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EVALUATION OF FLAPLESS DENTAL IMPLANT PLACEMENT IN CONTROLLED TYPE 2 DIABETIC PATIENTS TRIAL

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ABSTRACT

INTRODUCTION: Traditionally, when a dental implant is placed, a flap can be raised to better visualize the position of surgical site, so the bone fenestrations risk can be reduced when there is limited bone available. Recently, for patients with thick gingival biotype (≥2 mm) and sufficient bone volume in recipient site, flapless implant surgery is considered a new concept, where dental implants are inserted into crestal bone without flap elevation.

OBJECTIVES: To compare the outcome of dental implants placed in the maxillary posterior area with flapless technique versus conventional surgical technique in patients with controlled type 2 diabetes.

MATERIALS AND METHODS: A randomized clinical study was done on twenty controlled type 2 diabetic patients, with missing maxillary posterior teeth. The patients were separated into two groups: In group A, ten implants were inserted in maxillary posterior area using a flapless technique and in group B, ten implants were inserted in maxillary posterior area using a flap surgical technique. All patients underwent clinical and radiographical evaluations for 8 months.

RESULTS: The flap approach showed a statistically significant higher mean pain severity during the first, third and seventh day, higher swelling only on the first day and lesser implant stability after four months than the flapless technique. For both groups, during the fourth and eighth months period, there was no significant difference in crestal bone loss.

CONCLUSION: The flapless dental implant placement could be considered for controlled type 2 diabetic patients to reduce post-operative pain and swelling and for better implant stability.

KEYWORDS: Implant, Crestal bone, Flapless design, CBCT, Guided surgery.

RUNNING TITLE: Flapless dental implant in controlled type 2 diabetes.

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INTRODUCTION

When placing dental implants, a flap is traditionally elevated to better visualize the implant recipient site, providing that some anatomical landmarks are clearly identified and protected. When a limited amount of bone is available, a flap elevation can help implant placement to reduce the risk of bone fenestrations or perforations (1).

On the other hand, incisions with flap elevation might cause crestal bone-resorptions after the surgical procedure. This occurs unpredictably, as a result of the alteration in the vascularization of the bone periosteum after flap reflection (2). This is also evident after the insertion of dental implants, occurring remodelative processes around the implants, leading to different degrees of crestal bone loss (3).

Several experimental studies verified that avoiding flap reflection at the insertion of dental implants prevents the alteration of the vascularization of the area, improving the behaviour of mucosa, periosteum and peri-implant bone. The flapless techniques (no bone exposure) can reduce marginal bone resorption and affect the final aesthetic result (4,5). This, together with other advantages of flapless techniques as lower morbidity, better postoperative and the absence of sutures has made it a technique increasingly demanded and used by clinicians in implantology, both in conventional dental implant surgeries and in implant guided surgery (5).

The purposes for choosing a flapless approach are to reduce the likelihood of postoperative tissue loss and to overcome the difficulties of soft tissue management. Also it is considered less traumatic surgery, shorter operative times, faster postoperative healing, and lesser postoperative complications (6).

A disadvantage of this technique is that the true topography of the underlying available bone cannot be observed because the mucogingival tissues are not raised, which may increase the risk for unwanted perforations and a possible complete misplacement of the implant and inserted only

subperiosteal, which in its turn could lead to esthetical problems or implant losses. Moreover, there is the potential for thermal damage secondary to reduced access for external irrigation during osteotomy preparation (7).

Diabetes mellitus is a chronic metabolic disorder that is reaching epidemic proportions, recently projected as affecting over 350 million individuals worldwide. There are mainly two types of diabetes: Type I diabetes (insulin-dependent) which is characterized by a lack of insulin production and type II diabetes (noninsulin-dependent) which is caused by the body's ineffective use of insulin. Diabetic patients have several complications that may affect the osseointegration of endosseous implant caused by microvascular disease, susceptibility for infection, and delayed wound healing (8).

Moreover the implants in these patients could be subjected to mechanical overload resulting from diabetes-induced lower percentage of bone to implant contact, immature bone, and incorrectly formed bone. Therefore, patients with diabetes were not considered suitable for implant treatment when the treatment with enossal implants was introduced in the eighties of the last century. However, over the past 2 decades, diabetes has been regarded as a relative (not absolute) contraindication for implant therapy related to the stability of the diabetic's blood sugar level (9).

The aim of this study was to evaluate clinically and radiographically the outcome of guided flapless technique for dental implant placement in maxillary posterior area in controlled type 2 diabetic patients compared with conventional flap-technique.

