Received: 26 April 2021 | Revised: 7 June 2021 | Accepted: 7 August 2021

DOI: 10.1111/cid.13044

ORIGINAL ARTICLE

WILEY

Effect of customized healing abutments on the peri-implant linear and volumetric tissue changes at maxillary immediate implant sites: A 1-year prospective randomized clinical trial

Danilo Fernandes DDS, MSc[1,2] | Sílvia Nunes DDS, MSc[2] | Gonzalo López-Castro DDS, MSc, PhD[3] | Tiago Marques DDS, MSc[4] | Javier Montero DDS, MSc, PhD[1] | Tiago Borges DDS, MSc, PhD[4]

[1]Department of Surgery, Faculty of Medicine, University of Salamanca, Salamanca, Spain

[2]Faculty of Dental Medicine, Universidade Católica Portuguesa, Viseu, Portugal

[3]Faculty of Medicine and Dental Medicine, Universidad de Santiago de Compostela, Santiago, Spain

[4]Faculty of Dental Medicine, Center for Interdisciplinary Research in Health, Universidade Católica Portuguesa, Viseu, Portugal

Correspondence
Tiago Borges, Faculty of Dental Medicine, Center for Interdisciplinary Research in Health, Universidade Católica Portuguesa, Estrada da Circunvalação, 3504-505 Viseu, Portugal.
Email: tborges@ucp.pt

Abstract

Background: Immediate implant placement (IIP) associated with the use of bone substitutes and collagen matrices (CM) seems to reduce the amount of resorption at peri-implant areas. Recently, customized healing abutments (CA) appeared as another solution in order to seal the socket and preserve the original soft tissue contour.

Purpose: To evaluate peri-implant tissues dimensional changes after using customized healing abutments compared with the use of xenogeneic collagen matrices as socket sealing options in flapless maxillary immediate implant placement.

Material and methods: The present study was designed as a prospective, randomized, controlled clinical trial. Patients were allocated into two groups depending on the socket sealing option: in the CM group a collagen matrix was used and in the CA group a customized abutment. Digital impressions were taken prior to extraction, 1, 4, and 12 months after implant insertion and the digital files allowed to evaluate linear buccal changes (MBC) and the buccal volumetric variation (BVv) between the different time points at peri-implant tissue areas. Additionally, mucosa variation was computed assessing the papilla presence and the midfacial mucosa height. Statistical significance was set at 0.05.

Results: Twenty-eight patients were observed during a 12-month period. Significant differences between mean values of BVv at the first month were observed at the CM and CA group (−9.75 ± 6.65% and −4.76 ± 5.29%, respectively) ($p = 0.043$). At the 1-year follow-up, no significant differences were found in terms of BVv between the two groups, although the thin bone phenotype (≤1 mm) significantly influenced the volumetric variations that occurred in each group. No significant differences were noticed in midfacial mucosa and papillae alteration between groups, after 1 year of treatment.

Conclusion: Both treatment options are predictable solutions for socket sealing in IIP, although a higher volumetric variation can be expected in the presence of thin bone phenotypes.

KEYWORDS
3-dimensional imaging, alveolar bone loss, alveolar ridge augmentation, dental implants, treatment outcome, wound healing

What is known

- The utilization of a customized healing abutments aims to maintain the soft tissue contours during the healing of the peri-implant mucosa, providing a favorable outcome while reducing the number of surgeries and postoperative discomfort.
- Xenogeneic collagen matrices seem to reduce the amount of soft tissue resorption after tooth extraction.
- Lack of randomized controlled trials on this topic.

What this study adds

- This study is the first registered randomized controlled trial that compares the use of a xenogeneic collagen matrix or a customized healing abutment, considering both treatments as predictable solutions of socket sealing in IIP.
- Customized healing abutments showed significantly less volumetric variation compared with the use of collagen matrices at the first month of follow-up, although no significant differences were found between groups after the first year of treatment.
- Also, both treatment modalities should be used with caution as thin bone phenotypes are present at the extraction site.

1 | INTRODUCTION

Immediate implant placement (IIP) presents as a highly reliable solution when a replacement of a hopeless tooth is needed, either for single-tooth treatments or full-arch rehabilitations.[1–4] Nevertheless, implant insertion should follow strict criteria to achieve functional satisfactory outcomes, especially at anterior fresh extraction sockets where a finer aesthetic demand is mandatory.[5] The presence of a sufficient 3-dimensional bone volume, a fully intact buccal bone plate and a thick gingival biotype, have been presented as favorable indicators to a better prognosis at this treatment option.[5] Borges and colleagues,[6] in a recent study with a novel digital assessment protocol, have proven the influence of buccal bone plate thickness and the dimensional changes that occur after flapless maxillary IIP.

In order to compensate hard and soft tissue changes, some investigators stated different strategies to compensate the volume contraction that include the use of bone grafts such as autogenous bone[7] and deproteinized bovine bone mineral (DBBM)[8,9] and also the use of a connective tissue graft (CTG).[10] As an alternative to a CTG, xenogeneic collagen matrices have been also tested for ridge preservation after tooth extraction.[11,12] Moreover, a flapless approach that aims to minimize tooth extraction trauma, followed by IIP and immediate provisionalization, seems to achieve satisfactory results regarding interproximal bone levels, survival rates, and aesthetics after a 5-year follow-up.[13] This procedure allows to maintain the peri-implant mucosa contours, improving aesthetics until the definitive crown placement.[14] Recently, studies evaluating the use of customized healing abutments/screws have been performed aiming to assess possible advantages associated with this treatment modality.[15–18] The utilization of a CAD/CAM technique to fabricate a perfectly adapted polymethyl methacrylate (PMMA) healing abutment aims to reproduce the precise contours of the cervical root area and maintain the soft tissue contours during osseointegration and the healing of the peri-implant mucosa. Also, they seem to provide a predictable outcome while reducing the number of surgeries, postoperative discomfort, morbidity related to open-flap technique, and the length of treatment.[19]

Thus, the aim of this study was to evaluate peri-implant tissues dimensional changes after using customized healing abutments compared with the use of xenogeneic collagen matrices as socket sealing options in flapless maxillary IIP.

2 | MATERIAL AND METHODS

2.1 | Study design

The present study was conducted as a prospective, controlled clinical trial with a parallel-group design and balanced randomization (ratio 1:1) to document the peri-implant tissues response in using a xenogeneic collagen matrix (group CM) or a customized healing abutment (group CA) as different treatment methods for socket closure in flapless maxillary immediate implants. The protocol was reviewed and approved by the Institute of Bioethics of the Catholic University of Portugal (ESR 06.2019) and the patients included were previously informed and agreed to participate in this investigation signing an informed consent considering the 1975 Declaration of Helsinki, revised in 2013. In addition, this investigation has been registered at

U.S. National Library of Medicine (ClinicalTrials.gov) website under the reference number NCT04432519. Group designation was kept in opaque-sealed envelopes that were opened after implant insertion by an investigator (Danilo Fernandes), not involved in surgical procedures, randomly allocating participants to one of the two treatment groups. Twenty-eight patients in need of a single implant restoration in the maxillary arch following tooth extraction were included in this study. Patients were treated between June 2019 and June 2020. Study participants selection was adapted from Borges and colleagues.[6] Patients' inclusion criteria were (1) ≥18 years of age; (2) patients who had a failing tooth and needed an implant placing therapy in the aesthetic zone (between 15 and 25); (3) the failing tooth has adjacent and opposing natural teeth; (4) sufficient mesial-distal and interocclusal space for placement of the implant and definitive restoration; (5) had an intact socket wall previously to the extraction; (6) had sufficient apical bone to place an immediate implant with minimum primary stability of 30 Ncm. Exclusion criteria were (1) individuals diagnosed with periodontal disease; (2) medical and general contraindications for the surgical procedure; (3) heavy smokers (>10 cigarettes/day); (4) an active infection at the implant site. A CONSORT 2010 check-list was performed in order to consider an appropriate guideline for the present randomized trial study.[20]

2.2 | Surgical protocol

All surgical procedures were conducted under appropriate local anesthesia 4% articaine with adrenaline 1:100000 (UbistesinTM, 3M-ESPE, St. Paul, MN). In both groups, flapless tooth extractions were performed after sectioning the tooth, followed by the use of periotomes and elevators to separate the two parts of the tooth, avoiding damage to the buccal and palatal bone plates. The socket was inspected to search for any fenestration or dehiscence of the bone walls, which would have led to the exclusion of the patient. All patients were treated with cylindrical shape implants (OsseoSpeed EV, Astra Tech Implant System, Dentsply Implants, Möhndal, Sweden) with a narrow diameter internal connection platform following the surgical sequence protocol provided by the manufacturer. The implant was placed in a correct 3-dimensional position, engaging the palatal and apical bone to achieve high primary stability (Figure 1(A), (C)).[21] After implant insertion, a gap of at least 2 mm between the inner cortical buccal bone plate and the implant surface was filled with DBBM material (Symbios, Dentsply Implants, Möhndal, Sweden).

