AJDS LAZHAR Al-Azhar Journal of Dental Science
Vol. 26- No. 2- 229:239- April 2023
Print ISSN 1110-6751 | online ISSN 2682 - 3314
https://ajdsm.journals.ekb.eg
Oral Biology, Medicine & Surgical Sciences Issue *(Oral Biology, Oral Pathology, Oral Periodontology, Medicine, Oral & Maxillofacial Surgery)*

CLINICAL AND RADIOGRAPHIC EVALUATION OF PERI-IMPLANT TISSUE CHANGES ASSOCIATED WITH USE OF STANDARD VERSUS CUSTOMIZED HEALING ABUTMENTS

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ABSTRACT

Objective: Risks of esthetic complications has been reported following dental implant insertion; hence it was hypothesis that a customized healing abutment could improve the peri-implant tissue healing. This study aims to evaluate healing around implants received a customized compared to a standard healing abutment. **Patients & Methods:** Twelve patients (eight females and four males aged 33-43) had two nearly comparable partial edentulous spaces on both sides of one jaw, split mouth technique were applied to divide theme into two groups: Group 1 sites received delayed implant with standard healing abutment; Group 2 sites received delayed implant with a customized healing abutment that was fabricated in resin. **Results:** Twenty four implants were inserted successfully in the two groups. The Papilla Index was significantly higher in the customized than in the standard group at 2 and 3 months. The bone loss at mesial and distal sites was significantly higher in the customized than in the standard group at 6 and 9 months. **Conclusion:** Customized healing abutment group showed most favorable outcomes compared with that of standard healing abutment assessed with the criteria of PI and MBL.

KEY WORDS: Healing abutment, peri-implant soft tissue, gingival emergence profile, delayed implant, template for customization.

INTRODUCTION

There is overwhelming evidence that, dental implant is an optimal method to restore missing teeth; both functionally as well as esthetically. An optimal aesthetic implant restoration is a combination of a visually pleasing prosthesis and adequate surrounding peri-implant soft tissue architecture. Fulfilling the aesthetic expectations of patients is one of the most challenging tasks in implant dentistry[(1)]. Factors that can influence the aesthetic outcome of an implant-supported rehabilitation include, position of the implant [(2)], quantity and quality of hard and soft tissues, as well as their adaptation over time[(3)].

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DOI: *10.21608/ajdsm.2023.179122.1389*

Dental implant surrounding framework of both hard and soft tissues must be either be preserved at the time of tooth extraction or subsequently regenerated in a manner that permit the implant-supported restoration emerges out of the gingival tissue similar to that of an adjacent natural tooth. Thus, healing abutment guide the healing process of surrounded hard and soft tissues, to desired form after the placement of an implant in a single-stage surgical protocol. [4] Development of ideal supra-implant soft tissue architecture can be achieved by step-wise conditioning using a provisional crown [3]. Customized healing abutment can be used, particularly, with placement of dental implant to protect and contain the bone substitute during healing as well as to preserve alveolar contour, prevent food impaction, and eliminate the need for a second surgery and provisional restoration.

The healing process of the underlying bone also reduces support for the soft tissue which covers it[5]. Maintaining or reconstructing the original soft tissue contours is essential to create a dental implant-supported crown with a natural appearance. Various hard and soft tissue augmentation techniques have been described[6]. In addition, a properly fabricated interim crown or Healing Abutment can add to the stability and maintenance of the soft tissue contours in immediate implant placement sites and in healed sites[5].

It has been postulated that, a method that is commonly used to evaluate both the functional and aesthetic results is the Functional Implant Prosthodontics Score (FIPS)[7]. In this way of evaluation, the soft tissue outcomes (Papilla Index and Pink Esthetic Score) of implants can be performed. Thus, it was felt that studying the effects of the use of two types of healing abutments during placement of dental implants, i.e., customized vs a standard healing abutment will be of value. Hence, this study was designed to clarify this aspect clinically as well as using radiographic examination.

PATIENTS AND METHODS

Subjects:

Twelve patients (four males and eight females) which participated in this study, were selected from outpatient clinic, Department of Oral Medicine, Periodontology, Diagnosis and Oral Radiology, Faculty of Dental Medicine (Boys- Cairo) Al- Azhar University. Patients had two partial edentulous spaces nearly similar on both sides of one jaw (Fig.1), there ages were ranged from 25 to 45 and they had teeth extraction within the last year indicated for single crown implant-supported restoration were included in the study and split mouth technique was applied to minimize individual variation. Heavy smokers (more than 10 cigarettes/day), Medically compromised patients", Patients with a full mouth plaque and bleeding score higher than 25%, Patients who had highly scalloped periodontal phenotype at the selected site; need for bone augmentation procedures, Suffering from Bruxism, Pregnant or lactating females were excluded from the study.

