minimized enough to compare test and control group.

In the present study, the DIB of the external hex connection tended to increase at 1 year postloading despite of no significance between the baseline and the 1 year postloading due to the small sample size. In this study, the effect size of Cohen's d was calculated. It was interpreted as small, medium and large corresponding to values of 0.2, 0.5, and 0.8, respectively.[26] Although the differences could not be confirmed in PA and DIB in terms of P-value, the effect size in DIB was observed to be medium. In this point of view, internal connection type might be favorable to peri-implant bone response compared to external hex type. However, no differences between control and test group in PA were observed. Initial marginal bone loss is considered to progress linearly to the apical direction and then expand peri-implant area. As a result, one-dimensional parameter, DIB seems to show a medium effect size (Cohen's d = 0.67), whereas, PA, two-dimensional parameter,

exhibit small effect size (Cohen's d = 0.02). However, this result should be accepted carefully and further clinical long-term studies with larger sample size are needed to elucidate the effect of implant-abutment connection type.

Although there are some limits to making direct comparisons, similar studies have shown that internal connection structures exhibited lower values of marginal bone loss with no statistical difference between the connections.[20,27] Some other studies have shown that internal connection structures exhibited lower levels of marginal bone loss, showing a statistical difference compared with external connection structures.[28,29,30] Those authors concluded that the platform switching concept was largely responsible for marginal bone loss**.** This concept is based on research that a bacterial contamination of the implant–abutment interface appears to provoke the inflammatory response. Preventing microbial leakage at the implant–abutment junction has been reported to be a major challenge to minimize inflammatory reactions and to maintain the bone crest level at the junction.[31] However, there has been a study demonstrating that no difference in bacterial infiltration (*Escherichia coli and Streptococcus sanguis*) was found between the implant–abutment connection structures.[32]

The different biomechanics of implant-abutment connection structures can explain the different tendency in crestal bone responses to implant-supported restorations. The connection type exerts a significant influence on the stress distribution in bone because of the different load transfer mechanisms and

differences in the spread of the contact area between the abutment and implant. Stress around the peri-implant area has been shown to be higher in the external hex connection compared with that in the internal friction.[33] More importantly, peri-implant bone strain, which is a key factor to stimulate the bone response, significantly varies depending on the type of implant–abutment connection.[13] This study used strain gauge analysis to compare the strain distribution during cyclic loading. In the strain-gauge part of this study, it was found that the external hex connection had lower strains than internal friction connection, particularly under vertical cyclic loads. This finding suggests that the bone-implant interface of external hex connection implants may be at risk for debonding under dynamic loads, which would eventually lead to disuse atrophy and bone resorption.[34,35] The different strain values of implant-abutment connection type suggested that the local strain distribution had a major effect on the biological response of the marginal bone tissue around an implant.[36] The internal friction connection is considered to show more favorable tendency to maintain the bone level by effectively distributing the stress of masticatory or functional load in the mouth, and by efficiently converting the load to the peri-implant bone strain. However, the clinical relevance of these absolute strain values remains speculative only as the physiological strain thresholds of human jaw bones have not been quantified so far.[34]

The limitations of these randomized controlled trial and strain gauge investigation should be noted. Small sample sizes were contributed to no

significance in the data analysis. The evaluation at just one year follow-up was considered to be too short to find difference in the horizontal bony change. Further study with more samples and long-term follow-up are required to determine the relationship of implant–abutment connection structure and marginal bone response.

CONCLUSIONS

Within the limitations of this study, the results of this one-year comparative clinical trial suggested the possibility of the internal friction connection in more effective maintenance of the marginal bone level despite of no significant differences in the bone level between the implant–abutment connection structures, considering the effect size in the vertical bone level change.