The two groups differ on distinct methods in order to seal the fresh sockets. Group CM (Figure 1(A), (B)) sockets were sealed with a resorbable collagen matrix (Mucograf Seal, Geistlish Biomaterials, Wolhusen, Switzerland) stabilized with single interrupted 6/0 polyamide sutures (SeralonTM, Serag-Wiessner, Nalia, Germany), whereas group CA (Figure 1(C), (D)) received a healing abutment customized with a PMMA material allowing to close the socket without sutures. All customized healing abutments were manufactured in a CAD/CAM software (CEREC in LAB MC XL, Sirona Dental Systems Gmbh, Bensheim, Germany) and milled by a specific milling machine (Sirona MCX5, Sirona Dental Systems Gmbh, Bensheim, Germany).

All surgical procedures were performed by one experienced surgeon (Tiago Borges). The patients had provisional resin bonded crowns to the adjacent teeth on the same day as the implant surgery, being removed after 16 weeks. Postoperative instructions were given to the patients, which included a soft diet, oral hygiene procedures, and chlorhexidine 0.12% rinsing twice per day during 2 weeks. Systemic antibiotics (amoxicillin 1 g twice per day for 7 days) and paracetamol 1000 mg, three times per day, for pain control, were prescribed. Sutures were removed 10 days after surgery. A screw-retained provisional crown was delivered after 4 months of healing and definitive restorations were inserted at the 6-month appointment, consisting in a screw-retained all-ceramic crown and a customized titanium abutment (Atlantis, Dentsply Implants, Möhndal, Sweden).

2.3 | Clinical observation and data acquisition

Examination protocol and data collection were adapted from Borges and colleagues[6] and consisted of four appointments: (1) T0 (flapless tooth extraction and implant insertion); (2) T1 (1-month follow-up after implant placement); (3) T2 (4-month follow-up after implant insertion); and (4) T3 (1-year postoperative follow-up). An intraoral optical scan (Cerec Omnicam, Sirona Dental Systems GmbH, Bensheim, Germany) of the upper arch and a cone-beam computer tomography (CBCT) evaluation (Ortophos XG 3D, Sirona Dental Systems GmbH, Bensheim, Germany) were performed before tooth extraction and implant placement (T0). At this point, two clinical parameters were assessed with a periodontal probe (PCB 12; Hu-Friedy, Chicago, IL) to the nearest millimeter: BID (distance between implant shoulder and the buccal bone plate) and KM (distance between the gingival groove and the mucogingival junction). Intraoral scans were completed post-implant placement at 1 month (T1), 4 months (T2), and 12 months (T3). In all follow-up appointments, hygiene instructions were given to the patients and periodontal care was executed when necessary. Biologic complications such as mucositis or periimplantitis were recorded based at the peri-implant disease clinical and radiographic diagnosis. Technical complications were registered as the prosthetic problems such as screw loosening, abutment fracture, ceramic chipping, or ceramic fracture.

2.4 | Intraobserver agreement

A protocol was elaborated to study the variables of interest in three distinct computer software. One examiner (Danilo Fernandes), blinded for the surgical procedure, was calibrated through an intraexaminer test (Dahlberg *d*-value), consisting in a double consecutive data collection of 10 randomly chosen patients included in this study. An intraclass coefficient of 0.93 was obtained.

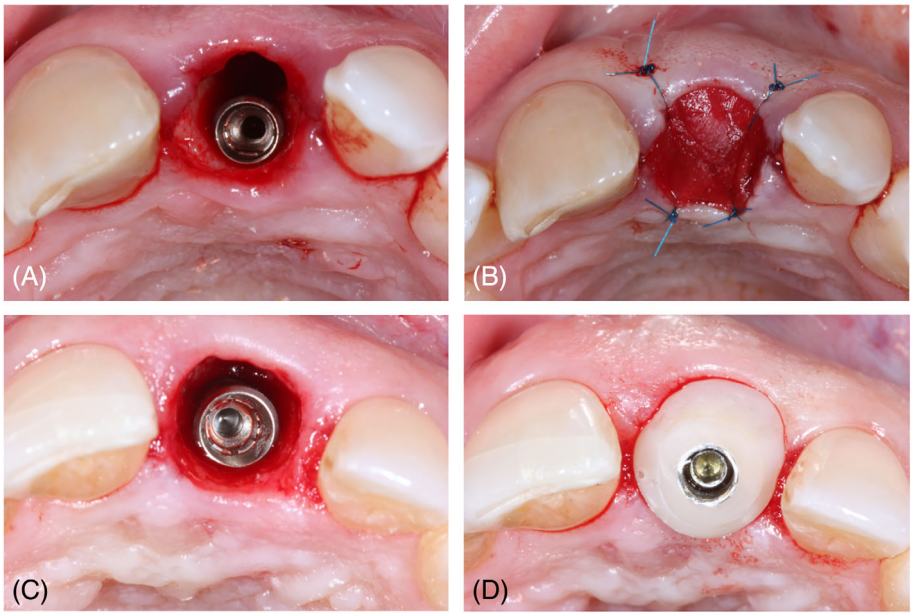

FIGURE 1 CM and CA groups socket closure methods. (A, B) IIP and a xenogeneic collagen matrix (CM); (B, C) IIP and a customized healing abutment (CA)

2.5 | Matching digital models

All digital models were exported from the intraoral optical scanner software (Cerec Omnicam, Sirona Dental Systems GmbH, Bensheim, Germany) in stereolithography (STL) format and were examined with a specially designed software (Geomagic Control X, Geomagic, Inc., Cary, NC). The T0 and T1, T0 and T2, and T0 and T3 STL files were superimposed and a strict alignment was made into a common coordinate system. The final alignment was carried out through the *best fit* alignment algorithm for a perfect match of digital models.[6]

2.6 | Linear and volumetric measurements

The digital analysis protocol was performed as described by Borges and colleagues.[6] After the superimposition of study models, a color map was created allowing to quantitatively analyze dimensional variations occurring in the surgical areas and surrounding tissues. Green color represents areas where no 3-dimensional changes were found, while variations between yellow and red represent volume increase and variations between light blue and dark blue represent volume decrease (Figure 2(A)). A region of interest (ROI) composed with 10 section planes, perpendicular to the coronal section of the tooth, was computed at the buccal and palatal aspect of the ridge (Figure 2(A), (B)). These sections were set at the most apical point of the gingival margin and ended 5 mm above it. Mesially and distally, a line passing through the interproximal area limited the ROI. The same ROI was used in each patient, at the different comparison follow-ups. The intersection of these sections with the superimposed models resulted in the linear changes to be obtained in each area. The mean buccal change (MBC_{T0-T1}, MBC_{T0-T2}, and MBC_{T0-T3}) representing the buccal area and mean total change (MTC_{T0-T1}, MTC_{T0-T2}, and MTC_{T0-T3}) representing the buccal and palatal aspects were calculated in millimeters (mm) to evaluate the variations that occurred in the peri-implant area.

Moreover, the superimposed STL files were exported to another computer program (Materialise Magics, Materialise, Leuven, Belgium) for volumetric assessment. A 3-dimensional volumetric ROI was manually selected with "cut or punch" function considering interproximal areas as mesial and distal limits (Figure 2(C)). All cuts were performed in the same areas in all digital models ensuring that all measurements were carried out in the same regions. The use of "Boolean" function was performed to create STL files related to volume reduction and volume increase occurred at different time points. Volumetric variation considering volume increase and volume reduction were represented as buccal volume variation (BVv_{T0-T1}, BVv_{T0-T2}, and BVv_{T0-T3}) and total volume variation (TVv_{T0-T1}, TVv_{T0-T2}, and TVv_{T0-T3}) in cubic millimeters (mm^3) and relative percentages (%). The initial total volumes evaluated from each ROI at the buccal (BVt) and palatal (PVt) aspect were also computed for further comparison with volume variations at the different appointments (Figure 2(D)). These calculations allowed to create relative percentages of volume variations which is essential to directly compare different patients due to anatomical variances. All measurements were recorded to the nearest 0.01 mm.

