

# Osseointegration of maxillary dental implants in diabetes mellitus patients: A one-year clinical outcome of dental implant treatment and the correlation between histomorphometric study and dental implant stability

➤ J. BUNCHONGRUCHAKUL<sup>1</sup>, V. CHATUPOS<sup>1</sup>, S. KHONGKHUNTHIAN<sup>2</sup>, L. SAM<sup>3</sup>, P. KHONGKHUNTHIAN<sup>3</sup>

<sup>1</sup>DDS - Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chiang Mai university, Chiang Mai, Thailand

<sup>2</sup>DDS, PhD - Department of Restorative Dentistry and Periodontology, Faculty of Dentistry, Chiang Mai University, Chiang Mai, Thailand

<sup>3</sup>DDS, PhD - Center of Excellence for Dental Implantology, Faculty of Dentistry, Chiang Mai University, Chiang Mai, Thailand

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**KEYWORDS** Type 2 diabetes, Implant stability, Resonance Frequency Analysis, ISQ

## ABSTRACT

**Aim** Osseointegration in type 2 diabetic mellitus (T2DM) seems to be inferior in healthy patients. However, the clinical outcome of dental treatment in well controlled T2DM is comparable to healthy patients. The purposes of the study were to compare dental implant success at one-year follow-up, implant stability (ISQ), and the correlation among these parameters (ISQ, bone implant contact, new bone formation) in T2DM and healthy patients.

**Materials and methods** Ten well-controlled T2DM (HbA1c<8%) patients (test group) and 10 healthy patients (control group) received one micro-implant (2.5 mmx 5 mm) in the maxilla (premolar/molar area). The micro-implant was retrieved after 2 months for histomorphometric evaluation and a conventional implant (4.2 mm/5 mm diameter x 10mm/12mm length) was placed immediately after bone preparation. Implant stability, by resonance frequency analysis (ISQ), was recorded at the following timepoints: immediate post surgical implant placement, 1 week, 2 week, 4 week, 6 week, 8 week, 12 week after placement and 1 year after prosthetic function. Implant success at one-year was evaluated following Pisa consensus conference guideline. Patients' satisfaction with visual analog scale (VAS) was also registered. Statistical analysis on the correlation among those mentioned parameters was performed.

**Results** 1 out of 10 implants (90%) in T2DM group failed comparing to 100% success in control group, and the marginal bone change ( $0.11 \pm 0.07$  mm vs  $0.24 \pm 0.10$  mm,  $p > 0.05$ ) was not significantly different after one-year functioning. Resonance frequency analysis demonstrated the normal pattern of bone healing around implants in both groups. All the integrated implants showed high mean ISQ value ( $81.03 \pm 0.68$  in T2DM vs  $81.66 \pm 0.67$ ) at one-year follow-up. All patients with successful implants (19 out of 20) were satisfied with the implant treatment in terms of function, esthetic and ease of cleaning. However, no correlation among ISQ, BIC and new bone formation from histomorphometric evaluation was found ( $p > 0.05$ ).

**Conclusion** Within the limitation of the study, it may be concluded that clinical success and implant stability of dental implant treatment in well-controlled T2DM is comparable to healthy individuals after one-year of function. No correlation was found among ISQ, BIC and bone formation around dental implant.

## INTRODUCTION

One of the common systemic diseases in elderly population is type 2 diabetes (T2DM), which dramatically increased in the last few decades according to World Health Organization (WHO) report of 2016 (1). The hyperglycemia in T2DM results in several oral complications, such as risk of periodontal diseases, impaired oral immunity, and delayed oral wound healing (2, 3). As a result, these complications contribute to increased number of tooth loss in this group of patients. For decades, dental implant treatment has been a more reliable and effective treatment option to replace missing teeth, than other treatment varieties such as dental bridges and removable dentures. There were concerns in the past as to whether T2DM patients were favorable candidates for dental implant treatment. Therefore, there have been several research studies on peri-implant complications, such as marginal bone loss and peri-implantitis in the diabetic group (4-7). In addition, several prospective clinical studies investigated diabetic effect on soft and hard tissue healing. In these, it was concluded that the glycemic control can play an important role in increasing dental implant success

