Original Article

SUBCRESTAL INCISION: AN ALTERNATIVE FLAP DESIGN FOR DENTAL IMPLANT PLACEMENT – A RANDOMIZED CONTROLLED SPLIT-MOUTH DESIGN CLINICAL TRIAL

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ABSTRACT

This randomized controlled trial aimed at comparing a novel incision design with a conventional mid-crestal incision design for implant placement to achieve complete closure of the surgical site. Proper flap margin approximation is pivotal for surgical wound healing in patients undergoing dental implant treatment with or without bone augmentation. A clinical study was conducted at the department of implantology with a total number of 30 patients. Patients with bilateral edentulous sites for whom dental implant placement was planned were included in the study. Mid-crestal incision design on one side and subcrestal incision design on other side were performed. Healing was evaluated at 1- and 4-week intervals postoperatively using an early wound healing score (EHS). The pain perception from the patient was also noted after 1 week on the day of suture removal using Visual Analogue Scale (VAS) values ranging from 0 to 10.
Wound healing in the subcrestal incision design sites were showing higher EHS at 1-week and 4-week intervals, which was statistically significant when compared to the sites with mid-crestal incision design. VAS values were also showing higher pain perception toward mid-crestal incision design over subcrestal incision design. With the limitations of the present study, it can be concluded that subcrestal incision design stands as a promising flap design over mid-crestal incision design for dental implant placement.

Key words: Dental implants, Flap design, Para-crestal incision, Subcrestal incision.

Introduction

Dental implant treatment is a widely accepted modality for the replacement of missing dentition and is the treatment of choice for patients requiring such rehabilitation. Advances in implantology and surgical technique have paved the way for managing cases with defective bone architecture to successfully undertake dental implant treatment and thereby restore the esthetics and functional demands [1–3]. However, the defective bony architecture of the alveolar ridge instigated by periodontal disease, tooth loss, trauma, or through a history of traumatic extraction may still limit or hinder the placement of dental implants [4].

Therefore, various techniques have been established so far, which aim at augmenting the hard and soft-tissue defects, thus creating a favorable bony architecture for the sound placement of dental implants. Whatever the techniques maybe, a predictable outcome would depend on various factors such as the severity of the defect in either soft tissue or hard tissue, type of biomaterial being used for grafting, vascular supply of the grafted site, and favorable wound closure by flap approximation [5–7]. Among all the factors implied, complete closure of the surgical site plays a vital role in soft-tissue healing, thus paving the way for successful osseointegration of the dental implants. A full-thickness mucoperiosteal flap must typically be reflected during bone and/or tissue augmentation surgeries, making the form of the flap of the utmost relevance in surgical implantology.

Several studies have shown that wound dehiscence that occurs during the first stage of healing could severely affect the outcome of bone augmentation procedures [8]. The outcome of a clinical study reported that wound dehiscence that occurred between stage-one and stage-two implant surgeries might increase the rate of alveolar bone loss [9]. Another study reported that wound dehiscence was a vexatious concern encountered after hard tissue augmentation, with an incidence of up to 2.5%–10% of cases [10]. Therefore, wound dehiscence can pose a serious challenge to the healing of a surgical site and subsequently lead to complications such as infection, loss of graft, and ultimately engender implant failure [11].

As wound dehiscence could play a pivotal role in the postoperative healing of implants *in situ* after stage 1 surgery, finding alternate techniques to avoid such wound dehiscence is imperative. Hence, this randomized controlled trial was designed to compare and evaluate the effectiveness of an alternative incision design which could enhance the complete closure and healing of the surgical site following implant placement as well as after bone augmentation procedures.

Materials and Methods

A randomized split-mouth clinical trial was conducted at the

department of implantology, on 30 patients, comprising bilateral edentulous sites (n = 60) who required dental implant placement in the maxilla or mandible, under the age group of 30–60 years, with no particular gender predilection **(Figure 1)**. All the study subjects consented voluntarily to participate and were free to disassociate from the study according to their own volition. The study had obtained clearance from the Institutional Ethics. Committee and registered with the Clinical Trials Registry India (CTRI/2023/10/059263) for human subjects and the study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000.