2.7 | Midfacial mucosa and papillae outcomes

Midfacial mucosa and papillae height variation at the 1-year follow-up were analyzed using a computer software (Materialise Magics, Materialise). After precisely overlapping the T0 and T3 STL files in a common coordinate system, a standardized line (red) was created connecting the marginal gingiva two most apical points of adjacent teeth, which served as a horizontal reference for the vertical measurements (Figure 3). Three measurements were computed in each STL file to calculate marginal gingiva mucosa and mesial and distal papilla height

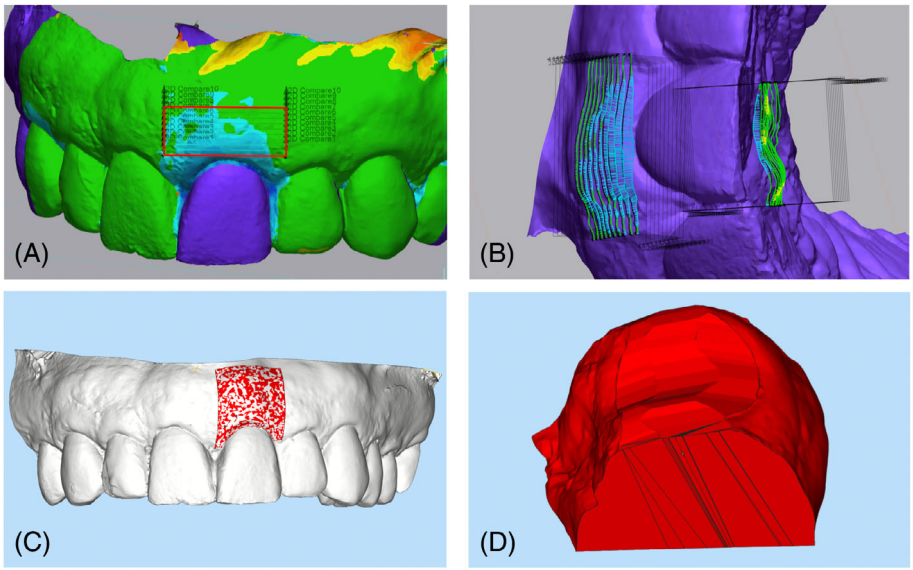

FIGURE 2 Linear and volumetric digital assessment. (A) Linear ROI selection (red); (B) buccal and palatal sections; (C) volumetric ROI assessment (red); (D) initial total volume

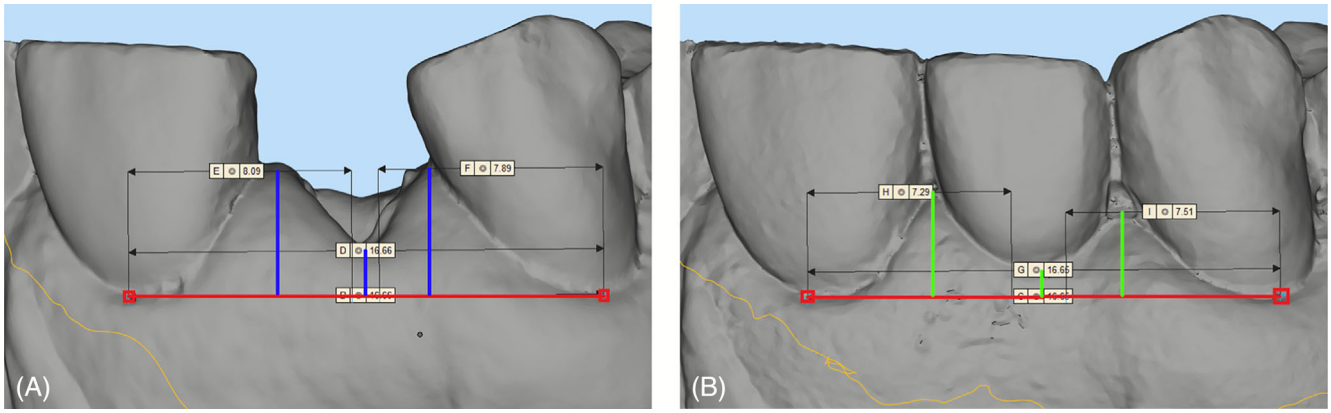

FIGURE 3 Assessment of midfacial mucosa and papillae height at T0 (A) and T3 (B) for height variation calculation

at T0 (Figure 3(A)) and T3 (Figure 3(B)). The mean differences of these measurements allowed to calculate variables representing MGHv (mm) related to the marginal gingiva height variation and MPHv (mm) and DPHv (mm), both associated to mesial and distal papilla height variation, respectively. PHv (mm) variable was established as the mean difference considering both papillae.

2.8 | Radiographic assessment

Radiographic examination was performed with a volumetric dimension of 8 × 8 cm for 14 s with the XG 3-dimensional tomography acquisition protocol, with a voxel size of 0.1 mm in high-definition mode. The obtained CBCT images were imported in a digital imaging and communications in medicine (DICOM) format to a specific software for radiographic assessment (Materialise Mimics, Materialise) in order to calculate buccal bone thickness (BT). All measurements were obtained through coronal slice reconstructions, using an adjacent line to the sinus/nasal plate as a reference as described by Borges and colleagues.[6] BT was measured 1 mm above the coronal bone margin using a central slice, as well at the mesial and distal slices, ranging 1 mm from the central slice. Mean BT values were obtained as the average values of the three slices.

2.9 | Statistical analysis

The statistical analysis was performed using a computer software (SPSS, Statistical Package for the Social Sciences, version 21.0, IBM Corp., Armonk, NY) by an independent statistician who was not involved in the surgical procedure or study design.

Sample size and power calculation were computed taking into consideration a significance value of $\alpha = 0.05$ (type I error) based on the MBC evolution as primary outcome, obtaining a sample size power of 80% for at least 13 patients per group. The sample size computation for the present investigation was performed post factum using the sample size calculator G*Power version 3.1.9.6 (Franz Faul, University of Kiel, Kiel, Germany) taking in consideration the changes

TABLE 1 Patients demographic data and characterization

Subject characterization	Group	*N*	Min	Max	$\overline{X}$	*SD*	*p*-value
Patients	CM	14					
	CA	14					
Gender (male/female)	CM	5♂/9♀ (36/64%)					0.449[a]
	CA	8♂/6♀ (57/43%)					
Age	CM	14	36	76	53.43	12.33	0.810[b]
	CA	14	37	85	54.57	12.51	
Implant site incisive/premolar	CM	4I/10 PM (40/60%)					0.252[a]
	CA	8I/6 PM (57/43%)					
BT (mm)	CM	14	0.10	2.53	0.98	0.73	0.589[b]
	CA	14	0.10	1.95	1.11	0.48	
BID (mm)	CM	14	2	5	2.86	0.86	0.329[c]
	CA	14	2	5	3.21	0.97	
KM (mm)	CM	14	2	6	3.79	1.53	0.427[c]
	CA	14	3	6	4.07	0.73	
BVt (mm^3)	CM	14	177.73	313.16	264.25	41.21	0.596[b]
	CA	14	136.54	457.03	278.42	89.85	
PVt (mm^3)	CM	14	135.19	287.29	223.53	43.60	0.247[b]
	CA	14	142.16	377.61	252.13	79.19	

Abbreviations: BID, buccal implant distance (mm); BT, buccal thickness (mm); BVt, buccal volume total (mm^3); KM, keratinized mucosa (mm); Min, minimum; Max, maximum; PVt, palatal volume total (mm^3); *SD*, standard deviation; $\overline{X}$, mean.

[a]Qui-square with Yates correction.

[b]*T*-test.

[c]Mann–Whitney test.

that were assessed between the initial situation and 1-year post-implant insertion.

The established variables were presented as mean values, standard deviation, minimum, maximum, and 95% confidence interval. Variables related to participant's characterization such as age, gender, implant site (incisive/premolar), BT, BID, KM, BVt, and PVt were evaluated with chi-square test, *t* test, or Mann–Whitney test, to examine possible significant differences between the initial characteristics of the groups. Linear and volumetric variables at the different time points (T1, T2, and T3) were evaluated with *t* test and the Mann–Whitney test was conducted to disclose differences for continuous nonpaired variables. The implant was defined as the statistical unit.

Moreover, a two-way ANOVA analysis was computed to understand the buccal bone thickness effect on study volumetric variables. All hypothesis tests were considered at the 5% level of significance.

3 | RESULTS

3.1 | Patients and implants

Participants characteristics and distribution data are detailed in Table 1. A total of twenty-eight participants with a mean age of 54.00 ± 12.20 years were enrolled in this randomized clinical trial, with 14 individuals allocated to each experimental group. In CM group, 36% of the patients were males and 64% females, whereas CA group had 57% males and 43% females. All participants were healthy and nonsmokers. Nonbiological and technical complications were found in patients or implants within the 1-year follow-up, revealing a 100% success rate. Also, no significant differences were found between groups in patient's initial demographic variable.