MATERIALS AND METHODS

The study was performed as a randomized controlled clinical trial with a 1:1 allocation ratio that was carried out after obtaining approval of the Research Ethics Committee at the Faculty of Dentistry, Alexandria University, on 19/9/2021. Ethics Committee No: 0288-09/2021. Prior to the procedure, all patients signed an informed consent form at Alexandria University's Faculty of Dentistry's Oral and Maxillofacial Surgery Department, to ensure and confirm their understanding of the outcome of the procedure and the risks they might be subjected to during the intervention.

Patients

The study was done on twenty controlled type 2 diabetic patients of both gender; who complained from missing maxillary posterior teeth. Patients were recruited from the out clinic of Alexandria Main University Hospital. This trial was designed and reported according to CONSORT guidelines (10).

Sample randomization

Patients were divided randomly into two groups through a website (Randomizer.org). Group A (Study group): ten patients had received dental implants in maxillary posterior area by guided flapless technique. Group B (Control group): ten patients had received dental implants in maxillary posterior area by conventional flap techniques.

The inclusion criteria were patients with age 30-60 years, with extraction site healed at least 6 months in the maxillary posterior area, with glycosylated hemoglobin (HbA1C) levels less than 7%, absence of diabetic microvascular complications like nephropathy, neuropathy, and retinopathy, sufficient bone height (>10 mm) and width (>6.5 mm) and adequate keratinized gingiva (KG) (>2 mm). While the exclusion criteria were; patient with uncontrolled glycemic index (HBA1c > 7 %), with a history of systemic diseases that would contraindicate surgical treatment, presence of parafunctional habits as clenching, bruxism, patients with bad oral hygiene, generalized periodontitis and patients need bone augmentation procedure before or during implant placement.

Materials

Dentium Super Line Implant System (dentinum company, Seoul, Korea) (Figure 1A&B).

Osstell (Osstell, Göteborg, Sweden).

Tissue punch size range from (4-6)mm with a speed not exceeding 35 rpm (Dentis Co.,Ltd., South Korea).

3/0 PROLENE suture materil (© Johnson & Johnson Medical N.V., Belgium).

Methods

Pre-surgical assessment

Clinical examination

The patients were evaluated by taking full personal, dental and medical histories regarding type 2 diabetes mellitus, hypertension, past investigations, drug history, drug allergy or any medications. Soft tissue was examined for any suppuration, discharge and swelling. The interarch Space was measured by a millimeter ruler. The occlusion was checked According to the normal maximum intercuspation. The gingival biotype was checked by the the periodontal probe.

Radiographical examination

Panoramic radiography was done for evaluation the existing bone and to detect any hidden bony abnormalities.

Cone beam computed tomography (CBCT) was done for evaluation of the quality and quantity of the existing bone and for determination of length and diameter of the proposed dental implant.

Lab tests

HbA1c was done for All patients and the results must be ≥6.5% and <7%.

Fabrication of the computerized surgical guide stent (11) (Figure 1C)

Impressions were taken from the patients, casted and then sent to the dental prosthesis technician. The whole structure was converted into a tomographic guide with acrylic resin. Number of holes about five to six holes were drilled in the guide with spherical hand piece burs (Jet Burs, Kerr), then radiopaque material (Gutta-Percha Points, Dentsply Maillefer) was filled in these holes. Then the guides were clinically tested and adjusted. The DICOM (Digital Imaging and Communications in Medicine) format files were converted into the open source planning software (DDS-PRO). The designing of the virtual implant was carried out taking on consideration the available bone and the maximal rehabilitation position in each case. The virtual design was sent to the prototyping center to create a stereolithographic guide where 3D impressions of the guides were performed.

Surgical phase

Preoperative medications (12)

Prophylactic antibiotics were prescribed in the form of Clavulanic acid 125mg + Amoxicillin 875mg (Augmentin®, GlaxoSmithKline, UK) orally 1 hour before operation and rinsing with mouth wash (0.12% chlorhexidine gluconate) for 30 seconds immediately preoperatively. All patients received infiltration local anesthesia (Articaine HCL 4% with vasoconstrictors (1; 200. 000) (Septodent, Articaine HCL with vasoconstrictors), Novocol Pharmacutical, Canada)

Study group (flapless technique)