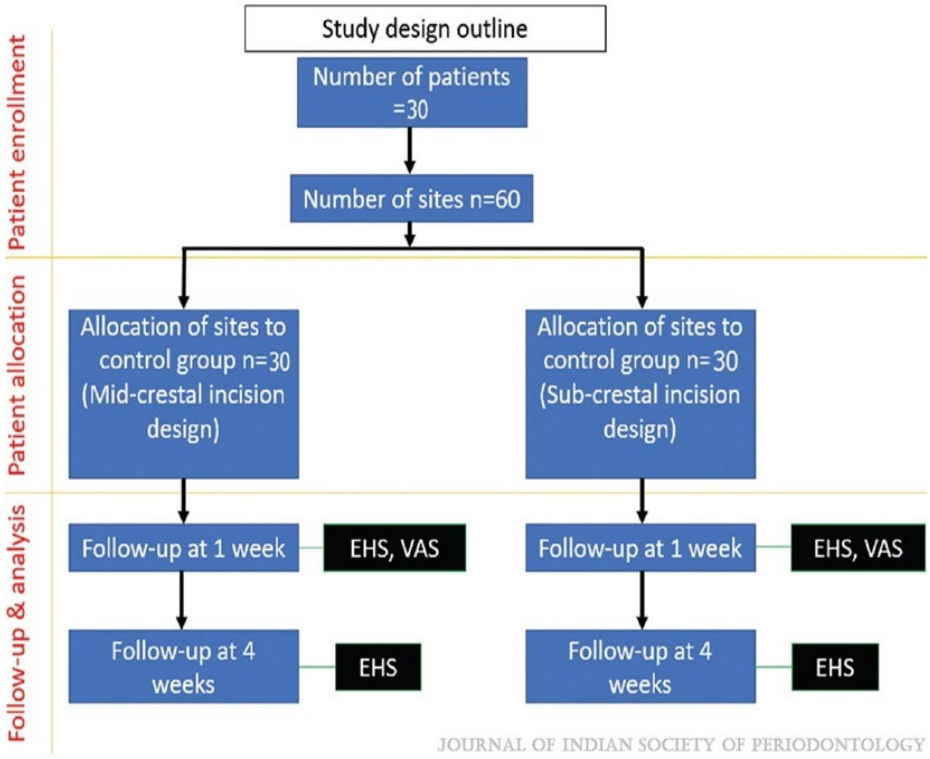


Figure 1. Study design

Patients with the bilateral edentulous ridge (Kennedy's class III modification 1 situation) [12], with or without hard tissue deficiency, were taken as inclusion criteria for the study. In contrast, patients with systemic diseases, smokers, pregnant women, and patients with a recent history of extraction (<3 months), having retained root stumps, harboring an active periodontal infection or periapical abscess were excluded from the study.

All the patients were explained about the study, and informed consent was obtained before implant placement. All the participants were subjected to a thorough clinical examination, which included bone mapping of the edentulous site, radiographic investigations comprising of cone-beam computed tomography imaging, and the blood profile relevant to implant surgery, which consists of bleeding time, clotting time, hemoglobin, HbA1c, serum cholesterol, and Vitamin D3.

The surgical field before implant placement was prepared, and the corresponding areas were anesthetized by either infiltration or nerve block using 2% lignocaine hydrochloride with adrenaline (1:80,000). Each patient's edentulous sites were categorized as site A or site B **(Figure 2)**, either on the opposite arch or the contralateral side of the same dental arch as per the study design. The edentulous sites for the two different flap designs were assigned randomly using the coin toss method by a third operator. Among the two sites, one site (site A) was prepared for implant placement by raising a full-thickness flap using a mid-crestal incision design **(Figure 3a)** on the edentulous ridge along with crevicular incision extending to the adjacent teeth both mesially and distally [13].

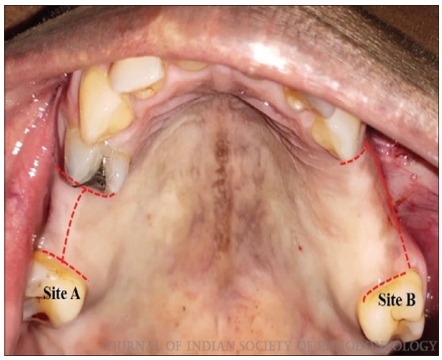
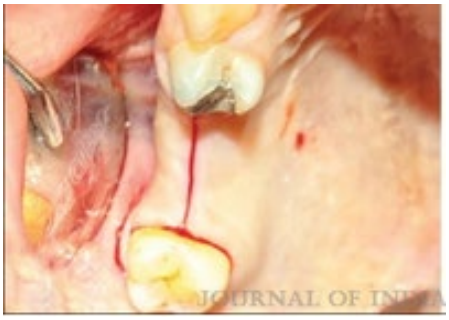