Ethical consideration: nature of the study was explained to patients upon their agreement, they were asked to sign a written consent form. (Ethical reference number 544/3077)

Grouping:

Sites divided into two groups: Group 1: sites received delayed implant with standard healing abutment; Group 2: sites received delayed implant with a customized healing abutment that fabricated in resin.

Intervention:

Clinical examination was done consisted of medical and dental history, general an oral health status an assessment of future implant site. A Cone-beam computed tomography (CBCT) scanning was performed to assess bone height and thickness as well as to aid in implant site analysis. Prior to surgery, each patient was given careful instruction on proper oral hygiene measures. Full mouth, supra and sub gingival scaling and root planning procedures were performed by using a combination

of hand Gracy curettes (Hu Friedy, Chicago, IL) and ultrasonic scaler (Cavitron Corp., Long Island city, NY) to provide a more favorable oral environment for wound healing and a clinician was evaluated the implant site in terms of favorable clinical conditions and absence of any pathological lesions.

Dental Implant insertion

All surgical procedures were performed by the same surgeon and Antibiotic prophylaxis consisting of Amoxicillin clavulanate 2g 1 h before surgery to reduce the risk of infections. Local anesthesia with mepivacaine 2% with epinephrine 1:100.000 was applied. A mucoperiosteal flap was raised following middle crestal incision. Implant bed preparation were performed, and implants ((NucleOSS™ T6, Izmir, Turkey) were inserted according to the manufacturer's instructions. The implant platform was placed at the marginal level of the buccal bone wall, to obtain the implant platforms sub-crestal at mesial and distal sites. Once the implant was inserted in the site, clinician received the information if the healing abutment had to be standard or customized, then the other site of the mouth received implant with other type of healing abutment.

Customized healing abutment was fabricated in resin using special template "One piece template", pre-designed on Blen-der software then modified for one piece implant on Meshmixer software[8]. The fabrication was done by adapting final abutment of implant in the template and then flowable composite nano-hybrid material introduced into the open space available in the template around the final abutment (Fig.2), until the space was completely filled and it was subsequently light cured for 40 seconds. The customizing healing abutment was then removed from the template, and it was light cured for an additional 20 seconds. Minor height adjustments were done and the composite surface was highly polished using polishing brushes and paste, then the customized healing abutment adapted to the implant. Then other site of jaw received standard healing abutment and suturing around the two types of healing abutments were done. Periapical intraoral radiographs were taken for all implants immediately after healing abutment connection (Fig.3). Patients were seen at 1 and 2 weeks for suture removal and control (Fig.4).

FIG (1) Patient has two bilateral partial edentulous spaces.

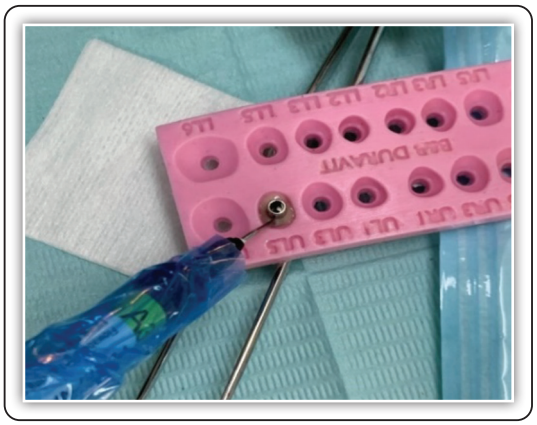

FIG (2) Flowable composite nano-hybrid material introduced into the open space available in the template around the final abutment.

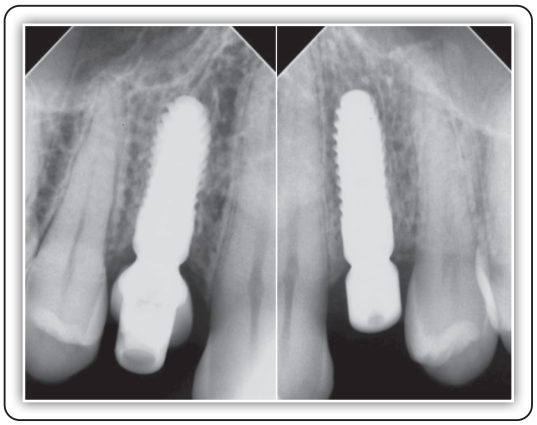

FIG (3) Periapical intraoral radiographs were taken for all implants immediately after healing abutment connection.

