Neo Biotech

Satisfaction to Dentists

CMI Implant for Anytime/Immediate Loading

台灣 紐白特

李在熙

Overview

CMI Implant Solutions
for Anytime(Immediate) loading+

+IS-II active overview

+IS-III active overview

+Difference of IS-II active & IS-III active

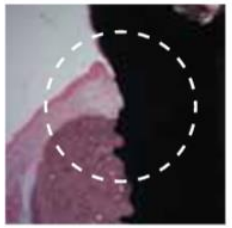
+Product concept of IS-II active & IS-III active

+IS-III active S-narrow

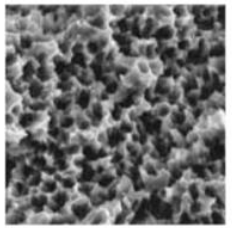
+Clinical literature

CMI Implant Solutions for Anytime(Immediate) loading

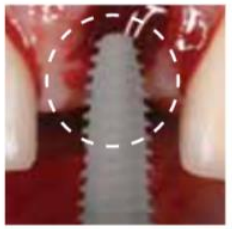
IS-II active overview (Released in 2011)



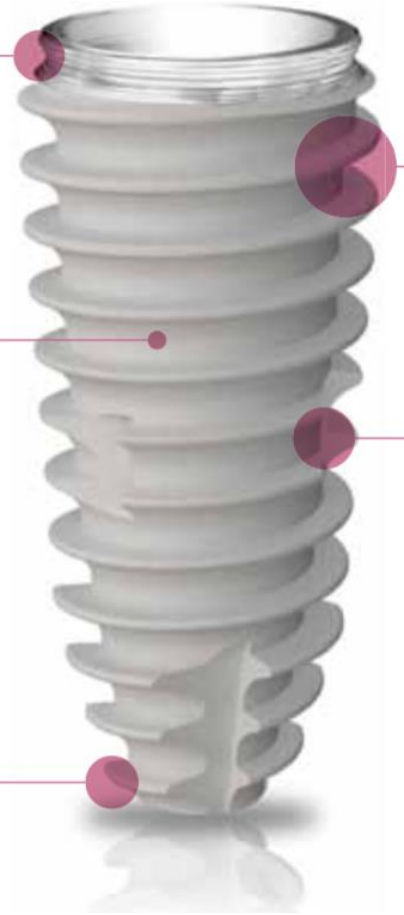
BioSeal (0.5mm)
Increase sealing of soft tissue and mini-mize bone loss



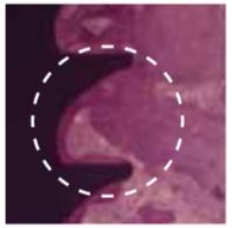
S.L.A. Surface
Under 50㎛ Hydroxy Apatite powder blasting and dual acid etching



Apex
Excellent for both immediate place-ment and immediate loading

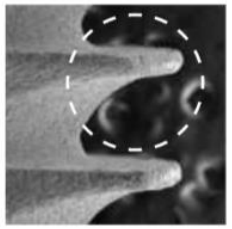


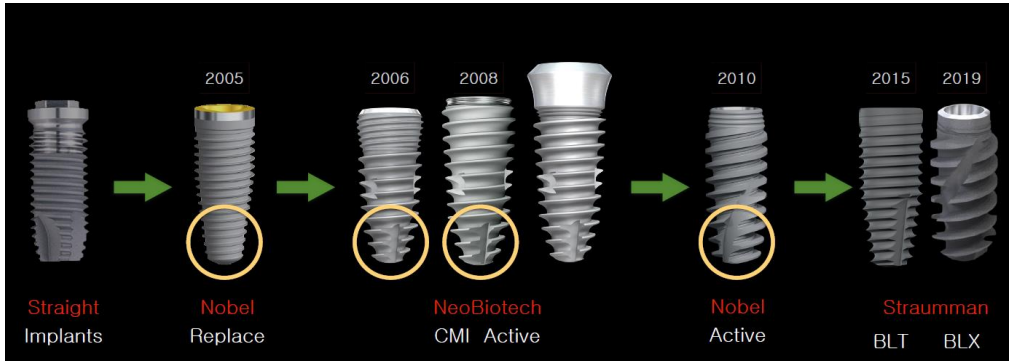
Coronal Macro Thread
(Thread pitch 0.8mm)
Excellent primary stability at cortical bone



Reverse Thread

Magic Thread
Specially designed to endure vertical and lateral force

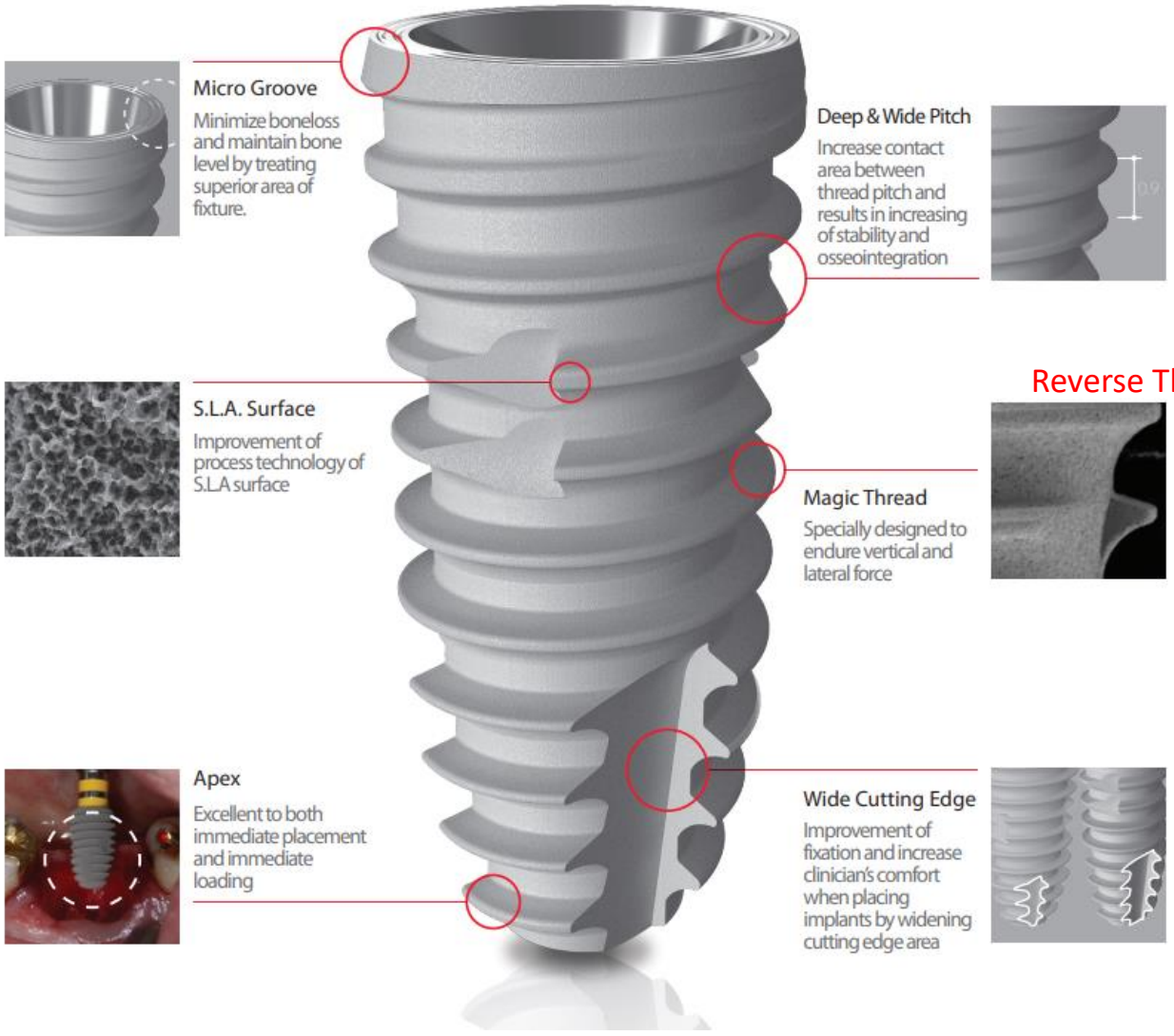




CMI Implant Solutions for Anytime(Immediate) loading

- +IS-II active overview
- +IS-III active overview
- +Difference of IS-II active & IS-III active
- +Product concept of IS-II active & IS-III active
- +IS-III active S-narrow
- +Clinical literature