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FIGURES

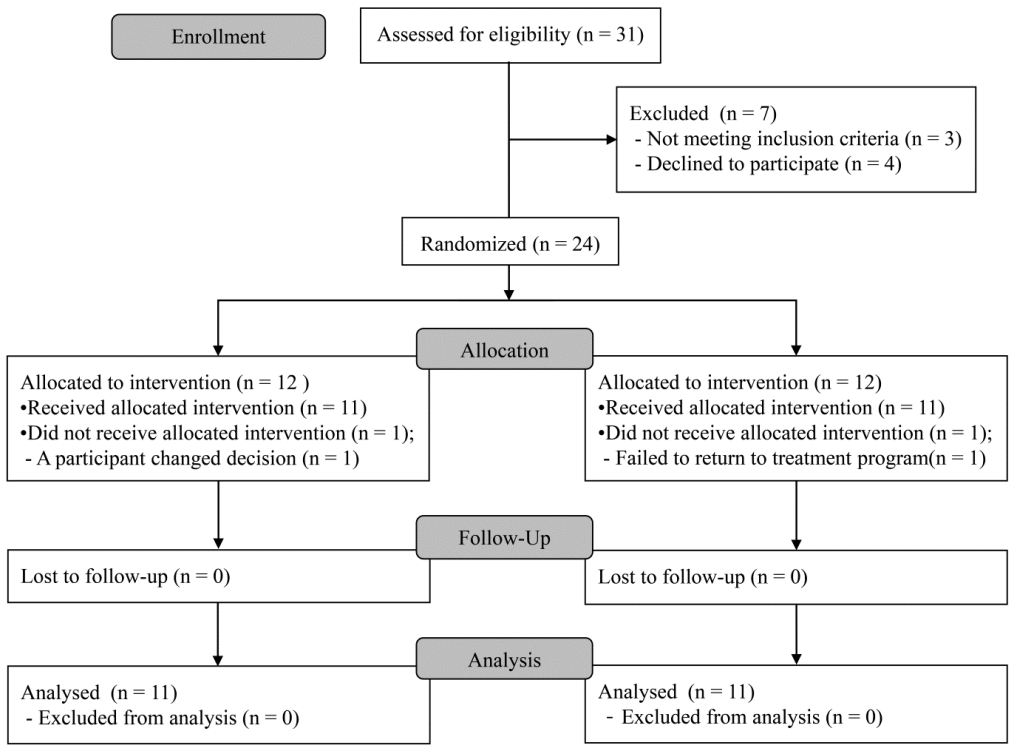

Fig. 1. Flow chart of the study. Twelve subjects were allocated to the control and test groups each. Two patients did not receive allocated interventions. One participant in the control group changed decision and one in the test group did not return to the treatment program. In total, 11 subjects in the control group and 11 in the test group received treatment and were analyzed.