3.2 | Digital assessment of linear and volumetric variations

Linear and volumetric peri-implant tissue variations from baseline to 1-year follow-up are shown in Table 2. At T1, MBC of −0.36 ± 0.34 mm at CM group and −0.19 ± 0.29 mm at CA group was assessed, while MTC showed a linear variation of −0.62 ± 0.47 mm at CM group compared with −0.32 ± 0.50 mm at CA group ($p = 0.167$ and $p = 0.152$, respectively). Volumetric analysis revealed a change in $BV_{(\%)}$ of −9.75 ± 6.65% at CM group and −4.76 ± 5.29% at CA group ($p = 0.043$) at T1, and $TV_{(\%)}$ showed values of −8.90 ± 5.03% for CM group, whereas CA group reported a significantly less $TV_{(\%)}$ of −4.17 ± 4.52% ($p = 0.021$) (Figure 4). At T3, CM group revealed less tissue variation than CA group in all evaluated variables, yet no statistical significance was detected. A $BV_{(\%)}$ of −9.76 ± 7.24% at CM group and −10.45 ± 3.99% at CA group were exhibited at T3 ($p = 0.616$).

TABLE 2 Linear and volumetric peri-implant tissue variations from baseline to 1-year follow-up

Variable	Time	Group	*N*	Min, max	$\overline{X}$	*SD*	CI (95%) Lower, upper	*p*-value
MBC (mm)	T0–T1	CM	14	−1.15, 0.20	−0.36	0.34	−0.58, −0.15	0.167
		CA	14	−0.86, 0.19	−0.19	0.29	−0.35, −0.02	
	T0–T2	CM	14	−1.03, 0.13	−0.35	0.36	−0.57, −0.13	0.418
		CA	14	−0.96, 0.06	−0.24	0.27	−0.41, −0.08	
	T0–T3	CM	14	−1.01, −0.04	−0.42	0.31	−0.60, −0.24	0.720
		CA	14	−1.13, −0.10	−0.46	0.31	−0.65, −0.28	
MTC (mm)	T0–T1	CM	14	−1.62, 0.10	−0.62	0.47	−0.93, −0.30	0.152
		CA	14	−1.60, 0.16	−0.32	0.50	−0.61, −0.03	
	T0–T2	CM	14	−1.37, −0.01	−0.50	0.44	−0.77, −0.23	0.880
		CA	14	−1.66, −0.11	−0.47	0.43	−0.73, −0.21	
	T0–T3	CM	14	−1.44, −0.06	−0.56	0.45	−0.82, −0.30	0.346
		CA	14	−1.51, −0.26	−0.71	0.37	−0.94, 0.49	
BVv (mm^3)	T0–T1	CM	14	−5.32, 9.73	−25.20	17.44	−36.28, −14.12	0.049*
		CA	14	−4.55, 7.81	−12.98	14.53	−21.37, −4.60	
	T0–T2	CM	14	−7.07, 7.05	−23.47	20.90	−36.10, −10.84	0.425
		CA	14	−56.86, 3.42	−17.52	16.14	−27.28, −7.77	
	T0–T3	CM	14	−69.26, 7.05	−25.79	19.75	−37.19, −14.38	0.553
		CA	14	−50.78, −7.30	−29.80	14.32	−38.46, −21.15	
BVv (%)	T0–T1	CM	14	−19.16, 3.53	−9.75	6.65	−13.98, −5.53	0.043*
		CA	14	−18.40, 3.05	−4.76	5.29	−7.81, −1.70	
	T0–T2	CM	14	−25.68, 2.56	−8.98	7.56	−13.54, −4.41	0.336
		CA	14	−22.47, 1.34	−6.39	5.65	−9.80, −2.97	
	T0–T3	CM	14	−25.38, 2.56	−9.76	7.24	−13.94, −5.58	0.616
		CA	14	−19.18, −5.35	−10.45	3.99	−12.86, −8.04	
TVv (mm^3)	T0–T1	CM	14	−82.23, −6.09	−44.52	26.06	−62.03, −27.02	0.068
		CA	14	−98.00, 6.03	−23.06	29.01	−39.81, −6.30	
	T0–T2	CM	14	−95.49, −7.38	−37.31	26.79	−53.50, −21.12	0.663
		CA	14	−10.85, −9.44	−34.40	29.97	−52.5, −16.28	
	T0–T3	CM	14	−96.35, −11.80	−37.12	26.05	−52.16, −22.08	0.300
		CA	14	−89.20, 23.27	−46.85	21.25	−59.69, 34.01	
TVv (%)	T0–T1	CM	14	−16.11, 1.19	−8.90	5.03	−12.28, −5.52	0.021*
		CA	14	−15.90, 0.85	−4.17	4.52	−6.78, −1.56	
	T0–T2	CM	14	−20.15, −1.38	−7.65	5.20	−10.80, −4.51	0.597
		CA	14	−17.18, −2.07	−6.63	4.46	−9.33, −3.94	
	T0–T3	CM	14	−20.33, −2.35	−7.57	5.16	−10.55, −4.59	0.141
		CA	14	−13.24, −3.59	−8.75	2.59	−10.31, −7.18	

Abbreviations: BV_V, buccal volume variation (mm^3/%); CI, confidence interval; MBC, mean buccal change (mm); Min, minimum; Max, maximum; MTC, mean total change (mm); $\overline{X}$, mean; *SD*, standard deviation; TV_V, total volume variation (mm^3/%).
*Statistically significant changes at the 5% level.

3.3 | Midfacial mucosa and papillae height variation

Midfacial mucosa and papillae height variation after the 1-year follow-up were computed and outcome data are shown in Table 3. No statistical differences were found in any variable related to midfacial mucosa and papilla height variation. At the final observation follow-up, CM group showed a more coronal position of midfacial mucosa compared to CA group (−0.37 ± 0.55 mm and −0.55 ± 0.64 mm, respectively). On the contrary, both papilla sites had slightly less height variation at CA group participants when compared with the CM group. A height variation of −0.35 ± 0.30 mm at mesial site and

