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Original research

Management of jump space in immediate implants with and without demineralised freeze dried bone allograft: a randomised controlled trial

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Purpose
The present study aimed to evaluate and compare the management of Jump space (JS) in immediate implants with and without Demineralised freeze-dried bone allograft (DFDBA) with flapless approach.

Materials and Methods
The present study included 40 sites with immediate implant placement in the maxillary anterior region. Group 1 patients were treated without augmentation while Group 2 patients with DFDBA in the JS. Both the groups were further subdivided according to the horizontal dimensions as JS less (G1S1, G2S1) or more than 2mm (G1S2, G2S2). Plaque index (PI), Gingival Index (GI), Probing depth (PD), Testori esthetic score (TS), VAS score, Crestal Bone height (CBH), Ridge width (RW), Vertical distance (VD) and radiolucent area (RA) were evaluated radiographically with CBCT at baseline and 12 months' post therapy.

Results
Significant differences were observed in CBH in the midfacial region in G1S1-G2S1 with the mean of 0.34±0.19mm and G1S2 –G2S2 with 0.75±0.26 mm at 12 months. Significant differences in TS were observed in G1S1 and G2S1 with mean value of 0.55±0.53 while G1S2 and G2S2 exhibited value of 1.33±0.82.

Conclusion
DFDBA shows better CBH preservation in midfacial region, reduction in RA indicating greater resolution of JS thereby leading to better hard and soft tissue healing.

Keywords: *Immediate implants, jumping gap, peri implant tissues, bone graft, tissue healing*

Introduction

The advent of immediate flapless dental implants marked a significant stride in the realm of minimally invasive implantology, revolutionizing treatment protocols by streamlining procedures and maximizing patient comfort, all while boasting an impressive success rate (1). Within this innovative approach lies a pivotal challenge: effectively managing the space, known as the jump space (JS), between the implant periphery and the surrounding bone, particularly when implants are inserted into fresh extraction sockets (2). Navigating the intricacies of the JS and achieving primary socket closure present ongoing hurdles for implantologists, demanding meticulous attention, especially in the aesthetic zone where the buccal bony plate tends to be thin. The potential for soft tissue recession due to buccal bone resorption underscores the critical importance of surgical interventions to optimize outcome. However, the landscape of tech-

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niques for managing the buccal space remains marked by controversy and confusion. The quest for an ideal approach encompasses three key objectives: facilitating optimal bone fill within the space, attaining the most coronal level of bone-to-implant contact (BIC) and mitigating buccal bone resorption and soft-tissue recession to the greatest extent possible.

Various techniques and materials have been developed to reliably facilitate tissue regeneration in implant dentistry, aiming to achieve optimal peri-implant hard and soft tissue quantity and quality. Among these advancements, human decalcified freeze-dried bone allografts (DFDBA) provides a vital solution serving in periodontal regeneration and alveolar ridge maintenance ensuring adequate bone volume for endosseous implant placement (3). DFDBA operates as a multifaceted material, functioning to maintain space, promote bone growth and harnessing the potential of bone morphogenetic proteins to induce new bone formation (4).

The space between socket walls and the implant surface presents a crucial consideration, often necessitating augmentation to reliably achieve bone-to-implant contact (BIC) and mitigate the risk of soft tissue collapse (5). Nonetheless, conflicting viewpoints within the literature have stirred controversy on this matter. While certain studies have reported successful horizontal space regeneration, even in cases where the space is smaller than 2 mm and a stable blood clot is present (6,7), recent investigations have revealed a contrasting trend. These newer findings suggest that spaces exceeding 2 mm tend to exhibit superior fill rates, even in the absence of additional grafting material (8).

Numerous biomaterials have been tried with varying results to fill the JS between the implant body and the buccal cortex (9). However, there remains a notable paucity in the literature concerning the efficacy of using DFDBA specifically for filling the vertical distance and JS around immediate implants placed using a flapless approach, as well as its impact on soft tissue dimensions. Consequently, the present study was devised to examine the influence of DFDBA in immediate implants with JS measuring 2 mm or more on both hard and soft tissue dimensions. The null hypothesis was that there is no significant difference in the hard and soft tissue dimensions with the use of DFDBA in immediate implants with JS measuring 2mm or more.

Materials and Methods

Ethical approval

The study was carried out between February 2021 and March 2022. Approval for this clinical trial was obtained from the Institutional Ethics Committee of our institute, aligning with the updated principles of the Helsinki Declaration for biomedical research. The Institutional Ethics Committee (IEC) provided approval under the registration number IEC/VSPMDCRC/06/2019. Furthermore, the trial was registered with the Clinical Trials Registry of India under registration number CTRI/2021/01/030620 and adhered to the CONSORT statement and EQUATOR guidelines for reporting.