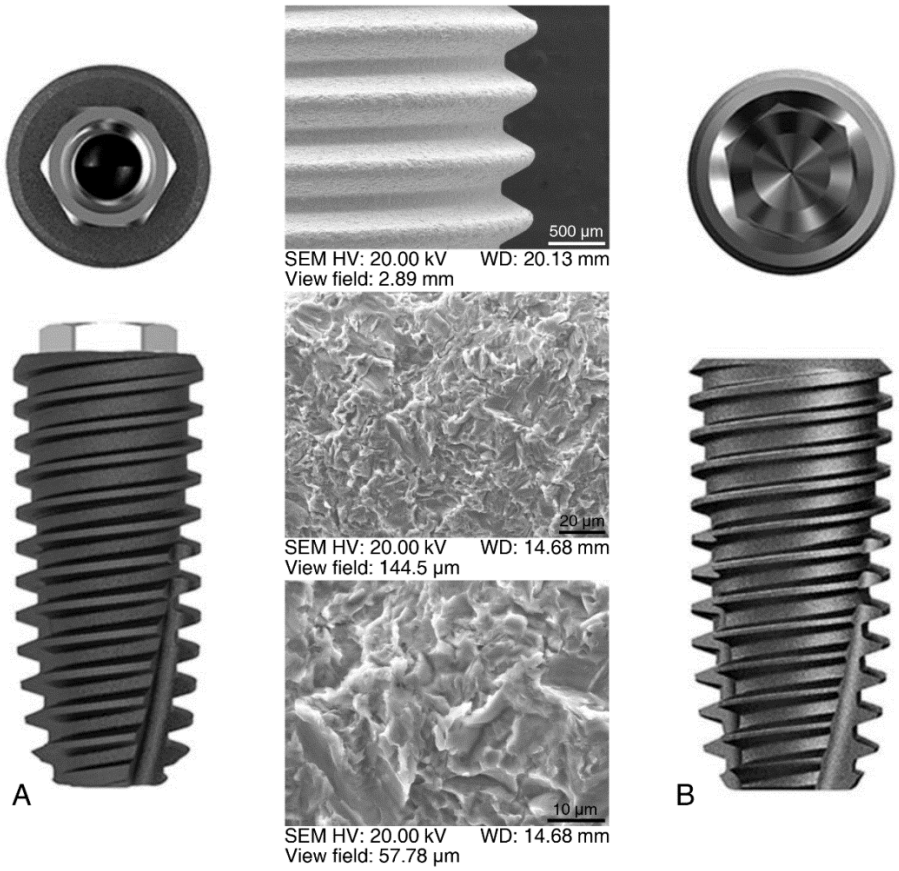

Fig. 2. Two implants with different implant–abutment connection structures were used in this study. The control group was an external connection structure (a), and the test group was an internal connection structure (b). Two implants have an identical design such as thread geometry, implant body profile, and surface topography (middle) with the exception of implant–abutment connection structure. The implant thread pitch is 0.8 mm, the thread depth is 0.3 – 0.45 mm, and the inclination angle of thread flank is 35°. Implant surface was blasted by resorbable blast media, and its arithmetic mean height (R_a) was 1.50 – 2.00 μm.

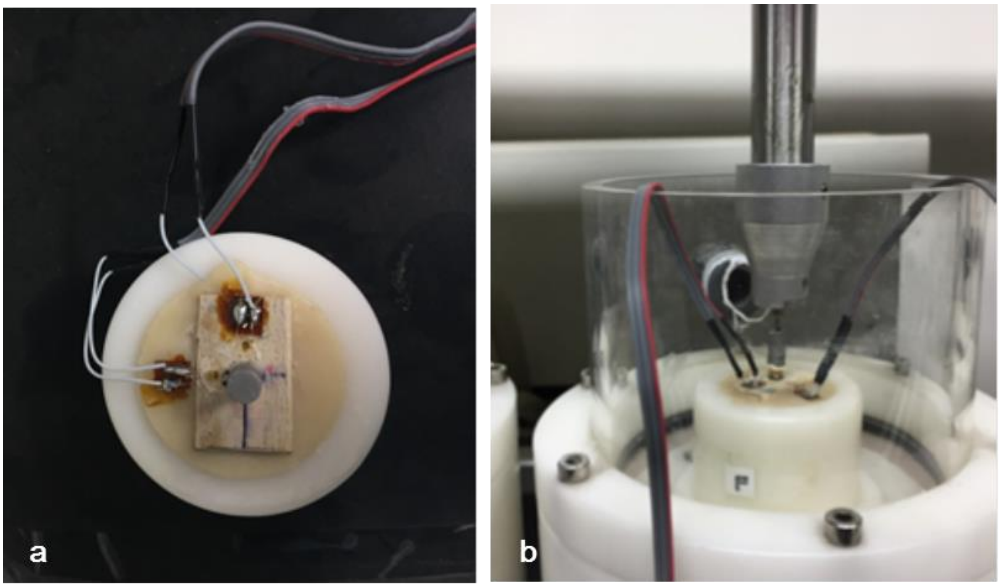

Fig. 3. (a) Strain gauges adjacent to the implant were fixed on the wood surface with a Z70 bond (cyanoacrylate glue). (b) Axial cyclic loading of 60 N was applied to metal cap by chewing simulator.

