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BIOACTIVE MICROSTRUCTURED ANTI MICROBIAL PRECOATED SURFACE IMPLANT VERSUS NON-COATED SURFACE IMPLANT IN TYPE 2 DIABETIC PATIENT IN THE MANDIBLE (A RANDOMIZED CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: Dental implants Surface properties significantly influence both biological and mechanical integration. As surface bio-treatment could accelerate and enhance bone regeneration, ensuring more successful implantation.

OBJECTIVES: to compare the implant stability, pain intensity, wound healing and bone densification around two different implants one with bioactive surface coating and implant with non-coated surface in controlled type 2 diabetic patients.

MATERIALS AND METHODS: In a randomized clinical trial, ten patients with controlled type 2 diabetes and bilateral missing mandibular posterior teeth participated. Using a split-mouth technique, each patient received a non-coated implant on one side and a pre-coated surface implant on the opposite side of the posterior mandible than implants stability, postoperative pain intensity, wound healing, and bone density formation were compared between bioactive antimicrobial coated surface implants and non-coated implants.. Clinical and radiographic Assessments were conducted within the following postoperative 6-month for all patients.

RESULTS: The study compared non-coated titanium dental implants to bioactive Ca-P coated implants. the Ca-P pre-coated implants exhibited significantly higher primary and secondary stability than non-coated implants ($p < 0.001$). While, the non-coated implants reported lower postoperative pain levels ($p = 0.05$, $p = 0.046$). No statistically significant difference reported in wound healing ($p > 0.05$). However, Ca-P pre-coated implants demonstrated greater bone densification over time ($p < 0.001$) then non-coated implants.

CONCLUSION: Both groups of implants showed satisfactory results; however, implants coated with Ca-P were particularly noted for enhancing implant stability and promoting bone density formation. Consequently, the pre-coated implants outperformed the non-coated implants.

KEYWORDS: Non-coated, Pre-coated Ca-P, Implant, Density, stability.

RUNNING TITLE: Pre-coated versus non-coated dental implants in controlled type-2 diabetic patients.

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INTRODUCTION

The World Health Organization has counted over 171 million diabetic individuals present worldwide, making diabetes a prevalent global health issue. Predictions indicate that this figure will double by year 2030. Diabetes mellitus, is an endocrine disorder, poses a substantial challenge to global public health (1,2). For diabetic individuals, maintaining optimal glycemic control is crucial, for preventive wounds complication and infections (3).

A traditionally regarded significant parameter is to assess glycemic control, as it can heighten susceptibility to microvascular complications when neglected, which has the potential to adversely impact the post-surgical healing procedure (3,4). So, achieving stable glycemic control, considered a preventative measurement against infection, and eliminating harmful factors such as smoking, periodontitis, and inadequate oral hygiene are essential components of effective healthcare (5).

In the past, diabetic individuals had no options but dentures or fixed bridges for oral rehabilitation due to the concerns about implantation failure. As diabetic individuals may have uncontrolled condition sometimes making them more receptive to infections (1).

But, recent studies have uncovered impressive rates of successful implantation of bio-treated improved implants surface and design in controlled type 2 diabetic patients (6). With high survival rates up to 12 years of follow-up and probing pocket depths below

3mm around the placed implants. Thus, the chances for implantation success increased up to 85-95%. (6)
Surface bio-treatment and topography of an implant, can significantly enhance osseointegration by optimizing healing processes, reducing time to functional loading, and improving overall implant survival rates leading to very thriving outcomes. (7,8).
The purpose of this study, was to compare between the implant stability and bone density formation around micro-structured bioactive antimicrobial precoated surface implants and the non-coated surface implants in controlled type 2 diabetic patients through the cone beam computerized tomography (CBCT) for bone density assessment and the Osstell device for stability measurement.

MATERIALS AND METHODS

The study was executed as a randomized controlled clinical trial and implemented in accordance with the approval of the Research Ethics Committee at the Faculty of Dentistry, Alexandria University, on 16/01/2022. Ethics Committee No: 0375-01/2022. Each patient was provided with an informed consent about the surgical procedure, to guarantee their comprehension of the treatment outcomes and the hazards they are conceivably exposed to throughout the intervention and to obtain their approval.

Patients:

The study was designed and documented following the CONSORT guidelines. (3). As the clinical part of the study No. IORG0008839 was conducted after an ethical approval from the Scientific Research Ethics Committee No:0375-01/2022 at the Faculty of Dentistry in Alexandria University was obtained on 1/16/2022 and, clinically registered with Identification No. NCT06528327. ten controlled type 2 diabetic patients were chosen in accordance with the inclusion criteria from the outpatient clinic of the Oral and Maxillofacial Department at the Faculty of Dentistry of Alexandria University and the surgical placement of the implants was done in the clinics of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University.
The process of randomizing the samples was carried out using the split mouth technique, where the mandible of a single patient was randomly divided into two sides. Each side was assigned to different implant type to eliminate any variations which may exist between subjects.
The inclusion criteria for the study were as follows: patients age ranged from 35 to 60 years old, regardless of their gender. Sufficient inter dental and inter-arch spaces were mandatory to be available to allow comfortable installation of the implant and implant components as abutments and crowns and to allow for proper oral hygiene maintaining later at home. The anatomical location of the implant site needed to be easily accessible and clearly within sight during the surgical procedure. Lastly, all patients had to have their medical condition under control, with glycosylated hemoglobin (HbA1C) levels not exceeding 7%.
On the other hand, the exclusion criteria for the study were as follows: patients who had a parafunctional dependency that may lead to implant failure, patients with implant site harboring pathologies, patients undergoing radiotherapy targeted in the head and neck region, and patients with excessive tobacco consumption.

