

# Implant stability, marginal bone change and success rate of DIO<sup>®</sup> SM submerged internal-type implants placed at the posterior missing area: A prospective single arm clinical trial

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## I. Introduction

A variety of endosseous implant systems are developed and introduced in the clinical dentistry. Recently, DIO<sup>®</sup> SM submerged internal-type implants (Kyungnam, Korea) has been developed with the features as: (1) double thread to prevent damage to the cortical bone, enhance initial stability and prevent cortical absorption from bacterial infection; (2) tapered profile body thread (root form design) to facilitate ease of initial insertion, provide high primary stability on soft bone, and prevent damage to adjacent root; (3) dual cutting edges on the double thread and body thread to enhance ease of self tapping and facilitate stability by minimizing bone resistance; (4) an apex profile to facilitate ease of insertion, reduce potential run out, and minimize bone resistance; and (5) a machined resorbable blast media (RBM) surface consisting of hydroxyapatite (beta-tricalcium phosphate, Alpha-Acp.TTcp. and calcium pyrophosphate (CPP)) to enhance implant

insertion depth. This provides an even roughness without leaving embedded debris and acid residue on the implant surface. Such design and surface treatments are important elements for the long-term success of dental implants, and have been shown to play roles in achieving primary stability at the insertion and preventing marginal bone loss. Additionally, surface treatments enhance the second stability after insertion, promoting osseointegration. Good clinical results have been reported, however, until now, there has not been any prospective analysis on the clinical success of these systems. The purpose of present clinical study was undertaken to evaluate the implant stability, marginal bone change and success rate of DIO<sup>®</sup> SM submerged internal-type implants placed at the partially edentulous posterior missing area.

## II. Patients and Methods

### Experimental design and study population

A prospective single arm clinical trial was conducted to test the implant survival rate, implant stability and marginal bone loss. Seventy six participants satisfied the following inclusion criteria and were selected for

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this study. All participants had unilateral loss of one or two molars from the mandible or maxilla; the tooth had been extracted more than 6 months previously; the recipient bed had sufficient bone width ( $\geq 5$  mm) and height ( $\geq 10$  mm) to house at least 3.3 x 8 mm implant; the antagonist teeth were natural or had been repaired with fixed prostheses. The participants were generally healthy and good plaque control. The study protocol and consent form were reviewed and approved by the Institutional Review Board of Seoul National University Dental Hospital Oral and maxillofacial surgery Dept.

### **Surgical procedures and variables**

All implants were inserted by one surgeon following the same protocol. A three-month healing period was allowed in the mandible before prosthetic loading, while six-month in maxilla. During surgical intervention, implant length, diameter and location were recorded.

### **Prosthetic procedure**

The commercially available solid abutments from each implant system were connected to the fixture at 10 weeks after surgery at the torques suggested by the manufacturer (35 Ncm). An impression was obtained at the time of connection, and the final prostheses were attached at 12 weeks after surgery using resin cement (C&B™, CEMENT; Bisco, Schaumburg, IL, USA). In participants who had lost two molars, two-unit fixed prostheses were used.

### **Implant Stability evaluation**

The magnetic RFA was measured using a Mentor™, device (Ostell AB, Göteborg, Sweden). To increase the reliability of the measurements and reduce the magnitude of the differences in ISQ, the evaluators practiced matching 4.0 Ncm of insertion torque by

rotating the SmartPeg™, in a digital torque gauge (MGT; MARK-10, Copiague, NY, USA) using with a plastic mount for the metal peg in advance of the full-scale clinical trial. In the clinical trial, the Type 4 Smartpeg™, was connected to a plastic mount and inserted manually into the implant fixture. The plastic probe of the measuring instrument was brought to a distance of approximately 2-3 mm from the peg, and the ISQ could be read automatically. The damping capacity was assessed using a Periotest™ device (Siemens, Bensheim, Germany).

ISQ and PTV measurements were collected at the immediate installation and the first Op and PTV value after crown installation allows for the assessment of low degrees of implant mobility and thus determination of the osseointegration status of the implant restoration.