Sample size determination

The sample size was determined based on the findings of a study by Paknejad M. *et al*. (9), wherein the authors examined the impact of flapless implant placement combined with graft material on the height of buccal bone. A power analysis indicated an effect size of 1.25. To achieve this effect with 95% confidence and 80% power, the estimated number of sites per group was determined to be 12 (total: 24). Anticipating potential attrition, 20 sites per group were enrolled in the study.

Study design and patient selection

This study was designed as a parallel-group, randomized clinical trial with four arms, each with an equal allocation ratio 1:1:1:1. Patients indicated for immediate implant therapy in the maxillary anterior region up to premolars i.e from teeth number 15 to 25 (according FDI tooth numbering system) on either sides were recruited from the Department of Periodontics and Implantology of our institute. Prior to their participation, written informed consent was obtained from all study participants.

The inclusion criteria for the trial were as follows: participants were required to be systemically healthy with stable soft tissue morphology, demonstrate cooperation and a commitment to oral hygiene, present with root stumps or non-restorable teeth, fractured teeth, and possess approximately 4mm or more of apical bone to ensure primary stability. Additionally, sites were included if a minimum torque of 35N cm was achieved during implant insertion. Patients were excluded from the study if they exhibited general contraindications to implant surgical procedures, had a history of radiotherapy and/or chemotherapy, were undergoing or had previously undergone treatment with intravenous amino-bisphosphonates, were smokers or exhibited poor oral hygiene, or displayed para-functional habits.

Suitable sites in patients requiring dental implants and meeting the inclusion criteria were randomly assigned using computer-generated random tables and the simple randomization method. Allocation concealment was ensured through the use of sequentially numbered, opaque, sealed envelopes (SNOSE) technique. Each envelope contained a piece of paper indicating the assigned randomization group, and these envelopes were labelled with serial numbers to maintain anonymity and prevent bias. Once the patient provided consent to participate in the study, the investigator opened the sealed envelope and assigned the treatment group accordingly. This clinical trial employed a double-blinded approach, wherein both the patients and the assessor were blinded to treatment allocation. Selection bias was mitigated through randomization, ensuring equal distribution of participants across treatment groups. Performance bias was minimized as all patients received treatment from the same operator. To further control for potential confounding variables, patients were matched for demographics such as age and gender, as well as for relevant risk factors. Additionally, the reliability of the data collected was assessed through a test-retest method, enhancing the robustness and accuracy of the findings.

Based on the specified criteria, the study population was divided into two groups:

Group 1: Immediate implants without DFDBA in the JS (n=20 sites)

- Group 1 Subgroup 1 (G1S1): JS less than 2mm.
- Group 1 Subgroup 2 (G1S2): JS more than 2mm.
- Group 2: Immediate implants with DFDBA in the JS (n=20 sites)
- Group 2 Subgroup 1 (G2S1)-JS less than 2mm.
- Group 2 Subgroup 2 (G2S2)-JS more than 2mm.

Pre-surgical therapy

Before undergoing surgery, all patients received thorough pre-surgical hygiene therapy. This included a comprehensive case history review, a detailed intraoral examination, personalized oral hygiene instructions, and professional scaling and root planning.

Evaluation of Clinical and Radiographic Parameters

The clinical data for all patients was meticulously recorded by a single examiner (MP), who underwent pre-calibration for precise measurements. Moreover, the assessor remained blinded to the treatment group information. All parameters were documented at two separate time points, and the intra-observer reliability of the measurements was assessed using the intra-class correlation coefficient. Plaque index (PI) (10), Gingival Index (GI) (11) was assessed at baseline and post operatively at 6 and 12 months. Probing depth (PD), Soft tissue assessment using Testori esthetic score (TS) (12) and VAS scale was used for post–operative pain evaluation. Following radiographic parameters were evaluated using CBCT at baseline and 12 months' post therapy. (Figure 1) Scans were performed with standardized scanning parameters at 85 kV, 7 mA, and 3.6 s of exposure time using a field of view of 5 cm × 5 cm and a resolution of 150 µ. Interactive CBCT Processing software (3Diagnosys 4.2) was used to obtain reformatted coronal, sagittal, cross-sectional, and panoramic views.

1. Crestal bone height (CBH) was assessed at mesial, midfacial and distal aspects as the distance between tooth CEJ/implant shoulder to the most coronal point of interproximal crestal bone using CBCT.
2. Ridge width (RW) was measured at 2mm and 4mm from the alveolar crest.
3. Radiolucent area (RA) was measured as area between shoulder of implant and bone crest.
4. Vertical distance (VD) was measured as the distance between the first BIC to the first thread of the implant on the mesial (VDM) and distal (VDD) sides.
5. JS was measured on buccal, palatal, mesial and distal aspects as the distance between inner aspect of the alveolar bone to the outer surface of the implant.

