Buccal Plate Augmentation Using Sticky Bone versus usage of sticky bone as a jumping gap filling material with simultaneous immediate implant placement in the maxillary esthetic zone :A Randomized Controlled Clinical Trial

Protocol submitted to Faculty of Dentistry, Cairo University for partial fulfillment of the requirements for the Master's degree in Periodontology

By

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I. Administrative information:

1. Title:

Buccal Plate Augmentation Using Sticky Bone Versus Usage of sticky bone as a jumping gap filling material with Simultaneous Immediate Implant Placement in The Maxillary Esthetic Zone: A Randomized Controlled Clinical Trial

2. Protocol Registration:

Will be registered in www.clinicaltrial.gov

3. Protocol version:

(13 Jan 2024 Protocol number: 1)

4. Funding:

Self-funding

5. Roles and responsibilities:

Supervisors and principal investigator:

Main supervisor :

• Prof. Enji Ahmed Mahmoud.

Professor of Oral Medicine and Periodontology- Cairo University, Faculty of Dentistry, Cairo University.

Role:

• Initiation and idea of the clinical trial.
• Randomization and allocation of cases.
• Supervision of the clinical procedures.
• Auditing for writing and final report result.

Co-Supervisor:

Dr. Samah Bahaa .

Lecturer of Oral Medicine , Periodontology and Oral diagnosis , Faculty of Dentistry, Cairo University.

Role :

• Randomization and allocation of cases
• Supervise the surgical procedures.
• Collection, management, interpretation, and analysis of data.
• Auditing for writing and final report result

Co-Supervisor:

Ass. Prof. Shaimaa Saieed Nasr

Associate Professor of Periodontics, Faculty of Dentistry, Fayoum University, MSA University.

Role:
• Initiation and idea of the clinical trial.
• Randomization and allocation of cases
• Supervise the surgical procedures.
• Collection, management, interpretation, and analysis of data.
• Auditing for writing and final report result

Principal Investigator:
• Yara Khaled Mahmoud .
Master's degree candidate, Department of Oral Medicine and Periodontology, Faculty of Dentistry, Cairo University.

Role:
• Follow up recording.
• Writing the thesis.
• Protocol writing.
• Collection, management, interpretation, and analysis of data.
• Enrolment of study population.
• Performing surgical procedures (treatment).
• Data collection.
• Submitting the report for publication.

Trial responsibility:
Department of Oral Medicine and Periodontology, Faculty of Dentistry, Cairo University.

Committees:
• Research plan committee.
• Periodontology department council.
• Evidence based dentistry committee.
• Faculty Council.
• Ethics committee

II. Introduction:

6. Background and rationale:

Research question:

In patients with non-restorable dentition in the maxillary esthetic zone indicated for immediate implant placement, will buccal plate augmentation using sticky bone results in superior pink esthetic score compared to sticky bone used to fill the jumping gap?

Statement of the problem:

Following removal of a tooth, the healing socket undergoes an inevitable series of events that have the potential to remodel the adjacent areas of the alveolar ridge. Such remodeling can result in the loss in both bone width and height [3], especially on the facial side [4], which often leads to adversities from both functional and esthetic perspectives during the restoration. Particularly concerning is the phenomenon of bone resorption, which reduces the amount of available bone required for implant fixture placement and stability [5].

Successful management of dental extraction sockets in the maxillary anterior esthetic zone is a challenging problem that clinicians encounter routinely.

Many techniques have been proposed in the literature with the common aim to counteract or minimize possible resorption of the alveolus in this region and maintain the three-dimensional topography of the socket. Two common examples include socket preservation with placement of bone graft material into the socket or placing an implant immediately after extraction [6, 7]

The outcomes following intra-socket grafting are variable and controversial, especially from the biological point of view, due to the fact that placing a graft into the socket always hinders the self-healing response of the site [8].