### **Radiographic evaluation for marginal bone change**

The marginal bone was evaluated using digital radiographs taken immediately after the surgery and 1-24 months following with a mean of 17.2 months. A paralleling technique was used, with an impression bite block that was fabricated for the individual participant attached to the aiming device (Rinn Corp, Elgin, IL, USA). This technique was chosen to reduce possible errors in measurement between pairs of images, which were acquired serially at planned intervals. A FOCUS X-ray machine (Instrumentarium Corp., Tuusula, Finland) was used in the study at 70 kVp, 7 mA, with a focal spot of 0.7 x 0.7mm and a 0.26 second exposure time. The digital radiographic images were acquired using a charge-coupled device (CCD) detector (Suni Corp., San Jose, CA, USA) in combination with SDR™, software (Mjrad Co, Seoul, Korea). From the series of periapical radiographs taken during the longitudinal evaluation, the

immediate and every third month radiographs were selected. The landmarks were taken twice randomly by one experienced dentist.

Measurements were used to calculate (i) the true bone resorption, i.e., the distance from the initial bone level to the bone level at follow-up examinations, and (ii) the marginal bone level in relation to the lower corner of the coronal cylinder. The following linear measurements between landmarks were taken (1) AMBLE: average mesio-distal MBLE; (2) TCBL: total marginal bone loss (initial AMBLE-final AMBLE), at the mesio side, distal side or the average mean.

**Success rate**

Implant success was evaluated using the four-point table defined by Albrektsson & Zarb<sup>1)</sup> with the following criteria for success: absence of implant mobility, absence of pain, neuropathy and 1mm of bone loss was acceptable during the first year and <0.2mm annually thereafter.

**Statistical analysis**

Origin 7.0 software was applied to analyze experimental data, and results were expressed as means ± S.D. All data were evaluated with analysis of variance (ANOVA) following by Dunnett’s t-test for multiple comparisons and p<0.05 indicates that the difference was statistically significant.

**III. Results**

**Participants and implant placed**

From April 2007, 76 consecutive patients were treated with 117 implants after the loss of a single or multiple teeth at the Department of Oral and Maxillofacial Surgery, Seoul National University Dental Hospital.

The patient drop-out rate was 2.7% (four patients), which accounted for 5.6% (six implants) of the implants because of missing follow-ups. In addition, although radiographic evaluation showed favorable results, two patients (three implants) were not included in the radiographic analysis due to the inability to observe clearly visible threads. The final sample included 111 implants placed in 72 patients. Sixty-two (56.00%) implants were placed in women and 49 (44.00 %) in men. The mean age of the patients was 56.6 years (range: 27-76 years). Most implants were inserted with lengths of 10mm or 12 mm and diameters of 4.5mm to 5.3mm (69.37%) (Table1). Twenty-one implants (18.92%) were placed in the mandible and 90 (81.01%) were placed in the maxilla. 17 (18.89%) and 73 (81.11%) implants replaced a premolar or molar unit at the maxillary

■ Table 1. Distribution of dimension of implant fixtures used in the clinical trial

	8mm	10mm	12mm	14mm	Total
3.8mm	0	2	3	4	9
4.5mm	2	27	20	7	67
5.3mm	13	13	12	5	35
Total	42	42	35	16	111

■ Table 2. Marginal bone loss at 3 months according to the location (mm)

	Location	
	Premolar(N=17)	Molar (N=73)
Maxilla N=90 0.34±1.41	0.24±0.43	0.22±0.68
	Proximal	Distal
	0.38±1.43	0.36±1.40
Mandible N=21 0.13±0.58	Premolar n=4	Molar n=17
	0.51±0.58	0.14±0.45
	Proximal	Distal
	0.15±0.61	0.31±0.46
Mean ±SD	0.22±0.61	

area, respectively, while four (19.05%) and 17 (80.96%) replaced a premolar or molar unit at the mandible area, respectively (Table 2).

### Implant stability

The average initial and final ISQs were  $69.94 \pm 8.04$  (MD:  $71.08 \pm 8.73$ ; BL:  $70.03 \pm 8.24$ ) and  $74.18 \pm 8.22$  (MD:  $75.55 \pm 10.86$ ; BL:  $74.42 \pm 10.69$ ), respectively. The differences between the initial and final ISQ values were statistically significant (ANOVA,  $p < 0.005$ ); however, there was no significance between MD and BL (Fig. 1, Table 3). The discrepancy between

the initial and final PTV was steady at 0.5-1 and a decrease was statistically significant.