Patients were taken up for the surgical intervention by a single experienced clinician (AK) and atraumatic extraction was done followed by implant placement without raising the flap. The JS when more than 2mm was filled with DFDBA in the Group 2 and was left un-grafted in the Group 1 (Figure 2). Post-operative instructions, antibiotics and anti-inflammatory drugs were given to the patients and regular follow up appointments were scheduled.

Statistical analysis

The data collected from all groups was analysed using Statistical Package for Social Sciences (SPSS) for Windows software, version 26.0. (IBM SPSS Inc., Armonk, NY, USA). The standard descriptive methods such as the mean, standard deviation, median, frequency, were applied to determine the characteristics of the sample. The demographic characteristics like age and sex were summarized according to scale of measurement. The comparison of mean age between treatment groups was performed using t-test for independent samples, while sex distribution was compared using chi-square test. The parameters PI, GI, PD, RW, GT, VD, CBH and JS were summarized in terms of mean and standard deviation. The VAS score was compared using Mann-Whitney U test. The confidence interval was set to 95% and $p < 0.05$ was considered statistically significant.

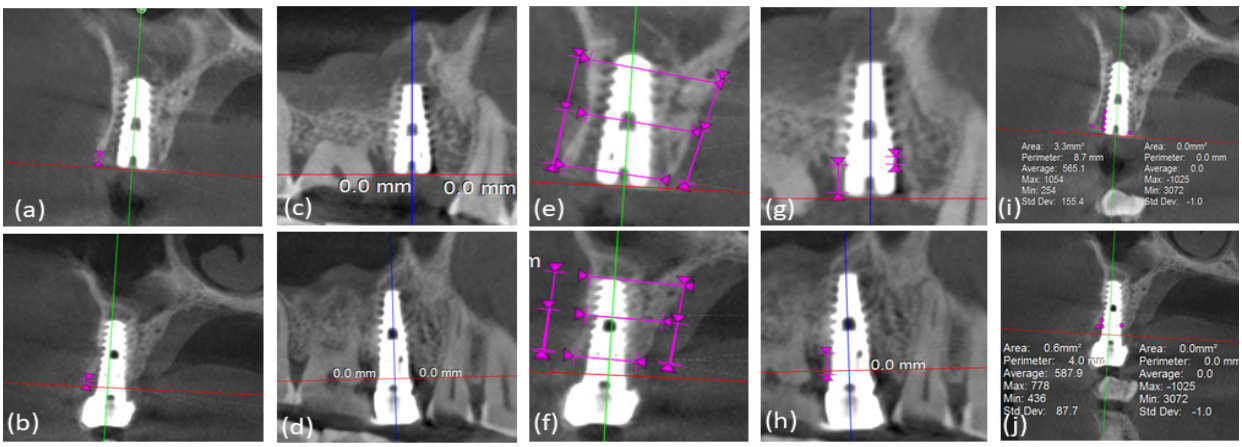

Figure 1. *(a): Measurement of Crestal bone height (CBH) baseline midcrestal, (b) Measurement of Crestal bone height (CBH) 12 months follow up midcrestal (c) Measurement of Crestal bone height (CBH) baseline mesial and distal, (d) Measurement of Crestal bone height (CBH) 12 months mesial and distal (e) Measurement of the Ridge Width (RW) baseline (f) Measurement of the Ridge Width (RW) 12 months follow up (g) Measurement of the vertical distance (VD) baseline, (h)Measurement of the vertical distance (VD) 12 months follow up, (i)Measurement of the Radiolucent area (RA) baseline, (j)Measurement of the Radiolucent area (RA) 12 months follow up.*