Materials

- SGS Implant system: (SGS Swiss implant system (IDS-Trading.net https//www.Sgs-dental.com/index.php/suface-treatment)

SGS dental implant system: which is precoated surface implant with (SBTC) smart bioactive trabecular coating of calcium phosphate on its surface, to allow better osteointegration with the bone due to its high osteoconductivity. Also, its significant surface microporosity enlargement and high hydrophilic reaction with blood make it biocompatible and increase the primary stability, and reduce the healing time.
Implant fixture design: it has a tapered design with internal hexagon connection
The implant design has varieties of sizes:

- Available Implant diameters: 3.2 mm - 3.75 mm - 4.2 mm - 4.5 mm - 5 mm - 6mm.
- Available lengths: 6 mm -8 mm - 10 mm - 11.5 mm - 13 mm - 16 mm).

- Dentium implant system: (Dentium Korean implant system)

Non-coated dental implant surface, double threaded tapered fixture for Higher bone-to-implant contact and faster bone gathering on the surface, and it has a long internal hexagon connection which improved recognition and a range of sizes

- Available Implant diameter :3.6 mm - 4 mm - 4.4 mm -4.9 mm.- 6mm -7 mm
- Available Implant length :7 mm - 8 mm -10 mm - 12 mm -14 mm.

Osstell device: (Osstell, Göteborg, Sweden)

Methods

Pre-surgical assessment

1. Clinical examination (9):

The medical records of the patients were thoroughly documented, and a comprehensive intraoral dental examination was conducted, along with obtaining clinical photographic pictures.

2. Radiographic examination (10):

For presurgical assessment, CBCT were obtained to verify the bone quality, width, height, long axis of alveolar bone, the vital anatomical structures as the

inferior alveolar nerve and mandibular canal and to detect any pathosis at the intended implant site.

3. Laboratory Investigations (11):

Complete Blood Count (CBC) was conducted, along with the Glycated Hemoglobin test (HbA1c) with a conformed demand for the results to of the (HbA1c) test not to exceed 7%.

The Surgical Steps: (Figure 1)

The surgical steps conducted were the same for each mandibular side except for the type of the implant were different. In which, one side received the non-coated (Dentium) implant while the other side received the precoated (SGS) implant. The surgical steps were conducted on the following order:

An antiseptic with Betadine1% mouth wash, gargle 120 ML was used to disinfect the oral cavity. Local anesthetic of Arti-Caine (4%) with epinephrine (1:200,000) was injected to block the inferior alveolar nerve at both sides. A mid-crestal incision with blade No. 15 was done at the site of the implants then an intrasulcular incisions were made at the adjacent teeth to join the mid-crestal incisions at 90^0 angles creating full-thickness flaps, then with a fine periosteal elevator, the flaps were raised. After exposing the jawbone, osteotomies sites for the implants to be inserted in, were created through drilling using surgical drills according to each implant manufacturer guidelines at both sides.

The dental implants were inserted, in which one side received SGS implant while the other side received Dentium implant. The primary stability was recorded using the Osstell device for both dental implants than the flaps were adapted and properly trimmed with a scissors and stabilized with a 0/3 surgical non-resorbable silk sutures which were removed 10 days after the surgery.

- **Post-operative care:**

Patients were advised to place ice packs externally on face for the initial 24 hours post-operatively with a recommended frequency of 3 to 6 times per day for 10-minute intervals, and to apply warm packs for the following two days.

Written and verbal postoperative instructions along with prescribed medications were provided to the patients including:

Duricef antibiotics tablets given every once daily for 5 days; (Cefadroxil 1g/tab) manufactured by: SmithKline Beecham-Egypt L.L.C. An affiliated co. to GlaxoSmithKline

Catafast Analgesic, Anti-inflammatory drug every 12 hours for 3 days; (Diclofenac potassium 50 mg /Sachet) manufactured by Novartis for pharmaceuticals industry-Egypt.

alphintern® Anti-edematous: 1 tablet 3 times/day before meals (Chymotrypsin 300 U /tablet) manufactured by Amoun Pharmaceutical Company-Egypt.

Oral hygiene was maintained by teeth brushing with soft brush and gargling once daily for 1 week with 1% antiseptic Betadine Gargle & Mouthwash (Povidone Iodine /120 ml (about 4.06 oz) from mundi pharma mouth wash-Egypt.

- **Follow up:**

A. Clinical assessment involved:

a) **Early follow-up**:

It was conducted on the surgical day and on the 1st, 3rd, and 7th days post-surgical placement. This evaluation aimed to assess:

1. Implant stability assessment (12, 13):

Primary stability was gauged using the Osstell device immediately after implant placement during surgery. This involved connecting the appropriate smart peg to the implant and the Osstell Beacon was activated near the smart peg to obtain stability readings.

2. Pain intensity assessment (14): (Figure 2)

Pain levels were measured through utilizing the Visual Analog Scale (VAS) on the 1st, 3rd, and 7thpostoperative days. The VAS ranges from 0 to 10, in which 0 represented the lowest score of no pain at all and 10 represented the highest score of un-tolerated pain. Thus, when the VAS score increased so did the pain intensity.

3. The wound healing assessment (15):

It was performed using healing index scoring system during the 2 weeks after the surgery.