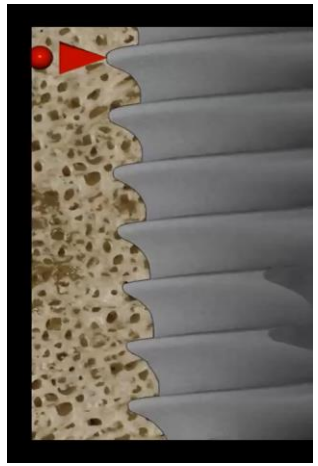
IS-III active overview (Released in 2016)



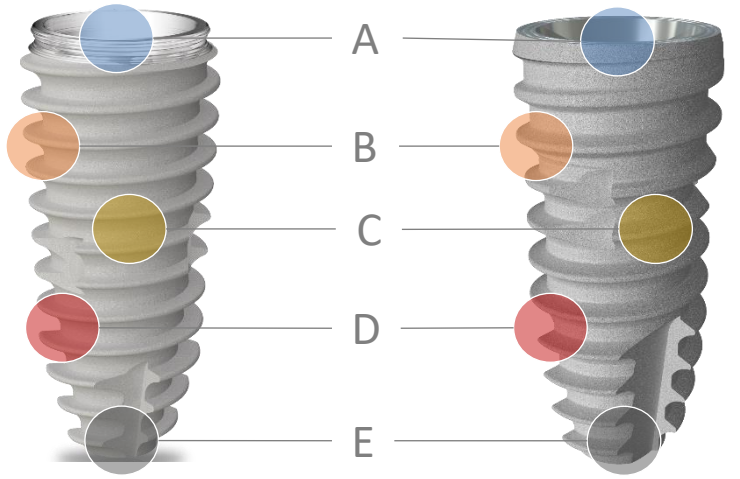
TS System

V Thread

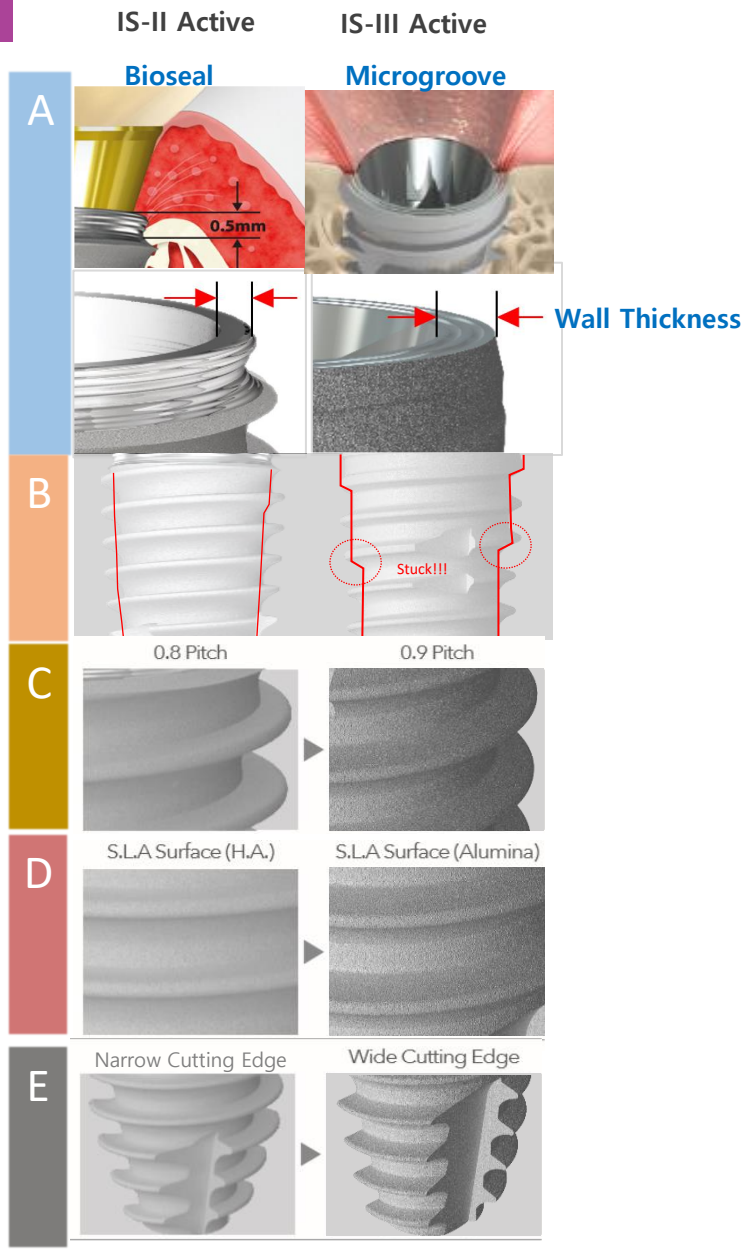
Reverse Thread



Difference of IS-II active & IS-III active (Overview)



IS-II Active IS-III Active



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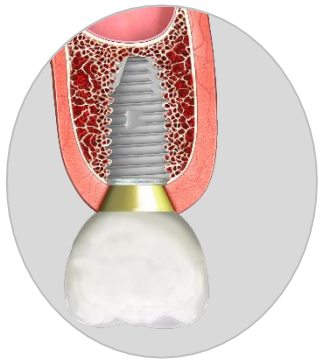
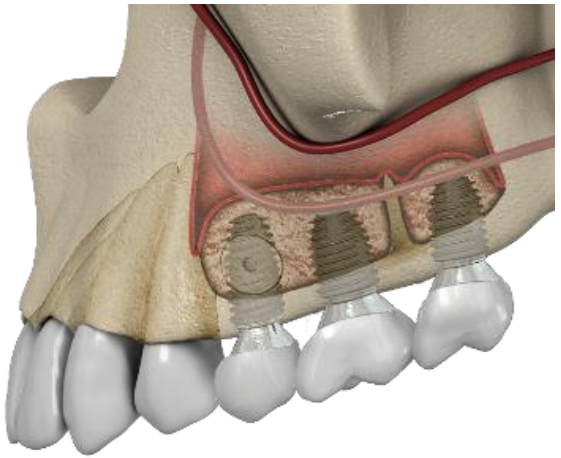
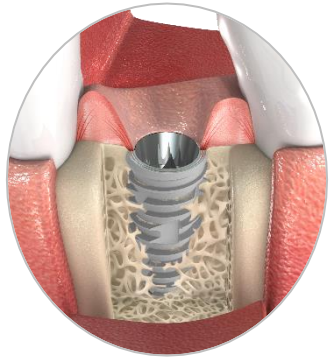
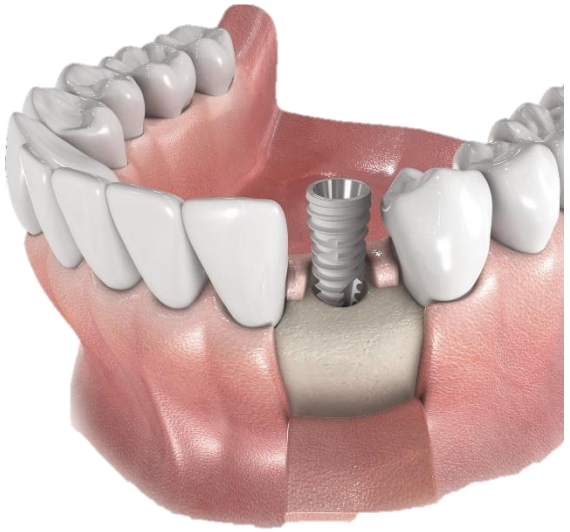
Product Concept of IS-II active & IS-III active