Figure 2. Bilaterally edentulous sites with midcrestal flap design and subcrestal flap design, respectively



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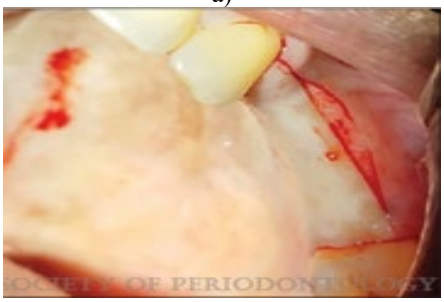
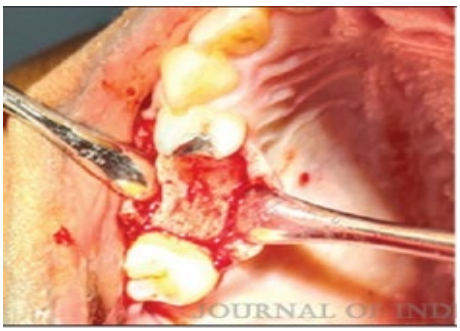


b)

Figure 3. (a) Mid-crestal incision design in site A; (b) Subcrestal flap design in site B

Whereas, the alternative site (site B) was prepared using a modified incision design which consisted of a subcrestal incision below the crest of the ridge **(Figure 3b)**. The criteria for deciding the level at which the incision had to be placed was based on the level of the mucogingival junction of that site. The subcrestal incision was given 2–3 mm above the mucogingival junction. A palatal or labial approach subcrestal incision design was performed in case of the maxilla, whereas in the mandible, only labial subcrestal approach was performed because of the nonkeratinized lingual mucosa. For both subcrestal and mid crestal incisions, the incisions were extended with a crevicular incision to the adjacent teeth both mesially and distally, i.e., if a palatal incision was given, the crevicular incision was extended to the buccal side and vice-versa following which a full-thickness flap was raised on both the sides **(Figures 4a and 4b)**.



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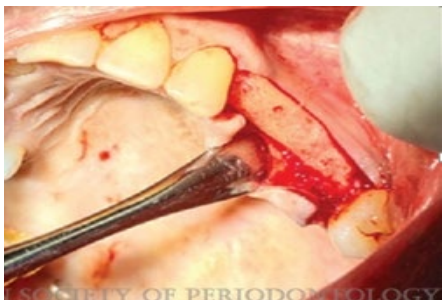

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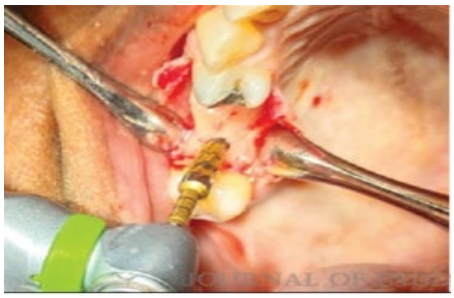
Implants were placed at crestal level using standard osseodensification protocols **(Figures 5a and 5b)** [14]. Following the placement of dental implants **(Figures 6a and 6b)** in both site A and B the flaps were positioned back to its original state, and mild digital compression was given **(Figures 7a and 7b)**. This step ensures that the flap is approximated back to its original position. Once the flap was approximated, simple interrupted sutures were placed using 3.0 silk to achieve complete closure of the surgical site **(Figures 8a and 8b)**.



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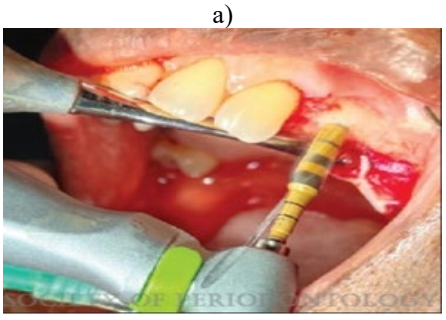
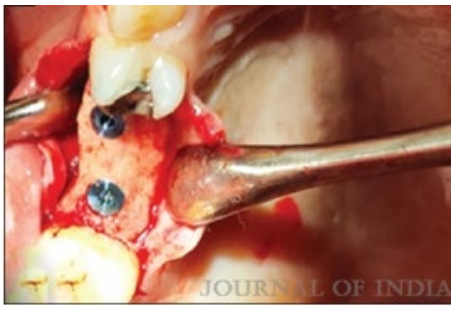


b)