- **Very poor**: tissue color ≥ 50% of gingiva is red, responses to palpation bleeding granulation tissue are present, incision margin not epithelialized, and suppuration is present.
- **Poor:** tissue color ≥ 50% of gingiva is red and responses to palpation: bleeding granulation tissue is present, incision margin not epithelialized with connective tissue exposed
- **Good:** tissue color ≥ 25% and < 50% of the gingiva response to palpation: No bleeding and granulation tissue not present
- **Very good:** < 25% of the gingiva response to palpation: No bleeding with no granulation tissue present
- **Excellent:** All tissue is pink, and no bleeding is present, no granulation tissue and no connective tissue exposed at the incision margin.

b) Delayed follow-up included:

1. Post-operative complication assessment and management (16): Over the first six months post-operatively, patients were recalled and asked to report if any infection manifestations as sever pain, fever, or tenderness were noted, so it can be promptly addressed as soon as possible.

2. Implant stability assessment (17): Four months post-operatively, implant stability was evaluated using the Osstell device to assess secondary stability.

B. Radiographic assessment involved (18) (Figure 3) (Figure 4)

The bone density was assessed using CBCT post-operatively first at two weeks and then four months later. The difference in the Progression of bone density around each implant type was measured using 3D OnDemand software. The bone density measurements results were graphically displayed with mean values and standard deviations inside and outside the implants, then the results were compared between the two implants types to decide which implant had better bone densification around it.

C. Prosthetic phase (19): After a period of 4 months since the implantation procedure, a dental implants abutments were installed and permanent fixed prosthodontic crowns were fabricated and placed over the abutments.

Statistical analysis:

The study used IBM SPSS software version 24.0 to analyze data on bone density, wound healing, ISQ, and VAS. The Kolmogorov-Smirnov test was used to test the normality of bone density data, with significance set at $P \leq 0.05$. The Mann-Whitney U-test was used to test the normality of wound healing data, with significance set at $P \leq 0.05$. The Shapiro-Wilk test was used to test the normality of ISQ and VAS data, with significance set at $P \leq 0.05$. Quantitative data were described using mean and standard deviation for normally distributed data. Comparisons between two independent populations were done using independent t-tests for normally distributed data, and the Mann-Whitney test was used for non-parametric data. Significant test results were quoted as two-tailed probabilities, and the significance of the results was judged at the 5% level.

RESULTS

The demographic data:

The distribution of gender among the 10 participants was 40% males and 60% females, (4 males and 6 females). And their ages ranged from a range of 35 to 52. with a mean of 44.8 years old, in which 40% were below the age of 50 and 60% were above the age of 50 years old

A. Clinical assessment results:

1. **The implant stability** (Table 1) (Table 2)

The ISQ values of the SGS and Dentium groups primary stability were measured by the Osstell device than were compared. The ISQ mean values were up to par for both groups. However, the SGS group primary stability mean values were higher in than Dentium group mean values on all sides, buccally p value =0.012, lingually p value = 0.30, mesially p value =0.002 and distally p value = 0.001, this caused high statistically significance different between the two implants groups with *P* value = (0.001) in favour of the SGS group. As for the secondary the ISQ values of the SGS and Dentium groups, which were then subjected to comparative analysis. Notably, both groups showed a significant increase in secondary stability ISQ values. However, the statistical analysis revealed that the SGS group exhibited notably higher secondary stability differences compared to the Dentium group across all directions, with corresponding P values of (0.004) buccally, (0.001) lingually, (0.001) mesially, and (0.001) distally.

2. **Pain intensity assessment** (Figure 5)

The pain intensity of the SGS and Dentium implant groups was compared on the 1st, 3rd, and 7th days after the surgery. On day 1, both groups reported moderate pain with SGS group mean score = 4.63 and Dentium group mean score = 4.75 and, on day 3, the pain intensity level escalated in both groups, with SGS group mean score = 7.25 and Dentium group mean score = 7, indicating severe pain in both groups On day 7, both implant groups showed a decrease in pain intensity levels with SGS group mean score =3.75, which indicated moderate pain, while Dentium group mean score = 2.88, which indicated mild pain. The results were in favor of Dentuim group as the SGS group had higher VAS scores on all post operative days.

3. **Wound healing assessment** (Table 3)

The wound healing index was used to compare wound healing around SGS implant group to the Dentium implant groups at different follow-up days. On the 3rd day post-operatively, the SGS group had a mean healing index of (2.226) with (SD = 1.96), while the Dentium group had a mean healing index of (2.347) with (SD = 1.77). On the 7th day, the SGS group had a mean healing index of (3.801) with (SD = 2.34), while the Dentium group had a mean healing index of (3.711) with (SD = 2.00). And on the 14th day, the SGS group had a mean healing index of (4.562) with (SD = 3.39), while the Dentium group had a mean healing index of (4.619) with (SD = 3.46). The wound healing statistical significance on the 3rd day was *P* value = (0.0994), and the 7th day it was *P* value = (0.970), and on the 14th day it was *P* value = (0.0974). These values indicated that there was no statistical significance difference in wound healing between the SGS and Dentium implant groups at all post-operative time points.

B. Radiographical evaluation

- **The bone density** (Figure 6)