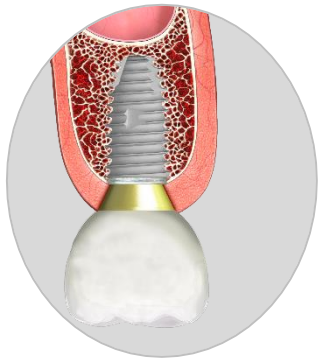
IS-II active

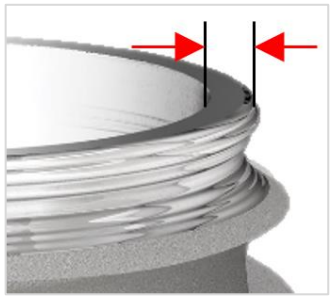
IS-III active

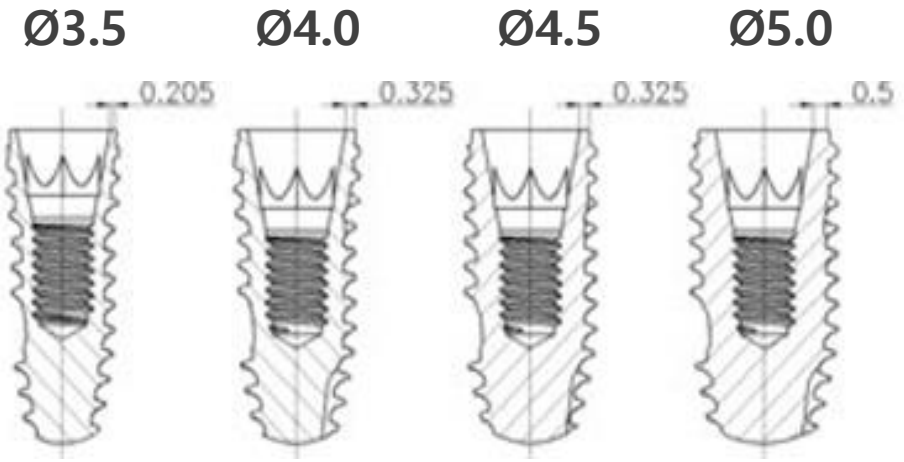
CMI Implant Solutions for Anytime(Immediate) loading

Product Concept of IS-II active & IS-III active (Wall Thickness)

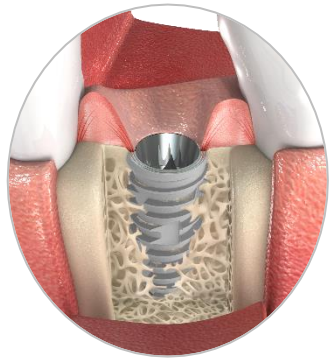
IS-II active

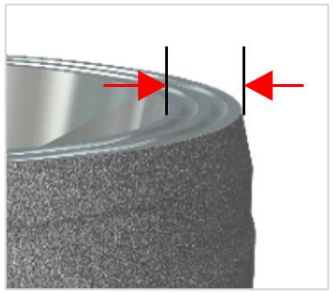


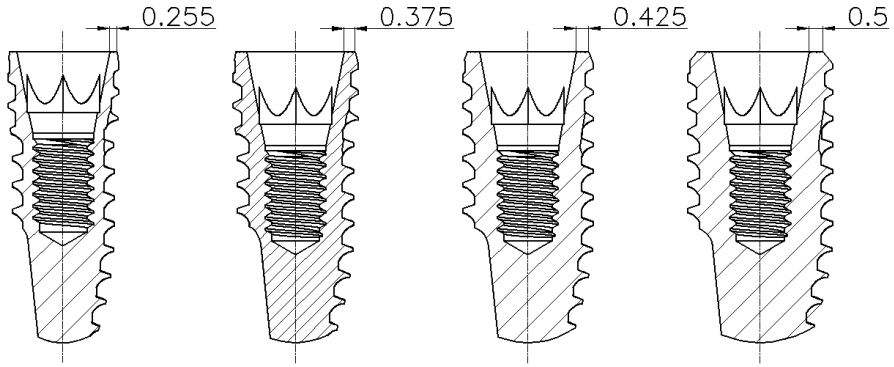




IS-III active

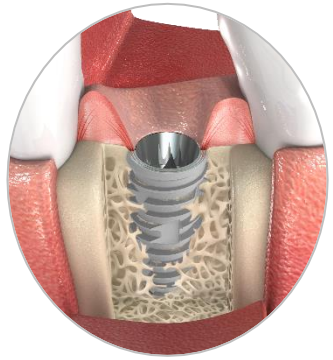


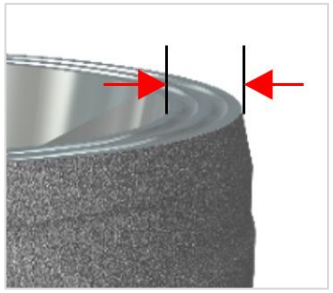




Product Concept of IS-III active (Wall Thickness)

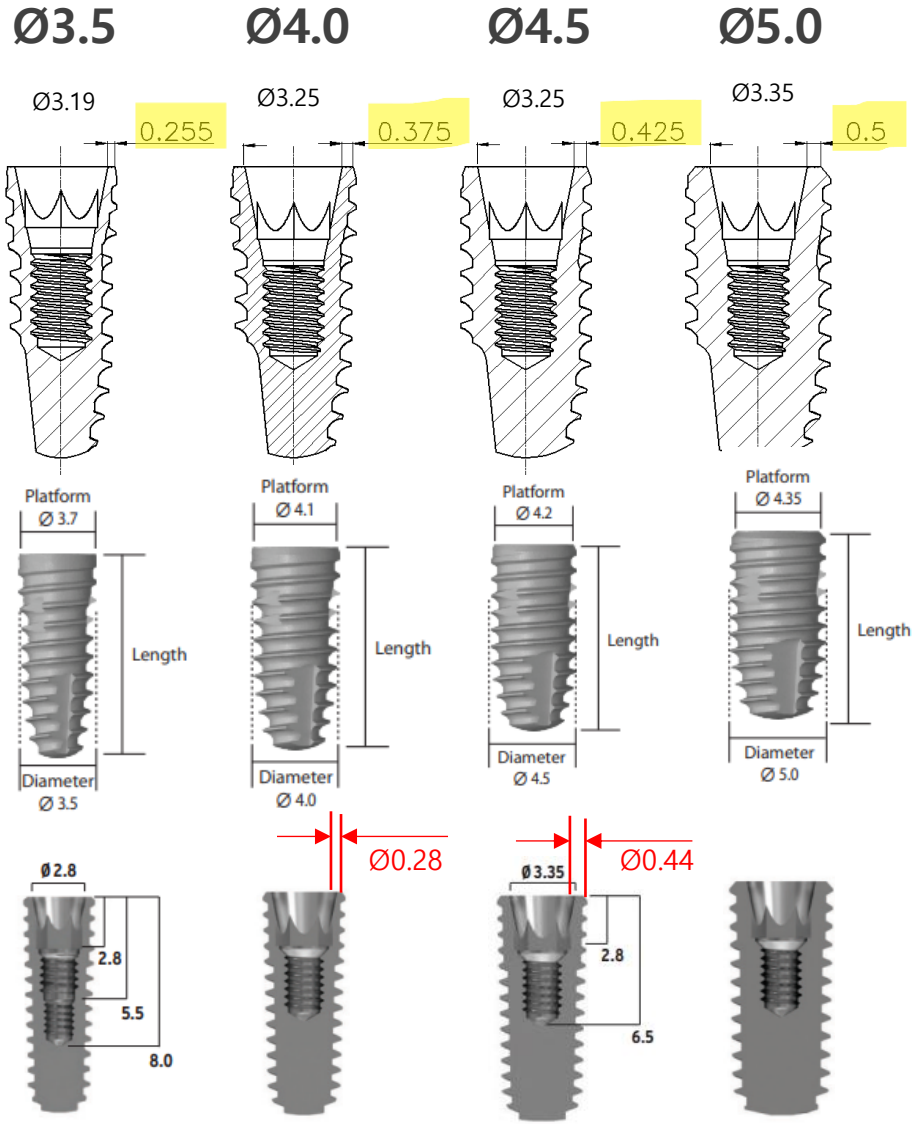
IS-III active





Implant system	Manufacturer	Taper angle (degrees)	Diameter (mm)	Inner connecting dimension (mm)	Thinnest wall thickness (mm)
Astra Tech OsseoSpeed TX	Dentsply	11	4.0[a] 4.5	3.5 3.5	0.22 0.32
NobelActive	Nobel Biocare	12	4.3	3.4	0.45
NobelReplaceConical Connection			4.3	3.4	0.49
Bone Level RC Implant	Straumann	15	4.1	3.3	0.44
TS III	Osstem	11	4.2 4.4	3.35 3.35	0.28 0.44
Implantium	Dentium	11	4.0 4.5	3.35 3.35	0.35 0.53