### Marginal bone change

The average marginal bone loss (MBL) was  $0.24 \pm 0.22$ mm for all implants at three months,  $0.44 \pm 0.31$  mm at six months,  $0.67 \pm 0.44$ mm at nine months,  $0.70 \pm 0.42$ mm at 12 months and  $0.68 \pm 0.46$ mm at 15 months (Fig. 2). Marginal bone resorption increased with time. When grouping implants according to radiographic follow-up, the analysis showed an average bone loss of  $0.36 \pm 1.39$ mm after 1-3 months

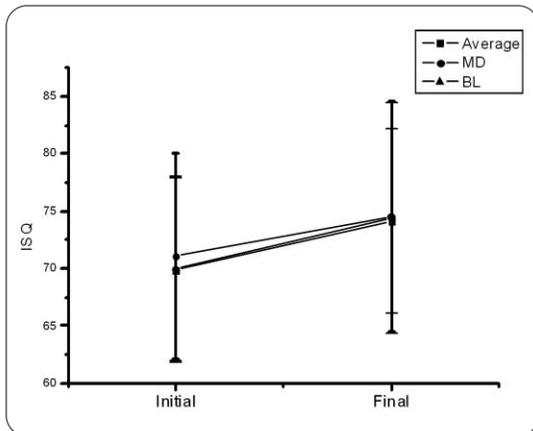


Fig. 1 ISQ between 1st and 2nd operation.

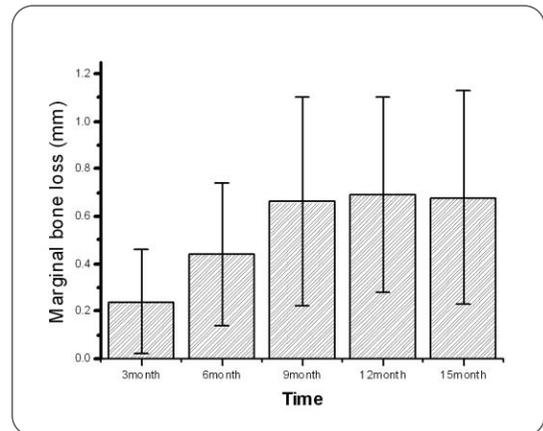


Fig. 2 Cumulative marginal bone loss during follow-up.

■ Table3. Implant stability expressed by ISQ separate at 1st and 2nd operation

		Premolar	Molar	All	
Maxilla	MD	1st	$68.12 \pm 23.12$	$69.34 \pm 21.34$	$71.01 \pm 25.56$
		2nd	$71.21 \pm 22.34$	$73.88 \pm 24.45$	$75.00 \pm 24.12$
	BL	1st	$68.44 \pm 16.32$	$70.12 \pm 17.45$	$69.67 \pm 23.79$
		2nd	$70.38 \pm 21.23$	$74.03 \pm 23.21$	$73.56 \pm 18.35$
Mandible	MD	1st	$71.24 \pm 23.51$	$70.67 \pm 20.47$	$69.56 \pm 19.35$
		2nd	$73.89 \pm 20.45$	$74.01 \pm 20.84$	$72.97 \pm 22.48$
	BL	1st	$69.56 \pm 21.64$	$70.56 \pm 18.98$	$70.13 \pm 21.35$
		2nd	$73.78 \pm 21.24$	$73.56 \pm 21.45$	$74.00 \pm 19.36$
Mean		$69.89 \pm 23.21$		$70.09 \pm 19.96$	

(n=78),  $0.13 \pm 0.28$ mm after 4-6 months (n=34),  $0.26 \pm 0.43$  after 7-9 months (n=35) and  $0.13 \pm 0.11$  after 10-12 months (n=19) (Fig. 3).