outcome (4, 8). A recent systematic review demonstrated that healthy patients experiencing high implant survival rate (86.1 – 100%), depends on duration of observation while the results were inconsistent for T2DM group (9). T2DM patients, with well-controlled glycemic status, were able to achieve implant survival similar to their healthy counterpart. However, as the fasting plasma glucose (FPG) and HbA1c increased, the test group (T2DM) demonstrated significant lower success rate and higher peri-implant complications, such as peri-implantitis and crestal bone loss (7, 10). This suggests that the dental implant treatment outcome of diabetes is predictable, effective and safe under good metabolic condition (7, 10). However, questions arise whether T2DM with poor-controlled glycemia should be candidates for implant treatment, regardless of their less than optimum outcome.

Research studies regarding dental implant have applied different clinical parameters to evaluate the successful outcome. Albrektsson and colleagues (1986) suggested 4 criteria, which consists of: immobility of dental implant, absence of peri-implant radiolucency, annual bone loss minor to 0.2 mm per year, and absence of complications (pain, infection, neuropathies and paresthesia) (11). However, other parameters were also introduced, such as: peri-implant health (probing depth, bleeding on probing index), peri-implant soft tissue appearance and prosthetic complications (12). Moreover, the International Congress of Oral Implantologist (ICOI) Pisa consensus conference in 2008 suggested success, survival or failure of dental implants based on clinical assessment. A successful implant must present these following criteria: absence of pain or tenderness upon function, absence of mobility, radiographic bone loss inferior to 2 mm from baseline, and absence of exudate history. These simplified and up-to-date criteria are suitable for the assessment of implant health quality (13).

Apart from the clinical aspects, dental implant stability also plays an important role in implant success evaluation, such as: insertion torque, percussion test, reverse torque test, periotest, and resonance frequency analysis (RFA) (14, 15). Among these tests, RFA was frequently used to determine implant micro-movement by application of vibration. The RFA device provides numeric scale of implant stability quotient (ISQ) ranging from 0-100. There were many research studies using RFA for implant stability assessment (6, 16, 17), as it is a non-invasive and more reliable method, and the outcome can be statistically analyzed and interpreted. It was speculated that higher implant stability was related to higher bone implant contact (BIC) in histologic study of bone implant connection. Histomorphometric analysis is a reliable method to study implant osseointegration, in order to determine the BIC amount, new bone formation (BF) and bone quality around the integrated dental implant (18-20). Up to date, the result is still controversial related to the correlation between ISQ and BIC from histomorphometric study, as there were reports of different outcomes. In

addition, there were not many reports of implant stability test in T2DM group. In the literature, there were only studies comparing implant stability of T2DM patients (6, 21, 22) and a few other studies were conducted to find any correlation between ISQ and BIC in healthy patients (16, 17). However, no studies were found regarding to the correlation of ISQ and BIC between well-controlled T2DM and healthy groups.

This randomized clinical trial aims to evaluate the clinical outcomes of implant placement in the maxillary edentulous area of well controlled diabetic patients compared with healthy patients, to compare patients' satisfaction of both groups, and to find the correlation between the ISQ value and bone implant contact and bone formation, which were reported in our previous study (19).

## MATERIALS AND METHODS

The present study was designed as a case-control clinical study. It was approved by The Human Experimentation Committee, Office of Research Ethics, Faculty of Dentistry, Chiang Mai University (No. 20/2020) and Thai Clinical Trials Registry (TCTR20201216002).