FIG (4) Patient after follow up

Evaluation:

a. Clinical evaluation of soft tissue:

The Papilla Index[9] and Pink Esthetic Score (PES) [10] were evaluated and changes between the two groups were compared at baseline, 1,2 and 3 months.

Papilla Index

Variables	0	1	2	3	4
Papilla	No papilla	Less than the half of the height	Half or more of height	Papilla fill up entire proximal space	Papilla hyperplastic

Pink Aesthetic Score

Variables	0	1	2
Papilla - M	Missing	Incomplete	Complete
Papilla - D	Missing	Incomplete	Complete
Tissue contours	Unnatural	Virtually natural	Natural
Gingival level	>2 mm	1—2 mm	<1 mm
Alveolar process	Clearly resorbed	Slightly resorbed	No difference
Coloring	Clear difference	Slight difference	No difference
Soft tissue texture	Clear difference	Slight difference	No difference

b. Radiographic Evaluation (Hard tissue evaluation):

Peri-implant marginal bone level were measured at baseline (after healing abutment connection), then at 3,6 and 9 months on intraoral periapical radiographs at the mesial and distal aspects. It was set as the distance between the reference point and the most apical point of contact between the implant surface and the bone. The reference point is the fixture-abutment interface. Care was taken to standardize the performing of intraoral radiography by using long cone parallel technique with the use of RVG.

Statistical analysis of the data:

Data was collected and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Shapiro-Wilk test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. Significance of the obtained results was judged at the 5% level.

RESULTS

Demographic data of two groups is mentioned in Table (1)

TABLE (1) Distribution of the studied cases according to demographic data (n = 12)

	No.	%
Gender		
Male	4	33.3
Female	8	66.7
Age (years)		
Min. – Max.	33.0 – 43.0	
Mean ± SD.	37.33 ± 3.61	
Median	36.50	

I. Evaluation of soft tissue

1. Pink aesthetic score

The comparison between the different time periods in each group according to pink aesthetic score are presented in Table (2b). For Standard abutment, pink aesthetic score was 1.24±0.23 at baseline, 1.24±0.23 at 1 month, 1.26±0.28 at 2 months, 1.24 ± 0.28 at 3 months. For Customized abutment, pink aesthetic score was 1.60±0.31 at baseline, 1.60±0.31 at 1 month, 1.71±0.18at 2 months, 1.79±0.17 at 3 months. Both groups showed a statistically non-significant difference in mean Pink aesthetic score measurements at 1, 2, and 3 months.

Table (2b): Comparison between standard and customized healing abutment according to pink aesthetic score. At baseline: there was a statistically non-significant difference in mean pink aesthetic score in the two groups (p=0.059). After 1 months: there was a statistically non-significant difference in mean pink aesthetic score in the two groups (p=0.059). After 2 months: there was a statistically significant difference in mean pink aesthetic score in the two groups. Customized healing abutment group showing a higher pink aesthetic score than Standard healing abutment group (p=0.010*). After 3 months: there was a statistically significant difference in mean pink aesthetic score in the two groups. Customized healing abutment group showing a higher pink aesthetic score than Standard healing abutment group (p=0.007*).

TABLE (2A): Descriptive statistics of pink aesthetic score in each group

Groups	Time	Pink aesthetic score					
		Min.	Max.	Mean ± SD.	Median	95% CI	
						LL	UL
Standard healing abutment (n = 12)	**Baseline**	1.0	1.57	1.24 ± 0.23	1.21	0.99	1.48
	After 1 months	1.0	1.57	1.24 ± 0.23	1.21	0.99	1.48
	After 2 months	1.0	1.71	1.26 ± 0.28	1.21	0.97	1.55
	After 3 months	1.0	1.71	1.24 ± 0.28	1.14	0.94	1.53
Customized healing abutment (n = 12)	**Baseline**	1.14	1.86	1.60 ± 0.31	1.71	1.27	1.92
	After 1 months	1.14	1.86	1.60 ± 0.31	1.71	1.27	1.92
	After 2 months	1.57	2.0	1.71 ± 0.18	1.64	1.52	1.90
	After 3 months	1.57	2.0	1.79 ± 0.17	1.86	1.60	1.97