Nonetheless, placement of an implant immediately after tooth extraction may be beneficial to maintain the bone crest and can facilitate ideal implant positioning from a prosthetic point of view. [9, 10] Therefore, authors have advocated the use of immediate implants. [11-16]

The therapeutical advantages of immediate implant placement entail morbidity reduction, shorter treatment time required, preservation of residual ridge width and height, desired esthetic outcomes, guidance of implant placement through the bone socket and better tendency for osseointegration due to the healing potential of fresh extraction site. [10, 17-20]

However, these advantages are often presented along with one disadvantage, namely the failure of adaptation of the alveolar bone, particularly in the cervical aspect of the implant. [19, 21, 22] This area is identical to a circumferential vertical defect and can give shelter to soft tissues. [19, 23,24]

Despite socket preservation and/or immediate implant placement, resorption of the buccal plate after dental extraction continues to pose esthetic challenges to clinicians.

Rationale for conducting the research:

Buccal plate preservation (BPP) is a technique that has been recently proposed with an aim to reduce the incidence of such resorption.[29]

Buccal plate augmentation (BPA) is a novel approach for ridge preservation aiming to avoid recession of the facial wall of the socket without interfering with the natural healing mechanism of the extraction socket. It consists of placement of bone graft material over an

intact buccal plate, underneath the soft tissues in a surgically created pouch with the aim of maintaining or augmenting soft tissue esthetics of the region [28].

BPP has been previously proposed as an effective alternative to socket grafting and has multiple advantages over the latter including but not limited to the following: (1) does not interfere with the natural, physiological healing of the socket healing process; (2) allows for immediate implant placement; and (3) cost savings since augmenting the labial plate externally requires lesser graft material than intra-socket grafting.[29]

Review of literature:

Tooth loss is a serious health problem that affects an individual's functional abilities, aesthetics, and social interactions. Accordingly, replacing those missing teeth has become a necessity to restore function and esthetics.

After teeth extraction, the alveolar process goes through a remodeling process that leads to dimensional changes resulting in a decrease in the width and height of the alveolar bone; these changes happening following tooth loss proves that the alveolar process bone is tooth dependent [30]. Alveolar bone remodeling is a physiological process observed after tooth extraction that may compromise the subsequent dental implant rehabilitation. Most of the alveolar bone loss occurs during the first 3–6 months after tooth extraction, resulting in a bone width loss of 29–63% [31], which leads to difficulties restoring the teeth either with conventional prosthesis or with implant supported prosthesis and in many cases implant placement becomes a challenge [32]. Studies have reported that alveolar bone resorption following extraction continues for a long time, reaching a peak during the 1st year. The most pronounced resorption occurs through the first 3 months after extraction. Numerous studies have shown that after tooth extraction, approximately 30% of the alveolar ridge is lost due to resorption. Studies have shown that during the first three months after extraction, approximately two-thirds of the affected hard and soft tissues undergo some degree of resorption. Most bone loss occurs during the first six months following the procedure. [30]

While delayed implants are placed in healed boney sites, necessitating a healing period of 6 months [34], immediate implant placement refers to the placement of implants into fresh extraction sockets immediately after extraction.[35] This method is regarded as a predictable therapeutic approach for both anterior and posterior affected sites, with survival rates comparable to implants placed in healed ridges i.e., delayed implant placement [36]. Immediate implant placement offers numerous advantages, such as minimizing the number of surgical interventions and shortening the overall treatment course. [37] Furthermore, it preserves the alveolar ridge, and decreases the morbidity and rehabilitation time associated with tooth replacement. Consequently, it increases patient satisfaction with the treatment. [38]

Nonetheless, several approaches have been described in addition to the immediate implant placement for contouring the socket alterations caused by tooth extraction: positioning of the implant on the palatal wall; performing the surgery using the flapless technique to maintain vascularization; and using soft tissue or bone grafts to maintain the dimension of the ridge by socket augmentation. [33]