### 2.1. Patient selection

Ten well-controlled T2DM (HbA1c did not exceed 8 %) and 10 healthy volunteers, who needed an implant in maxillary premolar or molar edentulous area were recruited in the study. General inclusion criteria were: physically (ASA I or II) and psychologically health, no smoking, history of extraction at least of 6 months, sufficient keratinized gingiva (>4mm). After the initial recruitment, all participants underwent dental cone-beam computed tomography to determined adequate bone width and height to accommodate a conventional implant. All inclusion and exclusion criteria were shown in Table 1. All participants were required of HbA1c and fasting plasma glucose (FPG) evaluation as a baseline. Microimplants were surgically placed in patients prior to this study, as described in the previous study (19). Both groups were placed with 4.2/ 5mm x 10 /12 mm implant under local anesthesia, depending on the width of the edentulous area, and dental prosthesis were delivered after 12 weeks of osseointegration. All patients were informed about the overall process of this study and signed the consent form.

### Surgical procedure

Surgical procedures were performed under 4% articaine with epinephrine 1:100,000 (Septanest SP, Septodont, France). Mid-crestal incision with a full-thickness flap was made by a 15c scalpel blade (Swann-Morton, England). After removing the 2.5 mm x 5 mm micro-implant, which was reported in our previous study (19), a surgical stent was placed to localize the conventional implant position. The implant bed was prepared following the

Inclusion criteria	
•	Healthy (ASA II classification)
•	Age ≥18 years
•	In diabetes group, HbA1c level is does not exceed 8%
•	The patient requires replacement of maxillary premolar or molar edentulous area with an implant, which has a history of extraction at least 6 months.
•	Normal occlusion
•	Normal psychological condition.
•	No smoking
•	Good cooperation with an available appointment and follow clinician's instruction
•	Accept process of the study and sign a consent form
•	Adequate keratinized tissue at least 4 mm.
•	The appropriate size of edentulous ridge with at least 6 mm in width and 12 mm in height
•	No bone augmentation at the surgery site
Exclusion criteria	
•	Pregnant or breastfeeding period
•	On NSAID or immunosuppressive drug
•	Osteoporosis
•	HIV
•	Diabetes patient with major complication, such as cardiovascular, peripheral vascular, nervous system and nephrotic system
•	History of head and neck chemotherapy and radiotherapy
•	Anterior and third molar edentulous area
•	HbA1c level above 8%
Discontinuation criteria	
•	Un-cooperation
•	Not compliant with the proposed procedure
•	Request for termination of treatment

TABLE 1 List of inclusion and exclusion criteria.

manufacturer's instruction and a commercial bone-level dental implant (Novem, PW plus, Thailand), with diameter of 4.2/ 5 mm and 10/12 mm in length, was placed. The insertion torque was required to be greater than 30 Ncm. The resonance frequency analysis (Osstell AB Stampgatan, Gotenburg, Sweden) was used to measure the implant stability quotients (ISQ value). According to the recommendations of Osstell on ISQ value, if the ISQ is more than 70, transmucosal healing abutment will be tightened on top of the implant fixture, followed by suturing with 4-0 nylon (Sofilon, Novamedic, Thailand). Initial periapical radiograph with paralleling technique was taken. One-week follow-up and sutures removal were appointed. The dental prosthesis was delivered after 12 weeks. All surgical procedures were performed by the same dental surgeon.

## Blood test

All participants (T2DM and healthy) were required to fast for a minimum of 10-hour for blood testing of FPG and HbA1c and other lipid profiles (cholesterol, HDL, LDL, Triglycerides) before surgery, as one of criteria for participating in the project. Only T2DM with HbA1c of less than 8% were allowed as test group.

## Parameters for measurement

•Success evaluation: The Pisa consensus conference of 2008 criteria were chosen to evaluate the success of all dental implants at 1 year after prosthesis (13). Success criteria includes no pain during function, no mobility, no radiographic bone loss exceed 2 mm and no history of exudate.

•Marginal bone loss: A periapical radiograph was taken at the day of implant placement as baseline, 12th week of osseointegration and 1 year after prosthesis loading, using paralleling technique. Marginal bone losses were measured to compare with baseline.

• Implant stability: The resonance frequency analysis (RFA) method is used for measuring the implant stability quotients (ISQ). After the implant placement, ISQ was measured immediately after implant placement and used as the baseline value. The ISQ measurement was repeated at 1, 2, 3, 4, 6, 8, 10, and 12 week during the osseointegration period. After osseointegration, a prosthesis will be installed for functional loading, and an additional measurement was recorded after one year. All ISQ data will be analyzed to compare between T2DM and healthy group, and to find any correlation between ISQ and histomorphometric value of BIC and bone formation which were reported in our previous study (19).