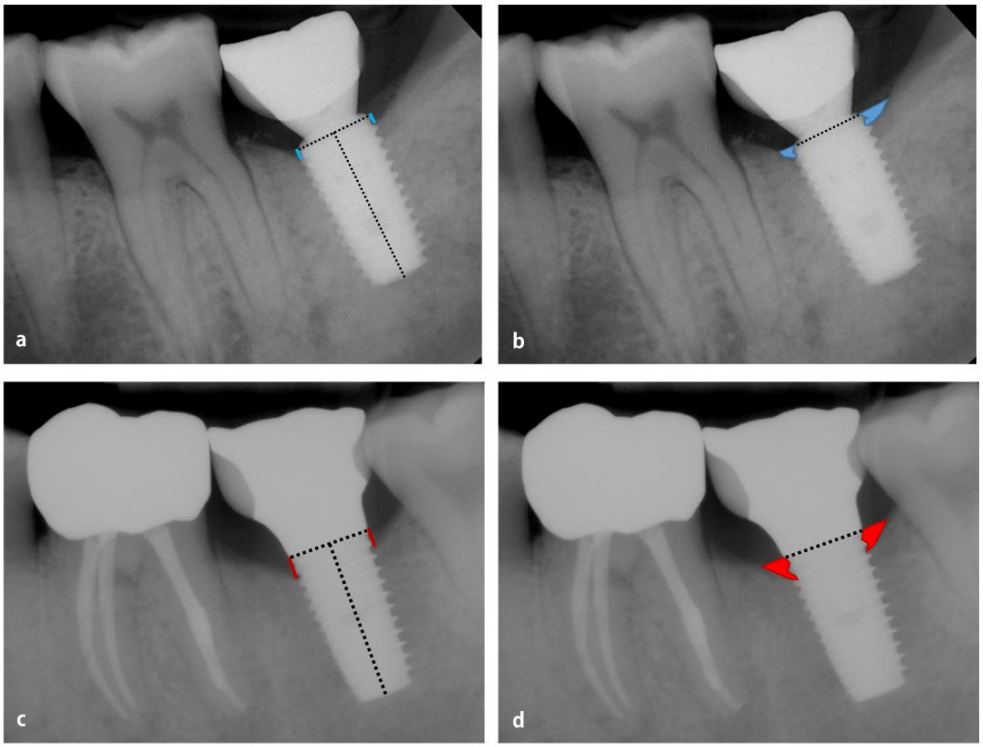

Fig. 4. Schematic of parameters performed in the radiographic analysis. Distance from implant shoulder to first bone-to-implant contact (DIB, blue lines) (a) and peri-implant area (PA, blue area) (b) of the test group (internal connection structure) were calculated. In the control group, DIB (c, red lines) and PA (d, red area) were also measured. The black dotted line represents an imaginary line parallel to vertical and horizontal axis of the implants. Digital processing of a radiographic image was performed using ImageJ 1.60 Image Tool software.