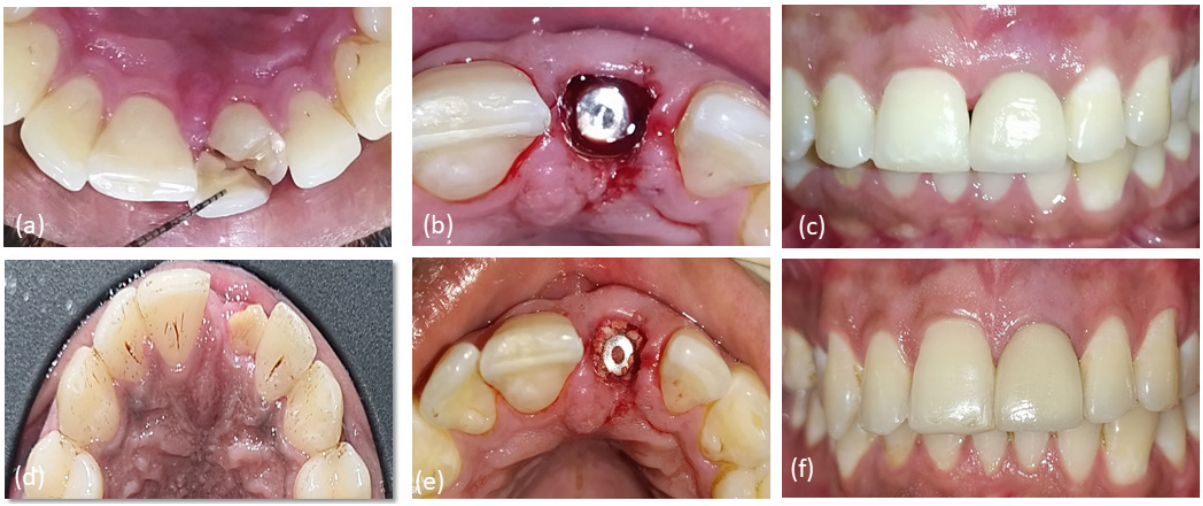

Figure 2. *(a): Pre-operative Group 1, (b): Non grafted Jump Space in Group 1 (c): Follow up of Group 1 after 12 months (d): Pre-operative Group 2, (e): DFDBA graft in Jump Space in Group 2, (f): Follow up of Group 2 after 12 months.*

Results

Table 1 presents the demographic characteristics of the patients, revealing a mean age of 44 ± 12.22 years in Group 1 and 42.33 ± 11.6 years in Group 2. In Table 2, a comparison of CBH at baseline and 12 months is provided for the G1S1, G1S2, G2S1, and G2S2. The comparison encompassed the mesial, midfacial, and distal sides at both time points. Interestingly, a statistically significant difference ($p < 0.0001$) was observed only in the midfacial region at the 12-month mark between the subgroups G1S1-G2S1 and G1S2-G2S2.

Table 3 provides the comparison for RW at baseline and 12 months in G1S1, G1S2, G2S1 and G2S2 categories. The difference of means at 2mm and 4mm from crest, showed statistically insignificant differences between the subgroups G1S1-G2S1 and G1S2 –G2S2 at baseline and 12 months. Table 4 gives the comparison of RA at baseline and 12 months in G1S1, G1S2, G2S1 and G2S2 categories. The difference of means between the two treatment groups was statistically significant on buccal aspect at 12 months with ($p<0.004$) in case G1S1 and G2S1. While on palatal and distal aspect it was found to be statistically insignificant. However, in case of G1S2 and G2S2 the mean differences were found to be statistically significant on buccal and mesial aspect with ($p<0.0001$).

Table 1*. Demographic characteristics of patients in study groups.*

	Parameter	With DFDBA	Without DFDBA	P-value
Age in years	N	20	20	0.704
	Mean	42.33	44	
	SD	11.6	12.22	
	Median	42	42	
	Minimum	28	28	
	Maximum	65	65	
Sex	Male (No. (%))	16(80%)	11 (53.3%)	0.245
	Female (No. (%))	4 (20%)	9 (46.7%)	

Table 5 gives the comparison of VD at baseline and 12 months in G1S1, G1S2, G2S1 and G2S2 categories. The paired differences were statistically insignificant all the groups on mesial aspect; except for the distal aspect of G1S1 and G2S1 which was found to be highly significant ($p<0.0001$).

Table 6 depicts comparison of Jumping Space (JS) in both the treatment groups at baseline and 12 months. On comparison of JS in G1S1 a significant difference was observed at the buccal ($p =0.002$) and mesial site ($p=0.007$) while in G1S2 significant difference was observed on buccal site ($p=0.004$). In G2S1 significant differences were observed after 12 months on buccal ($p<0.0001$) mesial ($p=0.001$) and distal ($p=0.003$) site whereas in G2S2 significant differences were observed on all sites buccal ($p<0.0001$), palatal ($p=0.029$), mesial ($p=0.037$), distal ($p =0.014$) with time. Table 7 shows the comparison of Testori Score (TS) in both the

Table 2*. Comparative statistics for crestal bone height (CBH) at baseline and 12 months.*

Groups	Site	Time period	Mean ± Standard deviation (in mm)	Significance (p value)
G1S1-G2S1 (JS<2mm)	Mesial	Baseline	0.20 ±0.40	0.15
		12 months	0.04±0.13	0.33
	Midfacial	Baseline	-	-
		12 months	0.34±0.19	**<0.0001***
	Distal	Baseline	-	-
		12 months	0.05±0.37	0.64
G1S2-G2S2 (JS>2mm)	Mesial	Baseline	-	-
		12 months	0.10±0.24	0.34
	Midfacial	Baseline	-	-
		12 months	0.75±0.26	**<0.0001***
	Distal	Baseline	-	-
		12 months	0.38±0.45	0.06

CBH: Crestal bone height; G1S1: Group 1subgroup 1, G1S2: Group 1subgroup 2; G2S1: Group 2 subgroup1, G2S2: Group 2 subgroup 2; JS: Jumping Space; P value is significant if <0.05; p- Probability.