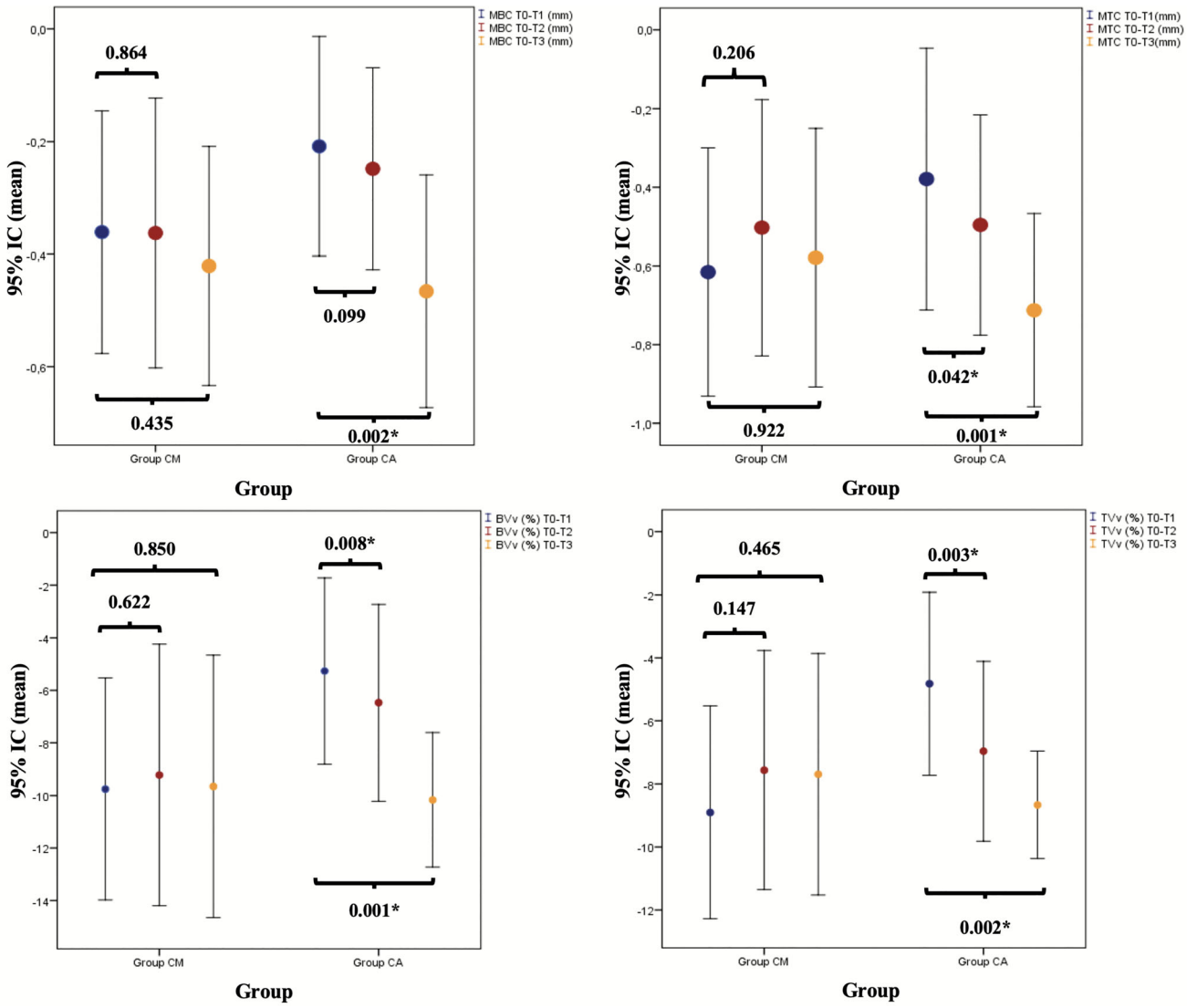

FIGURE 4 Intragroup comparison of linear (MBC and MTC) and volumetric (BVv and TVv) alterations between the different follow-up appointments (T1, T2, and T3). Statistical significance at 5% level (*)

TABLE 3 Midfacial mucosa and papillae height variation after 1-year of treatment

Variable	Time	Group	*N*	Min	Max	$\overline{X}$	*SD*	CI (95%)		*p*-value
								Lower bound	Upper bound	
MFHv (mm)	T3	Group CM	14	−1.64	0.42	−0.37	0.53	−0.68	−0.06	0.806 (0.428)
		Group CA	14	−1.43	0.51	−0.55	0.64	−0.92	−0.19	
MPHv (mm)	T3	Group CM	14	−1.66	0.14	−0.54	0.51	−0.83	−0.25	−1190 (0.245)
		Group CA	14	−0.88	0.12	−0.35	0.30	−0.52	−0.18	
DPHv (mm)	T3	Group CM	14	−1.55	0.18	−0.60	0.55	−0.92	−0.28	−1146 (0.262)
		Group CA	14	−1.45	0.53	−0.38	0.49	−0.66	−0.10	
PHv (mm)	T3	Group CM	14	−1.56	0.09	−0.57	0.39	−0.80	−0.35	−1574 (0.128)
		Group CA	14	−0.96	0.16	−0.37	0.25	−0.53	−0.20	

Abbreviations: DPHv, distal papilla height variation (mm); ET, Wilcoxon signed-rank test; MFHv, midfacial mucosa height variation (mm); MPHv, mesial papilla height variation (mm); TV_V, total volume variation (mm^3/%).

TABLE 4 Buccal bone plate thickness effect on peri-implant tissues volumetric variation in both groups

	Group		BT (≤1 mm)	BT (>1 mm)	ANOVA
BVv T0–T3 (mm^3)	CM	$\overline{X}$	−30.88	−13.05	Group factor: $p = 0.074$ BT factor: $p = 0.001$**
		SD	20.85	9.16	
	CA	$\overline{X}$	−45.73	−19.85	
		SD	3.82	6.98	
BVv T0–T3 (%)	CM	$\overline{X}$	−11.84	−4.57	Group factor: $p = 0.180$ BT factor: $p = 0.005$*
		SD	7.50	2.83	
	CA	$\overline{X}$	−14.11	−8.16	
		SD	3.03	2.54	
TVv T0–T3 (mm^3)	CM	$\overline{X}$	−43.91	−20.16	Group factor: $p = 0.024$* BT factor: $p = 0.001$**
		SD	27.42	12.17	
	CA	$\overline{X}$	−69.36	−32.77	
		SD	13.55	8.97	
TVv T0–T3 (%)	CM	$\overline{X}$	−9.02	−3.94	Group factor: $p = 0.103$ BT factor: $p = 0.015$*
		SD	5.39	1.90	
	CA	$\overline{X}$	−10.63	−7.57	
		SD	1.98	2.26	

Abbreviations: BT, buccal bone thickness; BV_V, buccal volume variation (mm^3/%); ET, statistical test; $\overline{X}$, mean; *SD*, standard deviation; TV_V, total volume variation (mm^3/%).
*Statistically significant changes at the 5% level.
**Statistically significant changes at the 1% level.

−0.38 ± 0.49 mm at the distal site at the CA implants was in contrast with a height variation at the mesial and distal papilla of −0.54 ± 0.51 mm and −0.60 ± 0.55, respectively, at the CM implants. No significance was found between the two groups in terms of papilla variation at mesial or distal sites ($p = 0.128$).

3.4 | Buccal bone features and volumetric variation

A two-way ANOVA analysis was conducted to understand the effect of buccal bone thickness (BT) on peri-implant tissues volumetric alterations, creating two classes of BT (BT ≤ 1 mm and BT > 1 mm) for the comparison evaluation (Table 4). The initial bone phenotype characterization proved to influence the volumetric changes that occur at the implant sites, despite of the treatment modality. At T3, either CA group or CM group showed less volume variation (mm^3 and %) at the buccal and total aspects of the ridge when the treatment was conducted in sites with BT > 1 mm.

4 | DISCUSSION

The present investigation was conducted in order to understand the behavior of peri-implant soft and hard tissues after the use of customized healing abutments and xenogeneic collagen matrices as socket sealing materials after flapless IIP in the maxilla. Immediate implant procedures have been considered as predictable solutions when the replacement of a hopeless tooth is required and when optimal socket conditions are verified after tooth extraction.[1,2,5] The use of collagen matrices for alveolar closure and peri-implant keratinized mucosa increase is well documented in the literature and has been proved as an efficient material and an alternative to a CTG, aiming to reduce patient morbidity, reduce chair time and improve the healing cascade compared with spontaneous healing.[11,12,22] The main purpose of this matrix is to behave as a biological scaffold that potentially enhances reepithelization and accumulate inflammatory cells such as fibroblasts, blood vessels, and epithelium, transforming into keratinized tissue.[22,23] On the other hand, the use of customized healing abutments in IIP is a growing subject but almost limited to description of techniques and case reports in terms of scientific evidence.[15–18,24,25] Recently, an RCT from Perez and colleagues,[26] comparing customized healing abutments and standard healing abutments at IIP sites, showed favorable results in terms of papilla presence and marginal bone loss at the sites treated with customized abutments, when compared with the standard healing abutments sites. In our investigation, all the experimental sites were carefully selected and classified as type 1 extraction sockets. Satisfactory periodontal conditions, including a thick gingival biotype and no soft tissue defects or recessions at the implant site, were also mandatory. All the inserted implants of the present study obtained a 100% success rate after 1-year of treatment.

It is well known that following the insertion of an immediate implant, dimensional alterations at the surrounding soft and hard tissues will still take place, mainly because of the complete resorption of

