

Clinical Study of SLA Surface Coated With a pH-buffering Agent After Vacuum UV Treatment Implant for Osteoporosis/Osteopenia Patient

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Introduction

Background

Osteoporotic patient addresses decreased bone density. This study utilized surface-treated **Osstem Super Osseointegration Implants(SOI)** to enhance bone-implant contact in osteoporotic patients. Osseointegration and periimplant bone loss analyzed over one year, while also assessing the impact of discontinuing osteoporosis treatment through bone metabolism parameters.

Purpose

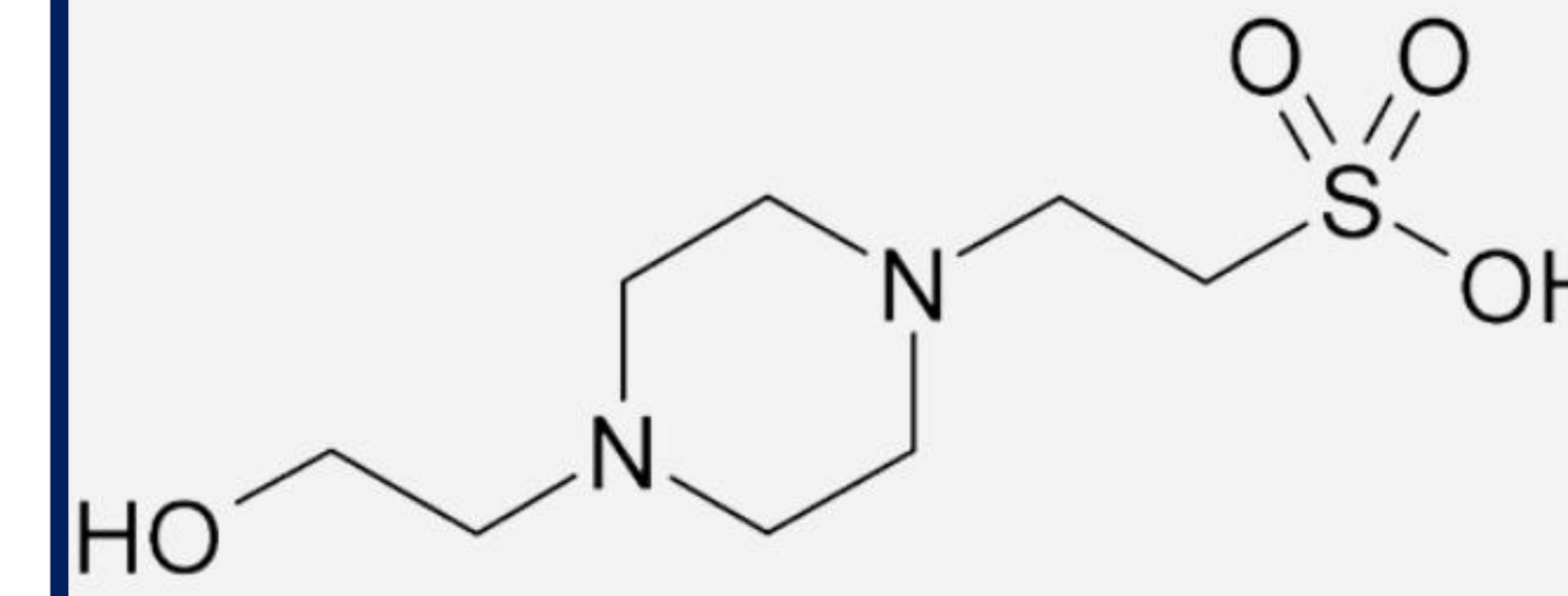
The purpose of this study was to evaluate whether Osstem SOI implant shows high success rate for postmenopausal women including osteoporosis patient.

SOI? (Super OsseoIntegration)

A surface that undergoes SA surface treatment and then, is coated with a **special substance** to form ample blood clots, activate fibrin network, and increases bone attachment 50% from SA.



Special Substance ?



HEPES (Hydroxyethyl piperazine ethane sulfonic acid)



- ✓ Maintain physiological pH to Neutral
- ✓ Implant surgery **inevitably requires incision** → **acidify**
- ✓ HEPES **neutralizes the acidified site,**
 - **restrains Osteoclast(eat bone)**
 - **promotes Osteoblast(form new bone)**

Fast formation of blood clot

- ✓ Humid coating with special ingredients **coalesce fast into blood clots when they contact blood**
- ✓ When the fibrin network in blood clots is activated to facilitate the mobility of proteins (osteoblasts) needed for bone formation, fast bone formation becomes possible



Materials & Methods

From April 2022 to May 2023, a total of 45 Osstem SOI implants were placed in 36 postmenopausal women who visited Yonsei university dental hospital, department of oral and maxillofacial surgery. Patients were divided into two research groups based on each patient's lowest T-score.