Figure 5. (a and b) Osteotomy using standard osseodensification protocol



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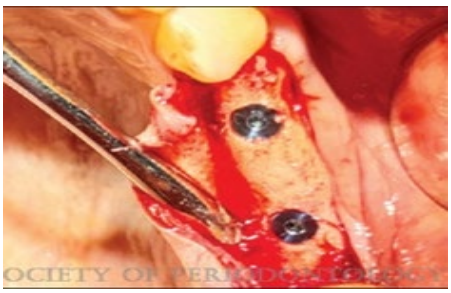

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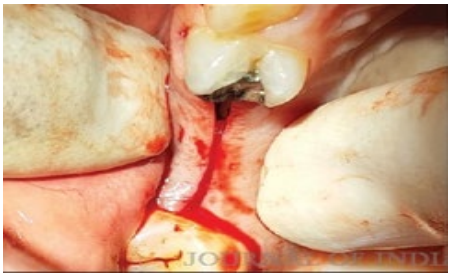
Figure 6. (a and b) Implants placed at crestal level



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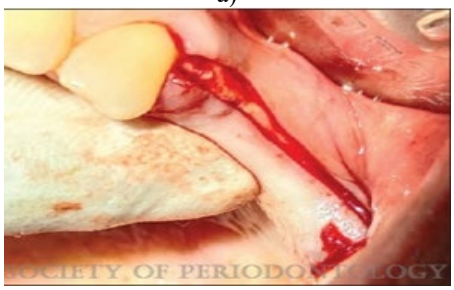

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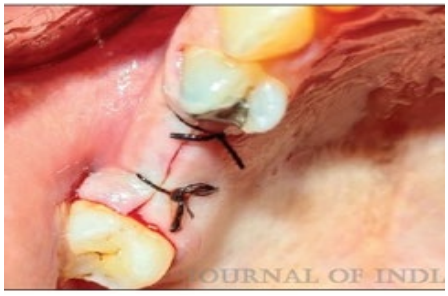
Figure 7. (a and b) Flap adaption to its original position with mild digital compression



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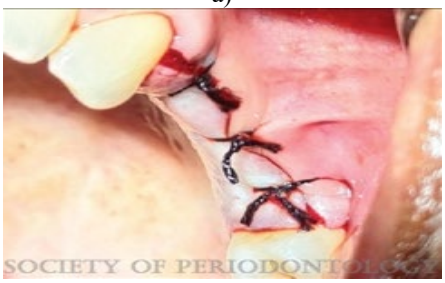
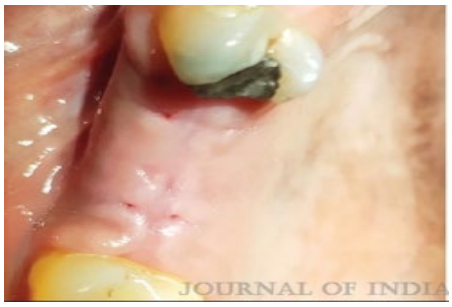


b)

Figure 8. (a and b) Simple interrupted sutures placed using 3.0 silk

Postoperative instructions along with antibiotics and analgesics were prescribed for 5 days and suture removal was performed after 7 days **(Figures 9a and 9b)**. Postoperative healing was evaluated using early wound healing (EHS) [15] score at 1-week and 4-week intervals **(Figures 10a and 10b)**. The pain perception from the patient was also recorded after 1 week on the day of suture removal using Visual Analog Scale (VAS) [16] values ranging from 0 to 10 **(Figure 11)**.



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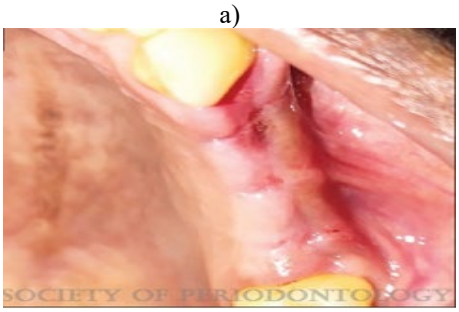

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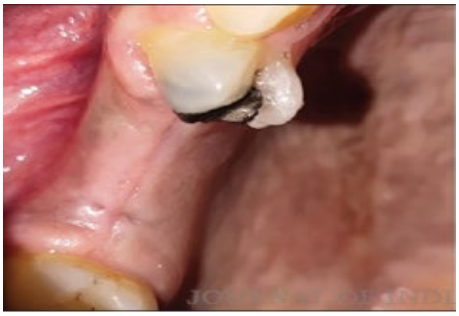
Figure 9. (a and b) Soft tissues after one week, postoperative