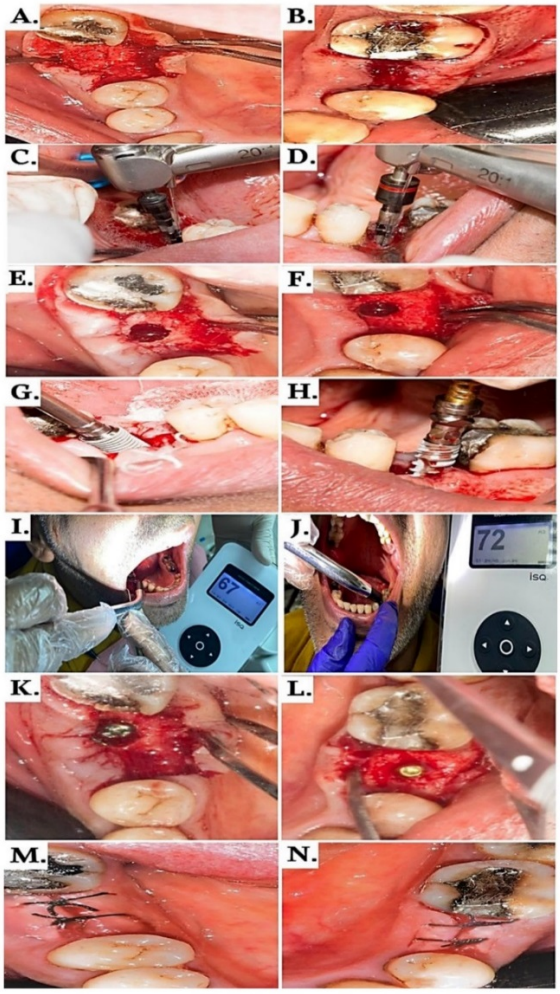

Figure 1: Surgical Steps of Dentium and SGS Implants Placements: A. & B. Flaps Reflection C. & D. Surgical drilling E&F: Osteotomies Sites G. Dentium implant placing H. SGS implant placing. I. & J. Measuring primary stability K. & L. Implant in place M. & N. Suturing.

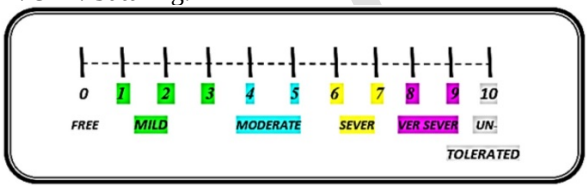

Figure 2: The visual analogue scale for pain intensity assessment.

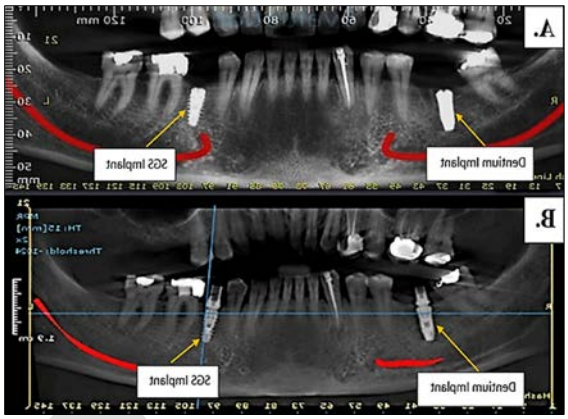

Figure 3: CBCT (Panoramic View) of implants both SGS and Dentium. **A.** After 2-weeks post-operatively. **B.** Implants with abutments after 4 month post-operatively.

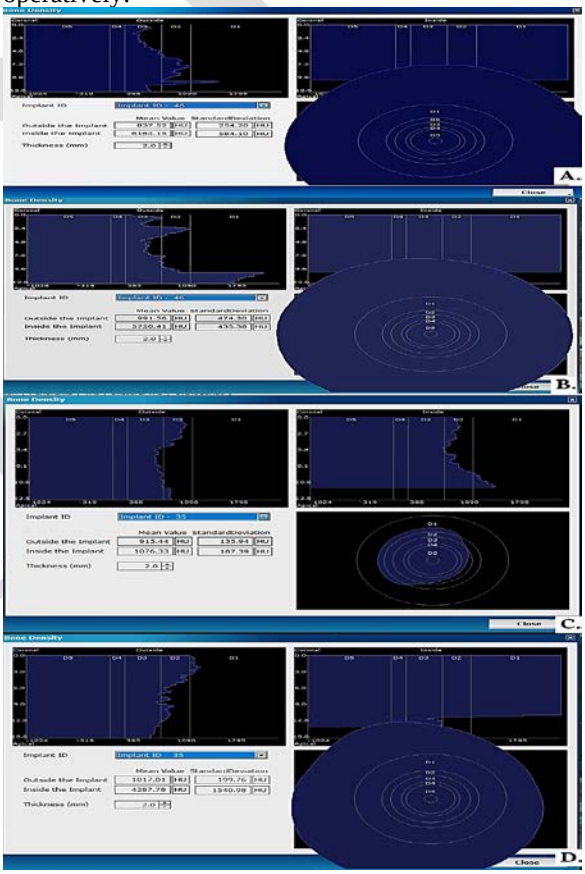

Figure 4: Bone density measurements within 2 mm thickness around each implant **A.** Bone density measurements at 2-weeks and **B.** At 4 months post-operatively for the non-coated implant, and **C.** Bone density measurements at 2-weeks and **D.** At 4 months post-operatively for the bioactive pre-coated implant.

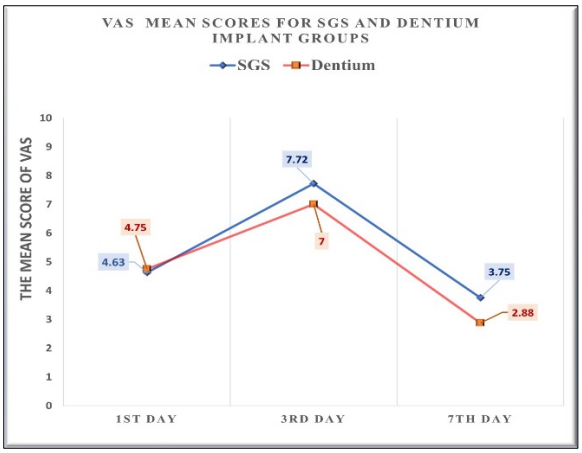

Figure 5: Comparison between SGS and Dentium studied implant groups regarding pain level assessment by VAS.