-Group A (T-score ≥ -2 , n=17)

-Group B (T-score < -2 , n=19)

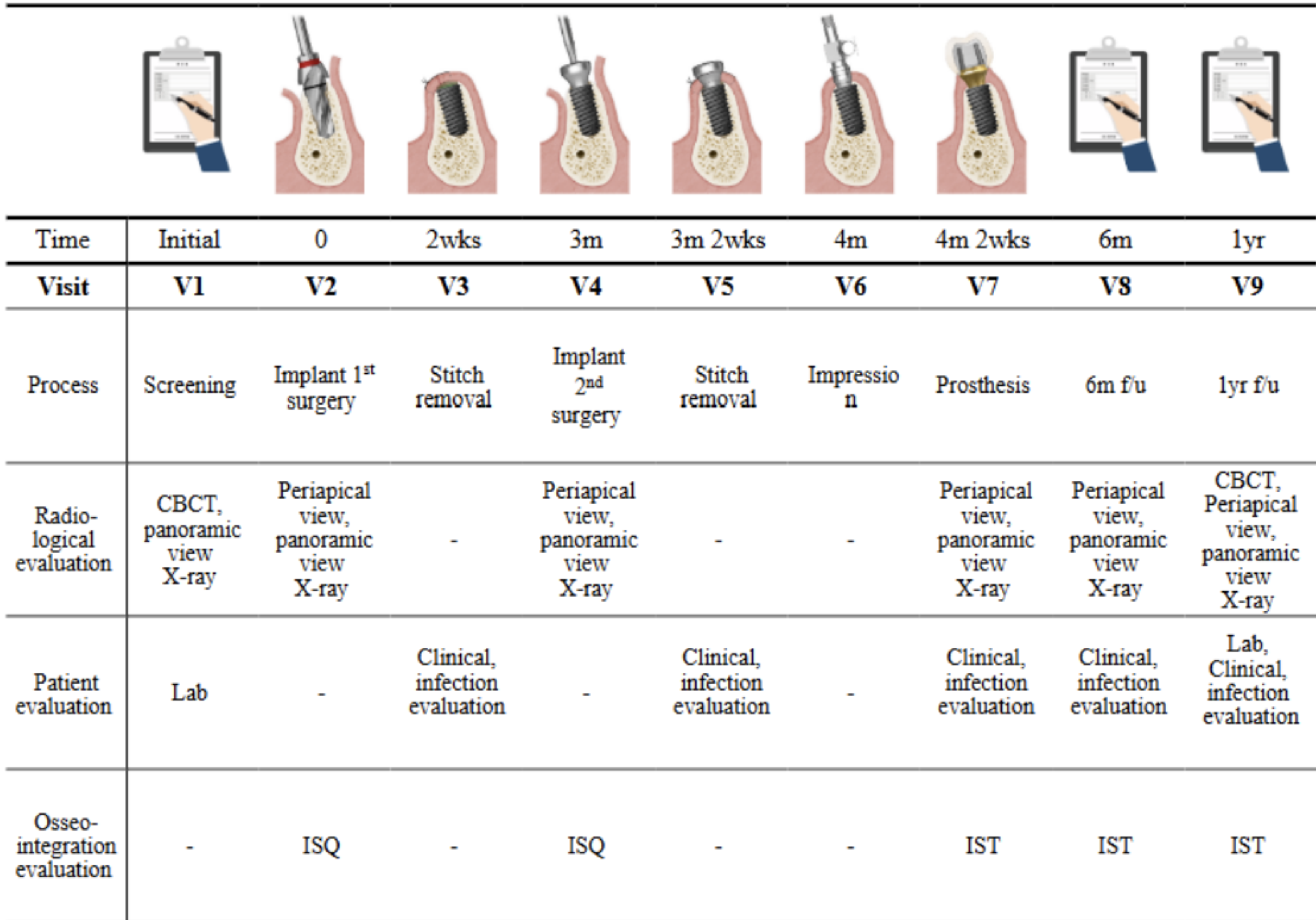


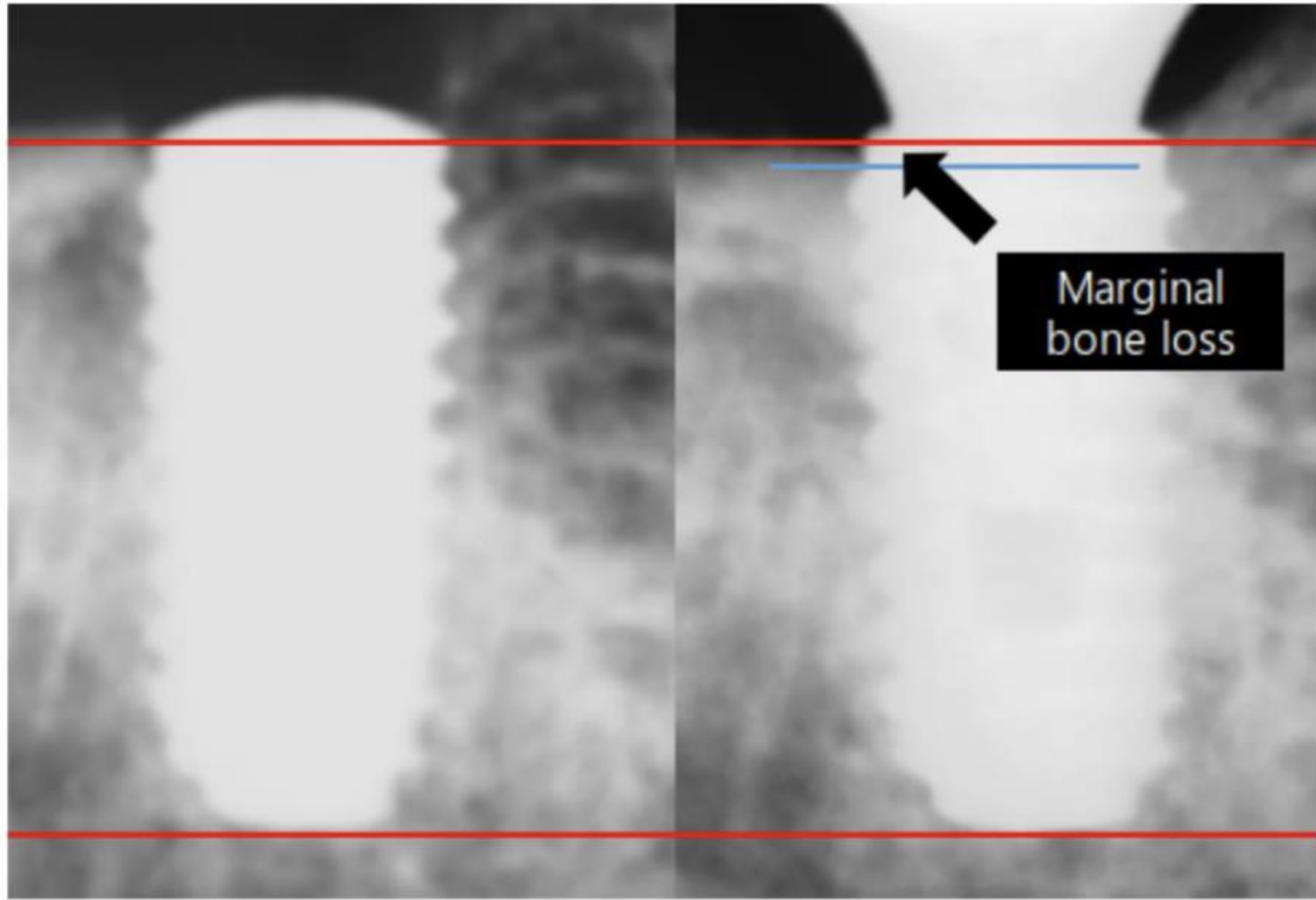
Fig. 1. Schematic design of study process

	Total(n=36)	Group A(n=17)	Group B(n=19)
Sample characteristics			
Gender		Female	
Age(mean ± 1SD)	67.92± 8.10	65.59± 7.68	70.00± 8.08
Smoker(%)	0(0%)	0(0%)	0(0%)
Hypertension	17(47.2%)	6(35.3%)	11(57.9%)
Diabetes	6(16.7%)	1(5.9%)	5(26.3%)
Steroid hx.	0(0%)	2(11.8%)	0 (0%)
Anamnesis			
General	no chemotherapy, no radiotherapy, no glucocorticosteroidtherapy		
Osteoporosis screening		T score > -2	T score ≤ -2
T-score			
Spine			
L1-L4	-1.62± 0.65	-1.20± 0.25	-2.0± 0.29
Femur and Neck			
Total Hip	-0.91± 0.83	-0.39± 0.54	-1.38± 0.36
Therapy			
Implant system	OsstemSOI Implant		
Surface coating	HEPES		
Number	45	21	24
Antibiotic therapy	Yes	Yes	Yes
Results			
Success rateof implants*	100%	100%	100%