After adaptation of the computerized surgical guide stent, with a speed not more than 35 rpm, a rotary tissue punch was used to make a round cut in the soft tissue at the site of implant at the top of the alveolar bone (Figure 2A), by using tissue forceps, the round soft tissue cut was removed. According to the manufacturer's protocol, Sequential drilling up to the final drill was done so that the final drill diameter was smaller than that of the implant diameter to gain more primary stability (13). A high torque externally irrigated low speed hand piece was used with an electric motor to prepare the implant site. For irrigation while preparing the implant site, a sterile saline was used. Once osteotomy was finished, the implant was placed in situ. The implant stability (base line) was measured with an instrument (Osstell Mentor®) (Figure 3A). Every implant has ISQ value scaled (1–100), which was measured from the four sites (mesial, distal, buccal, and palatal). The mean of all measurements were rounded to a whole number and regarded as the mean ISQ of the implant. Lastly, the cover screw was inserted into the implant and tightened. (Figure 4A)

Control group (Conventional flap technique)

The pyramidal mucoperiosteal incision was done by blade no. 15 in both sides of the proposed implant site, then the mucoperiosteal flap was elevated as accurate as possible to avoid injury to the periosteium (Figure 2B). After adaptation of the computerized surgical guide, the osteotomy was done, the implant was palced in situ. The implant stability (base line) was measured with an instrument (Osstell Mentor®) (Figure 3B). Lastly the cover screw was inserted into the implant and tightened and the mucoperiosteal flap was readapted over the alveolar bone and sutured using PROLENE suture material. (Figure 4B&C)

Post-surgical phase

Postoperative care (14): Patients were given comprehensive oral hygiene care and postoperative instructions, including: Avoid rinsing for 24 hours after surgery. Application of cold fomentation post-operative for 24 hours with 10 minute interval per hour. Soft, high protein, caloric diet and fluids for 2 weeks postoperatively.

Postoperative medication (12): They were advised to take the prescribed medications, which include: Clavulanic acid 125mg + Amoxicillin 875mg (Augmentin®, GlaxoSmithKline, UK) for 7 days every 12 hours. Non Steroidal Anti Inflammatory drugs (Cataflam: Diclofenac potassium 50mg: Novartis. Switzerland) for 4 days every 8 hours. Chymotrypsin +Trypsin 300 E.A.U (Alphintern: Chemotrypsin 300 E.A.U (14microkatals) +Trypsin 300 E.A.U (5microkatals): Amoun Pharmaceutical Co. S.A.E) for 5 days every 8 hours. Mouth wash 0.12% chlorhexidine (Hexitol: Chlorhexidine 125mg/100ml concentration 0.125%: Arabic drug company, ADC) for 2 weeks daily. After 1 week of surgery, sutures will be removed.

Follow up phase

Clinical follow up

Postoperative pain (15): It was recorded for each patient after 1, 3, 7 days postoperatively through a visual analogue scale (VAS) from 0 to 10. (0-1= none, 2-4= mild, 5-7= moderate, 8-10= severe).

Postoperative swelling (16): It was recorded for each patient after 1, 3, 7 days postoperatively through a scale with 4 parameters: None (no swelling), light (localized intraoral), moderate (localized extraoral), and severe (extraoral swelling extending beyond the treated area).

Implant stability (17): It was measured immediately postoperative (primary stability) and after 4 months by implant stability meter (Osstell™) with Smart peg.

Radiographical follow up

Immediate postoperative (base line), after 4 months (crown placement) and 8 months, CBCT was requested for evaluation the crestal bone loss.

Crestal bone loss (18)

For measuring the crestal bone loss, distal and mesial crestal bone levels were calculated from the reconstructed sagittal views by drawing a line parallel to the long axis of the implant extending from the crestal bone to the implant's apical end. The mean of readings of the two sides at each

interval were calculated and tabulated for statistical analysis. (Figure 5A&B).

Prosthetic phase

The patients of both groups were recalled after 4 months for delivery of porcelain fused to metal (PFM) definitive restoration (Figure 6A&B)

Statistical analysis

Results were collected and entered into a computer for statistical analysis version 25 with the Statistical Package for Social Science (SPSS) program (19). The Kolmogorov-Smirnov normality test showed significant difference in the most variables distribution, so a nonparametric statistic has been adopted. The maximum, minimum, median and 95% Confidence Interval (CI) of the median were used in description of data.