***Table 3**. Comparative statistics for ridge width (RW) at baseline and 12 months.*

Groups	Level from the crest	Time period	Mean ± Standard deviation (in mm)	Significance (p value)
G1S1-G2S1 (JS<2mm)	2 mm	Baseline	0.01±0.50	0.957
		12 months	0.47±0.33	0.068
	4 mm	Baseline	0.07±0.52	0.748
		12 months	0.50±0.40	0.052
G1S2-G2S2 (JS>2mm)	2 mm	Baseline	0.55±1.04	0.191
		12 months	0.63±1.15	0.153
	4 mm	Baseline	0.30±0.99	0.441
		12 months	0.36±1.03	0.382

G1S1: Group 1subgroup 1, G1S2: Group 1subgroup 2; G2S1: Group 2 subgroup1, G2S2: Group 2 subgroup 2; JS: Jumping Space; P value is significant if <0.05; P-probability

***Table 4.** Comparative statistics for radiolucent area (RA) at baseline and 12 months.*

Groups	Side	Time period	Mean ± Standard deviation (in mm)	Significance (p-value)
G1S1-G2S1 (JS<2mm)	Buccal	Baseline	0.12 ± 0.20	0.42
		12 months	0.27 ± 0.25	**0.004***
	Palatal	Baseline	0.75 ± 1.24	0.09
		12 months	-	-
	Mesial	Baseline	0.37 ± 1.61	0.49
		12 months	0.04 ± 0.69	0.86
	Distal	Baseline	1.73 ± 3.24	0.10
		12 months	0.06 ± 0.98	0.82
G1S2-G2S2 (JS>2mm)	Buccal	Baseline	2.13 ± 0.25	**<0.0001***
		12 months	0.87 ± 0.41	**<0.0001***
	Palatal	Baseline	1.54 ± 2.28	**0.007***
		12 months	-	-
	Mesial	Baseline	1.05 ± 2.72	0.18
		12 months	0.92 ± 0.93	**0.010***
	Distal	Baseline	2.37 ± 2.29	**0.001***
		12 months	0.30 ± 1.52	0.68

G1S1: Group 1subgroup 1, G1S2: Group 1subgroup 2; G2S1: Group 2 subgroup1, G2S2: Group 2 subgroup 2; JS: Jumping Space; P value is significant if <0.05; P-probability

treatment groups at all the time points. Significant differences (p=0.001) were found after 12 months when G1S1-G2S1 and G1S2 –G2S2 were compared.

Discussion

Various biomaterials have been suggested in existing literature for effectively filling the JS (9,13,14). However, there's a notable concern regarding residual particles potentially

***Table 5**. Comparative statistics for vertical distance (VD) at baseline and 12 months.*

Groups	Side	Time period	Mean ± Standard deviation (in mm)	Significance (p)
G1S1-G2S1 (JS<2mm)	Mesial	Baseline	1.50±2.33	0.05
		12 months	0.45±0.90	0.17
	Distal	Baseline	3.12±2.01	**<0.0001***
		12 months	0.36±2.02	0.55
G1S2-G2S2 (JS>2mm)	Mesial	Baseline	0.18±3.12	0.88
		12 months	1.37±2.41	0.18
	Distal	Baseline	0.87±3.34	0.48
		12 months	0.57±0.85	0.17

G1S1: Group 1subgroup 1, G1S2: Group 1subgroup 2; G2S1: Group 2 subgroup1, G2S2: Group 2 subgroup 2; JS: Jumping Space; P value is significant if <0.05; P-probability