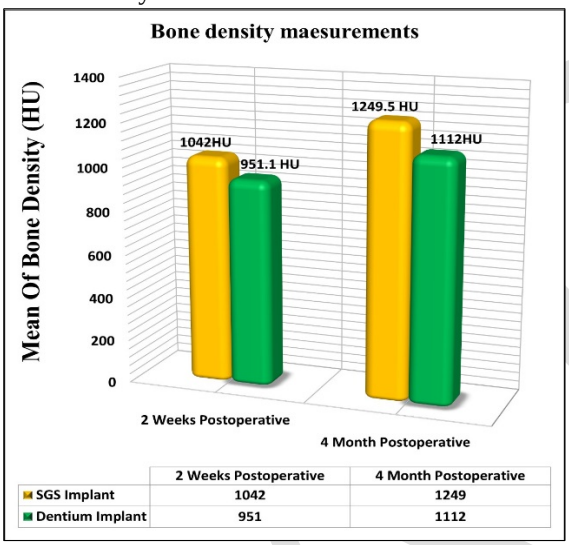

Figure 6: Comparison between bone density within 2mm thickness at 2 weeks and at 4 months in the two studied implant groups.

Sides	ISQ values	Primary stability		*P* values
		Precoated (SGS) Group	Non – Precoated (Dentium) Group	
Buccal	Range	65.2-82.01	56.4-70.2	0.012*
	Mean	70.9	64.3	
	S.D.	6.7	6.2	
	Median	68.7	66.9	
Lingual	Range	65.2-82.01	59.33-71.01	0.030*
	Mean	70.9	64.7	
	S.D.	6.7	4.8	
	Median	68.7	64.5	
Mesial	Range	66.7-84.3	56.8-70.9	0.002*
	Mean	72.1	65.2	
	S.D.	6.0	5.9	
	Median	81.2	69.2	
Distal	Range	67.8-88	57.13-71.45	0.004*
	Mean	70.9	67.9	
	S.D.	5.6	4.5	
	Median	72.7	69.5	
Significance differences between the two implants' groups	Range	68.7-81.2	64.3-67.9	0.001*
	Mean	71.2	65.5	
	S.D.	0.51	1.37	
	Median	70.9	64.85	

Table 1: Comparison between SGS and Dentium implant groups regarding primary stability.

Sides	ISQ values	Secondary stability		P value
		Precoated (SGS) Group	Non – Precoated (Dentium) Group	
Buccal	Range	82.1-91.12	55.18-86.03	0.004*
	Mean	84.9	74.1	
	S.D.	3.0	12.0	
	Median	85.1	77.4	
Lingual	Range	81.88-88.3	58.98-81.88	0.001*
	Mean	83.7	72.6	
	S.D.	2.0	8.9	
	Median	82.9	73.0	
Mesial	Range	80.3-86.2	56.77-85.56	0.003*
	Mean	81.6	70.7	
	S.D.	1.8	10.0	
	Median	83.9	72.1	
Distal	Range	79.8-87	63.2-82.3	0.002*
	Mean	80.3	71.7	
	S.D.	2.6	7.1	
	Median	84.5	69.2	
The significance differences between the two implants groups	Range	80.3-84.9	70.7-74.1	0.002*
	Mean	82.6	72.2	
	S.D.	2.05	1.53	
	Median	82.8	73.1	

Table 2: Comparison between SGS and Dentium implant groups regarding secondar

Post operative Days	Wound healing Measurements	SGS Implant Group	Dentium Implant Group	P value
3rd day Post operative	Range	2.2±476	2.5±0.593	
	Mean	2.226	2.347	0.0994
	S.D.	1.96	1.77	*N.S.*
	Median	1.841	1.847	
7th day Post operative	Range	3.8±0.589	3.7±0.862	
	Mean	3.801	3.711	0.970
	S.D.	2.34	2.00	*N.S.*
	Median	2.246	2.288	
14th day Post operative	Range	4.8±0	4.7±0	
	Mean	4.562	4.619	0.0974
	S.D.	3.39	3.46	N.S.
	Median	2.41	2.48	

Table 3: Comparison between the two studied implants groups regarding the wound healing at different post operative days of follow-up.

The bone density was recorded within 2mm thickness around each implant group at 2 weeks and 4 months postoperatively. The HU values obtained from the 3D OnDemand software. At 2 weeks, SGS group had an average mean value of (1042) HU, and at 4 months, it was (1249.0) HU. This difference in the two measurements recording was statistically significant, with a *P* value of (0.021), Similarly, Dentium group had an average mean value of (951.1) HU at 2 weeks, which increased to (1112.8) HU at 4 months. This increase was also statistically significant, with a *P* value of (0.033). This suggested statistically significant improvement in bone densification for both implant groups. However, SGS group *P* value of (0.021) was found to be more statistically significant than Dentium group with *P* value of (0.033). this suggested that the SGS group bone densification was superior than Dentium group.

***P** was significant if ≤0.05* ***N.S.** = Not significant* * Significant at level 0.05

DISCUSSION

This study intended to compare bone density progression encircling the non-coated titanium dental implants versus pre-coated implants with Ca-P coating. It also investigated the implant stability, wound healing, and post-implantation pain intensity levels. This study involved 10 individuals with controlled type 2 diabetes (4 males, 6 females) with HbA1c levels ≤ 7, aged 35-60 (mean age: 44.8 ± 13.7 years). They all suffered from bilateral posterior mandible dentition and required dental restoration.

Successful implants, abutments, and crowns placements require applicants to meet presurgical demands such as good sight, access to the surgical site, sufficient space and bone for implant insertion, and inter-jaw alignment. Unfit applicants were ruled unfit due to uncontrolled blood glucose levels, smoking, radiotherapy, parafunctional dependence, or pathology. This aligns with a 2006 study by Alberto Rebaudi et al (20), who highlighted the importance of inclusive and exclusive criteria for successful implantation procedures.