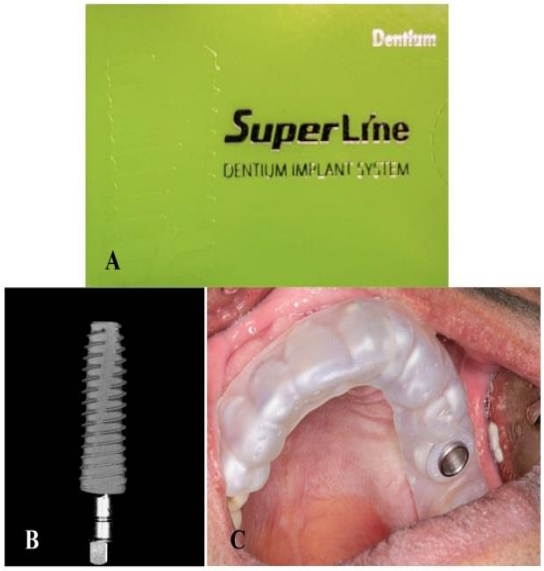

Figure (1): Photograph showing dentium implant system (A&B) and surgical guide (C)

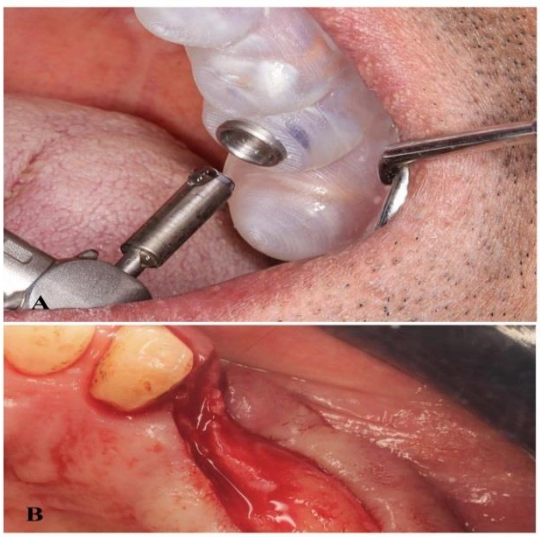

Figure (2): Photograph (A) showing rotary tissue punch in group A. Photograph (B) showing elevation of flap in group B.

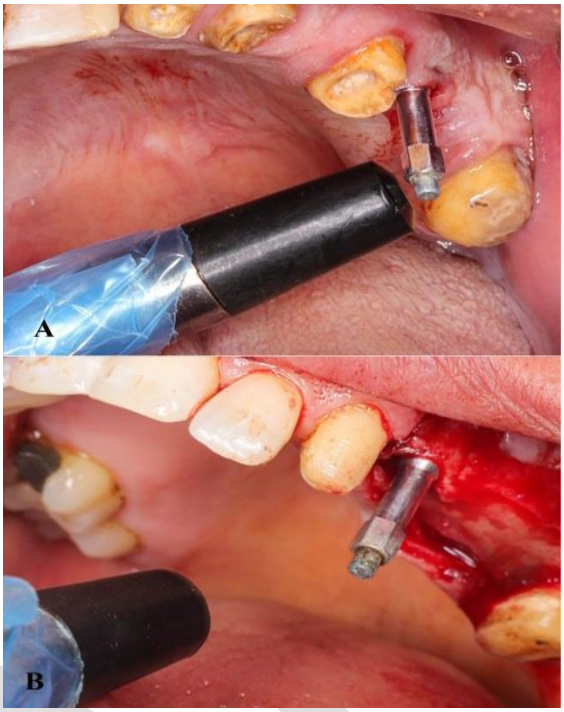

Figure (3): Photograph showing measuring primary stability. (**A)** In group A, **(B)** In group B.

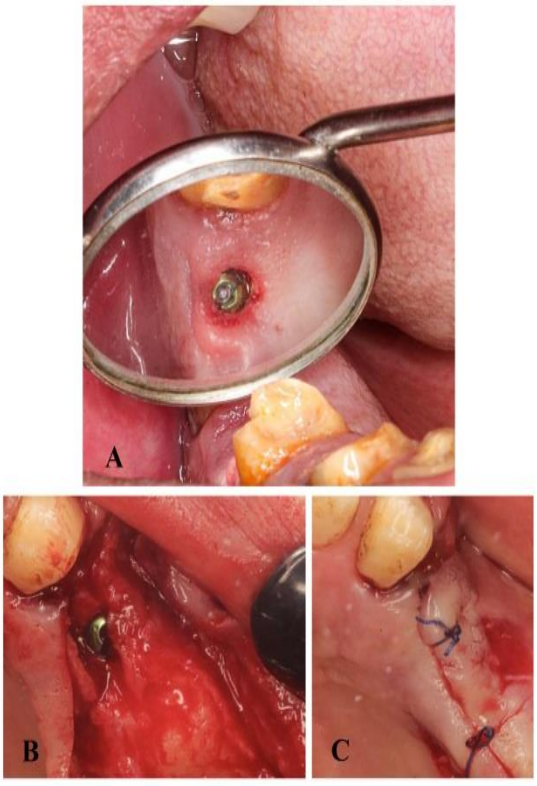

Figure (4): Photograph (A) showing the implant with cover screw in group A, **(B&C)** Showing flap sutures over implant with cover screw in group B.