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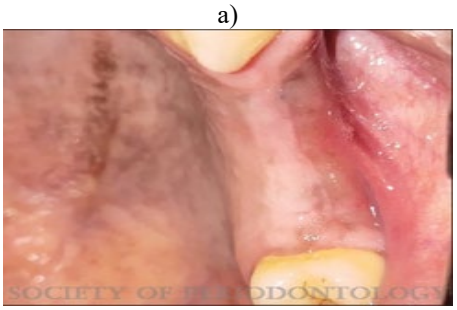

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Figure 10. (a and b) Soft tissues after four weeks, postoperative

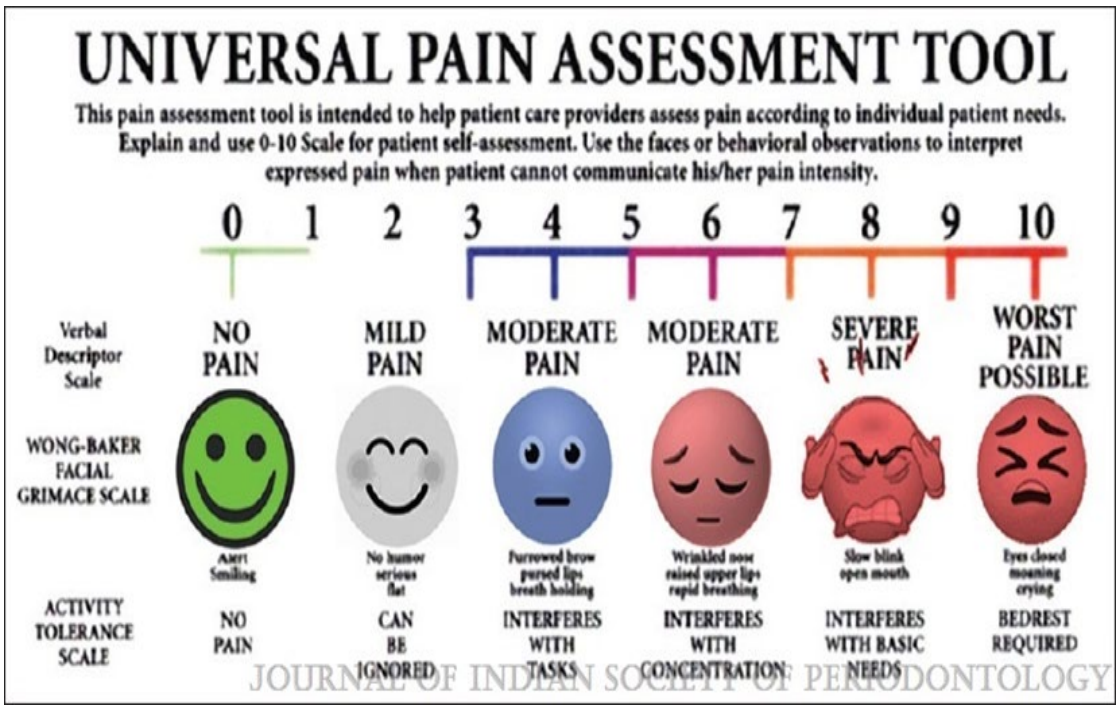

Figure 11. Visual Analog Scale for pain

The EHS is comprised of 3 indicators: clinical signs of reepithelization (CSR), clinical signs of hemostasis (CSH), and clinical signs of inflammation (CSI). For CSR, scores 0, 3, or 6 were used, and for CSH and CSI, scores 0, 1, or 2 were used **(Table 1)**.

Table 1. Early wound healing score

Parameter	Description	Score
CSR	Merged incision margins	6
	Incision margins in contact	3
	Visible distance between incision margins	0
CSH	Absence of fibrin on the incision margins	2
	Presence of fibrin on the incision margins	1
	Bleeding at the incision margins	0
CSI	Absence of redness along the incision length	2
	Redness involving <50% of the incision length	1
	Redness involving <50% of the incision length and/or pronounced swelling	0

EHS is the consolidation of the 3 parameters together (EHS = CSR + CSH + CSI) **CSR** – Clinical signs of re-epithelization; **CSH** – Clinical signs of hemostasis; **CSI** – Clinical signs of inflammation; **EHS** – Early wound healing score

The consolidation of the 3 parameters together makes EHS. The EHS for satisfactory wound healing was score 10, while the worst score was 0. Briefly,

1. CSR: 0 points, visible distance between incision margins; 3 points, incision margins in contact; 6 points, merged incision margins

3. CSI: 0 points, redness involving >50% of the incision length and/or pronounced swelling; 1 point, redness involving <50% of the incision length; 2 points, absence of redness along the incision length.