In our study, the posterior mandibular region was chosen as the primary site for implant placement due to its sufficient width and robust bone structure, facilitating safer procedures, precise bone density assessments, and accurate recording of implant stability. This approach resulted in successful implant placements compared to the anterior region, characterized by narrower dimensions and diminished bone structure, posing risks of measurement inaccuracies and instability, potentially compromising implant success. Our standpoint aligns with Estévez-Pérez et al.'s 2020 (21) findings, indicating superior outcomes for posterior mandibular implants in terms of bone preservation compared to those in the anterior region. However, Tolstunov et al.'s 2007 (22) study highlights a higher success rate for anterior implants, attributed primarily to superior bone quality rather than quantity and reduced proximity to critical structures like the inferior alveolar nerve, culminating in a 4% increase in success rates.

The split-mouth technique was employed to restore missing teeth, alongside post-surgical antibiotics and mouth rinse deployment, in our opinion it was to enhance the implantation success. This was in agreement with Oates et al. 2014 (23) who affirmed the utility of the systemic antibiotics and mouthwash application to mount-up implant survival rates in type 2 diabetic patients, with rates reaching 95% in poorly controlled patients, 92.6% in well-controlled patients, and 93% in non-diabetic patients. Conversely, Harold F. Morris et al. 2000 (24) observed higher implant failure rates in type 2 diabetics, compared to non-diabetic individuals, with no significant impact from mouthwash and antibiotics usage.

In our study, the implant stability was assessed using the Osstell device. This involved measuring ISQ values for both the SGS pre-coated and Dentium non-coated implant groups immediately after implant placement and after four months. Subsequently, the ISQ values of the primary and secondary stability were calculated for each group. Regarding primary stability, the Ca-P pre-coated implant group demonstrated a higher mean ISQ score of 71.2 compared to the non-coated implant group's mean ISQ score of 65.2. This difference was statistically significant with (P = 0.001) favoring the pre-coated implant group.

For secondary stability, the mean ISQ value for the Ca-P pre-coated implant group was 82.6 which was higher than the non-coated implant group as its mean was of

72.2. The statistical analysis revealed a significant difference favoring the Ca-P pre-coated group with (P = 0.001), which indicated better secondary stability compared to the non-coated group.

From our perspective, the Ca-P pre-coated implant group displayed superior primary stability compared to the non-coated group due to its advanced bone-collecting surface design of wider threads pitches spaces on the implant surface, which were clinically observed and it is believed they allowed for more bone fragment retention within those spaces. Therefore, enhancing implants stability.

Additionally, the sharp threads of the pre-coated implants have facilitated greater bone fragment compression between threads. While both groups demonstrated satisfactory primary stability. Yet, the Ca-P pre-coated group exhibited notably higher stability than the non-coated group. Our explanation about the primary stability finding was consistent with YC Huang et al.'s study in 2023 (25), who highlighted the significance of the implant topography role in creating strong mechanical interlocking for achieving great primary stability.

The Ca-P precoated group exhibited superior secondary stability compared to the non-coated group. We attribute this not only to the implant's fixture design but also to a biological factor which was the bioactive Ca-P coating on the implant surface. This coating likely attracted larger amount of bone tissue during the healing phase because its composition of Ca-P similar to that of human bone, which resulted in improved secondary stability for the precoated group. In contrast to the non-coated group, which relied solely on mechanical interlocking for achieving good secondary stability with no surface bio-treatment, the superior secondary stability of the precoated group can be attributed to both mechanical and biological factors together.

Our perspective aligns with Tabrizi et al. 2022 (26), who found satisfactory stability and osseointegration in both Ca-P coated and conventional non-coated SLA implants, with the former exhibiting superior stability. However, Ibrahim et al. 2020 (27), who disagreed with our viewpoint, as they stated that bone quality significantly influences stability, surpassing the influence of implant features such as surface design or surface treatment. They observed implants placed in defective bone demonstrated less stability and bone densification compared to implants placed in dense, non-defective bone, regardless of implant features.

The pain intensity was assessed postoperatively on 1st, 3rd, and 7th days using the VAS. On day 1, no statistically significant difference was found between the Ca-P precoated and non-coated groups (P = 0.460). However, by day 3, a statistically significant difference emerged of (P = 0.05), favoring the non-coated group. This trend persisted on day 7, with a statistically significant difference favoring the non-coated group side again with (P = 0.046). All VAS scores for the non-coated group were lower than those for the precoated group, which indicated less postoperative pain for the non-coated group .

In our perspective the elevated pain intensity for the precoated group was likely due to the increased drilling steps during the implantation. But through following the postoperative instructions, the pain intensity gradually subsided by day 7. Our perspective aligned with Senada et al. study in 2020 (28), who reported single-drill implant protocol induced less postoperative pain intensity than a multiple-drill protocol. Contrarily Rizzatto et al. 2023 (29), linked the drilling torque to the postoperative pain intensity, in which higher torque levels were correlated to increased pain intensity. However, AlQutub et al. 2021 (30) observed gender differences in pain perception, with females reporting higher pain levels than males, attributing this to the greater emotional expressiveness within the female's nature.

Nevertheless, Kim et al. 2013 (31) who found that when more implants were placed the more was the pain intensity. These findings added nuanced perspectives to the factors which can increase postoperative pain intensity, supplementing the initial study's focus on drills usage relation to postoperative pain intensity.