Guided bone regeneration (GBR) provides an evidence-based treatment modality for enabling predictable accommodation of dental implants with excellent long-term survival rates [49-51]. While autologous bone remains the gold standard among the biomaterials used for bone regeneration [52-54], limitations have also been reported including a second surgical site, additional morbidity, chance of complications to the harvested site, and faster than ideal resorption rates [51, 55]. The phenomenon of bone regeneration along with the removal of all the extra-skeletal non-osteogenic cells from an osseous defect is widely established in implant dentistry. [40] Several animal and clinical trials have demonstrated the efficacy of using regenerative procedures around immediately placed dental implants using a variety of materials. [39, 40-47] These publications have reported the stability of the regenerated hard tissues over time and their ability to provide support and aid in functioning of osseo-integrated implants. Hard tissue

reconstruction is facilitated by guided bone regeneration through prevention of epithelial cell migration in the defect area. The rate of osteogenesis extending inward from the adjacent bony margins should be greater than the rate of fibrogenesis growing in from the surrounding soft tissue. [48]

Commercially available bone substitute materials are most frequently available in a particulate form and are easy to disperse, making it difficult to adequately graft the particles in the bone defect and to maintain the desired shape of the rebuilt area. Furthermore, the majority of commercially available bone grafting materials (allografts, xenografts or synthetic alloplasts) contain only scaffolds for osteoconductive application, lacking osteoinductive factors such as living cells and growth factors [55]. A frequently used, thermally regulated, bone grafting material is the Deproteinized Bovine Bone Mineral (DBBM; owing to its lack of proteins/growth factors) or An-organic Bovine Bone Mineral (ABBM; owing to its lack of organic components) [56, 57].

Platelet concentrates are widely used for surgical procedures in various medical fields. The objective of these technologies is to extract (through centrifugation) all the elements from a blood sample that could be useful to additionally benefit healing as well as promote tissue regeneration.[58] Dohan et al., first developed PRF for use in oral and maxillofacial surgery. Platelets are trapped in the fibrin meshes and the success of this technique is completely dependent on the speed of blood collection and its transfer to the centrifuge.[59] Injectable PRF (I-PRF) is a platelet concentrate in the liquid form which can be polymerized with bone graft. Since I-PRF is autogenous, adverse reaction to the implanted material is reduced, which qualifies it as a suitable option in bone regeneration. The combination of i-PRF and bone graft is known as "sticky bone." It forms a well-agglutinated "steak for bone grafting" by allowing the incorporation of graft without the use of anticoagulants or additives. [60] Sticky bone also provides stabilization of bone graft in the defect, and therefore, accelerates tissue healing and minimizes bone loss during the healing period. [61]
Tarnow et al showed that bone grafting into the gap at the time of implant placement in combination with a provisional restoration or a contoured healing abutment resulted in the smallest amount of ridge contour changes [25].
Buccal plate preservation (BPP) is an alternative technique which has been a relatively recent approach aiming to preserve the buccal plate akin to socket preservation but via a different mechanism which includes surgical intervention and grafting on the external surface of the labial plate rather than within the socket [26].
Results of BPP showed stability in the long-term and effectiveness in resisting remodeling and resorption of the facial cortical plate of the alveolus of the extraction socket. [26] Sohn et al. reported that sticky bone is easy to generate and showed good results as a reconstruction material for the edentulous alveolar bone defect, based on the concept of minimally invasiveness in ridge augmentation [27].

Hence, the aim of this study is to clinically assess pink esthetic score following Buccal Plate Augmentation using Sticky Bone versus usage of Sticky Bone as a jumping gap filling material with simultaneous immediate implant placement in the maxillary esthetic zone.

Explanation for choice of comparators:
The main objective of immediate implant placement is to provide an osseointegrated fixture suitable for an aesthetic and functional restoration. Bone fill in the gap between the implant and the surrounding bone is important. The buccal aspect of an implant is of great concern, especially in the esthetic zone, because the buccal bony plate is usually thin [62,63] and its resorption can result in soft tissue recession. [64]

Sohn et al. reported that sticky bone is easy to make and they are a very effective materials for the reconstruction of edentulous alveolar bone defect, based on the concept of minimally invasiveness on ridge augmentation.[27]

7. Objectives:

Primary objectives:

The primary objective of this study is to clinically assess pink esthetic score following Buccal Plate Augmentation using Sticky Bone Versus usage of sticky bone as a jumping gap filling material with simultaneous immediate implant placement in the maxillary esthetic zone.