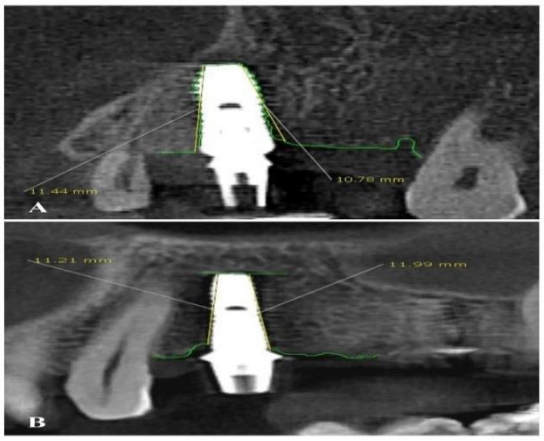

Figure (5): CBCT showing marginal bone loss after 4 months. (**A)** In group A, **(B)** In group B.

RESULTS

Biodata

This study included twenty type 2 diabetic patients; in ten of them flapless dental implant was placed, and in the other ten patients, a flap dental implant was placed. Data are presented as median (25^{th} – 75^{th} percentile) and 95% Confidence Interval (CI) of the median.

Clinical evaluation

Pain (Table 1)

On the days 1, 3 and 7, VAS was ranged from (1.00-3.00) with a median of 1.00, (0.00-6.00) with a median of 0.00 and (0.00-2.00) with a median of 0.00, respectively in a flapless dental implant group. While it was ranged from (1.00-4.00) with a median of 3.00, (0.00-7.00) with a median of 1.50 and (0.00-2.00) with a median of 0.00, respectively in a flap dental implant group. On the days 1, 3, and 7, VAS was statistically significantly higher in the flap group than the flapless group (p=.009), (*p*=.117) and (*p*=.349), respectively.

Swelling

In a flapless dental implant group, the no swelling on the first, third and seventh day was 10/10, 6/10 and 8/10, respectively. While in a flap dental implant group, it was 2/10, 5/10 and 8/10, respectively.

In a flapless dental implant group the mild swelling on the first, third and seventh day was 0/10, 2/10 and 2/10, respectively. While in a flap dental implant group, it was 6/10, 2/10 and 2/10, respectively.

In a flapless dental implant group the moderate swelling on the first, third and seventh day was 0/10, 2/10 and 0/10, respectively. While in a flap dental implant group it was 2/10, 1/10 and 0/10, respectively.

The severe swelling was represented in 2/10 in a flap dental implant group on the third day. While was represented in 0/10 in a flapless dental implant group.

On day 1, a statistically significant difference in swelling distribution was observed between the two groups (p=0.001). While on the days 3 and 7 a non-statistical significant difference in swelling distribution was observed between the two groups (p=.619) and (p=1.000), respectively.

Implant stability (Table 2)

Mean (ISQ) value was measured for all cases immediately postoperative (primary stability) and after 4 months. Mean ISQ for the implant primary stability and in the fourth month ranged from (55.25-66.25) with a median of 59.38 and (72.50-85.25) with a median of 77.63, respectively in a flapless dental implant group. While it ranged from (52.00-72.00) with a median of 62.88 and (70.50-82.00) with a median of 75.88, respectively in a flap dental implant group. There was no statistically significant difference between the two groups in the mean ISQ for the implant primary stability (p=.130) and in the fourth month (p=.325).

Mean ISQ for the implant percentage change (primary vs. fourth month) in a flapless group and in a flap group ranged from (23.40-46.35) with a median of 27.79 and (12.35-35.58) with a median of 21.13, respectively. There was statistically significant difference in the mean ISQ for the implant percentage change (primary vs. fourth months), which was higher in a flapless dental implant group when compared with a flap group (p=.019)

Radiographical evaluation

Crestal bone loss (Table 3)

Percentage change (%) of mean crestal bone loss

Mean crestal bone loss percentage change (baseline vs. fourth month) ranged from -13.57–7.05 (%) with a median of -6.05 (%), 95% CI -10.09 – -1.29 (%) in flapless dental implant group, while it ranged from -14.61 – 2.02 (%) with a median of -4.63 (%), 95% CI -5.59– - 3.85 (%) in the flap dental implant group.