In this current study, the wound healing was assessed using the early wound healing index on the 3rd, 7th, and 14th days post-surgery. Results showed no statistically significant difference in wound healing between the two implant groups, with P values of 0.0994 on day 3, 0.970 on day 7, and 0.0974 on day 14. However, one male patient experienced swelling and soft tissue dehiscence in both surgical wounds for both implant groups. The patient was recalled and the wounds were cleaned with sterile saline and povidone-iodine, and re-sutured back with emphasis on oral hygiene and medication adherence during early follow-up.

In our opinion, the improper wound healing incident can be attributed to the inadequate post-operative instructions following of oral hygiene maintenance and medication intake, which was reported by the patient. Our opinion was consistent with Annibali et al.'s 2008 (32) who linked impaired wound healing to disregarded oral hygiene instructions. Conversely, to our opinion Guo et al. in 2010 (33) has associated delayed wound healing with systemic factors such as age, corticosteroids, uncontrolled diabetes, anxiety and diet. Another result was reported by Miles et al. in 2006 (34) who found no significant advantage in administering postoperative antibiotics to improving wound healing.

In this study, the bone density measurements were conducted using CBCT scans and analyzed with the OnDemand 3D software program. These measurements were taken at two time points: two

weeks and four months post-surgery. Both studied implant groups exhibited statistically significant increasement in bone density. Notably, the precoated implant group demonstrated significantly more bone densification compared to the non-coated implant group, with respective P values of 0.184 at two weeks and 0.001 at four months post-surgery.

In our viewpoint, this disparity in the bone densification was attributed to the presence of a Ca-P bioactive coating on the implant surface, with its composition similarity to the human bone composition. It has facilitated and enhanced bone densification by establishing bony connection between the coat on the implant and the jawbone much faster than the non-coated group. Consequently, the precoated implant group exhibited greater bone density formation.

Our findings were corroborated by Malchiodi et al.'s 2011 (34), who observed superior bone densification in Ca-P-coated implants over a three-month period compared to conventional non-coated SLA implants. Similarly, Jain et al.'s 2022 (36) who reported that the Ca-P coated implants exhibit a higher level of effectiveness compared to SLA implant surfaces when it comes to enhancing the initial stability and bone densification at the site of implantation

But on the contrary, Ko K-A et al.'s 2019 (37) reported marginal bone loss of approximately 1 mm or less was detected within the first year after the implantation, regardless of surface treatment presence. They also noted that the bone density diminished around each implant during measurements. Interestingly, the success or failure of implants was not significantly influenced by surface treatments according to their findings.

CONCLUSIONS

In conclusion, the superiority of Ca-P coating was evident in enhancing stability and bone densification at the implantation site compared to non-coated implants. Both types exhibited adequate osseointegration, but Ca-P pre-coated implants demonstrated superior primary and secondary stability attributed to their surface design and bioactive coating. However, non-coated implants caused less postoperative pain, possibly due to simpler implantation. Wound healing assessment showed no significant difference, yet Ca-P pre-coated implants displayed higher bone density. Nonetheless further research is warranted to explore long-term outcomes and patient-specific factors affecting implant success.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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REFERENCES

1. Chalmers J, Joshi R, Patel A. Advances in reducing the burden of vascular disease in type 2 diabetes. Clin Exp Pharmacal Physiol. 2008;35:4:434–7.
2. Mellado-Valero A, Jc FG, Herrera BA, Labaig RC. Effects of diabetes on the osseointegration of dental implants. Med Oral Patol Oral Cir Bucal. 2007;12:1.
3. Katyayan PA, Katyayan M, Shah RJ. Rehabilitative considerations for dental implants in diabetic patients. J Indian Prosthodont Soc. 2012;13:3.
4. Oates TW, Dowell S, Robinson M, McMahan CA. Glycemic control and implant stabilization in type 2 diabetes mellitus. J Dent Res. 2009; 88:4:367–71.
5. Marchand F, Raskin A, Dionnes-Hornes A, Barry T, Dubois N, Valéro R, et al. Dental implants and diabetes: Conditions for success. Diabetes Metab. 2012; 38:1:14–9.
6. Michaeli E, Weinberg I, Nahlieli O. Dental implants in the diabetic patient: systemic and rehabilitative considerations. Quintessence Int. 2009;40:8.
7. Marchand F, Raskin A, Dionnes-Hornes A, Barry T, Dubois N, Valéro R, et al. Dental implants and diabetes: Conditions for success. Diabetes Metab. 2012;38:1:14–9.
8. Dohan Ehrenfest DM, Coelho PG, Kang B-S, Sul Y-T, Albrektsson T. Classification of osseointegrated implant surfaces: materials, chemistry and topography. Trends Biotechnol. 2010;28:4:198–206.
9. Pinto G dos S, Goettems ML, Brancher LC, da Silva FB, Boeira GF, Correa MB, et al. Validation of the digital photographic assessment to diagnose traumatic dental injuries. Dent Traumatol. 2016;32(1):37–42
10. Chua MKW, Koh WJ, Nimbalkar S, Patil PG. CBCT Evaluation of Buccolingual Orientation of Inferior Alveolar Canal in Mandibular Posterior Region for Implant Planning. 2022:1-8
11. Végh D, Bencze B, Banyai D, Vegh A, Rózsa N, Nagy Dobó C, et al. Preoperative HbA1c and blood glucose measurements in diabetes mellitus before oral surgery and implantology treatments. Int J Environ Res Public Health. 2023;20:6-4745
12. Talreja P, Gayathri GV, Mehta DS. Treatment of an early failing implant by guided bone regeneration using resorbable collagen membrane and bioactive glass. J Indian Soc Periodontol. 2013; 17:1-131.
13. Oh J-S, Kim S-G, Lim S-C, Ong JL. A comparative study of two noninvasive techniques to evaluate implant stability: Periotest and Osstell Mentor. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2009; 107:4:513–8.