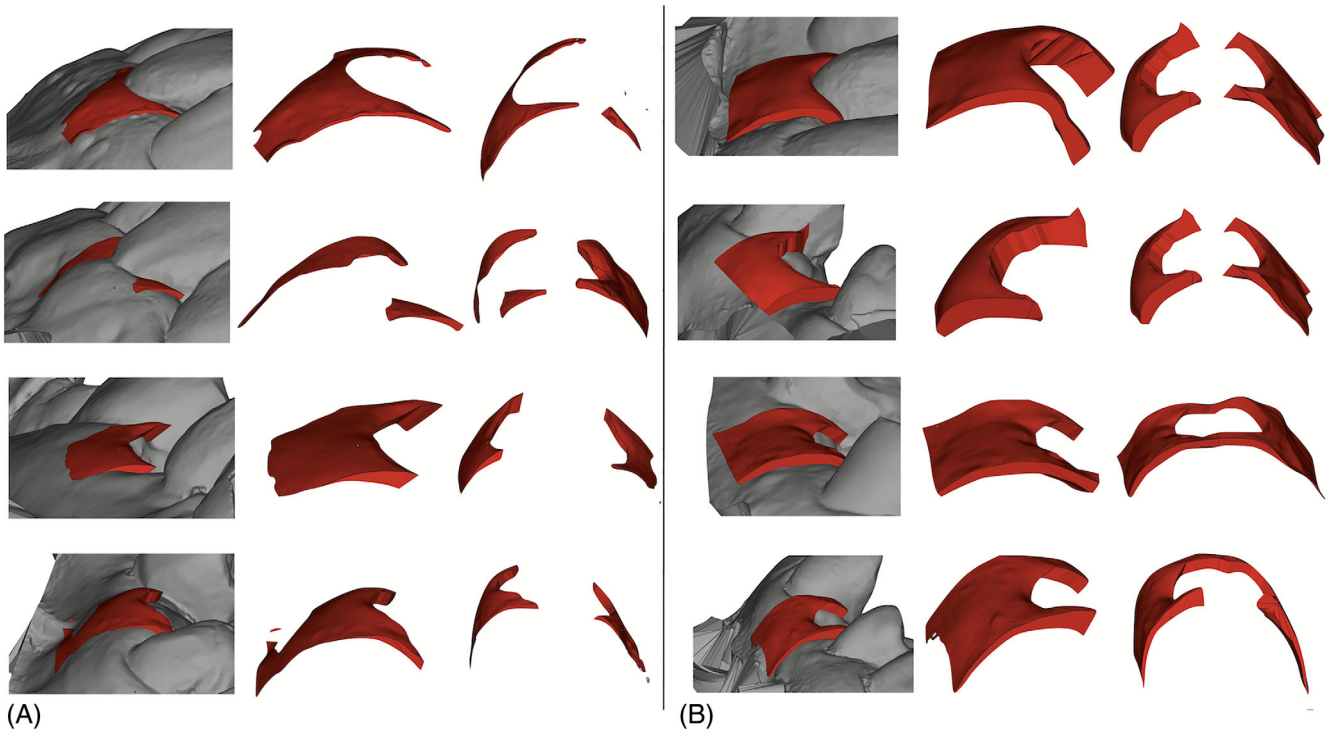

FIGURE 5 Volumetric variation (red) comparison between CA group (A) and CM group (B) at the first follow-up appointment

bundle bone.[27–29] These premises are in accordance with our findings, since we were able to observe a continuous reduction of the linear and volumetric variables at both groups treated with IIP. According to Buser and colleagues,[5] the surgical procedures are critical in achieving good functional and aesthetic outcomes in the type 1 implant insertion. A correct bone housing for the implant insertion and an adequate 3-dimensional orientation of the fixture are considered by the authors as prominent aspects for the treatment success. In our surgical protocol, a flapless approach was performed preventing the traumatic handling of adjacent soft tissue. Several studies consider the flapless approach as less related to the tissue changes that are expected to occur after tooth extraction in IIP.[30,31] In addition, all our patients received a DBBM material in the marginal gap between the inserted implant surface and the socket bone walls, known as capable of reducing the amount of horizontal and vertical bone resorption at the bony ridge after IIP.[8,32]

Over the years, reports on structural peri-implant tissue changes have been presented using clinical assessments,[33] stone model measurements,[34] the implant crown aesthetic index (ICAI),[35] or using aesthetic classifications such as PES index.[26,36] Although these tools are widely employed to assess the peri-implant tissue dimensional changes at different treatment modalities, digital investigations on soft and hard tissues dimensional changes in IIP, assessing the use of techniques such as customized healing abutments, are scarce. We must consider that an examiner-centered analysis has the limitation of the subjective interpretation of the data collected. On the other hand, our study data collection was conducted with the use of an intraoral optical scanner, which is being selected as a capable and precise method to capture 3-dimensional images from soft tissue anatomy and to perform digital analysis.[6,37,38] The analysis protocol used in the present investigation pretends to accomplish an objective evaluation of the dimensional linear and volumetric changes that occur at the two treatment modalities. Previous clinical studies have adopted a similar digital protocol that comprised the establishment of a ROI in each patient to compute standardized volumetric modifications.[6,39,45] Since the selected area was different in all subjects due to anatomical variation, absolute values were transformed in relative percentages, allowing to directly compare volumetric variations.[6] To test the reproducibility of this method, Szathvary and colleagues[40] evaluated the volume variation at peri-implant postextractive sites (test group) and the correspondent contra-lateral tooth (control site) after a 12 months observation period. The authors reported significant differences between the two groups since almost no changes were seen in the control group, assuming that the volume variations presented at the test group were a consequence of physiological events. Borges and colleagues[6] also used a comparable digital methodology and have established the buccal bone plate thickness as the main predictor of the surround tissues dimensional changes that occur after flapless immediate insertion, concluding that when the buccal bone plate is ≤1 mm we can expect an increased tendency for the buccal volume reduction during the first year of treatment. Our findings are in agreement with the ones reported by Borges and colleagues,[6] where the initial buccal bone thickness revealed a significant influence on buccal and total volume variation in each of the groups tested over 1 year of treatment (Table 4). Also, fresh sockets sealed with a collagen matrix exhibited less total volume variation in sites with BT ≤ 1 mm and

BT > 1 mm, compared with the customized abutment group, at the 1-year follow-up ($p = 0.024$), although these results should be interpreted with caution due to the small sample size that was obtained with the division of the two groups in the BT classes.

Considering the CM group, most of the peri-implant tissue changes occurred during the first month of observation compared with the period between the first and the 12th month (Table 2), both in linear and volumetric variation variables and it is noteworthy that 86.3% of the buccal volume variation occurred during the first month of treatment. This observation is in accordance with Sanz and colleagues[22] which found the majority of the tissue contraction within the first month, while studying the role of a collagen matrix and a free connective tissue graft in increasing keratinized tissue around dental implants with soft tissue defects. In CM group, since the major dimensional changes took place in the first month of follow-up, this period may present itself as an acceptable predictor in whether a CTG might be needed or not to compensate peri-implant tissue shrinkage and aesthetic unsatisfactory results. The use of a CTG to compensate for peri-implant tissue contraction has been widely studied, yet its advantages are still controversial.[41,42] A recent systematic review described the CTG as a beneficial treatment in postextractive implants; however, the morbidity associated with an autogenous soft tissue graft must be considered.[43] It is also possible to verify that at the fourth month of treatment part of the previously linear and volumetric variation had recovered, which might be explained by the delivery of provisional restorations.

Traditionally, a reopening surgery is needed after osseointegration of an immediate implant for the placement of the healing abutment. The use of customized healing abutments, when an implant is inserted in a fresh extraction socket, has been described as a beneficial solution that permits to personalize the peri-implant tissues architecture.[15–18,24,25] This study demonstrated that, in the first month of treatment, the use of customized healing abutments is favorable in preventing linear and volumetric peri-implant tissue loss (Figure 5). CA group exhibited approximately half less the volumetric dimensional variation than CM group ($-12.98 \pm 14.53\ mm^3$ and $-25.20 \pm 17.44\ mm^3$; $p = 0.049$, respectively). Some authors revealed that the use of customized healing abutments could maintain peri-implant soft tissue contour, eliminate the need for a reopening surgery, and retain the bone graft particles as a mechanical barrier.[17,26] Additionally, this solution could customize the emergency profile without placing a provisional restoration, which could lead to implant failure if adequate primary stability was not acquired.[18] Despite the results previously mentioned, both groups developed a completely different behavior after that first month healing period (Figure 4). Although not showing any statistical significance, at the final observation, CA group showed slightly more linear and volumetric variation at the facial and total aspect of the ridge compared to CM group, even having higher mean values in BT, BID, and KM, which are essential requisites to improve the outcome of immediate implant insertion treatment.[5]