TS Ⅲ

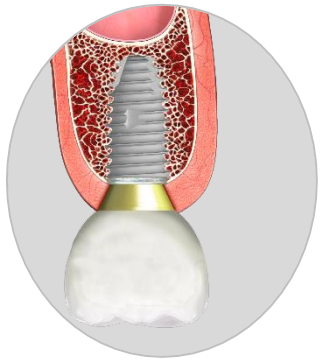


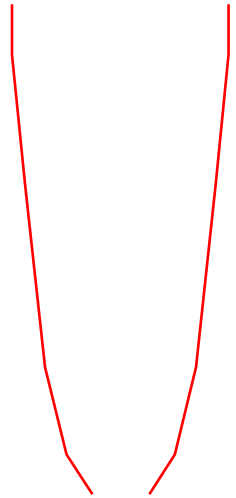
* Product dimension on before 2008

Effect of the Coronal Wall Thickness of Dental Implants on the Screw Joint Stability in the Internal Implant-Abutment Connection
September 2016, The International journal of oral & maxillofacial implants 31(5):1058-1065
DOI:10.11607/jomi.4600

Product Concept of IS-II active & IS-III active (Body design)

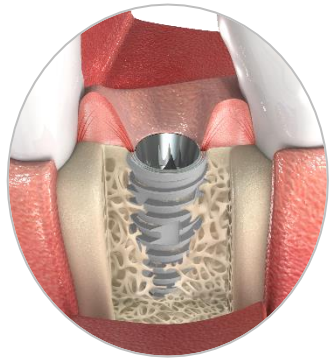
IS-II active

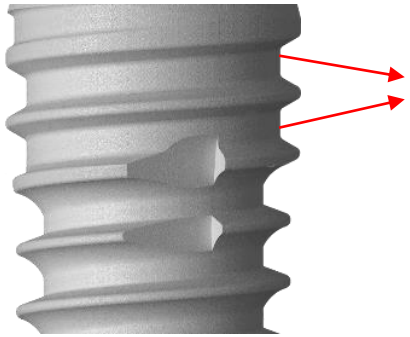




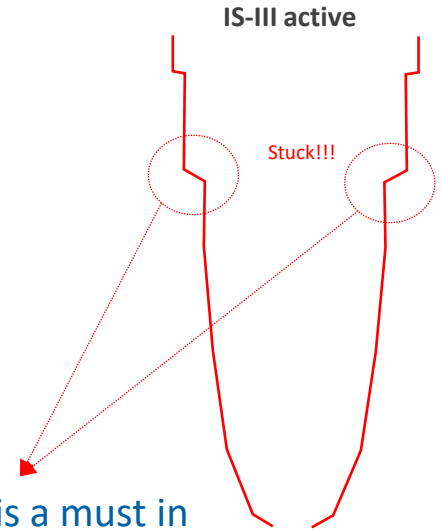
IS-II active has better penetration.

IS-III active





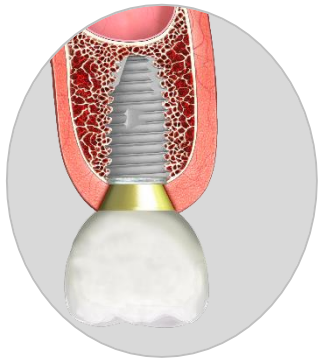
IS-III active has a shallow depth of thread in about 1/3 of the upper part of fixture

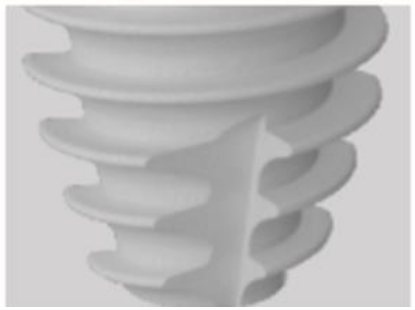


Tapping is a must in Hard Bone Case

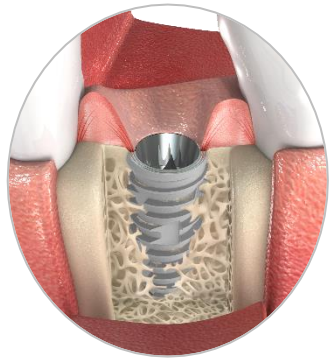
Product Concept of IS-II active & IS-III active (Cutting Edge)

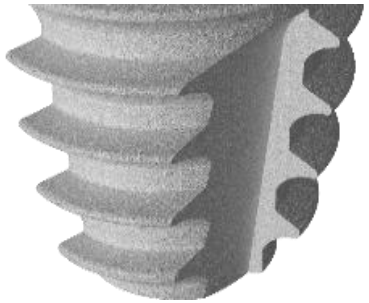
IS-II active

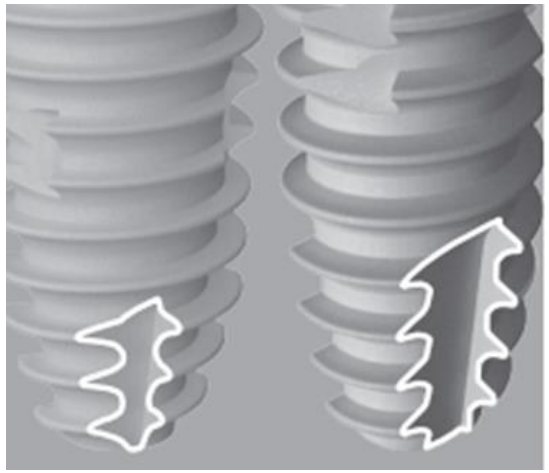




IS-III active





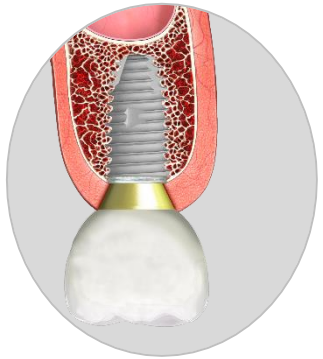


IS-II active IS-III active

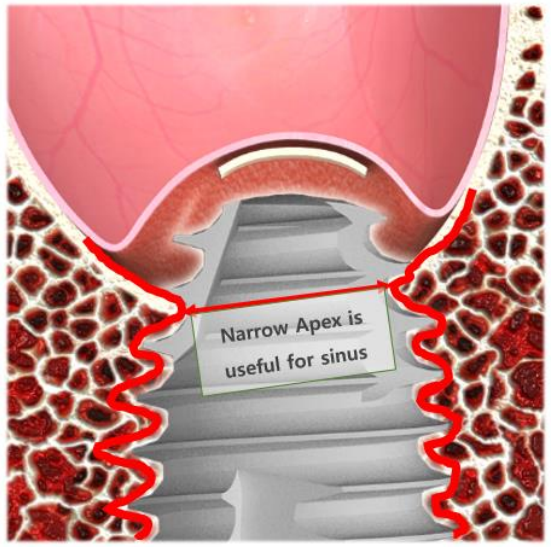
IS-III active improves self-tapping capability