For each indicator, the least score was recorded by a third and blinded operator to prevent bias.

An EHS of 0 was assigned in the presence of suppuration, independently of the ratings for the 3 indicators.

The clinical signs assessed for CSR include merging, approximation, and distance of margins, which denotes the

process of re-epithelialization.

Results and Discussion

Thirty patients comprising 60 edentulous sites bilaterally, either in the maxillary or mandibular arch, for whom dental implant-supported rehabilitation was planned, were included in the study.

The data obtained were entered into Microsoft Excel 2020 and analyzed using the IBM Corp. Released 2012, IBM SPSS® Statistics for Windows, Version 21.0. Armonk, NY, USA: IBM Corp. 1. The descriptive statistics were presented as mean ± standard deviation and as frequencies with percentages. Wilcoxon sign-rank test was carried out for the 1st and 4th weeks for comparison of study parameters, while Mann–Whitney *U*-test was used for intergroup comparison. Spearman's rank correlation coefficient test was carried out to check the relationship between total EHS and VAS. All statistical tests were performed at a significance level of 5% ($P \leq 0.05$).

Table 2 presents the comparison of total EHS scores observed in mid-crestal and subcrestal designs at different time intervals. **Table 3** presents the comparison of VAS scores observed in both groups after 1 week.

Table 2. Total early wound healing score in site A and site B after various time intervals

Group	1 week		4 weeks	
	Score	**n (%)**	**Score**	**n (%)**
Mid-crestal design	2	10 (33.3)	8	18 (60.0)
	3	4 (13.3)	9	12 (40.0)
	5	10 (33.3)		
	6	6 (20.0)		
	Total	**30 (100.0)**	**Total**	**30 (100.0)**
Subcrestal design	8	16 (53.3)	8	2 (6.7)
	9	6 (20.0)	9	6 (20.0)
	10	8 (26.7)	10	22 (73.3)
	Total	**30 (100.0)**	**Total**	**30 (100.0)**

All values are expressed as frequency with percentages (parentheses). n – Number of sites

Table 3. Visual Analog Scale score in site A and site B after 1 week

Group	Score	n (%)
Mid-crestal design	0	2 (6.7)
	1	8 (26.7)
	2	6 (20.0)
	3	8 (26.7)
	4	6 (20.0)
	Total	**30 (100.0)**
Subcrestal design	0	8 (26.7)
	1	10 (33.3)
	2	8 (26.7)
	3	4 (13.3)
	Total	**30 (100.0)**

All values are expressed as frequency with percentages (parentheses). *n* – Number of sites

Tables 4-6 summarize the comparison of CSR, CSH, and CSI scores between mid-crestal and subcrestal design at 1 and 4 weeks of follow-up, respectively. Overall, postoperative healing was found to be better in the subcrestal design as there is a significant improvement in CSR, CSH, and CSI scores at 1 and 4 weeks' follow-up.

Among all studies included in the final synthesis, 10 studies were reported from Riyadh, Saudi Arabia. The total study samples from the Riyadh region comprised of 6380 candidates out of which 3286 were females and 3094 were male. The origin or the study locations included in the synthesis is demonstrated within a Map of Saudi Arabia that also includes the Northern region, Western region, as well

as the eastern province of Saudi Arabia.

malocclusion and control among Saudi children was also 98%. However, the Z value in this analysis was 6.24. The comparative meta-analysis on Class 3 malocclusion in comparison to all other malocclusion and control among Saudi children revealed an I^2 value of 99% and Z value of 6.38 Therefore, it was clearly indicated that there was significant heterogeneity among studies.