Secondary objectives:

The secondary objectives of this study are to measure and assess :

- Crestal bone level .
- Thickness of labial plate of bone .
- Soft tissue profile /contour .
- Patient satisfaction .

Hypothesis:

Null hypothesis: there is no difference between pink esthetic score following buccal plate augmentation using sticky bone and that following sticky bone used to fill the jumping gap with simultaneous immediate implant placement in maxillary esthetic zone.

8. Trial design:

this trial is a randomized controlled clinical trial, two arms superiority trial with 1:1 Allocation.

III. Methods

A) Participants, interventions & outcomes

9. Study settings:

- The study is to be conducted in the Oral Medicine and Periodontology department, Faculty of Dentistry, Cairo University, Egypt.
- Patients are to be selected from the outpatient clinic of the department of Oral Medicine and Periodontology, Cairo University.

10. Eligibility criteria:[68]

Inclusion criteria:

- Patients aged 18 years or older.
- Presence of a non-restorable maxillary tooth in the esthetic zone including maxillary anteriors and premolars indicated for extraction.
- An intact buccal plate of bone after extraction.
- Full-mouth plaque and bleeding score not exceeding 20%.
- Patients showing motivation to comply with post-operative care instructions and follow-up appointments.

Exclusion criteria:

- Periapical infection involving the tooth to be extracted.
- Periodontal disease
- Systemic health conditions that contraindicate or affect healing of implant surgery (Diabetes Mellitus, Leukemia)
- Pregnant and nursing females.
- Smokers.

11. Interventions

Preoperative phase:

All patients will undergo pre-operative clinical examination: Patient's data will be collected; name, gender and age, medical and dental histories will be taken. Also, all patients will undergo standardized periapical radiograph to detect any pathosis and a pre-operative Cone beam computed tomography (CBCT) scans will be taken to evaluate the tooth root configuration and to confirm the presence of intact buccal wall, Vital structures related to the tooth, Vertical and horizontal dimensions of the alveolar bone and Bone density.[68]

Patient preparation for surgical procedure:

After extra oral disinfection of the surgical site ,the patients will be asked to rinse their mouths with Chlorohexidine HCL 1.25% mouthwash (Orovex mouthwash, Macro group, Egypt) immediately preoperatively. Local infiltration anesthesia [Articaine 4% 1:100,000 epinephrine] (Artinibsa 40mg/0.1 mg/Ml - epinephrine 1:100000, Spain) will be used for all procedures.[68]

Control group:

- The surgical procedure will be performed in sterile surgical field. Under local anesthesia, sharp dissection of the supracrestal fibers will be done with no.15 c scalpel blade. With the purpose of preserving the buccal and palatal bone walls, periotomes, elevators and maxillary root forceps will be used to facilitate atraumatic extraction.
- The socket will be well irrigated with saline and debrided with a bone curette. An intact buccal bone plate should be found after extraction of the tooth.
- Bony sockets will be prepared through sequential drilling for the placement of the implant.
- Achieving primary stability after implant placement will be followed by placement of cover screw.
- Venous blood will be withdrawn under aseptic conditions by veni puncture of the antecubital vein and transferred into sterile tubes which will be devoid of anticoagulants. I- PRF preparation will be done using the protocol developed by Mourãoet al. [67]
- Plastic PET tubes to create Liquid-PRF, while glass tubes will be used to obtain Solid-PRF.
- Blood will be centrifuged at a speed of 3000 rpm for 10 minutes to obtain autologous PRF plug.
- Blood will be centrifuged at a speed of 700 rpm for 3 minutes. An orange- colored fluid will be formed as the upper layer in the test tubes i.e., I- PRF. Approximately 1 ml of I-PRF will be collected in a syringe.
- Solid-PRF + Liquid-PRF mixed DBBM: Solid-PRF membranes will be mixed thoroughly with 0.25 g of DBBM particles. Then 1 mL Liquid PRF from the buffy coat layers will be added drop by drop to the DBBM.
- Following polymerization by 15-20 minutes, sticky bone will be ready to be grafted.
- The sticky bone graft will be condensed and adapted into the jumping gap as well as over the implants.
- the healing abutment will be screwed into the implant body .