Product Concept of IS-II active & IS-III active (Apex Design)

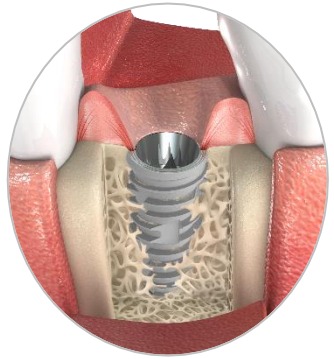
IS-II active

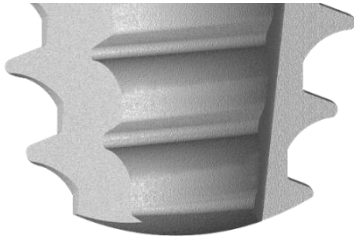


Apex

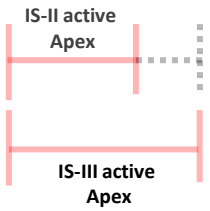


IS-III active





Apex



Apex	Ø3.5	Ø4	Ø4.5	Ø5
IS-II (Narrow)	2	2.4	2.9	3.4
IS-III	2.4	2.8	3.2	3.7

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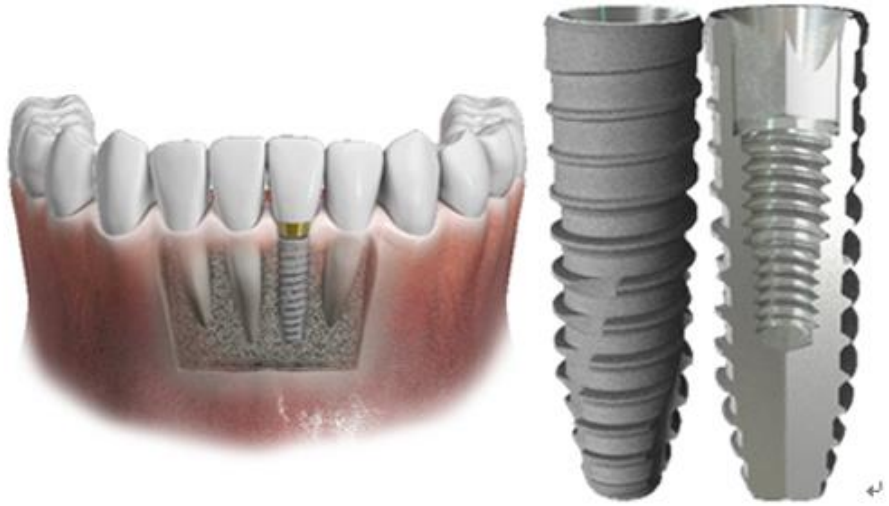
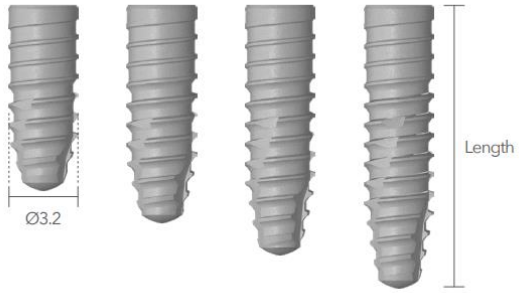
IS-III active S-narrow

Super Narrow
for Anterior Mandible
(Narrow Ridge)



Fixture



Diameter	Length	Code
Ø3.2	8.5 mm	IS3SN3008AP
	10.0 mm	IS3SN3010AP
	11.5 mm	IS3SN3011AP
	13.0 mm	IS3SN3013AP

* Cover Screw not included

Cover Screw

Diameter	Code
Ø3.0	ISC25S

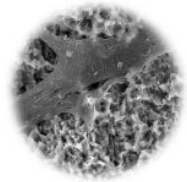
Healing Abutment

Diameter	Ø3.0	
Cuff	3 mm	5 mm
Code	ISH3003	ISH3005

Diameter	Ø3.8	
Cuff	3 mm	5 mm
Code	ISH3803	ISH3805

CMI Implant Solutions for Anytime(Immediate) loading

IS-III active S-narrow



S.L.A. Surface

The new S.L.A Surface with 40% greater sur-face area and 50% more cell adhesion promotes osseointegration

Straight Body

Easy to adjust implantation depth

Deep & Wide Pitch

Optimum Pitch for osseointegration (0.9Pitch)

Wide Cutting Edge

Wide cutting edge and enlarged surface area enhances initial fixation and offers clinicians more stable implant placement

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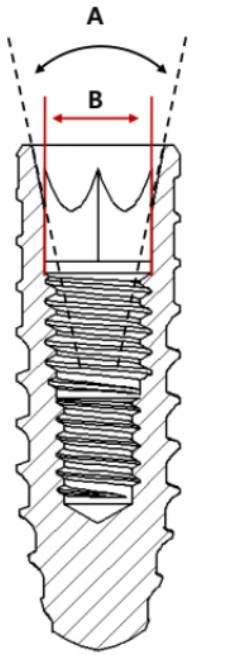
Difference of IS-III active S-narrow & IS-II/IS-III active



S-narrow Connection

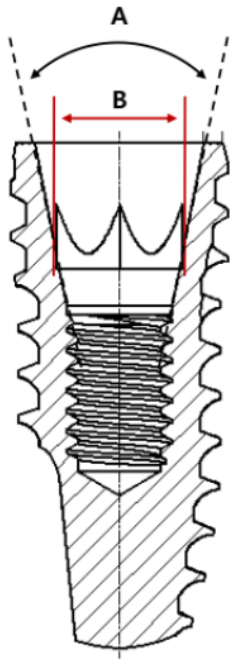
A : 11˚ Conical Seal

B : 2.1 Hex

Screw : M1.6 / M2.0

IS-III active S-narrow

(ø3.2)



IS Connection

A : 11˚ Conical Seal

B : 2.5 Hex

Screw : M2.0

IS-II active & IS-III active

(ø3.5/ø4.0/ø4.5/ø5.0)

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IS-III active clinical paper

applied sciences

MDPI

Article

One-Year Results of a Randomized Controlled Clinical Trial of Immediately Loaded Short Implants Placed in the Lower Posterior Single Molar Using a Complete Digital Workflow

Yeon-Wha Baek [1], Young-Jun Lim [1,*], Jungwon Lee [2], Ki-Tae Koo [3], Myung-Joo Kim [1] and Ho-Beom Kwon [1]

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Abstract: The purpose of this randomized clinical trial is to evaluate immediately loaded single implants with varying lengths in the posterior mandible using a fully digital, model-free prosthetic-driven implant planning pathway, and to compare clinical and radiological outcomes of short and long implants. The 52 patients with the single tooth missing in the posterior molar regions of the mandible were randomly assigned to the control (CMI IS-III active® long implant; 5.0 × 10 mm) and experimental (CMI IS-III active® short implant; 5.5 × 6.6, 7.3, 8.5 mm) groups. For each patient, a single implant was placed using the computer aided surgical template and all prostheses were fabricated by means of computer-aided design/computer-aided manufacturing (CAD/CAM) system on the virtual model. The patients received provisional and definitive monolithic zirconia prostheses at 1 week and 12 weeks after implant surgery, respectively. The implant stability quotient (ISQ) measurements and periapical radiographs were taken and peri-implant parameters were evaluated at 1, 3, 4, 8, 12, 24, 36, and 48 weeks after surgery. Nineteen long implants and 27 short implants were finally used for the statistical analysis. There was no significant difference between the groups in terms of insertion torque, ISQ values (except 3 weeks), marginal bone loss, and peri-implant soft tissue parameters ($p > 0.05$). Both groups exhibited no stability dip during the early phase of healing. The average marginal bone loss from the baseline of implant placement for the control and experimental groups was −0.07 and 0.03 mm after 12 weeks and 0.06 and 0.05 mm after 48 weeks. All of the soft tissue parameters were within normal limits. Within the limits of the short term follow up, immediate loading of short single implants can be considered as one of predictable treatment modality in mandible with reduced bone height when primary stability can be achieved.