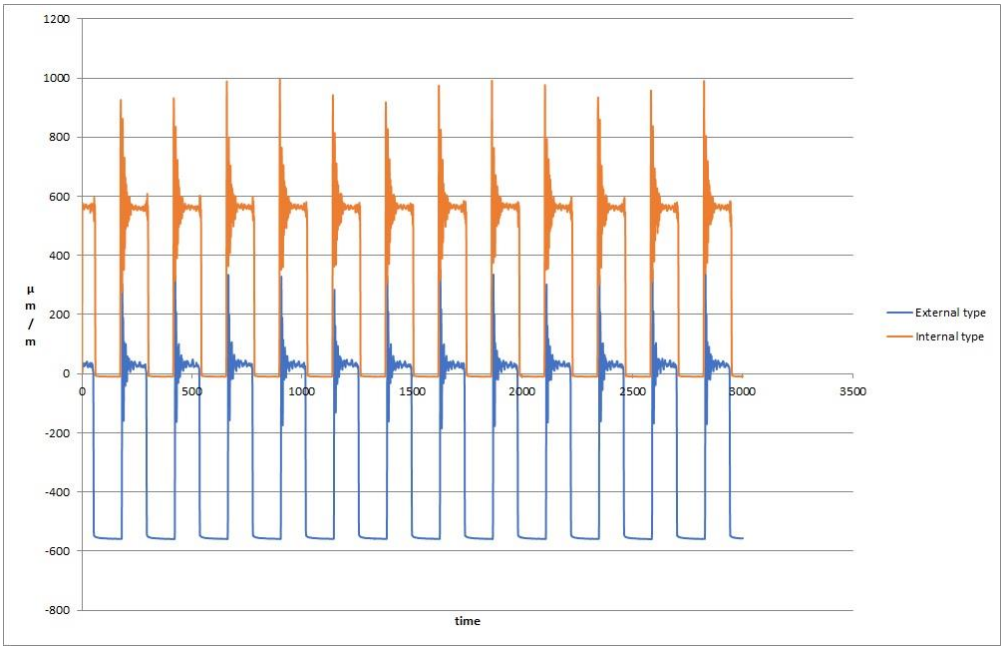

Fig. 5. Strain curves were obtained for the different implant abutment connection structures according to 100,000 cyclic loading.

TABLES

Table 1. Description of patient distribution recruited in this study

	Treatment group			
	Control (n = 11)	Test (n = 11)	Total (N = 22)	Significance
Sex				
Male	9	4	13	0.080
Female	2	7	9	
Age				
Under 45 years	5	4	9	1.000
≥.000ears old	6	7	13	
Smoking				
Non-smoker	7	10	17	
Former smoker	1	1	2	0.214
Mild smoker	3	0	3	
Systemic disease				
Hypertension	2	2	4	
Diabetes mellitus	1	0	1	1.000
None	8	9	17	
History of periodontitis				
Yes	5	2	7	0.361
No	6	9	15	
Reason for extraction				
Dental caries	1	2	3	
Endodontic failure	3	2	5	0.678
Periodontitis	4	6	9	
Root fracture/crack	3	1	4	
The 3rd molar				
Absence	8	11	19	0.534
Presence	3	0	3	
Gingival width				
<3 mm	4	5	9	1.000
≥. mm	7	6	13	
Bone quality*				
1	0	0	0	
2	6	5	11	0.230
3	3	6	9	
4	2	0	2	

* Bone quality was assessed at implant surgery according to the classification suggested by Lekholm and Zarb (1985).

Table 2. Comparative mean (SD) and changes in distance from implant shoulder to first bone-to-implant contact (DIB) and peri-implant area (PA) according to different implant connections

	External (n=11)	Internal (n=11)	P value[a]	Effect Size[c]
DIB at baseline	-0.06 (0.84)	0.21 (0.98)	0.813	
DIB at 1 year loading	0.53 (1.13)	0.26 (0.71)	0.105	
△DIB (baseline–1 year postloading)	0.59 (0.95)	0.01 (0.68)	0.116	0.67
P value[b]	0.067	0.837		
PA at baseline	0.34 (0.68)	0.31 (0.66)	0.917	
PA at 1 year loading	0.44 (0.98)	0.40 (0.63)	0.198	
△PA (baseline–1 year postloading)	0.10 (0.46)	0.09 (0.51)	0.923	0.02
P value[b]	0.495	0.566		

[a] P-value by independent samples *t* test.
[b] P-value by related samples paired *t* test.
[c] Cohen's d was used as the effect size.

