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ASSESSMENT OF INTRA OPERATIVE TIME FOR COMPUTER GUIDED POSTERIOR MANDIBLE ONLAY GRAFTING VERSUS FREE HAND ONLAY GRAFTING: A RANDAMIZED CLINICAL SPLIT MOUTH TRIAL

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ABSTRACT

Aim: The aim of this study was to evaluate the efficacy of onlay vertical bone augmentation using patient specific guide in the reduction of intra-operative time and postoperative pain compared to the free hand technique in the vertically deficient posterior mandible ridge using autogenous cortico-cancellous bone. **Materials and Methods:** This study included 10 patients that had bilateral vertically deficient posterior mandibular alveolar ridges. For each patient, half of the ridge was augmented using 3D printed patient specific surgical guide for fixation of autogenous onlay bone graft, while the other half was augmented using free hand autogenous onlay bone graft technique using 3D printed cutting guide for the harvesting of the blocks for both groups. This was followed by a second-stage surgery for screws removal and delayed implant placement 6 months postoperatively. **Results:** Mean value of the intra-operative time for the study group (31.29±3.72 minutes) was less than that of the control group (40.94±3.04 minutes) which was statistically significant ($p < 0.0001$). **Conclusion:** The use of patient specific surgical guide for the harvesting and fixation of onlay bone block in the vertically deficient posterior mandible is an efficient method for reducing the intra-operative time compared to the freehand technique.

1. INTRODUCTION

During implant planning and placement, edentulous ridges may prove to be insufficient for implants placement, this may be due to a substantial vertical alveolar ridge defect hindering the placement of the implants by providing a deficient bone volume required for the placement of appropriate sized implants.[1]

Onlay bone grafting technique with autogenous bone is regarded as the gold standard technique; against which other techniques are compared. Onlay grafts can be used in immediate or delayed implant placement and has been reported to have high success rate in vertical augmentation of alveolar ridges.[2]

Mandibular symphysis (chin) is rich in cortico-cancellous bone and easily accessible for bone graft harvesting, this enabled the procedure to be carried out safely in the dental clinics under local anaesthesia.[3] Nevertheless, insufficient reference position data for intraoral block bone harvesting might lead to either unintentional harm to important anatomical structures or an insufficient quantity of the harvested graft. Anatomical structural damage may lead to postoperative problems, including pain following surgery, neurosensory abnormalities, and numbness.[4,5]

A digital bone harvest guide was suggested by Osman and Atef in 2018 to decrease postoperative complications and technical sensitivity while harvesting bone blocks from the chin bone.[4] A computer-guided mandibular harvesting procedure was published by De stavola et al in 2017 in order to securely retrieve a suitable volume of block bone. These studies suggested a potential reduction in surgical complications.[6]

Introduction of computer aided surgical guides using CBCT data increased accuracy of bone grafting procedure by preparation of surgical guides capable of perfect adaptation to the defect margin and accurately securing the graft block to the defect, thus restoring the desired bone volume required for placement of suitable sized implants as planned preoperatively.[7] By reducing the duration of the procedure and the postoperative complications following it, using a guide might increase operational efficiency.[5]

Therefore, the aim of this study is evaluation of the efficacy of vertical bone augmentation achieved at posterior mandible using guided onlay technique in the reduction of intra-operative time and postoperative pain versus free hand onlay technique using bone blocks harvested from the symphysis by a surgical cutting guide.

2. MATERIALS AND METHODS

Study design:

This randomized clinical trial, with a split-mouth design, consisted of 10 patients who had bilateral vertically deficient posterior mandibular ridges. In this research, the autogenous onlay bone graft approach was used to augment one side utilising a patient-specific surgical guide for fixation, while the other side was grafted using a free-hand method. A 3D printed cutting guide was used to harvest the blocks for both groups. Each treatment modality was administered to 20 arches (10 patients).