Keywords: dental implants; short dental implants; immediate loading; primary stability; digital work flow

1. Introduction

Due to advancements in 3-dimensional (3D) imaging and computer-aided design/computer-aided manufacturing (CAD/CAM) technology, clinicians can not only obtain required diagnostic information in a single visit, but also complete the entire process from implant surgery to the definitive prosthesis

Another outcome variable included peri-implant soft tissue assessment such as probing depths, width of keratinized mucosa and plaque and calculus indices.

Body Shape		Straight body	Straight body
Thread Shape		Reverse Buttress	Reverse Buttress
Pitch Height		0.9mm	0.9mm
Thread Height		0.4mm	0.4mm
Implant-Abutment Interface		Internal Hex	Internal Hex
Inclination Angle of the thread flank		20	20
Surface Treatment		SLA surface	SLA surface
Microthreads		Bioseal or None	None

SLA, Sandblasting with Large grit and Acid etching

Figure 1. Characteristics of the implants systems used in this study: CMI IS-III active® (Neobiotech, Seoul, Korea), short and long implants.

2.2. Study Population and Entry Criteria

The required sample size was estimated based on the non-inferiority test using Chi-squared formulas:

$$N = \frac{\left\{ Z_\alpha \left[(1+\lambda)\bar{P}\left(1-\bar{P}\right) \right]^{0.5} + Z_\beta \left[\lambda P_c (1-P_c) + P_t (1-P_t) \right]^{0.5} \right\}^2}{\lambda (P_c - P_t - d)} = 18.133 \fallingdotseq 19 \text{ subject,}$$

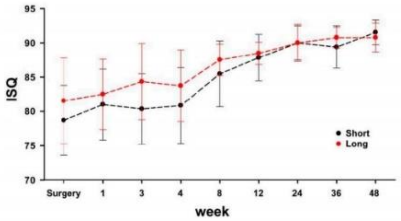
where Z_α = 5 %, Z_β = 20 %, λ = 1, $\bar{P}$ = P_t = 0.968, P_c = 0.971, and d = 0.145. A dropout rate of 30% was assumed. Since each subject received one implant, the number of participants required for each group was approximately 26.

A total of 108 potential participants were recruited via a subway car advertising. The study population was derived from participants under treatment at Seoul National University Dental Hospital between April 2016 and July 2018. Fifty-six of a total of 108 screened candidates were excluded by the entry criteria. A total of fifty-two patients were randomly assigned to one of the control (CMI IS-III active® long implant) and the experimental (CMI IS-III active® short implant) groups, using a computerized random number generator. The inclusion criteria were: (1) 18 years of age or older, (2) single tooth missing in the posterior molar regions of the mandible at least 3 months ago, (3) ability of patient to undergo surgical and restorative procedures, (4) sufficient bone volume in the site to allow implant placement without the need for bone augmentation: at least 8.0 mm diameter and 9.0 mm length, (5) the presence of the intact occlusal plane opposed with the edentulous surgical site, and (6) a lack of TMD (Temporomandibular disorders) or any other

Table 2. Comparison of primary stability between the long and short implants.

	Control Neobiotech CMI IS-III Active® Long Implant	Experimental Neobiotech CMI IS-III Active® Short Implant	*p*-value *
Participant number	19	27	
Insertion Torque (Ncm) (Mean ± SD)	40.53 ± 5.35	38.89 ± 4.85	0.298
ISQ at surgery (Mean ± SD)	81.53 ± 6.26	78.69 ± 5.08	0.120

* The *p*-values for insertion torque and ISQ were calculated by the t-test.
ISQ, implant stability quotient; SD, standard deviation.



	Number	Surgery	1-week	3-week	4-week	8-week	12-week	24-week	36-week	48-week
Control long Implant (Mean ± SD)	19	81.53 ± 6.26	82.49 ± 5.14	84.34 ± 5.57	83.74 ± 5.21	87.51 ± 2.29	88.46 ± 1.62	89.98 ± 2.67	90.75 ± 1.47	90.76 ± 2.09
Experimental short Implant (Mean ± SD)	27	78. 69 ± 5.08	80.99 ± 5.17	80.33 ± 5.16	80.83 ± 5.54	85.46 ± 4.80	87.82 ± 3.38	89.99 ± 2.46	89.39 ± 3.07	91.51 ± 1.79
P-value* between implant groups			0.105	0.348	0.018	0.087	0.098	0.454	0.994	0.086	0.207
Within-subjects effects (visits)						$P < 0.01$ (Huynh-Feldt, Sphericity Assumed)				
Within-subjects effects(visits & implant groups)						$P = 0.074$ (Huynh-Feldt, Sphericity Assumed)				

* The *P*-values were calculated using the two-way repeated measures ANOVA.
ISQ, implant stability quotient; SD, standard deviation.

Figure 6. Comparison of stability in terms of the pattern of change in implant stability quotient (ISQ) during the 48-week observation period after implant surgery.

IS-III active clinical paper

applied sciences

MDPI

Article

One-Year Results of a Randomized Controlled Clinical Trial of Immediately Loaded Short Implants Placed in the Lower Posterior Single Molar Using a Complete Digital Workflow

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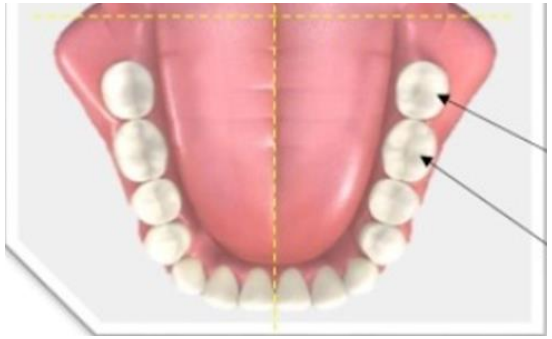
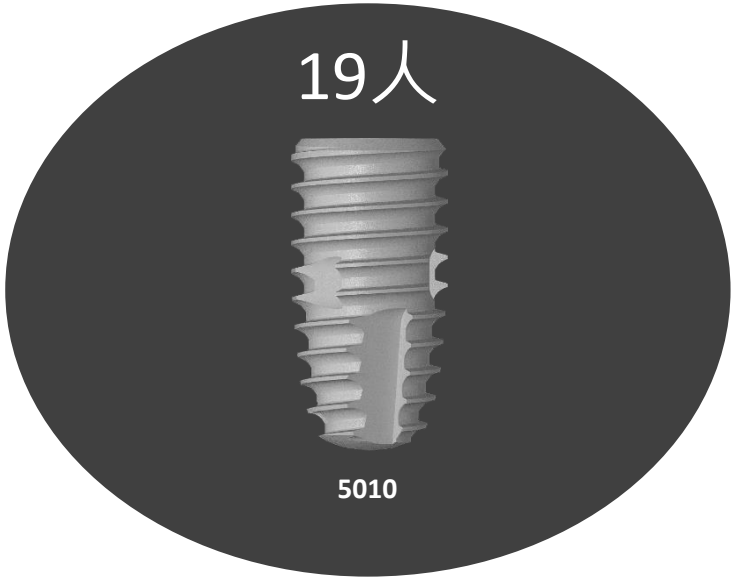
IS-III active clinical paper

- **52 patients** with the single tooth missing in the posterior molar regions of the mandible (6 participants excluded due to Consent withdrawal :1, Exclusion criteria 5)