TABLE (2B) Comparison between the different time periods in each group according to pink aesthetic score

Groups (Healing abutment)	Pink aesthetic score				p
	Baseline	After 1 months	After 2 months	After 3 months	
Standard	1.24 ± 0.23	1.24 ± 0.23	1.26 ± 0.28	1.24 ± 0.28	0.812
Customized	1.60 ± 0.31	1.60 ± 0.31	1.71 ± 0.18	1.79 ± 0.17	0.074

Data was expressed using Mean ± SD. SD: Standard deviation

p: p value for comparing between the four studied periods

2. Papilla index

TABLE (3A): Comparison between the different time periods in each group according to papilla index

Variables	Groups (Healing abutment)	Papilla Index				Fr	p
		Baseline	After 1 months	After 2 months	After 3 months		
Mesial aspect	**Standard**	1.0 (0.0 – 1.0)	1.0 (0.0 – 1.0)	1.0 (0.0 – 2.0)	1.0 (0.0 – 2.0)	3.000	0.392
	Customized	1.0 (1.0 – 2.0)	1.0 (1.0 – 2.0)	2.0 (1.0 – 2.0)	2.0 (1.0 – 2.0)	6.000	0.112
Distal aspect	**Standard**	1.0 (0.0 – 2.0)	1.0 (0.0 – 2.0)	1.50 (0.0 – 2.0)	1.0 (0.0 – 2.0)	3.000	0.392
	Customized	1.50 (1.0 – 2.0)	1.50 (1.0 – 2.0)	2.0 (1.0 – 3.0)	2.0 (2.0 – 3.0)	10.200*	0.017*
	p_0		1.000	0.180	0.046*		

Data was expressed using Median (Min. – Max.), Fr: Friedman test, *Sig. bet. Periods was done using* **Post Hoc Test (Dunn's).** *p: p value for comparing between the four studied periods*

p_0: p value for comparing between **Baseline** *and each other period in each group*

**: Statistically significant at p ≤ 0.05*

TABLE (3B) Comparison between standard healing abutment and customized healing abutment according to papilla index

Papilla Index	Standard healing abutment (n =12)	Customized healing abutment (n = 12)	Z	p
Mesial aspect				
Baseline	1.0 (0.0 – 1.0)	1.0 (1.0 – 2.0)	1.732	0.083
After 1 months	1.0 (0.0 – 1.0)	1.0 (1.0 – 2.0)	1.732	0.083
After 2 months	1.0 (0.0 – 2.0)	2.0 (1.0 – 2.0)	2.000*	0.046*
After 3 months	1.0 (0.0 – 2.0)	2.0 (1.0 – 2.0)	2.000*	0.046*
Distal aspect				
Baseline	1.0 (0.0 – 2.0)	1.50 (1.0 – 2.0)	1.633	0.102
After 1 months	1.0 (0.0 – 2.0)	1.50 (1.0 – 2.0)	1.633	0.102
After 2 months	1.50 (0.0 – 2.0)	2.0 (1.0 – 3.0)	1.890	0.059
After 3 months	1.0 (0.0 – 2.0)	2.0 (2.0 – 3.0)	2.070*	0.038*

Data was expressed using Median (Min. – Max.) *Z:* **Wilcoxon signed ranks test**

P: p value for comparing between **Standard healing abutment** *and* **Customized healing abutment.**

**: Statistically significant at p ≤ 0.05*

Table (3a,3b):

Regarding Mesial aspect

At baseline and After 1 months: there was a statistically non-significant difference in mean papilla index in the two groups (p=0.083).

After 2 months: there was a statistically significant difference in mean papilla index in the two groups. Customized healing abutment group a higher papilla index than Standard healing abutment group(p=0.046*).

After 3 months: there was a statistically significant difference in mean papilla index in the two groups. Customized healing abutment group a higher papilla index than Standard healing abutment group(p=0.046*).

Regarding Distal aspect

At baseline and After 1, and 2 months: there was a statistically non-significant difference in mean papilla index in the two groups (p=0.102, 0.102, and 0.059 respectively).

After 3 months: there was a statistically significant difference in mean papilla index in the two groups. Customized healing abutment group a higher papilla index than Standard healing abutment group(p=0.038*).