• Patients' satisfaction: A questionnaire to evaluate patients' satisfaction was prepared for both groups to answer after 1-year prosthetic function. The questionnaire from previous publication (23) was composed of 11 questions with visual analogue scale (VAS) as a measuring instrument. The questionnaire can be found in table 2.

## Statistical analysis

Based on the pilot study, the sample size was calculated using

$$n = \frac{\left[ Z_{\alpha/2} + Z_{\beta} \right]^2 (\sigma^1 + \sigma^2)}{e^2}$$

when  $Z_{\alpha/2} = 1.960$  ( $\alpha = 0.05$ ),  $Z_{\beta} = 0.8416$  ( $\beta = 0.20$ ),  $\sigma_1 = 2.398$ ,  $\sigma_2 = 2.097$ , and  $e = 3.6$

Shapiro-Wilk test was used as a normality test. An independent t-test was applied to compare between the two normal-distributed sample groups.

The Pearson correlation coefficient was utilized to find any correlation between ISQ-BIC and ISQ-BF. 95% confidence interval was considered a significant difference.

1.	Does your prosthesis have a comfort function?
2.	Between implant and natural teeth, which one do you prefer?
3.	Do you have a good phonetic function?
4.	Are you be pleased with the appearance?
5.	Are you able to clean the prosthesis?
6.	Between implant and natural teeth, which one is cleaning easier?
7.	Between implant and natural teeth, which one do you spend the timeless?
8.	Peri-implant tissue has more bleeding than soft tissue around the teeth?
9.	Does the implant treatment implement your expectation?
10.	If you have a choice to replace a tooth with implant again, would you prefer?
11.	Do you want to suggest friends and family have the implant treatment?

TABLE 2 Questionnaire for evaluating satisfaction of the patient.

## RESULTS

The sample size calculation indicated that 6 implants for each group is sufficient for statistical analysis. Twenty conventional implants were used in this study for all participants (10 for T2DM, 10 for control). All data were normally distributed. One implant disintegrated at 3 months after placement in one of T2DM patients, while all implants in healthy group were considered success following Pisa consensus conference criteria at one-year follow-up.

Comparison of FPG and HbA1c between the groups was showed in table 3. FPG and HbA1c in T2DM group were significantly higher than in control group around the time of surgery as expected ( $126.6 \pm 26.1 \text{mg/dL}$  vs  $77 \pm 6.4 \text{mg/dL}$ ,  $p < 0.05$  and  $6.47 \pm 0.6\%$  vs  $5.1 \pm 0.1\%$ ,  $p < 0.05$ , respectively).

All integrated implants (19 implants) showed no clinical complications, such as mobility, pain or any signs of inflammation.

Mean marginal bone change at 12 month follow-up in control group was  $0.24 \pm 0.10 \text{ mm}$ , while in the T2DM

Parameters	Male	Female	Age (years) Mean $\pm$ SE	FPG (mg/dL) Mean $\pm$ SE	HbA1c (%) Mean $\pm$ SE
Control	3	7	$50.3 \pm 3.1$	$77 \pm 6.4$	$5.1 \pm 0.1$
T2DM	5	5	$60.5 \pm 1.2^*$	$122.6 \pm 26.1^*$	$6.47 \pm 0.6^*$

\* Significant difference ( $p < 0.05$ )

TABLE 3 Comparison of FPG and HbA1c between T2DM and controls.