Control Group

Experimental Group

Clinical Study Design

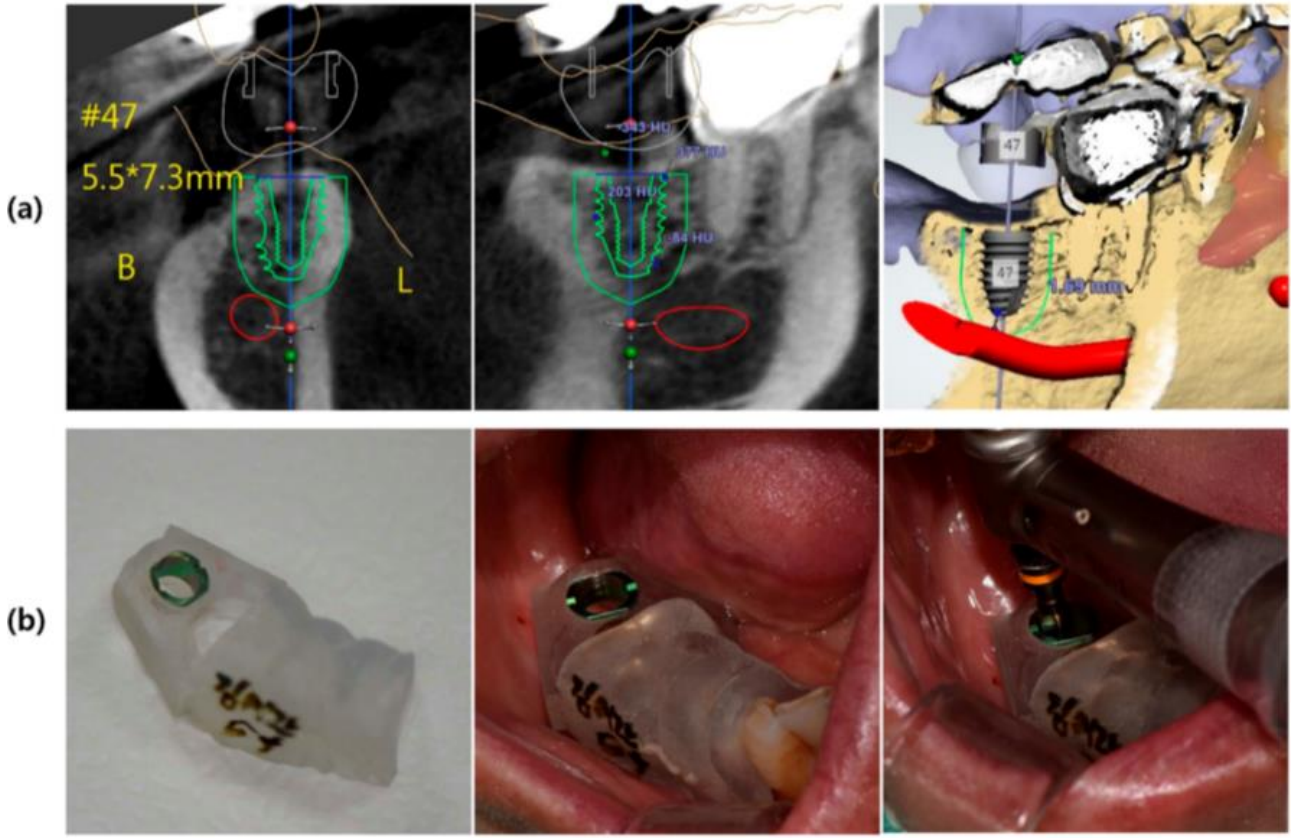
- CMI IS-III active® long implant (Neobiotech Co., Seoul, Korea) in the control group
- CMI IS-III active® short implant (Neobiotech Co., Seoul, Korea) in the experimental group

	Experimental group			Control group
	5.5X6.6mm	5.5X7.3mm	5.5X8.5mm	5.0X10.0mm
Body Shape	Straight body			Straight body
Thread Shape	Reverse Buttress			Reverse Buttress
Pitch Height	0.9mm			0.9mm
Thread Height	0.4mm			0.4mm
Implant-Abutment Interface	Internal Hex			Internal Hex
Inclination Angle of the thread flank	20			20
Surface Treatment	SLA surface			SLA surface
Microthreads	Bioseal or None			None

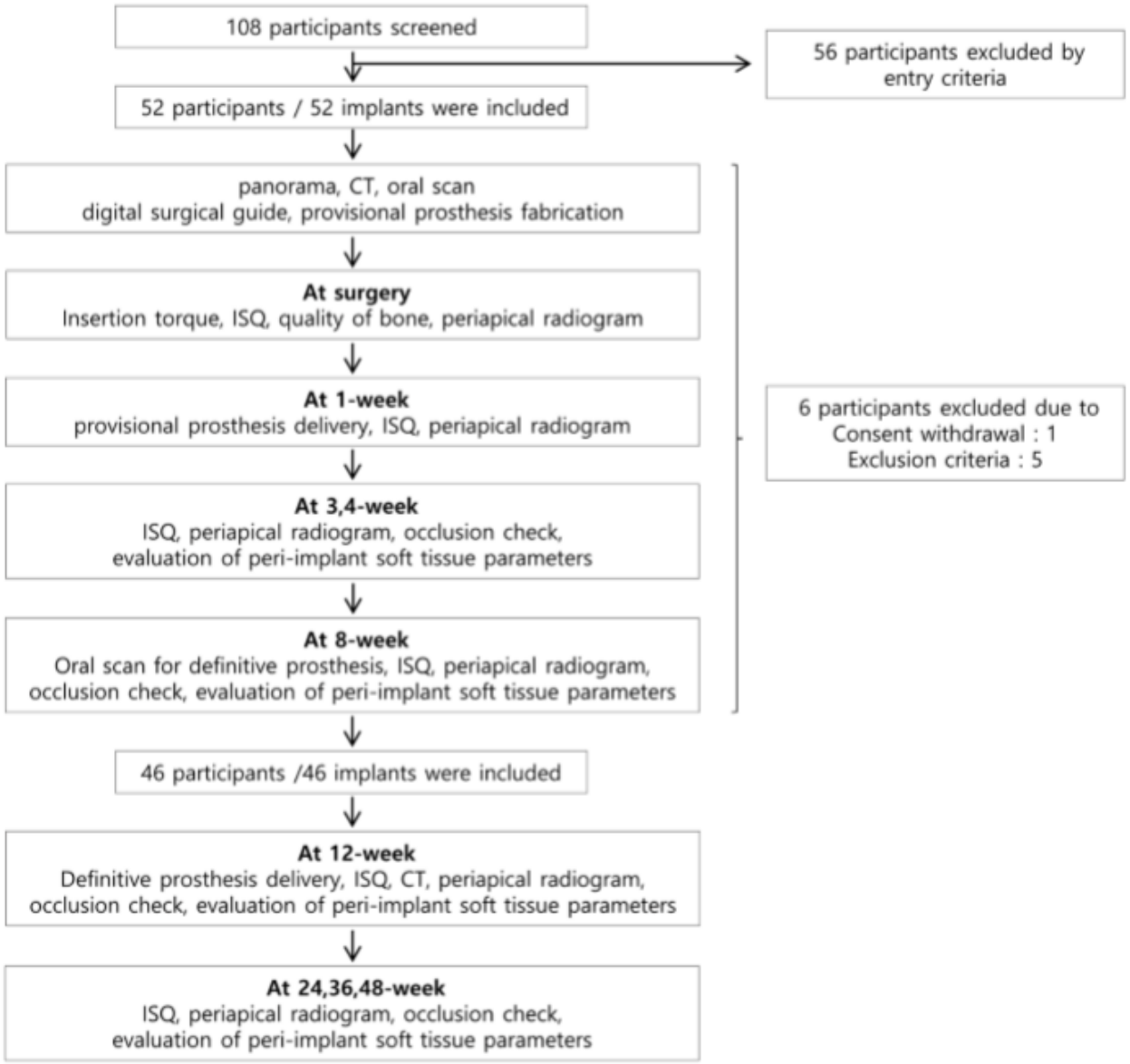
SLA, Sandblasting with Large grit and Acid etching

Treatment Procedure

- Planning : Implant Studio(3shape)
- Surgical guide : Neo Navi Guide
- Customized Prosthesis : DentalDesigner (3shape)



Treatment Procedure



- **Flow diagram of the controlled clinical trial protocol used in this study.**

Measurement of Marginal Bone Loss

- Peri-Implant marginal bone loss (PIMBL) was evaluated using **standard periapical radiographs** taken **immediately after surgery** and at **12** and **48 weeks after the implant installation** (Figures 4 and 5).
- In order to obtain the marginal bone level, the enlargement ratio of each image **was calculated from the manufacturer-specified thread pitch of 0.9 mm** that is known for each implant system used in this study

Figure 4. Standard periapical radiographs of implants placed in a patient in the control group (CMI IS-III active® long implant, Neobiotech Co., Seoul, Korea): (**a**) at surgery, (**b**) at 12 weeks, and (**c**) at 48 weeks.