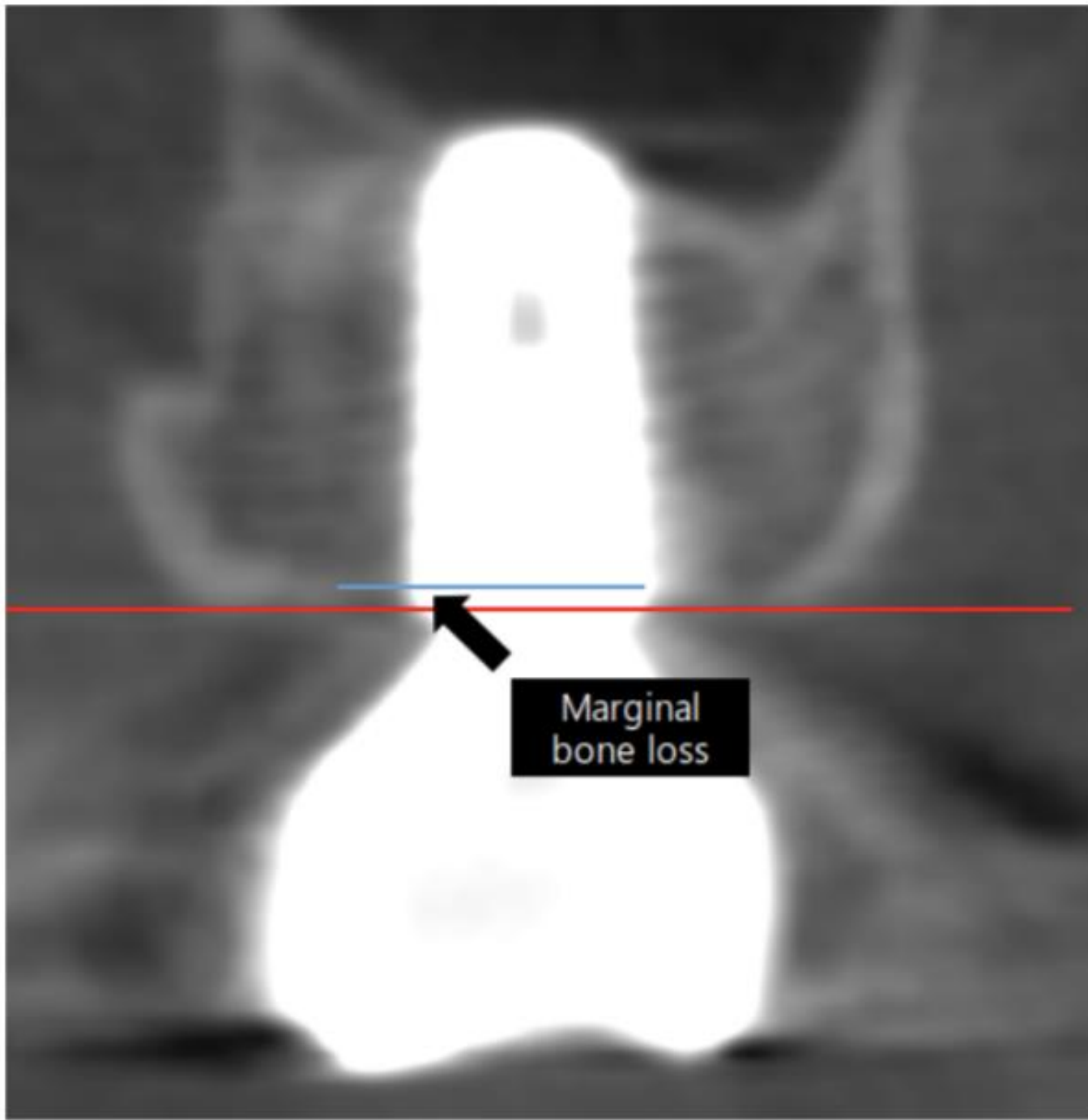
*Evaluated by Buser's criteria(18).