Maxillary implants showed a tendency toward greater

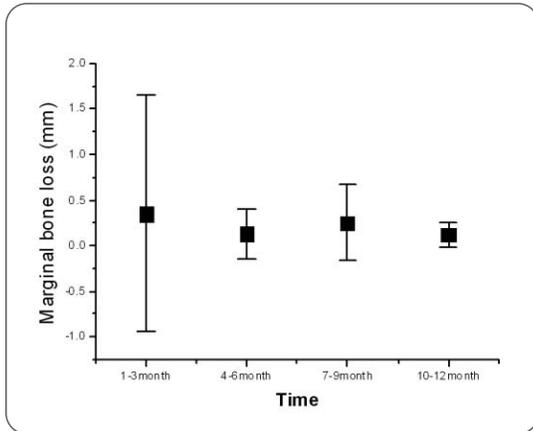


Fig. 3 Marginal bone loss at every each 3-month interval.

bone loss ( $0.34 \pm 1.41$ ) than did mandible implants ( $0.13 \pm 0.58$ ) at three months, though the difference was not significant (one-way ANOVA test). Premolar locations ( $0.36 \pm 0.49$ ) showed increased marginal bone loss than did molar locations ( $0.20 \pm 0.64$ ) (Table 2). The average marginal bone loss was slightly less for proximal sites than for distal sites:  $0.22 \pm 0.60$  and  $0.27 \pm 0.54$  at three month. The maxillary premolar area experienced more crestal bone loss than any other location, though again this was not statistically significant (one-way ANOVA test;  $p=0.304$ ). However, this still demonstrates that the premolar location had double the risk of bone loss. (In order to have a significant sample size of implant numbers, we only analyzed the MBL at three months).

The average marginal bone loss was slightly more for a single tooth (n=27) than for multiple teeth (n=63) ( $0.33 \pm 0.84$  mm and  $0.11 \pm 0.24$  mm, respectively). There was also no correlation between tooth number

and marginal bone loss ( $p=0.809$ ).

Women (n=31,  $0.26 \pm 0.81$ mm) and men (n=41,  $0.37 \pm 0.92$ mm) showed similar bone loss rates (one-way ANOVA;  $p=0.262$ ).

The annual bone loss in patients < 60 years old was  $0.34 \pm 1.0$ mm, while the average bone loss in patients >60 was  $0.20 \pm 0.77$ mm (one-way ANOVA;  $P=0.178$ ). Fixtures of 6-8mm showed a loss of  $0.28 \pm 1.10$ mm of crestal bone, while fixtures of 10-12 mm displayed a loss of  $0.34 \pm 0.81$ mm (ANOVA test:  $p=0.426$ ).

### Success rate

No implant was removed during follow up, yielding a 24-month cumulative survival rate of 100%. However, the success rate was decreased to 97.30% because 3(3 patints) out of 111 implants showed the marginal bone loss exceeding the Albrektsson & Zarb criteria<sup>1</sup>. No failures occurred during the osseointegration.

## IV. Discussion

The use of dental implants in clinical practice for the treatment of total and partial edentulism has become a well-documented surgical and prosthetic procedure in the past 30 years. Several evaluated parameters have been proposed as diagnostic markers for monitoring implant conditions. The ideal parameters for monitoring implant conditions should be sensitive enough to discriminate small bone level changes and their mobility. In our study, PTVs, ISQs and MBL were recorded as baseline.

PTVs and ISQs have been utilized to evaluate the damping characteristics around dental implants. Our study shows stable PTV and ISQ data. ISQ at the first operation was significantly higher than second operation, furthermore, at the side ISQ show higher stability than other side, however, with no

significantly. On other hand, there was no statistically significant difference in the PTV between 2 checking period. Although some authors have suggested that such quantities are useful for providing information on the early osseointegration status of implants, their values as monitors and prognostic tests for implant outcomes is under discussion. We note that, in this study, they did not correlate with marginal bone loss over time, confirming the lack of validity of these parameters as a predictor for marginal bone loss. This observation has also been reported in other studies.

In this study, DIO<sup>®</sup> SM dental implants showed excellent survival rates in the jaw. In addition, the average marginal bone resorptions were 0.7 and 0.81 mm at the one-year follow-up. When identifying different parameters, our data showed that implants placed in the maxillae had a significantly higher failure rate than those placed in the mandible. Furthermore, the maxillary premolar area experienced more crestal bone loss than any other location, which may indicate a high-risk area. Several factors were found to have an influence on the marginal bone loss at the implant. However, no significant differences in implant failure were observed when grouped according to age, gender or number of implants. Several scientists have tried to distinguish between acceptable levels of bone loss and bone loss indicating risk for future complications and failures. The results indicate a complexity of reasons for bone level changes at DIO<sup>®</sup> SM dental implants. Most of the differences in marginal bone loss, although statistically significant, are small from a clinical point of view.