***Table 6.** Comparison of Jumping Space (JS) in both the treatment groups at baseline and 12 months.*

Groups	Side	Time period	Mean ± Standard deviation (in mm)	Significance (p value)
Group 1 (JS<2mm)	Buccal	Baseline-12 months	0.43 ±0.28	**0.002***
	Palatal/ Lingual	Baseline-12 months	0.94±2.94	0.36
	Mesial	Baseline-12 months	0.42±0.35	**0.007***
	Distal	Baseline-12 months	0.14±0.33	0.23
Group 1 (JS>2mm)	Buccal	Baseline-12 months	1.73±0.85	**0.004***
	Palatal/ Lingual	Baseline-12 months	0.52±0.80	0.17
	Mesial	Baseline-12 months	0.08±0.68	0.77
	Distal	Baseline-12 months	0.30±0.39	0.12
Group 2 (JS<2mm)	Buccal	Baseline-12 months	0.71±0.35	**<0.0001***
	Palatal/ Lingual	Baseline-12 months	0.42±0.55	0.053
	Mesial	Baseline-12 months	0.52±0.30	**0.001***
	Distal	Baseline-12 months	0.73±0.53	**0.003***
Group 2 (JS>2mm)	Buccal	Baseline-12 months	2.41±0.29	**<0.0001***
	Palatal/ Lingual	Baseline-12 months	1.01±0.83	**0.029***
	Mesial	Baseline-12 months	1.13±0.98	**0.037***
	Distal	Baseline-12 months	0.8±0.58	**0.014***

G1S1: Group 1subgroup 1, G1S2: Group 1subgroup 2; G2S1: Group 2 subgroup1, G2S2: Group 2 subgroup 2; JS: Jumping Space; P value is significant if <0.05; P-probability

Table 7. *Comparison of Testori Score (TS) in both the treatment groups at all the time points.*

Groups	Time period	Mean ± Standard deviation (in mm)	Significance (p-value)
G1S1-G2S1 (JS<2mm)	Baseline	1.11±0.93	**<0.0001***
	6 months	0.44±0.73	0.10
	12 months	0.55±0.53	**0.01***
G1S2-G2S2 (JS>2mm)	Baseline	0.67±0.82	0.17
	6 months	0.17±0.75	0.55
	12 months	1.33±0.82	**0.001***

G1S1: Group 1subgroup 1, G1S2: Group 1subgroup 2; G2S1: Group 2 subgroup1, G2S2: Group 2 subgroup 2; JS: Jumping Space; P value is significant if <0.05; P-probability

impeding efficient BIC and the ability to fill both the vertical distance and the radiolucent area. DFDBA bone graft was preferred to be used in the present study because it contains bone morphogenetic protein (BMP), which induces new bone formation during healing process. DFDBA offers several advantages over other biomaterials used in bone grafting procedures: DFDBA contains growth factors and proteins that stimulate the recruitment and differentiation of osteogenic cells, promoting bone formation. This osteoinductive property enhances the bone regeneration process, leading to more predictable outcome. DFDBA undergoes gradual resorption over time as new bone forms, eventually being replaced by the patient's own bone tissue. This process mimics natural bone remodelling, resulting in long-term stability and integration with the surrounding anatomy. DFDBA is readily available in freeze-dried form, allowing for easy storage, handling, and use in clinical settings. Its availability reduces surgical time and complexity, contributing to overall procedural efficiency. Many clinical trials have reported effective bone augmentation and intrabony defect fill using DFDBA bone grafts (15,16,17). Overall, DFDBA bone graft offers a combination of biological, structural and clinical advantages hence we used it as preferred choice of bone graft over other biomaterials. The current study aimed to assess whether DFDBA bone grafting around immediate implants in the JS has any impact on enhancing both hard and soft tissues.

The outcome of this clinical trial revealed a notable enhancement in the PI within the G1S1 group compared to G2S1. This suggests that when the JS is less than 2mm, it favours oral hygiene procedures more effectively, as the surrounding soft tissues tend to heal faster and without deformity. Indeed, the observed improvement in the JS < 2 mm group may be attributed to several factors. Grafting in JS less than 2 mm helps preserve and stabilize the blood clot, aiding in bleeding control and preventing soft tissue collapse. Moreover, it serves as a protective barrier, guarding the wound area against food residue and bacteria. Similarly, the GI demonstrated significant improvement in the G1S1 group compared to G2S1 and other groups, further supporting the benefits of grafting in this context.

The inevitable crestal bone resorption following extraction is largely attributed to the loss of blood supply when the periodontal ligament is removed. Consequently, the disparity in CBH was deemed non-significant in the mesial and distal sides of both Group 1 and Group 2, regardless of the JS. However, a notable finding emerged; CBH was significantly reduced in G1S2 at the 12-month mark compared to other groups. This underscores the importance of grafting in JS greater than 2mm to mitigate crestal bone resorption. Chen *et al*. (18) conducted a study assessing the outcomes of immediate implants in the maxilla, comparing three treatment approaches. The authors in Control group left the gap unfilled, while in the other two groups the gap was filled with deproteinized bovine bone mineral (DBBM) alone or in combination with a native bilayer collagen membrane (CM). Interestingly, both experimental groups exhibited comparable outcomes, demonstrating a significant decrease in horizontal crestal bone resorption compared to the Control group (19).