There was no statistically significant difference in mean crestal bone loss percentage change (baseline vs. fourth month) between the two studied groups (p=.650).

Mean crestal bone loss percentage change (baseline vs. eighth month) ranged from -28.30– -5.86 (%) with a median of -8.99, 95 (%), 95% CI -23.27 – -7.24 (%) in flapless dental implant group, while it ranged from -19.22 – -1.87 (%) with a median of -11.99, 95% CI -18.62 – -4.29 (%) in the flap dental implant group.

There was no statistically significant difference in mean crestal bone loss percentage change (baseline vs. the eighth month) between the two studied groups (p=.450).

Mean crestal bone loss percentage change (fourth month vs. eighth month) ranged from -23.49– 5.12 (%) with a median of -11.38 (%), 95% CI -14.44– -4.64 (%) in flapless dental implant group, while it ranged from -15.05 - 3.14 (%) with a median of -6.31 (%), 95% CI -10.01– -3.19 (%) in the flap dental implant group.

There was no statistically significant difference in mean crestal bone loss percentage change (fourth month vs. the eighth month) between the two studied groups (p=.290).

Table (1): Comparison of VAS in the two studied groups at different points of measurements (days)

	Group		Test of significance *p-value*
	Flapless	**Flap**	
VAS (Day 1) n Min. – Max. Median 95% CI of the median 25th Percentile – 75th Percentile	10 1.00-3.00 1.00 0.0-0.0 1.00-2.00	10 2.00-3.20 3.00 3.00-4.00 2.00-3.00	$Z_{(MW)}$=2.622 *p*=.009*
VAS (Day 3) n Min. – Max. Median 95% CI of the median 25th Percentile – 75th Percentile	10 0.00-6.00 0.00 0.0-0.0 0.00-2.00	10 0.00-7.00 1.50 1.00-5.00 1.00-5.00	$Z_{(MW)}$=1.570 *p*=.117 NS
VAS (Day 7) n Min. – Max. Median 95% CI of the median 25th Percentile – 75th Percentile	10 0.00-2.00 0.00 0.00-0.00 0.00-0.00	10 0.00-2.00 0.00 0.0-0.0 0.00-1.00	$Z_{(MW)}$=0.936 *p*=.349 NS
Test of significance ***p***	$\chi^2_{(Fr)(df=2)}$=11.529 *p*=.003*	$\chi^2_{(Fr)(df=2)}$=14.105 *p*=.001*	
VAS percentage change D3 vs. D1 n Min. – Max. Median 95% CI of the median 25th Percentile – 75th Percentile	10 -100.00-100.00 -100.00 0.0-0.0 -100.00 - 100.00	10 -100.00-133.33 -41.67 -66.67 - 66.67 -66.67 - 66.67	$Z_{(MW)}$=1.254 *p*=.210 NS
VAS percentage change D7 vs. D1 n Min. – Max. Median 95% CI of the median 25th Percentile – 75th Percentile	10 -100.00- -33.33 -100.00 0.0-0.0 -100.00 - -100.00	10 -100.00- -33.33 -100.00 0.0-0.0 -100.00 - -66.67	$Z_{(MW)}$=0.841 *p*=.401 NS
VAS percentage change D7 vs. D3 n Min. – Max. Median 95% CI of the median 25th Percentile – 75th Percentile	4 -100.00 - -66.67 -87.50 -100.00 - -66.67 -100.00 - -70.83	8 -100.00 - -66.67 -90.00 -100.00 - -71.43 -100.00 - -71.43	$Z_{(MW)}$=0.091 *p*=.927 NS

Table (2): Comparison of Mean ISQ for the implant in the two studied groups at different points of measurements (months)

	Group		Test of significance *p-value*
	Flapless	**Flap**	
Mean ISQ for the implant (Primary) n Min. – Max. Median 95% CI of the median 25th Percentile – 75th Percentile	10 55.25-66.25 59.38 57.25-61.75 57.25-61.75	10 52.00-72.00 62.88 60.00-64.75 60.00-64.75	$Z_{(MW)}$=1.513 *p*=.130 NS
Mean ISQ for the implant (4 Months) n Min. – Max. Median 95% CI of the median 25th Percentile – 75th Percentile	10 72.50-85.25 77.63 73.50-81.75 73.50-81.75	10 70.50-82.00 75.88 73.25-78.75 73.25-78.75	$Z_{(MW)}$=0.983 *p*=.325 NS
Test of significance ***p***	$\chi^2_{(WSR)}$=2.803 *p*=.005*	$\chi^2_{(WSR)}$=2.805 *p*=.005*	
Mean ISQ for the implant percentage change (%) n Min. – Max. Median 95% CI of the median 25th Percentile – 75th Percentile	10 23.40-46.35 27.79 24.80-37.05 24.80-37.05	10 12.35-35.58 21.13 18.18-26.25 18.18-26.25	$Z_{(MW)}$=2.343 *p*=.019*