Control	$0.24 \pm 0.10 \text{ mm}$	$p = 0.31$
T2DM	$0.11 \pm 0.07 \text{ mm}$	

TABLE 4 Marginal bone loss after one year function (Mean $\pm$ SE)

Time (week)	Control (Mean $\pm$ SE)	T2DM (Mean $\pm$ SE)
0	$77.06 \pm 1.15$	$77.45 \pm 0.96$
1	$74.56 \pm 0.88$	$74.39 \pm 0.88$
2	$73.66 \pm 1.17$	$74.11 \pm 1.09$
3	$72.56 \pm 1.36$	$74.61 \pm 1.60$
4	$73.22 \pm 1.09$	$73.77 \pm 1.72$
6	$74.00 \pm 0.65$	$76.42 \pm 0.66$
8	$74.72 \pm 0.51$	$77.43 \pm 0.87$
10	$75.94 \pm 0.57$	$78.19 \pm 0.65$
12	$77.66 \pm 0.67$	$79.11 \pm 0.72$
1 yr after loading	$81.66 \pm 0.67$	$81.03 \pm 0.68$

TABLE 5 Implant Stability Quotients.

group was  $0.11 \pm 0.07 \text{ mm}$ , which was not significantly different (Table 4) ( $p=0.31$ ).

ISQ value was recorded at each time points (1, 2, 3, 4, 6, 8, 10, 12 weeks and 12 months after prosthesis) and a pattern of normal healing process, following dental implant, was observed by the drop of ISQ value between 2 and 4 week as shown in Figure 1.

The mean ISQ value of both groups was shown in table 5. There is no significant difference between ISQ of both group at all time points of measurement. The mean ISQ of all implants at 12 month showed high value (over 80). No significant difference was found between both groups.

For patients' satisfaction, VAS score indicated that

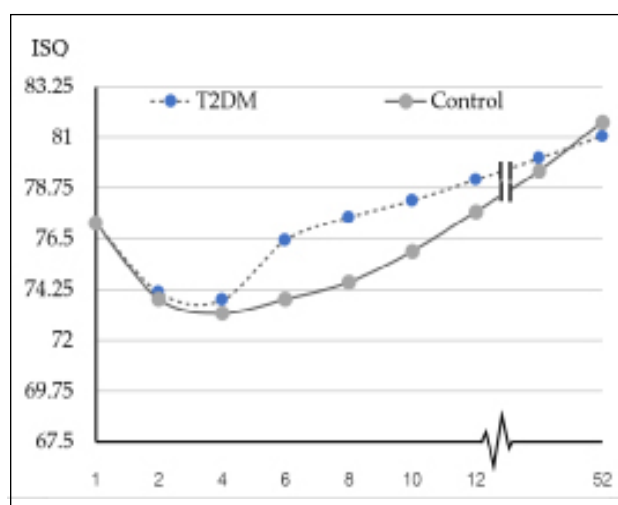


FIG. 1 Diagram of ISQ throughout all time-point up to 12th month after loading.

Question	Group	Mean±SD
1	Control	86.67 ± 4.90
	T2DM	77.37 ± 23.74
2	Control	53.67 ± 6.30
	T2DM	64.42 ± 12.92
3	Control	96.22 ± 1.96
	T2DM	98.11 ± 0.95
4	Control	92.00 ± 4.19
	T2DM	95.91 ± 2.30
5	Control	86.89 ± 6.46
	T2DM	91.86 ± 7.01
6	Control	61.78 ± 5.50
	T2DM	57.71 ± 4.91
7	Control	56.56 ± 3.90
	T2DM	72.43 ± 4.50
8	Control	54.22 ± 2.74
	T2DM	56.71 ± 4.17
9	Control	95.89 ± 2.49
	T2DM	91.06 ± 6.27
10	Control	96.67 ± 2.36
	T2DM	98.86 ± 0.77
11	Control	97.22 ± 1.39
	T2DM	98.57 ± 0.92

TABLE 6 Comparison of 11 Questions for patients' satisfaction.

both groups were satisfied with their treatment in the aspects of function, esthetic and cleaning. A comparison between natural teeth and the implant was similar and no significant difference was found (Table 6).

There was no correlation between ISQ value, BIC and bone formation (BF) both at 12 week of osseointegration and 12 month after loading as shown in Figure 2.