14. Delgado, D. A., Lambert, B. S., Boutris, N., McCulloch, P. C., Robbins, A. B., Moreno, M. R., & Harris, J. D. Validation of Digital Visual Analog Scale Pain Scoring with a Traditional Paper-based Visual Analog Scale in Adults. Journal of the American Academy of Orthopaedic Surgeons. 2018; 2:3-088
15. Lingamaneni, S., Mandadi, L. R., & Pathakota, K. R. Assessment of healing following low-level laser irradiation after gingivectomy operations using a novel soft tissue healing index: A randomized, double-blind, split-mouth clinical pilot study. 2019;23:1-53.
16. Zabaglo M, Sharman T. Postoperative wound infection. PubMed. Treasure Island (FL): Stat Pearls Publishing; 2023.
17. Ivanova V, Chenchev I, Zlatev S, Mijiritsky E. Correlation between Primary, Secondary Stability, Bone Density, Percentage of Vital Bone Formation and Implant Size. International Journal of Environmental Research and Public Health. 2021 Jun 30;18(13):6994.
18. Haghanifar S, Shafaroudi AM, Nasiri P, Amin MM, Sabet JM. Evaluation of bone density by cone-beam computed tomography and its relationship with primary stability of dental implants. Dental Research Journal. 2022; 19:207-9.
19. Bilhan H, Geckili O, Mumcu E. The use of definitive implant abutments for the fabrication of provisional crowns: a case series. Journal of Periodontal & Implant Science. 2011;41(5):248.
20. Alberto Rebaudi, Romeo Pascetta Romeo, et al. Presurgical implant-supported prosthesis: Technique for cementation of a definitive prosthesis immediately after surgery 2006 ;26(5):4395.
21. Estévez-Pérez D, Bustamante-Hernández N, Labaig-Rueda C, Solá-Ruíz MF, Amengual-Lorenzo J, García-Sala Bonmatí F, et al. Comparative analysis of Peri-implant bone loss in extra-short, short, and conventional implants. A 3-year retrospective study. Int J Environ Res Public Health. 2020 ;17(24):9278.
22. Tolstunov L. Implant zones of the jaws: Implant location and related success rate. J Oral Implantol. 2007;33(4):211–20.
23. Oates TW Jr, Galloway P, Alexander P, Green AV, Huynh-Ba G, Feine J, et al. The effects of elevated haemoglobin A1c in patients with type 2 diabetes mellitus on dental implants. J Am Dent Assoc. 2014;145(12):1218–26.
24. Morris HF, Ochi S, Winkler S. Implant survival in patients with Type 2 diabetes: Placement to 36 months. Ann Periodontol. 2000;5(1):157–65.
25. Huang Y-C, Huang Y-C, Ding S-J. Primary stability of implant placement and loading related to dental implant materials and designs: A literature review. J Dent Sci. 2023;18(4):1467–76.
26. Tabrizi R, Sadeghi HM, Ghasemi K, Khayati A, Jafarian M. Does biphasic calcium phosphate-coated surface increase the secondary stability in dental implants? A split-mouth study. J Maxillofac Oral Surg. 2022 ;21(2):557–61.
27. Ibrahim A, Heitzer M, Bock A, Peters F, Möhlhenrich SC, Hölzle F, et al. Relationship between implant geometry and primary stability in different bony defects and variant bone densities: An in vitro study. Materials (Basel). 2020;13(19):4349.
28. Senada, E., El Sheikh, S., Khalil, M. Evaluation of Success of Single Drilling Implant System (CLINICAL AND RADIOGRAPHIC STUDY). Alexandria Dental Journal, 2020; 45(2): 60-66. doi: 10.21608/adjalexu.2020.86759
29. Rizzatto LV, Di Domênico MB, Collares K, De Carli JP, Corazza PH. Pain factors related to dental implant surgery: A 7-day observational clinical study. Biosci J. 2023;39: e39036.
30. AlQutub AW. Pain experience after dental implant placement compared to tooth extraction. Int J Dent. 2021; 2021:1–5.
31. Kim S, Lee Y-J, Lee S, Moon H-S, Chung M-K. Assessment of pain and anxiety following surgical placement of dental implants. Int J Oral Maxillofac Implants. 2013;28(2):531–5.
32. Annibali S, Ripari M, La Monaca G, Tonoli F, Cristalli MP. Local complications in dental implant surgery: prevention and treatment. Oral & Implantology. 2008;1(1):21.
33. Guo S, DiPietro LA. Factors affecting wound healing. J Dent Res. 2010 ;89(3):219–29.
34. Miles BA, Potter JK, Ellis E III. The efficacy of postoperative antibiotic regimens in the open treatment of mandibular fractures: A prospective randomized trial. J Oral Maxillofac Surg. 2006;64(4):576–82.
35. Malchiodi L, Ghensi P, Cucchi A, Trisi P, Szmukler-Moncler S, Corrocher G, Gerosa R. Early bone formation around immediately loaded FBR-coated implants after 8, 10 and 12 weeks: A human histologic evaluation of three retrieved implants. Minerva Stomatol. 2011 Apr 1;60(4):205-16.
36. Jain C, Kaushik M, Wadhawan A, Agarwal M, Arun A. Comparative evaluation of osseointegration between sandblasted large grit, acid etched (SLA) and calcium phosphate coated implants. A randomized controlled clinical trial. J Osseointegr 2022;14(2):112-121.
37. Ko K-A, Kim S, Choi S-H, Lee J-S. Randomized controlled clinical trial on calcium phosphate coated and conventional SLA surface implants: 1-year study on survival rate and marginal bone level. Clin Implant Dent Relat Res .2019;21(5):995–1001.