Regarding peri-implant mucosa variation, no statistical significance was observed between the mean values of each group. While the CM group exhibited less recession in midfacial mucosa, CA group achieved slightly better results in the papilla measurements, both mesial and distal. De Bruyn and colleagues[44] reported that midfacial mucosa and papilla remain relatively stable after IIP and immediate provisionalization over the first 3 years of treatment. Other studies also show that this is an acceptable solution, demonstrating less recession in the midfacial area and both papillae when compared with delayed provisionalization.[45,46] Despite these outcomes, other investigations did not find any aesthetic outcome improvement on immediate over a delayed provisionalization procedure.[47] Nevertheless, it should be taken into account an important difference, since in these studies a provisional crown was delivered and, in our investigation, a customized healing abutment was inserted. In a clinical and histological analysis performed in dogs by Thoma and colleagues,[24] increased midfacial recession was reported in customized abutments compared with standard abutments even when a CTG was performed. Authors speculated that in the standardized abutments group more room could be available for soft tissue growth leading to a more coronal displacement of midfacial mucosa. Although these results cannot be fully compared with the outcomes of our study, we may consider that the greater recession of the facial mucosa, noticed at the CA group, can be related with the absence of space and greater pressure at the facial mucosa caused by the customized abutment placement. Other authors highlight the fact that plaque adhesion might happen at the PMMA material used in this type of treatment, considering that an increased bacterial concentration may jeopardize soft tissue attachment.[48] We can highlight as a limitation of our study the fact that the volumetric analysis was not performed separately between the hard and soft tissues. Through the digital scanning surface evaluation, we cannot conclude in which of the tissues the variation occurs, as stated by Chappuis and colleagues.[49] Interestingly, these authors found that after tooth extraction in thin bone phenotype sites (<1 mm), soft tissue contraction does not follow the bone reduction pattern, revealing a spontaneous increase and compensating hard tissue reduction during the first 8 weeks. On the contrary, in thick bone phenotypes (>1 mm) soft tissue thickness remained fairly stable. Also, we can highlight the fact that the initial gingival phenotype assessment was not used as a confounding variable for the peri-implant tissue variation calculation, limiting our investigation in showing the effect that a thin or thick soft tissue phenotype may had in the alveolar tissue changes over time. Another question that may arise is the fact that pre molars were also included in this investigation. Although we obtained a normal distribution of the BT variable in the two groups, it should be taken into account that pre molars are less technique sensitive in comparison with incisive teeth and traditionally present increased favorable anatomic conditions regarding the bone phenotype. It could consider in future studies to randomly distribute the implant site, so the anatomical characteristics of the different maxillary sites could prove its influence in a specific way.

5 | CONCLUSION

Since no statistical significance was reported on peri-implant tissue dimensional changes between both groups after the first year

following immediate implant insertion, we can consider the two treatment options as predictable solutions for socket sealing in IIP, although any of them was able to avoid tissue volume contraction over time. Also, a higher volumetric variation was seen in thin bone phonotypes, regardless of the treatment modality elected.

ACKNOWLEDGMENT

The authors thank Dr. Celeste Morais, Professor of Statistics, for the support with the statistical analysis.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

AUTHOR CONTRIBUTIONS

Danilo Fernandes: Data collection; data analysis; manuscript writing. **Sílvia Nunes**: Data interpretation; manuscript writing. **Gonzalo López Castro**: Data interpretation; manuscript revision. **Tiago Marques**: Data interpretation; manuscript revision. **Javier Montero**: Revision of statistical analysis; manuscript revision; study coordination. **Tiago Borges**: Clinical treatment of cases; data collection; manuscript writing; study coordination.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ORCID

Danilo Fernandes https://orcid.org/0000-0003-3817-4906
Tiago Marques https://orcid.org/0000-0003-2474-4613
Javier Montero https://orcid.org/0000-0003-3936-6539
Tiago Borges https://orcid.org/0000-0002-3507-9914

REFERENCES

1. Ortega-Martínez J, Pérez-Pascual T, Mareque-Bueno S, Hernández-Alfaro F, Ferrés-Padró E. Immediate implants following tooth extraction. A systematic review. *Med Oral Patol Oral Cir Bucal*. 2012;17(2):e251-e261. https://doi.org/10.4317/medoral.17469
2. Vignoletti F, Sanz M. Immediate implants at fresh extraction sockets: from myth to reality. *Periodontol 2000*. 2014;66(1):132-152. https://doi.org/10.1111/prd.12044
3. Moraschini V, Velloso G, Luz D, Barboza EP. Implant survival rates, marginal bone level changes, and complications in full-mouth rehabilitation with flapless computer-guided surgery: a systematic review and meta-analysis. *Int J Oral and Maxillofac Surg*. 2015;44(7):892-901. https://doi.org/10.1016/j.ijom.2015.02.013
4. Pieralli S, Kohal RJ, Rabel K, von Stein-Lausnitz M, Vach K, Spies BC. Clinical outcomes of partial and full-arch all-ceramic implant-supported fixed dental prostheses. A systematic review and meta-analysis. *Clin Oral Implants Res*. 2018;29(suppl 18):224-236. https://doi.org/10.1111/clr.13345
5. Buser D, Chappuis V, Belser UC, Chen S. Implant placement post extraction in esthetic single tooth sites: When immediate, when early, when late? *Periodontol 2000*. 2017;73(1):84-102. https://doi.org/10.1111/prd.12170
6. Borges T, Fernandes D, Almeida B, et al. Correlation between alveolar bone morphology and volumetric dimensional changes in immediate maxillary implant placement: a 1-year prospective cohort study. *J Periodontol*. 2020;91(9):1167-1176. https://doi.org/10.1002/JPER.19-0606
7. Becker W, Becker BE, Caffesse R. A comparison of demineralized freeze-dried bone and autologous bone to induce bone formation in human extraction sockets. *J Periodontol*. 1994;65(12):1128-1133. https://doi.org/10.1902/jop.1994.65.12.1128
8. Sanz M, Lindhe J, Alcaraz J, Sanz-Sanchez I, Cecchinato D. The effect of placing a bone replacement graft in the gap at immediately placed implants: a randomized clinical trial. *Clin Oral Implants Res*. 2017;28(8):902-910. https://doi.org/10.1111/clr.12896
9. Mastrangelo F, Gastaldi G, Vinci R, et al. Immediate postextractive implants with and without bone graft: 3-year follow-up results from a multicenter controlled randomized trial. *Implant Dent*. 2018;27(6):638-645. https://doi.org/10.1097/ID.0000000000000816
10. Hosseini M, Worsaae N, Gotfredsen K. Tissue changes at implant sites in the anterior maxilla with and without connective tissue grafting: a five-year prospective study. *Clin Oral Implants Res*. 2020;31(1):18-28. https://doi.org/10.1111/clr.13540
11. Jung RE, Philipp A, Annen BM, et al. Radiographic evaluation of different techniques for ridge preservation after tooth extraction: a randomized controlled clinical trial. *J Clin Periodontol*. 2013;40(1):90-98. https://doi.org/10.1111/jcpe.12027
12. Clementini M, Agostinelli A, Castelluzzo W, Cugnata F, Vignoletti F, De Sanctis M. The effect of immediate implant placement on alveolar ridge preservation compared to spontaneous healing after tooth extraction: radiographic results of a randomized controlled clinical trial. *J Clin Periodontol*. 2019;46(7):776-786. https://doi.org/10.1111/jcpe.13125
13. Noelken R, Moergel M, Kunkel M, Wagner W. Immediate and flapless implant insertion and provisionalization using autogenous bone grafts in the esthetic zone: 5-year results. *Clin Oral Implants Res*. 2018;29(3):320-327. https://doi.org/10.1111/clr.13119
14. Slagter KW, den Hartog L, Bakker NA, Vissink A, Meijer HJ, Raghoebar GM. Immediate placement of dental implants in the esthetic zone: a systematic review and pooled analysis. *J Periodontol*. 2014;85(7):e241-e250. https://doi.org/10.1902/jop.2014.130632
15. Joda T, Ferrari M, Braegger U. A digital approach for one-step formation of the supra-implant emergence profile with an individualized CAD/CAM healing abutment. *J Prosthodont Res*. 2016;60(3):220-223. https://doi.org/10.1016/j.jpor.2016.01.005
16. Finelle G, Lee SJ. Guided immediate implant placement with wound closure by computer-aided design/computer-assisted manufacture sealing socket abutment: case report. *Int J Oral Maxillofac Implants*. 2017;32(2):e63-e67. https://doi.org/10.11607/jomi.4770
17. Mihali SG, Freiman PC, Bratu EA. Maintaining tissue architecture in immediate implant placement following extraction of natural teeth using custom healing screw. *Biomed J Sci Tech Res*. 2018;7(5):1-6. https://doi.org/10.26717/BJSTR.2018.07.001554
18. Ruales-Carrera E, Pauletto P, Apaza-Bedoya K, Volpato C, Özcan M, Benfatti C. Peri-implant tissue management after immediate implant placement using a customized healing abutment. *J Esthet Restor Dent*. 2019;31(6):533-541. https://doi.org/10.1111/jerd.12512
19. Menchini-Fabris GB, Crespi R, Toti P, Crespi G, Rubino L, Covani U. A 3-year retrospective study of fresh socket implants: CAD/CAM customized healing abutment vs cover screws. *Int J Comput Dent*. 2020;23(2):109-117.
20. Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:c332. https://doi.org/10.1136/bmj.c332
21. Buser D, Martin W, Belser UC. Optimizing esthetics for implant restorations in the anterior maxilla: anatomic and surgical considerations. *Int J Oral Maxillofac Implants*. 2004;19:43-61.
22. Sanz M, Lorenzo R, Aranda JJ, Martin C, Orsini M. Clinical evaluation of a new collagen matrix (Mucograft prototype) to enhance the width of keratinized tissue in patients with fixed prosthetic restorations: a