Setting and locations:

The candidates for this split-mouth randomized clinical trial were recruited from the outpatient clinics of the Department of Oral and Maxillofacial Surgery, Faculty of Oral and Dental Medicine, Cairo University, Egypt. Enrolment of the first participant occurred on December 20, 2021 and the final participant was recruited on June 20, 2022.

Study registration:

The study was approved by Cairo University's Faculty of Dentistry Ethical Committee. The clinical trial was registered on www.clinicaltrials.gov.com (registration number NCT05512078). The study followed the declaration of Helsinki regarding the ethical principles for medical research involving human subjects. All participants provided written informed consent prior to enrollment. The individual deidentified participant data can be made available upon request to the corresponding author.

Eligibility criteria and selection method:

Patients were screened for the study based on the inclusion criteria of bilateral atrophic posterior mandibular ridges with vertical alveolar ridge height less than 7mm measured from the crest of the alveolar ridge to the inferior alveolar canal, good oral hygiene, no previous surgeries at the area of interest, and an age range of (25 to 55) years, meanwhile, excluding the patients with a history of alveolar surgical interventions and those with any systemic disease that may interfere with the typical bone and wound healing.

Randomization:

This split mouth study randomized treatment of the right and left posterior sides of the mandible in each patient. Allocation concealment was achieved using opaque sealed envelopes containing the group assignment for each side. The sequence generation and envelope preparation were carried out to remove bias. Patients were registered and then an envelope was selected to reveal the right and left side group allocation per the random sequence. The statistical analyst was blinded to group assignment; however, the assessors, participants, and surgeons were not blinded due to the nature of the surgical interventions.

Preoperative preparations:

A thorough medical and dental history was obtained from all patients, including chief complaint, dental condition, medical history, oral hygiene status, interarch space, mucosal tissue biotype, status of opposing dentition, and maxillomandibular relationship. Clinical evaluation included palpation to assess for swelling, undercuts, or tenderness. Preoperative CBCT scans were acquired for each patient using Planmeca ProMax 3D (Helsinki, Finland) to evaluate the vertical dimension of the deficient alveolar ridges and confirm study eligibility based on deficiency criteria. The nature of the procedure was explicitly explained to the patients and informed consents were signed by them.

Virtual planning and guides fabrication:

The DICOM files were imported from the CBCT scans for the patients of the test group into the planning software (Mimics21, Materialise, Leuven, Belgium). The virtual planning started with a Segmentation process that created a 3D model of the bony skeleton, through which the mandible was separated. The developed model was exported to the software (3-Matic, Materialise, Leuven, Belgium) for designing the surgical guides.

The first step in the virtual planning process was the digital design of the first guide, which was created to help with the precise harvesting of two symphyseal bone blocks with patient-specific dimensions predetermined so as to align the osteotomies at least 5 mm away from the inferior border of the mandible, the bilateral mental foramen, and the root apices of the anterior teeth. Next came the virtual designing of a second guide, which would ensure accurate intraoperative positioning and fixation of the onlay bone block to the defective site **(Figure 1).**

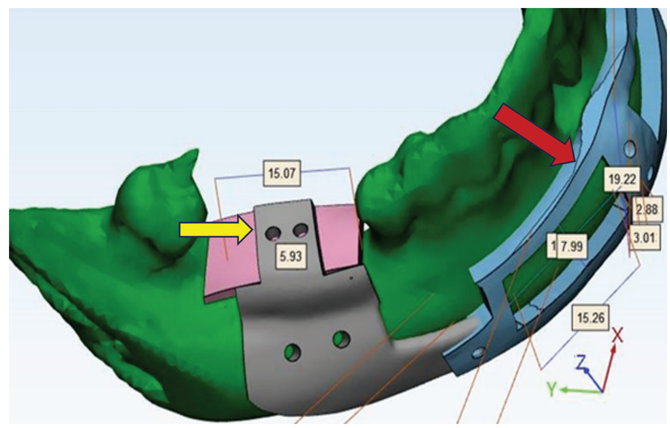

Figure (1) — The virtual plan of the harvesting guide (red arrow) and the fixation guide (yellow arrow).