Intervention group:

- A thin periosteal elevator will be used to reflect the soft tissue buccal to the bony buccal plate on the mid-facial aspect of the socket in a full-thickness manner, following a corono-apical direction, thereby creating a ‘surgical pouch.
- The dissection will be advanced beyond the mucogingival line to approximately two-thirds the depth of the socket, and the ‘pouch’ will be expanded in the mesio-distal direction to stretch the soft tissues away from the underlying bony plate.
- Sticky bone will be inserted into the pouch by a mean of a small periosteal elevator. Additional graft material will be added and compressed until adequate filling of the pouch is achieved without overstretching the soft tissues.
- the healing abutment will be screwed into the implant body .

Postoperative Care:

Administration of:

• 1 gm Amoxicillin 500 mg (Misr Co. for Pharmaceutical Industries, Egypt) three times a day for seven days, or doxycycline 100 mg (Nile Co. for Pharmaceuticals and Chemical Industries, Egypt) twice a day if they are penicillin sensitive. [68]

• Ibuprofen 400 mg (Brufen, Kahira Pharmaceuticals, Egypt) will be provided for severe pain. [68]

• 0.12% Chlorhexidine mouthwash twice daily for two weeks. [68]

Patient self-care instructions:

• Avoid any hard brushing and trauma to the surgical site for two weeks.

• Participants will be instructed to avoid causing any damage to the operated site and to avoid consuming hot meals or vigorous rinsing.

Postoperative Radiographs:

• A standardized periapical parallel radiograph will be taken on the same day after implant placement to assess crestal bone level then after 3 and 6 months. CBCT scan will be scheduled for six months postoperative.

12. Outcomes:

PICOT:

P: Patients with non-restorable tooth in the maxillary esthetic zone including anterior and premolars indicated for immediate implant placement.

I: Buccal plate augmentation using sticky bone

C: Sticky bone used as a jumping gap filling material

O: Pink Esthetic score (PES)

T: 6 months

Outcome	**Outcome name**	**Measuring device**	**Measuring unit**
Primary outcome	Pink esthetic score	using the PES scoring system for dental implants.[71]	Numerical
Secondary outcome	Crestal bone level	CBCT machine . [69]	Millimeter
	Thickness of labial plate of bone	CBCT machine . [29]	Millimeter
	Soft tissue profile /contour	Scanning of diagnostic casts by optical scanner.[69]	Millimeter
	Patient satisfaction	VAS based questionnaire.[70]	Binary

13. Participant timeline

	Preoperative assessment	Immediately after implant placement	3 months post operative	6 months post operative
Pink esthetic score			X	X
Crestal bone level	X			X
Thickness of labial plate of bone	X			X
Soft tissue profile /contour	X		X	X
Patient satisfaction		X	X	X

Clinical evaluation:

1) pink esthetic score :[71]

This pink esthetic score (PES) evaluates the esthetic outcome of soft tissue around implant-supported single crowns in the anterior zone by awarding seven points for the mesial and distal papilla, soft-tissue level, soft-tissue contour, soft-tissue color, soft-tissue texture, and alveolar process deficiency .With the exception of papilla formation, the evaluation is performed visually by comparing reference teeth (i.e., with the contralateral tooth in the incisor zone and adjacent tooth in the premolar zone). For the mesial and distal papilla, the categories are complete, incomplete, and absent. For each criterion it is possible to award a score between two points (for a very good outcome) and no points (for a poor outcome). The maximum score that can be achieved is 14 points indicating an outcome that reflects complete conformity between the soft tissue of the tooth being assessed and that of the reference tooth.