randomized prospective clinical trial. *J Clin Periodontol*. 2009;36(10):868-876. https://doi.org/10.1111/j.1600-051X.2009.01460.x
23. Thoma DS, Sancho-Puchades M, Ettlin DA, Hämmerle CH, Jung RE. Impact of a collagen matrix on early healing, aesthetics and patient morbidity in oral mucosal wounds—a randomized study in humans. *J Clin Periodontal*. 2012;39(2):157-165. https://doi.org/10.1111/j.1600-051X.2011.01823.x
24. Thoma DS, Jung UW, Gil A, et al. The effects of hard and soft tissue grafting and individualization of healing abutments at immediate implants: an experimental study in dogs. *J Periodontal Implant Sci*. 2019;49(3):171-184. https://doi.org/10.5051/jpis.2019.49.3.171
25. Finelle G, Sanz-Martín I, Knafo B, Figué M, Popelut A. Digitalized CAD/CAM protocol for the fabrication of customized sealing socket healing abutments in immediate implants in molar sites. *Int J Comput Dent*. 2019;22(2):187-204.
26. Perez A, Caiazzo A, Valente NA, Toti P, Alfonsi F, Barone A. Standard vs customized healing abutments with simultaneous bone grafting for tissue changes around immediate implants. 1-year outcomes from a randomized clinical trial. *Clin Implant Dent Relat Res*. 2020;22(1):42-53. https://doi.org/10.1111/cid.12871
27. Botticelli D, Berglundh T, Lindhe J. Hard-tissue alterations following immediate implant placement in extraction sites. *J Clin Periodontol*. 2004;31(10):820-828. https://doi.org/10.1111/j.1600-051X.2004.00565.x
28. Araújo MG, Sukekava F, Wennström J, Lindhe J. Tissue modeling following implant placement in fresh extraction sockets. *Clin Oral Implants Res*. 2006;17(6):615-624. https://doi.org/10.1111/j.1600-0501.2006.01317.x
29. Chappuis V, Engel O, Reyes M, Shahim K, Nolte LP, Buser D. Ridge alterations post-extraction in the esthetic zone: a 3D analysis with CBCT. *J Dent Res*. 2013;92(12):195S-201S. https://doi.org/10.1177/0022034513506713
30. Tarnow DP, Chu SJ, Salama MA, et al. Flapless postextraction socket implant placement in the esthetic zone: part 1. The effect of bone grafting and/or provisional restoration on facial-palatal ridge dimensional change-a retrospective cohort study. *Int J Periodontics Restorative Dent*. 2014;34(3):323-331. https://doi.org/10.11607/prd.1821
31. Mazzocco F, Jimenez D, Barallat L, Paniz G, Del Fabbro M, Nart J. Bone volume changes after immediate implant placement with or without flap elevation. *Clin Oral Implants Res*. 2017;28(4):495-501. https://doi.org/10.1111/clr.12826
32. Cardaropoli D, Gaveglio L, Gherlone E, Cardaropoli G. Soft tissue contour changes at immediate implants: a randomized controlled clinical study. *Int J Periodontics Restorative Dent*. 2014;34(5):631-637. https://doi.org/10.11607/prd.1845
33. Grunder U. Crestal ridge width changes when placing implants at the time of tooth extraction with and without soft tissue augmentation after a healing period of 6 months: report of 24 consecutive cases. *Int J Periodontics Restorative Dent*. 2011;31(1):9-17.
34. Lekovic V, Kenney EB, Weinlaender M, et al. A bone regenerative approach to alveolar ridge maintenance following tooth extraction. Report of 10 cases. *J Periodontol*. 1997;68(6):563-570. https://doi.org/10.1902/jop.1997.68.6.563
35. Meijer HJ, Stellingsma K, Meijndert L, Raghoebar GM. A new index for rating aesthetics of implant-supported single crowns and adjacent soft tissues—the implant crown aesthetic index. *Clin Oral Implants Res*. 2005;16(6):645-649. https://doi.org/10.1111/j.1600-0501.2005.01128.x
36. Arora H, Ivanovski S. Correlation between pre-operative buccal bone thickness and soft tissue changes around immediately placed and restored implants in the maxillary anterior region: a 2-year prospective study. *Clin Oral Implants Res*. 2017;28(10):1188-1194. https://doi.org/10.1111/clr.12939
37. Windisch SI, Jung RE, Sailer I, Studer SP, Ender A, Hämmerle CH. A new optical method to evaluate three-dimensional volume changes of alveolar contours: a methodological in vitro study. *Clin Oral Implants Res*. 2007;18(5):545-551. https://doi.org/10.1111/j.1600-0501.2007.01382.x
38. Tian J, Wei D, Zhao Y, Di P, Jiang X, Lin Y. Labial soft tissue contour dynamics following immediate implants and immediate provisionalization of single maxillary incisors: a 1-year prospective study. *Clin Implant Dent Relat Res*. 2019;21(3):492-502. https://doi.org/10.1111/cid.12786
39. Bienz SP, Sailer I, Sanz-Martín I, Jung RE, Hämmerle CH, Thoma DS. Volumetric changes at pontic sites with or without soft tissue grafting: a controlled clinical study with a 10-year follow-up. *J Clinical Periodontol*. 2017;44(2):178-184. https://doi.org/10.1111/jcpe.12651
40. Szathvary I, Caneva M, Bressen E, Botticelli D, Meneghello R. A volumetric 3-D digital analysis of dimensional changes to the alveolar process at implants placed immediately into extraction sockets. *J Oral Sci Rehab*. 2015;1:62-69.
41. van Nimwegen WG, Raghoebar GM, Zuiderveld EG, Jung RE, Meijer H, Mühlemann S. Immediate placement and provisionalization of implants in the aesthetic zone with or without a connective tissue graft: a 1-year randomized controlled trial and volumetric study. *Clin Oral Implants Res*. 2018;29(7):671-678. https://doi.org/10.1111/clr.13258
42. Papapetros D, Vassilis K, Antonis K, Danae AA. Interim tissue changes following connective tissue grafting and two-stage implant placement. A randomized clinical trial. *J Clin Periodontol*. 2019;46(9):958-968. https://doi.org/10.1111/jcpe.13159
43. Atieh MA, Alsabeeha N. Soft tissue changes after connective tissue grafts around immediately placed and restored dental implants in the esthetic zone: a systematic review and meta-analysis. *J Esthet Restor Dent*. 2020;32(3):280-290. https://doi.org/10.1111/jerd.12538
44. De Bruyn H, Raes F, Cooper LF, et al. Three-years clinical outcome of immediate provisionalization of single Osseospeed(™) implants in extraction sockets and healed ridges. *Clin Oral Implants Res*. 2013;24(2):217-223. https://doi.org/10.1111/j.1600-0501.2012.02449.x
45. Cosyn J, Hooghe N, De Bruyn H. A systematic review on the frequency of advanced recession following single immediate implant treatment. *J Clin Periodontol*. 2012;39(6):582-589. https://doi.org/10.1111/j.1600-051X.2012.01888.x
46. Kinaia BM, Ambrosio F, Lamble M, Hope K, Shah M, Neely AL. Soft tissue changes around immediately placed implants: a systematic review and meta-analyses with at least 12 months of follow-up after functional loading. *J Periodontol*. 2017;88(9):876-886. https://doi.org/10.1902/jop.2017.160698
47. Chan HL, George F, Wang IC, Suárez López Del Amo F, Kinney J, Wang HL. A randomized controlled trial to compare aesthetic outcomes of immediately placed implants with and without immediate provisionalization. *J Clin Periodontol*. 2019;46(10):1061-1069. https://doi.org/10.1111/jcpe.13171
48. Hahnel S, Rosentritt M, Bürgers R, Handel G. Adhesion of *Streptococcus mutans* NCTC 10449 to artificial teeth: an in vitro study. *J Prosthet Dent*. 2008;100(4):309-315. https://doi.org/10.1016/S0022-3913(08)60212-7
49. Chappuis V, Engel O, Shahim K, Reyes M, Katsaros C, Buser D. Soft tissue alterations in esthetic postextraction sites: a 3-dimensional analysis. *J Dent Res*. 2015;94(9):187S-193S. https://doi.org/10.1177/0022034515592869

How to cite this article: Fernandes D, Nunes S, López-Castro G, Marques T, Montero J, Borges T. Effect of customized healing abutments on the peri-implant linear and volumetric tissue changes at maxillary immediate implant sites: A 1-year prospective randomized clinical trial. *Clin Implant Dent Relat Res*. 2021;23(5):745-757. doi:10.1111/cid.13044