A prospective cohort study by Cardaropoli *et al*. (20) documented the soft tissue contour changes between implant placement and 1 year later of 26 single dental implants inserted in fresh extraction sockets which were immediately provisionalized, where the JS was grafted with a bovine bone mineral. The results showed reduction in the crestal bone changes and horizontal bone width stability after grafting in the bone implant gap. Our study findings corroborate the previously mentioned research outcomes. However, our study provides additional insights by comparing sites with JS less than and greater than 2 mm. Regardless of the JS extent, augmenting the defect was shown to preserve CBH, particularly in the midfacial region. While statistically significant reductions in crestal bone resorption were not achieved on all sides, our results indicate partial preservation of CBH. Preserving CBH in the midfacial region holds particular significance, as it contributes to improved hard and soft tissue healing post-therapy.

Clinical studies have consistently noted a high rate of spontaneous closure of JS at immediate implant sites, particularly in JS wider than 2 mm (21) with over 90% exhibiting this phenomenon. Moreover, the median percentage fill was reported to be 100% (22). However, despite these observations, recent recommendations advocate for filling marginal gaps with a bone replacement graft to enhance esthetic outcomes (23). Discrepancies in findings across studies regarding JS fill can be attributed to variations in the gap sizes, differences in buccal plate thickness, implant positioning, and diverse surgical techniques employed.

Our study stands out as one of the pioneering investigations to comprehensively evaluate bone fill around dental implants from all four sides. Notably, we observed that the greatest bone fill occurred on the buccal side for both Group 1 and Group 2. This phenomenon can be attributed to the implants being positioned more towards the palatal aspect. After a meticulous 12-month follow-up, our findings revealed a noteworthy observation: a significant disparity was observed solely in the filled buccal side of the JS between G2S1 and G2S2. This observation underscores the importance of our study in uncovering subtle yet critical differences in bone fill dynamics surrounding dental implants. Our findings align closely with the insights provided by Novaes Jr. *et al*. (24), whose animal studies illuminated the process of new bone growth within the JS, ultimately facilitating osseointegration. Notably, their research underscores that the

percentage of bone-to-implant contact diminishes notably when the space width exceeds 1.0 mm.

Remarkably, our study sheds new light on the significance of a 2.0 mm JS, a critical factor that has been overlooked in prior reports, which have typically relied on directed bone regeneration to achieve such fill. This novel observation highlights the intrinsic capacity for bone fill within this specific gap width, independent of additional interventions.

Furthermore, our findings substantiate earlier observations in one of the trials (25), which demonstrated that defects grafted with either bovine bone mineral or autograft exhibited significantly larger amounts of BIC compared to defects left without grafting. This underscores the pivotal role of grafting materials in promoting osseointegration and underscores the multifaceted nature of bone regeneration dynamics in implant dentistry.

Intriguingly, our investigation revealed no notable discrepancies in RW between the two groups. However, a crucial aspect to highlight is that throughout our study, the labial bone plate remained unexposed, and JS grafting was performed without the necessity of reflecting the periosteum. Moreover, a compelling finding emerged, a consistent decrease in VD was observed across both groups, indicative of vertical bone formation extending from the initial thread of the implant to the first point of BIC. Notably, Group 2 exhibited greater values, implying an enhanced benefit of bone augmentation in this cohort. This underscores the efficacy of our approach in fostering vertical bone growth, thus contributing to the overall success and stability of the implant site. Due to the anatomical difference between implant and socket wall, the horizontal and vertical defects were created, which was seen radiographically as a triangular RA. In the present study the difference in mean values of RA was significant when G1S1 was compared with G2S1 on the buccal side and in case of G1S2 and G2S2 on the buccal and mesial side after 12 months. This indicates that there was a certain amount of bone fill which occurred in the JS leading to reduction in RA. Additionally, our results align closely with those of a previous study (22), wherein the authors employed a flapless technique and used Tricalcium phosphate to fill the JS. The present study measured the RA throughout all four sites: buccal, palatal, mesial and distal and revealed that there was significant difference on all four sites during intragroup analysis in Group 2. While the Group 1 showed a significant difference only on the buccal side as compared to the baseline dimensions. Intergroup comparison revealed that the Group 2 had a greater reduction in RA on the buccal aspect thereby indicating substantial bone fill. Polyzois *et al.* (26) observed increased BIC and more bone within the threads in grafted areas relative to nongrafted areas with defects of the same diameter. Limited osseointegration was observed in the defect region in locations where no grafting was used. The wider grafted defects, on the other hand, managed to illustrate BIC more coronally than locations with defects of similar magnitude that did not contain grafts. The current study's results are consistent with these findings and found minimal RA across implants in Group 2, denoting more BIC and more JS fill implying a greater bone fill at the grafted sites.