## DISCUSSION

This study is a prospective randomized controlled trial to compare between T2DM and healthy control in regards to one-year survival of all implants, implant stability quotient (ISQ) by RFA, and to find any correlation among the ISQ, BIC and BF from histomorphometric study of the same patients, which were reported in our previous publication. (19) The advantages of this study design are that all surgeries were performed by the same surgeon, all T2DM patients were rigorously selected as well-controlled with HbA1c < 8%, and all implants were placed in only posterior maxilla which mostly consists of trabecular bone; therefore, some confounding factors such as experience of the surgeon, various glycemic status of DM patients and bone type due to location of implant placement, which might affect the result interpreted, can be eliminated. Moreover, to our best

knowledge, there have been no clinical studies regarding to the correlation between ISQ of dental implants in well-controlled T2DM patient and BIC percentage from histomorphometric analysis.

The survival of dental implant in T2DM group of this study is 9 out of 10 implants, compared to all 10 implants success in control group. Within one year follow-up, no significant difference indicated that dental implant treatment is safe and predictable for T2DM, provided that their glycemia is within controlled state. This result agrees with other reports (7, 10, 21) in terms of clinical survival and complications within the same period.

Our main focus on this study is comparing ISQ between the groups and finding any correlation among ISQ, BIC and bone formation from our previous histomorphometric evaluation. The result showed that the ISQ of all implants were comparable at all time-points, with high primary stability (ISQ>70) at implant placement and after one year loading (ISQ>80) (p>0.05). This is a potentially good glycemic state in T2DM patients with HbA1c of less than 8% which agreed with other publications (21, 22), although another study demonstrated that ISQ was not affected by the patient's glycemic condition (6). Therefore, more observations is required regarding to the correlation between ISQ and various HbA1c level. Interestingly, this result is contrary to what was found in our histomorphometric evaluation (19) that T2DM negatively affected BIC and new bone formation in tested titanium micro-implant.

In the literatures, there were several studies both in human and animal experiments about correlation between ISQ and BIC and the result is still controversial (16, 17, 24-27). Some studies reported a strong correlation between implant stability and bone implant contact percentage (17, 25, 26). In terms of biology of osseointegration, dental implants depend upon direct bone deposition on implant surface to stand firmly in the bone to support applying forces of mastication; therefore, it is convincing that clinical implant stability should reflect the amount of peri-implant *de novo* bone as shown in histomorphometric BIC percentage. However, other evaluations reported no correlation between the two parameters of (16, 24, 27). There are a few factors that might explain the controversies among the studies having same purpose to find the connection. It was found that different methods of research studies were conducted. Firstly, some studies (17, 28) also included primary stability to find correlation with the BIC. Primary stability is mostly affected by bone quality and implant topography which is not the representation of bone modeling/remodeling around implant surface. Bone is a living tissue which undergoes ongoing homeostasis and it is affected by any systemic diseases that affect bone such as T2DM and osteoporosis (29). Secondly, there were studies (28, 30, 31) comparing ISQ and BIC *in vitro*, which implants were placed in bone specimen block and so not in living bone. All of these might contribute to the inconsistency of the reported