Finally, using additive manufacturing technology, both guides were 3D printed from resin. They were then submerged in CIDEX Solution, which contained chelating agents, buffers, and a corrosion inhibitor (ASP International GmbH, Switzerland), for a duration of 12 hours, they were then cleaned with saline before surgery.

Surgical intervention:

All 10 patient were operated under general anesthesia supplemented by regional infiltration for hemostasis and pain control. The deficient alveolar ridges were surgically exposed by a vestibular incision positioned away from mucogingival junction with a with 45 degrees to expose the mentalis muscle, then 90 degrees down to the bone, the flap was extended to the midcrestal flaps of the recipient sites flaps mesiodistally by two releasing cuts followed by a complete mucoperiosteal flap that was reflected to expose the entire symphysis region. The mental nerve was exposed and visualized bilaterally and skeletonization of the nerve was done.

For the study group patients, the harvesting guide was seated and fixed in place using two titanium osteosynthesis mini.screws at the pre-planned position **(Figure 2)**, then the two bilateral bone blocks were obtained using a disc in a beveled direction to perform 4 osteotomy outlines guided by the fixed surgical stent, then both bone blocks were harvested by elevation that started from the medial cut (toward the midline). This was to prevent any unnecessary trauma to the mental neurovascular bundle. Unscrewing and removal of harvesting guide and separation of blocks was done using razor sharp straight bone chisels to connect the four osteotomy lines bilaterally, then

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the two corticocancellous bone blocks were tapped out using angled chisels and stored in cold saline solution. The lingual cortex was left intact to avoid alterations to vital structures in the floor of the mouth and the inherent risk of bleeding.

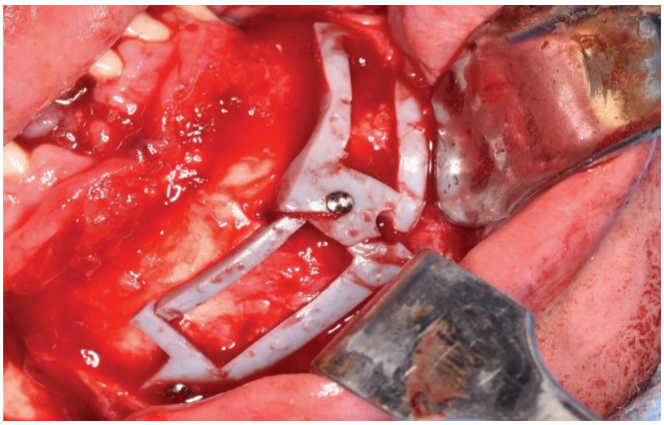

Figure (2) — The harvesting guide fixed to the donor site.

Using auto chip maker bur (ACM), spongy bone particulates were collected from the symphysis in a small dish and mixed with xenogenic bone graft with ratio 1:1. Afterwards, mono cortical micro screws were used to secure the extracted bone block to the second positioning guide's fitting surface outside the patient's mouth.

Decortication of the recipient site was done using 2 mm diameter tissue bur to increase the blood supply to the grafted block. The onlay guide was placed on the deficient ridge assigned for the intervention group, then two inferior screw holes were drilled as planned on the three-dimensional model then the guide was removed. The harvested block then was fixed to the positioning guide using two mini screws supracrestally as pre-designed on the 3D model with the guide covering a part of the onlay block only. Then the guide with the block was fixed on the ridge using two mini screws in the already drilled screw holes **(Figure 3).** Two more mini screws were drilled in the free part of the block that was not covered by the guide superiorly to fix it to the underlying ridge. The two superior screws fixing the guide to the block were removed and the inferior mini screws were removed followed by removal of the guide.