Specific measurement time point: 3 and 6 months postoperatively.

2) crestal bone level : [69]

Cone beam computed tomography (CBCT) machine with superimposition technique.

Specific measurement time point: baseline and 6 months postoperatively.

3) Thickness of labial plate of bone:[29]

Using CBCT machine . Using the axial view, one reference line will be drawn from the apex of the implant to its platform (long axis); another line, perpendicular to the one at the long axis, will be drawn at the apex of the implant. Parallel to this, two lines will be drawn, one at 1 mm from the implant collar (R1) and another 5 mm apical to it (R2) measuring the thickness of the bone (at the buccal plate) to the nearest 0.1 mm.

Specific measurement time point: baseline and 6 months postoperatively.

4) Soft tissue profile /contour:[69]

Scanning of diagnostic casts by optical scanner.

Specific measurement time point: baseline , 3 and 6 months postoperatively.

14. Sample size:

Pink Esthetic Score (PES) was chosen as the primary outcome variable and effect size was estimated to be 1.5 based on a previous study by Abdelraheem et al (2022). Power calculation was performed at α=0.05 and at β=0.20, equal to 80% of power. Under this assumption, at least 8 patients were needed for each group with a total number of 16 patients. This number was increased to 20 patients (10 patients in each group) to compensate for any possible dropouts.

15. Recruitment:

• Patients will be selected from the outpatient clinic of the Oral Medicine and Periodontology department, Faculty of Dentistry-Cairo University.

• Screening of patients will continue until the target sample is achieved. (Consecutive sampling)

B) Assignment of interventions

16. Allocation:

All patients who provide an informed consent for participation as well as fulfill the inclusion criteria will be included in the study.

16a. Randomization:

Patients will be randomly assigned to either test or control groups using computer generated randomization (www.randomizer.org) which will be performed by the main supervisor.

16b. Allocation concealment mechanism:

Allocation concealment will be done by creating opaque sealed envelopes. The envelope will be chosen by the patient and will only be opened after completion of extraction.

16c. Implementation

• The supervisor will generate the randomization sequence. The principal investigator will enroll the participants.

17. Masking/blinding:

• Blinding of the operator is not applicable.

• Participants, Outcome assessor (primary and secondary outcomes) & biostatistician will be blinded.

C) Data collection, management, and analysis:

18. Data collection methods

- The phone numbers and address of the patients included in the study will be recorded or extracted from the patients' files.
- The baseline outcomes data as well those at follow-up periods will be assessed by co-supervisor.

Plans to promote participant retention and complete follow- up:

- Telephone numbers of all patients included in the study will be recorded as a part of the written consent.
- All patients will receive a phone call at the time of the pre-determined follow up.

19. Data management:

• All data will be entered and saved electronically.
• Patients' files are to be stored in numerical order and stored in a secured file. Data will be encrypted using a password.
• All data will be maintained after completion of the study.

20. Statistical methods:

Data will be analyzed using IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 21 (SPSS Inc. Chicago, IL). Numerical data will be described as mean and standard deviation or median and range or interquartile range, as appropriate. Categorical data will be described as numbers and percentages. The data will be explored for normality using Kolmogrov-Smirov test and Shapiro-Wilk test. Comparisons between two groups and over time will be done by 2-way analysis of variance for repeated measures.

If the time factor is not considerable, comparisons between the two groups for normally distributed numeric variables will be done using the Student's t-test while for non- normally distributed numeric variables will be done by Mann-Whitney test.
A p-value less than or equal to 0.05 will be considered statistically significant. All tests will be two-tailed.

D) Data monitoring:

21. Monitoring

No formal data monitoring committee will be needed since it is a study with known.
minimal risks.

22. Harms

Any temporary or permanent adverse effect will be recorded and documented.
No Harms are expected.