Table 4. Comparison of clinical signs of re-epithelization score between site A and site B

Group	Mid-crestal design (*n*=30), mean±SD	Subcrestal design (*n*=30), mean±SD	Statistics	
			Z	***P*** †
	1			8 (26.7)
1 week	1.60±1.52	6.00±0.00	−7.244	<0.001*
4 weeks	6.00±0.00	6.00±0.00	<0.001*	1.000
Z	−4.932	0		
P ‡	<0.001*	1.000		

*Level of significance – *P*≤0.001 is considered statistically significant; ‡The statistical test used – Wilcoxon sign rank test; †Mann–Whitney *U*-test. SD – Standard deviation; *Z* – Z value; *P* – P value; *n* – Number of sites

Table 5. Comparison of clinical signs of re-epithelization between site A and site B

Group	Mid-crestal design (*n*=30), mean±SD	Subcrestal design (*n*=30), mean±SD	Statistics	
			Z	***P*** †
1 week	1.07±0.25	1.33±0.48	−2.560	0.010*
4 weeks	1.07±0.25	1.93±0.25	−6.657	<0.001*
Z	0	−4.243		
P ‡	1.000	<0.001*		

*Level of significance – P≤0.001 is considered statistically significant; ‡The statistical test used – Wilcoxon sign rank test; †Mann–Whitney U-test. SD – Standard deviation; Z – Z value; P – P value; n – Number of sites

Table 6. Comparison of clinical signs of re-epithelization score between site A and site B

Group	Mid-crestal design (*n*=30), mean±SD	Subcrestal design (*n*=30), mean±SD	Statistics	
			Z	***P*** †
1 week	1.27±0.45	1.40±0.50	−1.086	0.277
4 weeks	1.33±0.48	1.73±0.45	−3.079	0.002*
Z	−1.414	−3.162		
P ‡	0.157	0.002*		

*Level of significance – P≤0.001 is considered statistically significant; ‡The statistical test used – Wilcoxon sign rank test; †Mann–Whitney U-test. SD – Standard deviation; Z – Z value; P – P value; n – Number of sites

Table 7 presents the comparison of total EHS scores between mid-crestal and subcrestal designs at various time intervals. In the 1st week, there was a marked improvement in wound healing in the subcrestal group, as there was a statistically significant difference in the total EHS score in both the groups when Mann–Whitney *U*-test was applied ($P < 0.001$). However, in the 4th week, the subcrestal design showed better wound healing than mid-crestal when using the Wilcoxon sign-rank test.

Table 7. Comparison of total early wound healing score between site A and site B

Group	Mid-crestal design (*n*=30), mean±SD	Subcrestal design (*n*=30), mean±SD	Statistics	
			Z	***P*** †
1 week	3.93±1.64	8.73±0.87	−6.764	<0.001*
4 weeks	8.40±0.50	9.67±0.61	−5.840	<0.001*
Z	−4.902	−4.053		

P ‡	<0.001*	<0.001*

*Level of significance – P≤0.001 is considered statistically significant; ‡The statistical test used – Wilcoxon sign rank test; †Mann–Whitney U-test. SD – Standard deviation; Z – Z value; P – P value; n – Number of sites

Table 8 compares VAS scores between mid-crestal and subcrestal designs after 1 week. In the 1st week, on applying the Mann–Whitney *U*-test, a statistically significant reduction in the pain perception ($P = 0.003$) in the subcrestal design group is seen in comparison to the mid-crestal group.

Table 8. Comparison of total early wound healing score between site A and site B

Group	Mid-crestal	Subcrestal	Statistics	
	design (*n*=30), mean±SD	design (*n*=30), mean±SD	*Z*	*P*†
1 week	2.27±1.26	1.27±1.01	−3.008	0.003*

*Level of significance – P≤0.001 is considered statistically significant; †The statistical test used – Mann–Whitney U-test. SD – Standard deviation; Z – Z value; P – P value; n – Number of sites

Negative correlations were seen in both the designs between wound healing and pain perception when using the Spearman's rank correlation coefficient test **(Table 9)**. This indicated that there was a significant reduction in pain perception, as wound healing improved in both groups.

Table 9. Correlation between total early wound healing score and Visual Analog Scale at 1 week

Group	Spearman's rho	VAS after 1 week
Mid-crestal design (*n*=30) Total EHS after 1 week	*r*	−0.83
	P	<0.001*
Subcrestal design (*n*=30) Total EHS after 1 week	*r*	−0.58
	P	0.001*

*Level of significance – P≤0.001 is considered statistically significant correlation. The statistical test used: Spearman's rank correlation coefficient test. r – Correlation coefficient (−1≤ r ≤ +1); VAS – Visual analogue scale; EHS – Early wound healing score; P – P value; n – Number of sites

Conventional dental implant surgery requires reflection of both facial and palatal/lingual full-thickness mucoperiosteal flaps to provide access to the bone [17]. The surgical design of the flap determines critically important parameters for effective wound healing, such as maintaining reliable blood perfusion to the surgical site, ensuring blood clot stability. Consequently, this paves the way for the definitive provision of firm keratinized tissue around the implant abutment, thereby allowing a good emergence profile for the definitive prosthesis [18].