II. Radiographic Evaluation (Hard tissue evaluation): Marginal bone loss

TABLE (4A) Descriptive statistics of marginal bone loss in each group

Variables	Groups	Time	Marginal bone loss (mm)					
			Min.	Max.	Mean ± SD.	Median	95% CI	
							LL	UL
Mesial aspect (mm)	Standard healing abutment (n = 12)	Baseline	0.0	0.0	0.0 ± 0.0	0.0	–	–
		After 3 months	-0.40	-0.30	-0.37 ± 0.05	-0.40	-0.42	-0.31
		After 6 months	-0.70	-0.40	-0.57 ± 0.12	-0.55	-0.69	-0.44
		After 9 months	-0.80	-0.50	-0.65 ± 0.12	-0.60	-0.78	-0.52
	Customized healing abutment (n = 12)	Baseline	0.0	0.0	0.0 ± 0.0	0.0	–	–
		After 3 months	-0.40	-0.20	-0.30 ± 0.06	-0.30	-0.37	-0.23
		After 6 months	-0.50	-0.30	-0.40 ± 0.09	-0.40	-0.49	-0.31
		After 9 months	-0.60	-0.40	-0.50 ± 0.09	-0.50	-0.59	-0.41
Distal aspect (mm)	Standard healing abutment (n = 12)	Baseline	0.0	0.0	0.0 ± 0.0	0.0	–	–
		After 3 months	-0.50	-0.30	-0.37 ± 0.08	-0.35	-0.45	-0.28
		After 6 months	-0.60	-0.40	-0.52 ± 0.08	-0.50	-0.60	-0.44
		After 9 months	-0.70	-0.50	-0.67 ± 0.08	-0.70	-0.75	-0.58
	Customized healing abutment (n = 12)	Baseline	0.0	0.0	0.0 ± 0.0	0.0	–	–
		After 3 months	-0.40	-0.20	-0.25 ± 0.08	-0.20	-0.34	-0.16
		After 6 months	-0.50	-0.30	-0.37 ± 0.08	-0.35	-0.45	-0.28
		After 9 months	-0.50	-0.30	-0.43 ± 0.08	-0.45	-0.52	-0.35

TABLE (4B) Marginal bone loss at different time periods in each group.

Variables	Groups (Healing abutment)	Marginal bone loss (mm)				F	p
		Baseline	After 3 months	After 6 months	After 9 months		
Mesial aspect	Standard	0.0 ± 0.0	-0.37 ± 0.05	-0.57 ± 0.12	-0.65 ± 0.12	94.738*	<0.001*
	p_0		<0.001*	0.001*	<0.001*		
	Customized	0.0 ± 0.0	-0.30 ± 0.06	-0.40 ± 0.09	-0.50 ± 0.09	93.333*	<0.001*
	p_0		<0.001*	0.001*	<0.001*		
Distal aspect	Standard	0.0 ± 0.0	-0.37 ± 0.08	-0.52 ± 0.08	-0.67 ± 0.08	90.538*	<0.001*
	p_0		0.001*	<0.001*	<0.001*		
	Customized	0.0 ± 0.0	-0.25 ± 0.08	-0.37 ± 0.08	-0.43 ± 0.08	61.850*	<0.001*
	p_0		0.004*	0.001*	<0.001*		

Data was expressed using Mean ± SD. F: F test (ANOVA) with repeated measures, *Sig. bet. periods was done using* **Post Hoc Test.** *p: p value for comparing between the four studied periods*

p_0: p value for comparing between **Baseline** *and each other period in each group *: Statistically significant at p ≤ 0.05*

Table (4a,4b):

Regarding Mesial aspect

At baseline and After 1 months: there was a statistically non-significant difference in mean Marginal bone loss in the two groups.

After 3 months: there was a statistically non-significant difference in mean Marginal bone loss in the two groups (p=0.175).

After 6 and 9 months: there was a statistically significant difference in mean Marginal bone loss in the two groups. Customized healing abutment group a lower Marginal bone loss than Standard healing abutment group(p=0.001*)

Regarding Distal aspect

At baseline and After 1 months: there was a statistically non-significant difference in mean Marginal bone loss in the two groups.