Table (3): Comparison of percentage change (%) of Mean Crestal Bone Loss in the two studied groups at different points of measurements (months).

	Group		Test of significance *p value*
	Flapless	**Flap**	
Mean Crestal Bone Height (Baseline) (mm)			
- n	10	10	
- Min. – Max.	10.71-12.56	10.46-12.07	
- Mean ± SD	11.78±0.58	11.43±.54	$Z_{(MW)}$=1.436
- 95% CI of the mean	11.37-12.20	11.0511.82	*p*=.151 NS
- Median	11.89	11.38	
- 95% CI of the median	11.39-12.20	11.13-12.03	
- 25th Percentile – 75th Percentile	11.39-12.20	11.13-12.03	
Mean Crestal Bone Height (4 Months) (mm)			
- n	10	10	
- Min. – Max.	10.54-11.77	9.88-11.60	
- Mean ± SD	11.19±0.42	10.85±0.54	$Z_{(MW)}$=1.399
- 95% CI of the mean	10.90-11.49	10.47-11.24	*p*=0.162 NS
- Median	11.17	10.88	
- 95% CI of the median	10.92-11.46	10.50-11.21	
- 25th Percentile – 75th Percentile	10.92-11.46	10.50-11.21	
Mean Crestal Bone Height (8 Months) (mm)			
- n	10	10	
- Min. – Max.	9.00-11.08	8.50-11.00	
- Mean ± SD	10.06±0.79	10.14±0.73	$Z_{(MW)}$=0.076
- 95% CI of the mean	9.50-10.62	9.62-10.66	*p*=.940 NS
- Median	10.22	10.28	
- 95% CI of the median	9.14-10.64	9.79-10.69	
- 25th Percentile – 75th Percentile	9.14-10.64	9.79-10.69	
Test of significance *P*	$\chi^2_{(Fr)(df=2)}$=14.600 *p*=.001*	$\chi^2_{(Fr)(df=2)}$=16.200 *p*<.001*	
Mean Crestal Bone Loss percentage change (%) (4M vs Baseline)			
- n	10	10	
- Min. – Max.	-13.57-7.05	-14.61 - 2.02	
- Mean ± SD	-4.75±6.47	-4.99±4.03	$Z_{(MW)}$=0.454
- 95% CI of the mean	-9.38 - -0.12	-7.87 - -2.11	*p*=.650 NS
- Median	-6.05	-4.63	
- 95% CI of the median	-10.09 - -1.29	-5.59 - -3.85	
- 25th Percentile – 75th Percentile	-10.09 - -1.29	-5.59 - -3.85	
Mean Crestal Bone Loss percentage change (%) (8M vs Baseline)			
- n	10	10	
- Min. – Max.	-28.30 - -5.86	-19.22 - -1.87	
- Mean ± SD	-14.34±8.86	-11.19±6.78	$Z_{(MW)}$=0.756
- 95% CI of the mean	-20.68 - -8.01	-16.04 - -6.34	*p*=.450 NS
- Median	-8.99	-11.99	
- 95% CI of the median	-23.27 - -7.24	-18.62 - -4.29	
- 25th Percentile – 75th Percentile	-23.27 - -7.24	-18.62- -4.29	
Mean Crestal Bone Loss percentage change (%) (8M vs 4M)			
- n	10	10	
- Min. – Max.	-23.49 - 5.12	-15.05 - 3.14	
- Mean ± SD	-10.00±8.20	-6.54±5.74	$Z_{(MW)}$=1.058
- 95% CI of the mean	-15.86 - -4.14	-10.64 - -2.43	*p*=.290 NS
- Median	-11.38	-6.31	
- 95% CI of the median	-14.44 - -4.64	-10.01 - -3.19	
- 25th Percentile – 75th Percentile	-14.44 - -4.64	-10.01 - -3.19	

n : Number of patients Min-Max: Minimum – Maximum CI: Confidence interval
Z: Z test of Mann-Whitney U test df: degree of freedom *: Statistically significant (p<.05)
NS: Statistically not significant (p>.05) Fr: Friedman Test

DISCUSSION

Implant placement can be done by either flapless approach or elevation of a flap. Flapless implant placement has been gaining popularity among surgeons. The patient comfort and satisfaction are critical aspects of implant therapeutics, thus the present study evaluated questionnaires in patients, regarding pain severity and duration of the pain.