Table 3. Mean strain comparison of SG for abutment connection type

	External (n=1)	Internal (n=1)
100,000 axial cyclic loading	904 μm/m	993 μm/m

Supplementary Table 1

CONSORT 2010 checklist of information to include when reporting a randomized trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5-6
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	8
Sample size	7a	How sample size was determined	8-9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	6
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6

Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6-8
	11b	If relevant, description of the similarity of interventions	9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8-9
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9-10, Figure 1.
	13b	For each group, losses and exclusions after randomisation, together with reasons	10, Figure 1.
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10, Table 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for	10

		specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	11-13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	11-13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	11-13
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Title page

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org

국문초록

임플란트-지대주 연결 구조에 따른 골반응의 임상적 현상

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(지도교수 여 인 성)

김 진 철

1. 목 적

임플란트-지대주 연결 방식만 다른 동일한 디자인의 임플란트에 외부육각연결(external hex connection)형, 내부마찰연결(internal friction connection)형의 임플란트 지대주를 연결하고 부하(loading) 1년 후 임플란트-지대주의 연결 구조가 임플란트 변연골 흡수에 어떤 영향을 미치는지 알아보고자 하였다.

2. 방 법

이 연구는 CONSORT 2010 체크리스트를 따르는 무작위 대조 연구이다.

상, 하악 제2대구치가 결손된 22명의 환자를 대상으로 각 환자의 상,하악 제 2대구치 결손부에 같은 디자인의 임플란트 1개씩을 식립하고 임플란트 지대주 연결 부위를 외부육각연결, 내부마찰연결의 차이만 두었다. 임플란트 식립 4개월 후 임플란트 지지 금속 전장관을 최종적 수복 하였다. 변연골 흡수량 측정기준시점은 임플란트 최종 보철물을 장착한 직후로 설정하였다. 보철물 장착 1년 뒤를 최종 시점으로 총 2회 표준 치근단 방사선 사진 촬영을 시행, 이를 토대로 변연골 흡수량을 측정하였다. 방사선 사진상에서 임플란트 주변 변연골 흡수량을 수직 길이 변화량(DIB : distance from implant shoulder to first bone-to implant contact)과 면적 변화량(PA : peri-implant area)으로 구분하여 평가하였다. 두 가지 종류(외부육각연결과 내부마찰연결)의 임플란트-지대주 연결 구조에 대한 변연골 흡수량의 그룹간 비교는 독립 표본 t 검정을 사용하였다. 통계적 유의수준 $P < 0.05$로 검정하였다. 또한 외부육각연결, 내부마찰연결 각 1개의 임플란트에 100,000회의 수직적 반복 하중을 가하였을 때 임플란트 주변 골에서 발생하는 스트레인을 모형골 상에서 측정하였다.

3. 결 과

DIB의 평균 변화량은 외부육각연결 0.59 ± 0.95 mm, 내부마찰연결 0.01 ± 0.68 mm 이였다. PA는 외부육각연결 0.1 ± 0.46 mm, 내부마찰연결 0.09 ± 0.51 mm 이였으며, DIB 및 PA 모두 그룹간 통계적 유의성은 없었다. 그러나 DIB 변화량에 있어 연결방식이 중등도의 영향을 미친다는 결과가 효과크기(Effect Size, Cohen’s d=0.67)분석에서 나

타났다. 100,000회의 수직적 반복 하중을 가한 후 발생된 스트레인값은 내부마찰연결형 993 ㎛/m, 외부육각연결형 904 ㎛/m 로 내부마찰연결 임플란트-지대주 주변에서 발생되는 스트레인이 높았다

4. 결 론

이번 1년의 기간동안 무작위 대조 연구를 통해 임플란트-지대주의 구조 차이에 따른 변연골 수준은 통계적 유의성은 없었다. 하지만 중등도의 효과 크기가 변연골의 수직적 변화량에서 확인되는바, 내부마찰연결형이 외부육각연결형에 비해 변연골을 보존하는데 더 효과적이였다.

주요어 : 임상실험, 골과 임플란트 상호작용, 임플란트-지대주 연결, 변연골 수준

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