Soft-tissue dehiscence was a usual complication in cases where bone augmentation was performed. The clinical outcome of any regenerative therapy is adversely affected when primary closure is not achieved [19, 20].

Various studies have shown how primary flap closure is crucial for the success and uneventful healing in both immediate and delayed implant placements. Any surgical flap closure that is flawed or incomplete can cause early barrier membrane and/or implant exposure, leading to a negative impact on the process of bone repair [21, 22] or peri-implant bone healing. Successful treatment outcomes would, therefore, depend on primary flap closure without tension over the implanted fixtures and/or barrier membranes [23–25]. To achieve primary closure, vertical and periosteal releasing incisions enabling sufficient mobility of the buccal flap may be performed alternatively [26-28].

Implant placement is usually performed by raising a full-thickness flap using a mid-crestal incision design on the edentulous ridge along with crevicular incisions extending to the adjacent teeth both mesially and distally [13].

However, when bone augmentation procedures such as ridge splitting, ridge expansion, osseodensification, and onlay grafting are performed, it could be quite difficult to achieve such fastidious primary soft tissue closure with the mid-crestal flap design. Excessive tension on the flap is the most common causative factor that could lead to the opening of the incision line or dehiscence of sutures [29]. Hence, a modification of the conventional mid-crestal flap design was conceived and performed as a subcrestal flap design in this randomized control clinical trial to achieve tension-free complete primary wound closure [30–33].

To the best of our knowledge, very few studies in literature advocated the use of subcrestal flap design approach for the surgical placement of implants. Further, the validity of such an approach in terms of criteria for assessment of wound healing and patient perception of pain and comfort has not

been evaluated yet.

CSR was considered as the main outcome of evaluation in this study [34]. Therefore, the CSR component was pondered to be 60% of the EHS.

The clinical outcomes of different incisions, design of flap and their effect on healing and osseointegration have been studied [35] According to the Branemark protocol for implant placement, the mucosal incision has to be made in the mucobuccal fold. However, the mucobuccal incision has shown pain as compared to one made in keratinized tissue. During the early days, the vestibular approach introduced by Branemark permitted for the finest visualization of anatomic landmarks allowed suturing far from the surgical area, provided ample tissue coverage, coupled with enabling predictable primary closure and healing [36] However, the shortcomings include a subsequent decrease in the vestibule depth, postoperative edema, and difficulty in suture removal, all amounting to cumulative patient discomfort [37].

In an animal study consisting of a dog model, different incision designs such as the crestal, para-crestal, serpentine, and visor were compared histologically, and it was found that the visor incision was associated with the slowest healing, the most edema, and inflammation [38].

Another study in beagle dogs compared conventional alveolar crest incisions against a mucogingival junction incision to execute split-thickness flaps on the lingual side, with periosteum elevation on the buccal side for placement of implants along with autogenous bone ring grafting. For the study group on the left side, the flap was approximated and sutured with periosteal releasing on the buccal flaps conventionally. However, the split-thickness flaps on the right side were sutured with the elevated periosteum. On evaluation after 3 months, it was found that the mucogingival junction incision had effectively prevented first-stage wound dehiscence after autogenous bone ring grafting, and the study proved that this fidelity in ideal closure plays a significant role in preventing bone resorption [39].

The flap design used in this study was planned and rendered away from the mid crest of the alveolar ridge but within the limit of keratinized tissue, thus preserving the alveolar mucosal area from being on the terminal edge of the flap. The results of our study showed that postoperative healing was better in the subcrestal design as there was a significant improvement in CSR, CSH, and CSI scores at 1 and 4 weeks' follow-up. The VAS scores reported by the patients also showed a statistically significant reduction in the pain perception for site A when compared to the site B in the 1-week postoperative period.

We also found that sufficient width of attached gingiva may not always be available to perform this subcrestal incision design for raising a full-thickness flap in stage 1 implant surgery. However, various viable options and modalities are available for deepening the vestibule and, therefore, increasing the width of keratinized tissue, which would subsequently enable the execution of a subcrestal incision design, particularly for the mandibular arch, since the width of attached gingiva in the mandibular arch is minimum as compared to the maxillary arch.

Conclusion

With the limitations of the present study, it could be concluded that subcrestal incision design can be considered a promising alternative flap design over mid-crestal incision design for dental implant placement for ideal and uneventful healing outcomes.

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