After 3, 6 and 9 months: there was a statistically significant difference in mean Marginal bone loss in the two groups. Customized healing abutment group a lower Marginal bone loss than Standard healing abutment group (p= 0.034*, 0.001*,<0.001* respectively)

DISCUSSION

It is well known that predictable aesthetic result as been considered as crucial toward successful dental implant. To meet the aesthetic expectations of patients, precise 3D implant positioning is required, along with sufficient quantity and quality of peri-implant hard and soft tissues[11, 12]. Moreover, the natural profile plays a key role in the achievement of a satisfying aesthetic result[13]. the optimum healing abutment should allow tissues to maintain natural contours, respecting their volume and shape[14]. However, when using conventional prefabricated healing abutments, the surrounding soft tissues may be unfavorable for receiving the final restorations[15]. Knowing that an appropriate emergence profile of an implant supported restoration is important for optimizing hygiene and esthetics, it is fundamental to obtain harmonious soft tissue architecture around dental implants prior the final impression[15-17].

It was evident that there was a statistically a significant difference in mean pink aesthetic score in the two groups after 2 and 3 months. Customized healing abutment group showed a higher pink aesthetic score than Standard healing abutment group. This may be due to that the customized

healing support and maintain the soft and hard tissue contours after immediate implant placement in both the anterior and posterior regions. This approach could positively influence the long-term health of the implant while simplifying the entire treatment. These results agree with another study stated that Customized healing abutment seems to be effective to guide the soft tissue healing around dental implants[18]. In addition, another study proved that the higher aesthetic score in the Customized healing abutment group. Placing a custom abutment at surgical stage reduced contamination during prosthetic steps with biological advantages[19].

In the present study, after 2 and 3 months: there was a statistically a significant difference in mean papilla index score in the two groups. Customized healing abutment group a higher papilla index than Standard healing abutment group. This can be attributed to the organization of collagen fibers (after 4 weeks) and mature mucosal adhesion (after 6-8 weeks) During soft tissue healing,[20]. Hence, customized healing abutments could be used to preserve the soft tissue contour, eliminating the need for reopening surgery and the use of provisional restorations to condition the mucosal contour. Cellular adhesion to customized healing abutments may support the peri-implant mucosa and maintain its architecture[21]. These results agreed with study that evaluated and compared the soft and hard tissue healing around immediate implants that received bone grafting and a customized vs a standard healing abutment. The Papilla Index was significantly higher in the customized than in the standard group at 2 and 3 months. The bone loss at mesial sites was significantly higher in the control than in the test group (P = .0014). they concluded that, customized healing abutment group showed the most favorable outcomes (in terms of Papilla Index) in case of immediate implant that received a peri-implant bone grafting procedure[22].

In the present study, after 3, 6 and 9 months: there was a statistically a significant difference in mean Marginal bone loss in the two groups. Customized healing abutment group a lower Marginal bone loss than Standard healing abutment group ($p= 0.034^{*}$, 0.001^{*}, $<0.001^{*}$ respectively). This may be due to that the customized abutments have a tendentially concave and narrowed shape. The concave profile of these abutments is critical during the formation of peri-implant soft tissues, in fact some clinical investigations have shown that concave or convergent profiles at transmucosal level lead to better esthetic results not only at the level of soft tissues but also at the level of hard tissues[23, 24]. This is clearly explained by some histological studies on an animal model that showed that the transmucosal concavities guide pre-implant collagen fibers, during their formation, to position themselves within the concavity itself, thus migrating in a coronal sense, contributing not only to have better and healthier peri-implant tissues, but also to a more stable marginal bone with less initial marginal resorption[25, 26].

The results was agreed with study evaluated and compared the soft and hard tissue healing around immediate implants that received bone grafting and a customized vs a standard healing abutment. The bone loss at mesial sites was significantly higher in the control than in the test group. they concluded that, customized healing abutment group showed the most favorable outcomes (in terms of MBL) in case of immediate implant that receive8d a peri-implant bone grafting procedure[27]. Another study compared bone resorption when customized and stock abutments were used. There was a statistically significant difference—2.18 ± 0.59 mm horizontal bone loss in the group with stock abutments, and—0.08 ± 0.27 mm horizontal bone loss in the group with customized healing abutments; [28] customized healing abutments successfully preserve soft tissue, prevent the buccal bone from resorption during the osseointegration phase, and recreate the emergence profile of the natural teeth.

CONCLUSION

In view of the obtained results, it can be concluded that the use of customized abutments, as a treatment strategy, was potentially able to give better results in terms of both soft and hard tissues; simply customized healing abutment group showed the most favorable outcomes in terms of PI, PES and MBL, in delayed implant procedure.

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