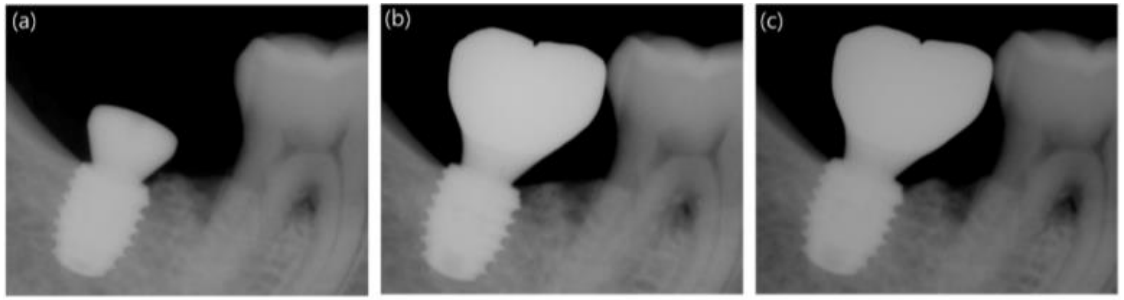


Figure 5. Standard periapical radiographs of implants placed in a patient in the experimental group (CMI IS-III active® short implant, Neobiotech Co., Seoul, Korea): (**a**) at surgery, (**b**) at 12 weeks, and (**c**) at 48 weeks.

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Result

- The statistical analysis showed that there were **no significant differences** in age, sex, implant type, and bone quality between the two groups ($p > 0.05$).

	Variables	Control (Neobiotech CMI IS-III Active® Long Implant)	Experimental (Neobiotech CMI IS-III Active® Short Implant)	*p*-Value
Participant based ($n = 46$)	Participant number	19	27	0.514
	Age (mean ± SD)	55.42 ± 11.75	52.06 ± 11.05	0.305
	20–60	13	18	0.740
	Over 60	6	9	
	Sex			
	Male /Female	15/4	19/8	0.514
Implant based ($n = 46$)	Implant number	19	27	
	Lower 1st molar / 2nd molar	9/10	4/23	
	Implant Type			
	Ø5.00 × 10 mm	19	/	
	Ø5.50 × 8.5 mm	/	10	1.000
	Ø5.50 × 7.3 mm	/	9	
	Ø5.00 × 6.6 mm	/	8	
	Bone quality			
	D112	0	4	
	D122	3	3	
	D211	0	1	
	D222	6	7	0.378
	D223	1	1	
	D232	0	1	
	D233	3	7	
	D333	6	3	

CMI Implant Solutions for Anytime(Immediate) loading

+IS-II active overview

+IS-III active overview

+Difference of IS-II active & IS-III active

+Product concept of IS-II active & IS-III active

+IS-III active S-narrow

+Clinical literature

Result (Comparison of Implant Stability)

Table 2. Comparison of primary stability between the long and short implants.

	Control Neobiotech CMI IS-III Active® Long Implant	Experimental Neobiotech CMI IS-III Active® Short Implant	
Participant number	19	27	*p*-value *
Insertion Torque (Ncm) (Mean ± SD)	40.53 ± 5.35	38.89 ± 4.85	0.298
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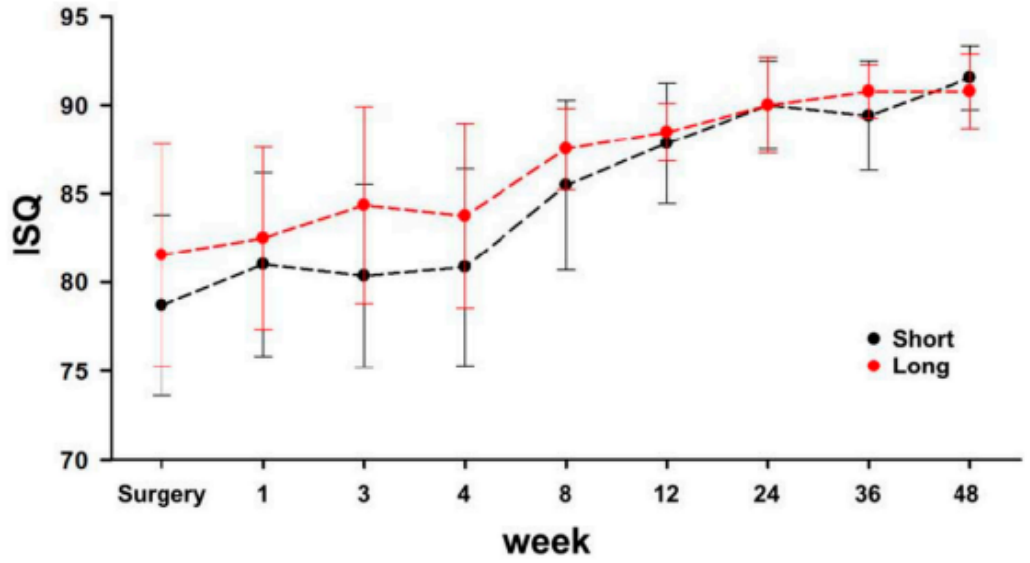
ISQ, implant stability quotient; SD, standard deviation.



- **Primary stability** was evaluated using the peak insertion torque and ISQ at surgery (Table 2).
- The control group had slightly greater average insertion torque and ISQ values at implant insertion than the experimental group, but **no statistically significant differences were observed between the long and short implants (p-value > 0.05).**

Result (Comparison of Marginal Bone Loss)

- The average marginal bone loss from the fixture platform top for the control and experimental groups was −0.07 ± 0.78 mm and 0.03 ± 0.63 mm after 12 weeks and 0.06 ± 0.82 mm and 0.05 ± 0.77 mm after 48 weeks, respectively.
- After a 12-week healing period, the distal surface exhibited slightly greater bone loss than the mesial side, but by the end of the trial, no differences in marginal bone loss between the two implant groups gained statistical significance (p-value > 0.05)

Table 3. Comparison of marginal bone loss between the long and short implants.

		Control Neobiotech CMI IS-III Active® Long Implant	Experimental Neobiotech CMI IS-III Active® Short Implant	
Participant number		19	27	
Duration	Area	Mean ± SD (mm)	Mean ± SD (mm)	*p*-value *
12-week follow up	Mesial	−0.22 ± 0.98	-0.15 ± 0.79	0.893
	Distal	0.08 ± 0.81	0.20 ± 0.78	0.728
	Avg.	−0.07 ± 0.78	0.03 ± 0.63	0.885
48-week follow up	Mesial	−0.15 ± 0.94	-0.13 ± 0.82	0.719
	Distal	0.27 ± 0.80	0.23 ± 0.92	0.573
	Avg.	0.06 ± 0.82	0.05 ± 0.77	0.655

* The *p*-values were calculated using the Mann–Whitney test.
Normality test was failed (Shapiro-Wilk, $p < 0.05$).
Area, the radiographic measurement area for calculation of marginal bone loss; Avg., the average value of mesial and distal bone loss; SD, standard deviation.

Conclusion

- The present study was performed with immediate loading protocol and used the completely digital pathway, short and standard-length implants supporting single prosthesis in the posterior mandible, showed no significant differences in terms of success rate, ISQ values, marginal bone loss, and peri-implant soft tissue parameters during the 1-year follow up period.
- Within the limitations of this study, the short implant supporting single crown with immediate loading protocol seems to be a successful treatment modality in the limited bone height mandible as long as adequate primary stability can be achieved; insertion torque of 35–45 Ncm and ISQ of more than 65. To consolidate this alternative solution for reduced bone, however, additional randomized controlled trials with larger sample sizes and longer follow-up periods are required.