Flapless implant technique was considered to be better than conventional flap technique due to reduced bleeding, shorter operative time, and reduced patient pain. Not many studies have compared patient outcome variables to confirm these predictions (20). In our study, patient pain is investigated using VAS (Visual Analogue Scale) to compare implant placement performed with a flapless approach with placement performed with a conventional flap approach. The patients in group B reported more pain severity and duration following surgery. The difference between the 2 groups was statistically significant.

Shamsan et al. (21) study was consistent with our results, which reported that the mean severity of pain in implant placement with a flap technique were statistically significantly higher. Also Fortin et al. (22) study stated that pain decreased faster with flapless procedure and the number of patients who felt no pain was higher with the same procedure. They stated that the objective of the flapless procedure is to reduce the invasiveness of surgery and thus reduce post-operative morbidity such as pain, edema and hematoma. While in the conventional flap technique, the cutting and raising flaps interrupts blood circulation within the mucosa and between mucosa/periosteum and bone and by this leads to haemostasis, lymphostasis, ecchymosis and temporary local oxygen deficiency. This generally agrees with results reported by Chang et al. (23).

In the present study, the swelling degree was assessed and determined by a modification of tape measuring method described by UStün et al. (24). The results showed that there was a statistically significant difference in the degree of swelling between the two studied groups with a higher degree in (group B) only on the first day. It was justified by prolonged reflection and retraction of flap in conventional surgical technique which was more traumatic with a higher degree of swelling following surgery when compared to the flapless technique. While there was no statistically significant difference in the distribution of swelling between the two studied groups on third and seventh day and this was attributed to compliance of patients to postoperative instructions and medication.

When implants are placed in maxillary posterior area, it can be difficult to achieve satisfactory and high primary stability. Since the primary stability is an important factor in determining success or failure of the implant treatment, it has been studied by many authors (25,26).

The current clinical trial assessed primary stability and its progression to secondary stability after 4 months. As a result of this study, there was a higher statistical significant increase in the mean ISQ for the implant percentage change (primary vs fourth month) in a flapless dental implant group when compared with a flap group.

It has been known that diabetes leads to impaired regeneration of bone, resulting in reduced formation and resorption. Regarding crestal bone loss, open flap surgery can expect an increase in crestal bone loss because of decreased periosteal blood supply after raising a tissue flap.

However, several studies have shown that flapless technique results in greater peri-implant bone loss. The authors of the articles reviewed here have provided many explanations for this (27,28).

De Bruyn et al. (29) explanation suggested that this may be due to over-doing of the countersinking procedure in their study. A wider extension of a cortical bone was required to remove sufficient bone to properly place the healing abutment. As they widen and deepen, the coronal part of implant does not always make tight contact with the bone. While in a flapped site, there was more control on the countersinking according to the manufacturer's instructions, as it allows for visual inspection on site.

On the other hand, Rousseau et al. (30) discussed that the no-flap technique places the implants deeper than the open-flap method because the implants are placed blindly. Therefore, the trans-mucosal portion of implant is alittle below the crestal bone level. Due to the coronal portion of the implant is soft titanium, it is normal for bone to be rearranged around implant neck. With open flap technique, implant is placed directly in right bone position under visual control, which reduces bone remodeling around the implant neck

In current study, we found no statistically significantly differences between the two studied groups in the fourth and eighth months in terms of crestal bone loss. In line with this results, Pisoni Luca et al. (31) noted that there was no statistically significant difference between the two studied groups in bone resorption around implant, both at baseline, implant load, and 3-year follow-up record. In contrast, it was reported that bone resorption after using flap technique was related to the thickness of flap elevated at surgical site by Campelo and Camara (32).

CONCLUSIONS

Within the limitations of our study, it was concluded that flapless dental implant surgery with computerized surgical guide stent for controlled

type 2 diabetic patients showed no significant difference in outcome regarding crestal bone loss, while on the other hand a better outcome in patient comfort and implant stability when compared with a conventional surgical technique, provided that accurate patient selection is mandatory for carrying out flapless implant surgery.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest.

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