When studying risk factors for failures related to loss of osseointegration, Rasmusson L and colleagues found poor bone quality and inadequate jaw bone volume to be of major importance<sup>2)</sup>. In our study,

several factors were found to have an influence on the marginal bone loss at the implant. Bone loss from prosthesis placement was found to increase significantly with increasing age of the patient at surgery. Significantly larger bone loss was also found for lower jaws compared to upper jaws for time intervals up to 10 years in function. More bone loss was found in patients with smoking habit than in other patient categories. The results indicate a complexity of reasons for bone level changes at DIO<sup>®</sup> SM dental implants. Most of the differences in marginal bone loss, although statistically significant, are small from a clinical point of view.

The DIO<sup>®</sup> SM dental implants success rate and survival are consistent with other author's report. One paper published in 2005 presented a pilot study of 51 acid etched Brånemark System implants of a prototype version, of which 30 were placed in the upper and 21 in the lower jaw<sup>3)</sup>. Survival of the implants was claimed to be 100% at 1 year after their placement. Such sparse data cannot be said to compare with our results due to the very small number of radiographs evaluated. Recently two papers have been published on the clinical outcome of Nobel Direct Implants; one of those papers reporting 11.8% of failures for 492 directly loaded implants vs. 1.7% of failures for 58 more conservatively treated implants at one year<sup>4)</sup>, the other paper presenting seemingly good results for the Nobel Direct implant over the same short term period<sup>5)</sup>. However success defined as those implants with a verified bone loss of 0.3mm at one year of follow-up<sup>1,6)</sup>.

Although we installed 111 fixtures in 72 patients, the number of fixtures available for statistical comparison was limited. In addition, the period of statistical comparison was short. Further study will continue.

## V. Conclusion

The DIO® SM implants exhibited the desired consequences over a short period with regard to the implant stability, marginal bone loss and success rate.

A prospective single arm clinical trial demonstrated a low frequency of progressive bone loss, stable implant stability, and 100% success rate.

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## Implant stability, marginal bone change and success rate of DIO<sup>®</sup> SM submerged internal-type implants placed at the posterior missing area: A prospective single arm clinical trial

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The present clinical study was undertaken to evaluate the implant stability, marginal bone change and the survival rate of DIO<sup>®</sup> SM submerged internal-type implants placed at the partially edentulous posterior missing area.

In this prospective study, 72 patients treated with 111 DIO<sup>®</sup> SM submerged internal-type implants placed at the posterior maxilla or mandible after loss of single or multiple teeth were included. The ISQ (implant stability quotient) value was measured after the first and second implant surgeries (three months apart) using Osstell Mentor. After prosthodontic rehabilitation, a PTV (periotest value) test was performed to check implant stability. Marginal bone loss was assessed using periapical film taken with a standardized technique with XCP device at three month intervals (range: 3- 24 months).

No implants were removed during follow up, yielding a 24-month cumulative survival rate of 100%. The average value of the implant fixtures (ISQ) was  $69.95 \pm 8.04$  at the immediate installation and  $74.18 \pm 8.22$  at the second surgery. The ISQ discrepancy between the two visits was  $3.59 \pm 7.62$ . Finally, the PTV was steady at 0.5-1. The average marginal bone loss (MBL) was  $0.25 \pm 0.22$ mm for all implants at three months,  $0.45 \pm 0.31$ mm at six months,  $0.67 \pm 0.44$ mm at nine months,  $0.70 \pm 0.42$ mm at 12 months and  $0.68 \pm 0.46$ mm at 15 months. The success rate was 97.30%.

The DIO<sup>®</sup> SM implants exhibited the desired consequences over a short period with regard to the implant stability, marginal bone loss and success rate. A prospective single arm clinical trial demonstrated a low frequency of progressive bone loss, stable implant stability, and 100% success rate. [*THE JOURNAL OF THE KOREAN ACADEMY OF IMPLANT DENTISTRY* 2010;29(1):71-78]

Key words : Dental implant, Survival rate, Clinical trial, Implant stability quotient (ISQ), Periotest value (PTV), Marginal bone loss