Table 1. Baseline demographics table and overall outcomes of implant therapy

Marginal bone loss was measured with 1-year of follow up x-ray and Conebeam CT. With x-ray, distal and mesial bone height was measured from machined thread at the day of operation, 3, 6, 12 months after operation. If bone level decreased under the first thread, we defined as peri-implant bone loss. With Conebeam CT, same measuring procedure was done on buccal and palatal surfaces.



(A) Measurement of MBL of mesial, distal side using periapical view x-ray



(B) Measurement of MBL of buccal, palatal side using CBCT.

Results

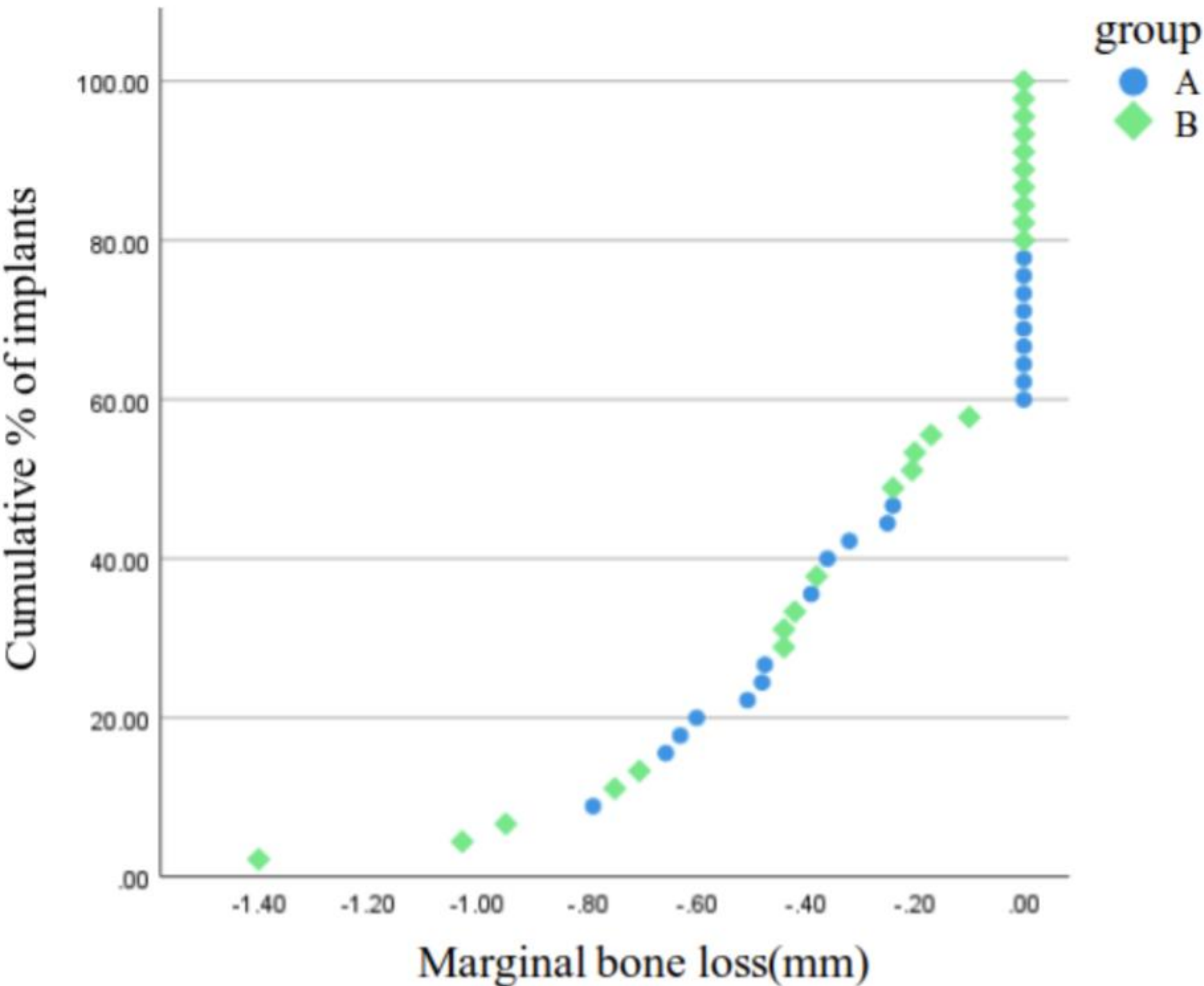


Fig. 2. Marginal bone loss ; 1 year after surgery

Peri-implant marginal bone loss at 1 year after surgery showed normal range in both group. (Fig. 2) Average of IST level showed over 70 of ISQ/IST value.(Table 2) Pocket probing depth after prosthesis showed favorable value.(Table 3) Bleeding on probing, plaque score at V7, V8, V9. (Table 4) There were no significant difference s on every clinical parameters.