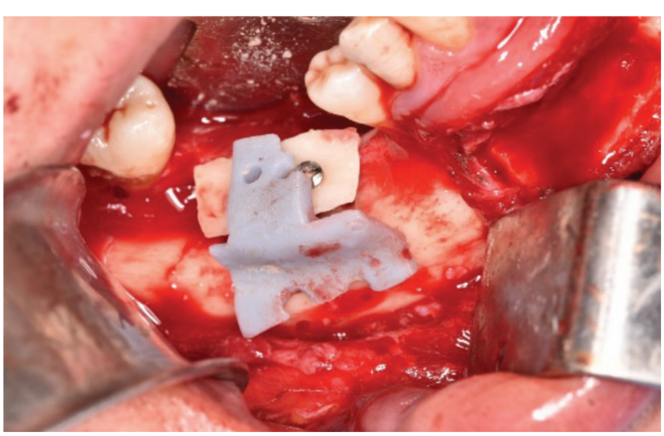

Figure (3) — The guide and the bone block fixed to the recipient ridge.

On the other hand, for the control group patients, the harvested onlay bone block was fixed with mini screws conventionally **(Figure 4)** and the gap between the ridge and the grafted block was filled the preprepared autogenous-xenograft bone particulate mix.

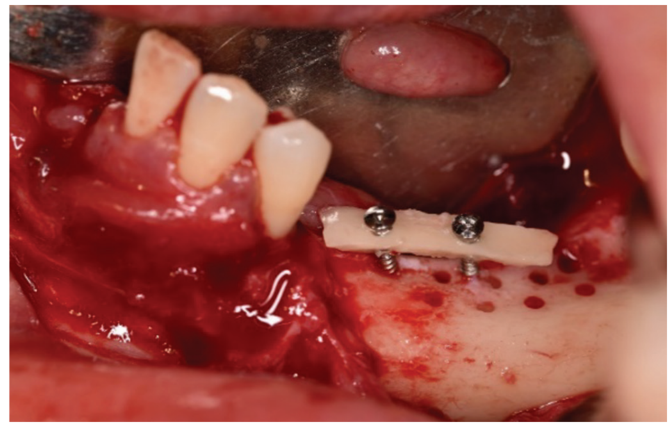

Figure (4) — Onlay block fixed to the ridge by the freehand technique.

All of the repaired alveolar ridges in both groups had their rough bony edges identified and smoothed, and the donor site was filled with a collagen sponge (SURGISPON® Aegis Lifesciences PVT.Ltd., India). Monofilament non-resorbable material (polyproline 4-0, Assucryl®, Assut sutures, Switzerland) was used for suturing.

Intra-operative time calculation:

The blocks harvesting and fixation time during the bone block augmentation surgery was calculated using a timer to measure the duration from the beginning of the incision of the donor site to the complete fixation of the harvested bone block. The time for guide placement was included in the study group. Similarly, the bone block trimming time was calculated to measure the duration from the finish of bone block harvesting to its placement at the recipient site in the control group.

Second stage surgery:

Six months following graft consolidation, patients underwent a second surgery for the exposure of the consolidated graft, 40 dental implants (Dual Implants®, Titan Industries, Egypt) were implanted after the fixation screws were taken out.

Statistical analysis

All Data were collected, tabulated, and subjected to statistical analysis. Statistical analysis was performed by SPSS (Statistical package for the social sciences- IBM Corp., Armonk, NY), while Microsoft Office Excel was used for data handling and graphical presentation. Quantitative variables were described by the Mean + Standard Deviation (SD) or median and range. Qualitative categorical variables were described by frequencies and Percentages. Data were explored for normality by checking the data distribution and using Kolmogorov-Smirnov and Shapiro-Wilk tests for further choice of appropriate parametric and non-parametric tests.

All the variables were found normally distributed, thus allowing the use of parametric tests. Independent samples t test was applied to compare the means of the two groups. Significance level is considered at $P < 0.05$ (S) Two Tailed tests are assumed throughout the analysis for all statistical tests.

3. RESULTS

Demographic data

The mean age of this split-mouth study participants was (43.2±6.86) years. The patients of this study consisted of 3 males (30%) and 7 females (70%).