When the Testori score for the soft tissue changes was compared, better scores were observed in Group 2 as opposed to Group 1. Amongst the Group 2 subgroups, the scores were better in G2S2 implying that grafting of JS with DFDBA not only restores the buccal bone but also conserves and improves the soft tissue architecture. The results of the present study confirmed that better bone levels with enhanced soft tissue contours appear to have been achieved when DFDBA was used. This modality can be considered as an effective and predictable option for replacing teeth with added advantage of improved esthetics. However, there are certain limitations such as smaller sample size and inability to conduct histological examination of the restored tissue and further studies are desired to improve our understanding and substantiate the results.

Conclusion

Within the study constraints it can be inferred that use of DFDBA showed significant CBH augmentation in the midfacial region leading to enhanced soft tissue levels. Also, a significant reduction in RA indicating radiographic bone fill was observed in G2S2. In spite of the small differences observed between the approaches, the overall results seem to indicate a trend towards better outcomes with the use of DFDBA. Future research endeavours should aim for more homogeneous study designs with extended follow-up periods to confirm and elucidate this observed tendency. Such studies will not only enhance our understanding but also provide valuable insights into optimizing treatment strategies for improved clinical outcomes in dental implantology.

Türkçe öz: *Demineralize dondurulmuş kurutulmuş kemik allogrefti kullanılan ve kullanılmayan immediat implantlarda kemik boşluğunun yönetimi: randomize kontrollü bir çalışma. Amaç: Bu çalışma, demoralize edilmiş dondurularak kurutulmuş kemik allogrefti (DFDBA) kullanılan ve kullanılmayan anında implantlarda atlayış boşluğunun (JS) yönetimini flepsiz yaklaşım ile değerlendirmeyi ve karşılaştırmayı amaçlamaktadır. Bireyler ve Yöntem: Bu çalışmaya, üst çene ön bölgesinde anında implant yerleştirilen 40 bölge dahil edilmiştir. Grup 1 hastaları herhangi bir augmentasyon yapılmadan tedavi edilirken, Grup 2 hastalarında JS içinde DFDBA kullanılmıştır. Her iki grup, yatay boyutlarına göre JS 2 mm'den az (G1S1, G2S1) veya fazla (G1S2, G2S2) olacak şekilde alt gruplara ayrılmıştır. Plak indeksi (PI), Dişeti İndeksi (GI), Sondalama derinliği (PD), Testori estetik skoru (TS), VAS skoru, Crestal Kemik yüksekliği (CBH), Sırt genişliği (RW), Dikey mesafe (VD) ve radyolüsent alan (RA), başlangıçta ve tedaviden 12 ay sonra CBCT ile radyografik olarak değerlendirilmiştir. Bulgular: G1S1-G2S1 ve G1S2-G2S2 gruplarında orta yüz bölgesinde CBH'de sırasıyla 0.34±0.19mm ve 0.75±0.26 mm ortalamaları ile 12 ayda anlamlı farklılıklar gözlenmiştir. G1S1 ve G2S1 gruplarında TS'de ortalama 0.55±0.53 iken, G1S2 ve G2S2 gruplarında 1.33±0.82 değerleri ile anlamlı farklılıklar gözlenmiştir. Sonuç: DFDBA, orta yüz bölgesinde daha iyi CBH korunumu, RA'da azalma göstererek JS'nin daha iyi çözünmesi ve dolayısıyla daha iyi sert ve yumuşak doku iyileşmesine yol açmaktadır. Anahtar Kelimeler: immediat implantlar, kemik boşluğu, peri-implant dokular, kemik grefti, doku iyileşmesi*

Ethics Committee Approval: The study was carried out between February 2021 and March 2022. Approval for this clinical trial was obtained from the Institutional Ethics Committee of our institute, aligning with the updated principles of the Helsinki Declaration for biomedical research. The Institutional Ethics Committee (IEC) provided approval under the registration number IEC/VSPMDCRC/06/2019. Furthermore, the trial was registered with the Clinical Trials Registry of India under registration number CTRI/2021/01/030620 and adhered to the CONSORT statement and EQUATOR guidelines for reporting.

Informed Consent: Participants provided informed consent.

Peer-review: Externally peer-reviewed.

Author contributions: APK, PVB participated in designing the study. MP participated in generating the data for the study. MP, RAK participated in gathering the data for the study. MP, PVB participated in the analysis of the data. PVB wrote the majority of the original draft of the paper. APK participated in writing the paper. MP has had access to all of the raw data of the study. RAK has reviewed the pertinent raw data on which the results and conclusions of this study are based. RAK have approved the final version of this paper. PVB guarantees that all individuals who meet the Journal's authorship criteria are included as authors of this paper.

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