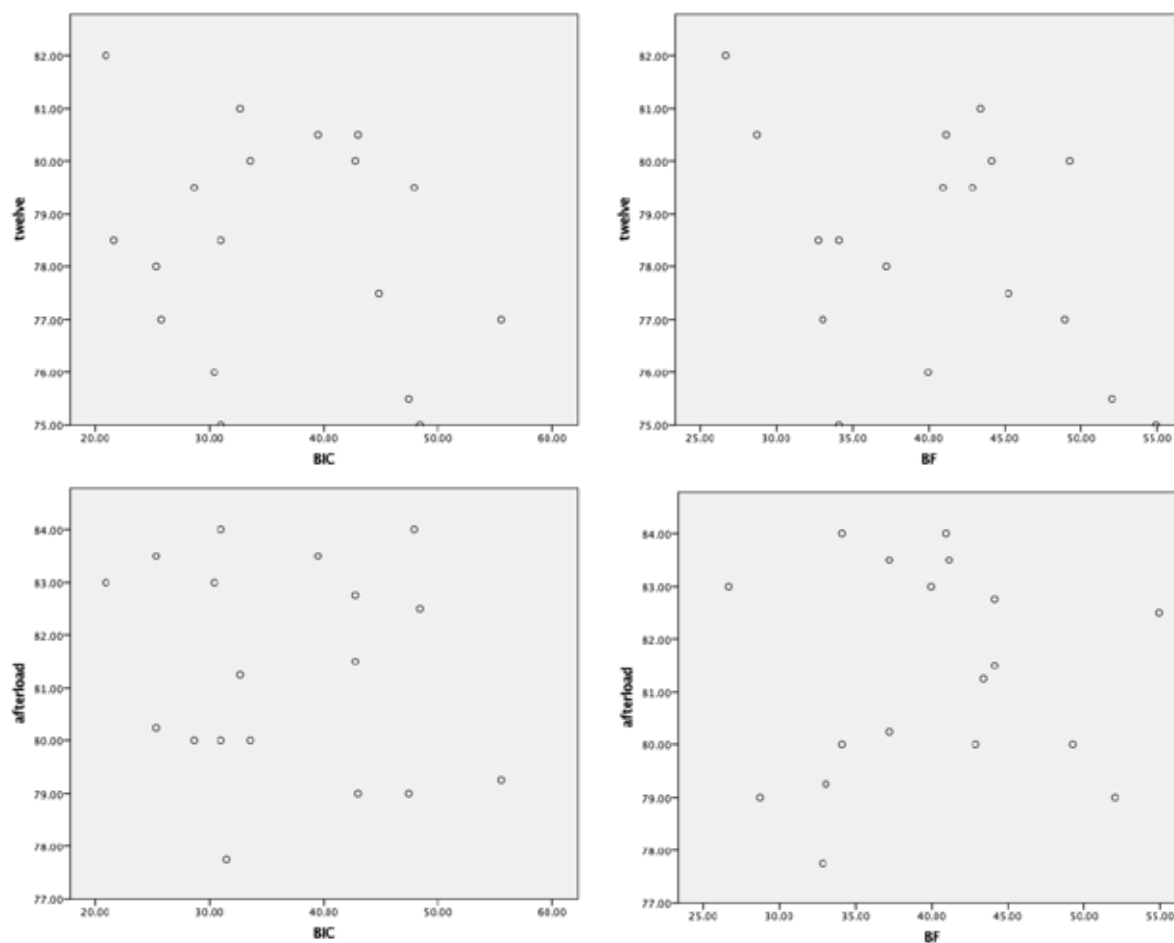


FIG. 2 Correlation between ISQ, BIC and BF. Scatter dots showed no relation between ISQ and BIC, ISQ and BF at 12 weeks (a, b), ISQ and BIC, ISQ and BF at 12 months after loading (c, d).

result of the correlation between ISQ and BIC percentage. In summary, our findings suggested that high implant stability in well-controlled T2DM patients is not correlated with reduced BIC and BF percentages. Therefore, these parameters should be reported as independent variables confirming the condition of osseointegration. However, our study confirmed the importance of high primary stability, which leads to the success of dental implant treatment. Furthermore, during the function of the dental implant after one year, the bone remodeling around dental implant has taken place. Therefore, BIC and BF percentages may improve and lead to the success of dental implant treatment in well controlled DM. Further studies are required to confirm the results. According to the previous study protocol (19) and the ethical concerning, the limitation of the study is the number of the participants, which are restricted to the sample size calculation. Therefore, the number of the patients included in the study are only 10 for each group. A prospective long-term clinical study with larger numbers of DM patients is required to evaluate the long-term success of dental implant in DM patients.

## CONCLUSION

Within limitation of this study, it may be concluded that dental implants in well-controlled T2DM showed comparable success rate and implant stability value (ISQ) at one year follow-up. In addition, patients' satisfaction in terms of mastication, speech, esthetics and cleaning feasibility showed no significant difference between the groups. However, this study did not find any correlation between ISQ and BIC and bone formation reported in our previously histomorphometric study.

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## Conflicts of Interest

The authors declare no conflicts of interest.

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