Intra-operative time

Mean value of operation time of Study group (31.29±3.72 minutes) was less than the mean value of control group (40.94±3.04 minutes) and the difference was statistically significant (p<0.0001) (**Table 1**).

Table (1) Mean and standard deviation (SD) values for operation time measured in minutes in both groups

Group	Minimum	Maximum	Mean	SD	Mean difference	t value	p-value
Study	25.2	38.1	31.29	3.72	-9.65	-6.35	<0.0001s
Control	38.1	45.3	40.94	3.04			

Significant level p≤0.05, ns=non-significant

4. DISCUSSION

Implant-based dental rehabilitation may be hampered by the resorption of alveolar bone brought on by tooth loss. There has been constant debate in the literature about the fact that there is no one augmentation strategy for rehabilitation of inadequate alveolar ridge that works in all circumstances.[8] Deficiency of the alveolar bone has been treated using a variety of ridge augmentation techniques, including guided bone regeneration, ridge splitting, and bone grafting. These techniques are essential for regenerating the mineralized tissue required for successful implant procedure.[9]

The literature provides helpful details on bone grafting procedures and their results. The best alternative for bone gain and volume enhancement is often autologous bone blocks, especially when there is substantial bone loss. According to many studies examined, these favorable parameters assist the integration of the graft and subsequent implant-supported prosthetic rehabilitation.[10,11]

Even though onlay bone grafting operations have improved from the first reported 50% failure rate, problems are frequently seen at the donor site which include the potential for vital structures to be damaged, the absence of anatomical guidance during fixation, which is always a difficult step, especially for inexperienced surgeons, and may lead to improper bone block angulation and ultimately insufficient augmentation or overenhancing of the ridge contour, making this procedure dependent on the operator's expertise.[12]

The 4th ITI Consensus Conference identified autogenous bone block from the symphysis of the mandible as one of the most reliable treatments for horizontal and vertical bone abnormalities. Although effective, this method has drawbacks, including the potential for anatomical structural harm, postoperative patient morbidity, and insufficient volume at the donor location. These factors have undoubtedly decreased this approach's clinical usefulness.[13,14]

Because the freehand technique is unpredictable with regard to the anatomical vital structures, no devices or procedures currently described or employed for cutting bone can prevent risk of anatomical structural damage. Due to the working direction enforced by the surgical guide, computer-guided implantation has been found to be more accurate than conventional freehand drilling operations.[15,16] This is why this study focused on the use of 3D printed surgical guides for the cutting and positioning of onlay bone block. The surgeon may pick the angle and range of the osteotomy, as well as the direction and depth of the screw route, with the use of guide templates, improving the procedure's accuracy, safety, and dependability.[17,18]

In the current study, the authors found that the use of a 3D printed patient specific guide decreased the operation time required for harvesting and fixation of the autogenous onlay block by mean difference value = 9.65 which was statistically significant (p < 0.0001). This means that the use of the guide can actively increase the efficacy of the whole procedure. This might be caused by a number of factors, such avoiding repeatedly placing the graft in the recipient region for inspection, as well as reducing the time consumed by the freehand manipulation and fixation of the block to the ridge that might be hindered by the rotation and movement of the block during drilling of the screws, in addition to the use of the fixation guide that uses the virtual design of the graft as a reference to accurately and easily fix the block to the ridge in the preplanned site, minimizing the rotation and undesired movement of the block to a minimum. Furthermore, it should be noted that shortening of the fixation duration is beneficial to maintaining the bone block biological activity.

The findings of this research are comparable to the study by **(Zhu *et al.*, 2022), who also** stated that the guide group's in vitro trimming time for the harvested bone block was significantly less than that of the control group (401.51±97.60 s vs. 602.36±160.57s, p <0.001).

5. CONCLUSION

The use of patient specific surgical guide for the harvesting and fixation of onlay bone block in the vertically deficient posterior mandible is an efficient method for reducing the intra-operative time compared to the freehand technique.

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