ISQ/IST value *	Group A			Group B			Total		
	V2	V4	V9	V2	V4	V9	V2	V4	V9
N	21	21	21	24	24	24	45	45	45
Mean	72.33	77.19	72.38	78.17	75.96	72.58	75.44	76.53	72.49
SD	9.24	5.80	5.45	6.68	6.42	5.98	8.41	6.10	5.67
Min	51	66	63	62	63	63	51	63	63
Median	72.0	76.0	72.0	77.5	77.0	73.50	77.00	77.00	72.00
Max	85	86	82	88	90	83	88	90	83
p							>0.05	>0.05	>0.05

Table 2. Renonance frequency analysis at V2, V4, V9 in each group

PPD(mm)	Group A			Group B			Total		
	V7	V8	V9	V7	V8	V9	V7	V8	V9
N	21	21	21	24	24	24	45	45	45
Mean	3.14	3.67	2.81	3.38	2.88	2.83	3.27	3.24	2.82
SD	1.39	1.42	1.06	1.55	1.27	1.31	1.48	1.40	1.18
Min	1	1	0	1	0	1	1	0	0
Median	3	4	3	3.5	3	3	3	3	3
Max	7	7	4	6	5	6	7	7	6

Table 3. Pocket probing depth(PPD) at V7, V8, V9 in each group

MBL(mm)	Group A			Group B			Total		
	V7	V8	V9	V7	V8	V9	V7	V8	V9
Bleeding	8(38.1%)	11(52.4%)	8(38.1%)	6(25.0%)	9(36.0%)	10(41.7%)	14(31.1%)	20(44.4%)	18(40%)
Plaque	0	3(14.3%)	5(23.8%)	0	4(16.7%)	4(16.7%)	0	7(15.6%)	9(20%)
Both	0	2(9.5%)	2 (9.5%)	0	3(12.5%)	4 (16.7%)	0	5(11.1%)	6(13.3%)

Table 4. Bleeding on probing and plaque score at V7, V8, V9 in each group

As a result, 45 implants for 36 patients, including osteopenia and osteoporosis patient, successfully achieved osseointegration which means 100% survival rate of implant within 1 year study.

	Group A (n = 17)	Group B (n = 19)	Total (n = 36)	P val
Age group(year)	65.59 ± 7.682	70.00 ± 8.08	67.92 ± 8.10	0.100 *
ΔTscore	-0.16 ± 0.35	-0.01 ± 0.31	-0.08 ± 0.33	0.244†
ΔL1_L4	-0.05 ± 0.41	0.12 ± 0.36	0.04 ± 0.39	0.186†
ΔFemurNeck	-0.14 ± 0.30	-0.04 ± 0.27	-0.09 ± 0.29	0.300†
ΔTotalHip	-0.08 ± 0.27	0.02 ± 0.27	-0.03 ± 0.27	0.175†
ΔPTH	2.82 ± 10.96	2.59 ± 17.65	2.70 ± 14.67	0.900†
Δ25_OH_vitD	1.17 ± 12.89	11.58 ± 12.62	6.67 ± 13.63	0.015†
ΔCTx	-0.07 ± 0.18	-0.08 ± 0.19	-0.08 ± 0.18	0.531†
ΔP1NP	-1.15 ± 19.05	-14.39 ± 16.96	59.94 ± 237.9	0.033†

Table 5. Changes of endocrine parameters(initial vs pod 1yr)

*mann-whitney U test
†paired t-test

In this study, every patient including osteoporosis patients discontinued antiresorptive therapy for implant surgery. Over the one-year study period, average of showed not significant decrease. No significant differences were observed between the groups except Vit D, P1NP level. (Table 5)

Conclusion

For dental clinicians, osteoporosis is challenging medical history to perform intraoral surgeries including extraction and dental implants. Even in osteoporotic patients with decreased bone metabolism, a **100% implant survival rate was achieved using Osstem SOI Implants**. With SOI implant, clinicians can achieve high success rate without special techniques. Secondary outcome quantitatively confirmed little change in bone mineral density and other serologic lab during the first year of study.