23. Audit

No formal auditing committee is available.

IV. Ethics and dissemination

24. Research ethics approval

This protocol and the template informed consent form will be reviewed by the Ethics Committee of Scientific Research -Faculty of Oral and Dental Medicine, Cairo University.

25. Protocol amendments

Any modifications to the protocol which may have an impact on the conduct of the study, potential benefit of the patient, or may affect patient safety, including changes of study objectives, study design, sample sizes, study

procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon by the Council of Periodontology Department.

26. Informed consent

Researcher will introduce the trial to patients and provide full explanation of its aim and benefits in plain language. Patients will then be able to have an informed discussion with the researcher. Researcher will obtain written consent from patients willing to participate in the trial. All consent forms will be translated into the Arabic language.

27. Confidentiality

All study-related information will be stored securely. All participant information will be stored in locked file cabinets in areas with limited access. All reports, data collection, process, and administrative forms will be identified by a coded ID (identification) number only to maintain participant confidentiality. All records that contain names or other personal identifiers will be stored separately from study records identified by code number. All local databases will be secured with password-protected access systems.

28. Declaration of interest

If there will be any conflict of interest, it will be declared.

29. Access to data

The principal investigator and the supervisors will be given access to the data sets. All data sets will be password protected. To ensure confidentiality, data dispersed to project team members will be blinded of any identifying participant information.

30. Post-trial care

All patients will be followed up for 6 months after the clinical trial is over.

31. Dissemination policy

• Study results will be published as partial fulfilment of the requirements for Master's Degree in Periodontology.
• Topics suggested for presentation or publication will be circulated to the authors.

V. Appendices

Vas for pain

Name:

0= no pain.

1-3= mild pain.

4-6=moderate pain.

7-9= severe pain.

10= very severe pain.

Days	Describe your pain
Saturday	
Sunday	
Monday	
Tuesday	
Wednesday	
Thursday	
Friday	

Vas for swelling

Name:

0= no swelling

1= mild swelling.

2=moderate swelling.

3= severe swelling.

4= very sever swelling.

Days	Describe your pain
Saturday	
Sunday	
Monday	
Tuesday	
Wednesday	
Thursday	
Friday	

32. Informed consent

Human Subjects

Research title:

Buccal Plate Augmentation Using Sticky Bone versus usage of sticky bone as a jumping gap filling material with simultaneous immediate implant placement in the maxillary esthetic zone: A

Randomized Controlled Clinical Trial

Full name of the researcher(s): Yara Khaled Mahmoud khalefa .

Objective of the research (study):

The aim of this study is to clinically assess pink esthetic score following Buccal Plate Augmentation using Sticky Bone versus usage of Sticky Bone as a jumping gap filling material with simultaneous immediate implant placement in the maxillary esthetic zone.

Steps in short:

□ The study is to be conducted in the Oral Medicine and Periodontology department, Faculty of Dentistry, Cairo University, Egypt. Patients are to be selected from the outpatient clinic of the department of Oral Medicine and Periodontology, Cairo University.

□ All patients will undergo pre-operative clinical examination: Patient's data will be collected; name, gender and age, medical and dental histories will be taken. Also, all patients will undergo standardized periapical radiograph to detect any pathosis and a pre-operative Cone beam computed tomography (CBCT) scans will be taken to evaluate the tooth root configuration and to confirm the presence of intact buccal wall.

□ Patient will be recruited into two groups (group A,b).

□ The surgical procedure will be performed in sterile surgical field. Under local anesthesia, atraumatic extraction for the affected tooth.

□ The socket will be well irrigated with saline and debrided with a bone curette

□ Bony sockets will be prepared through sequential drilling for the placement of the implant.

□ Venous blood will be withdrawn under aseptic conditions by veni
puncture of the antecubital vein and transferred into sterile tubes which will be devoid of anticoagulants. I- PRF preparation will be done.

□ In control group: The sticky bone graft will be condensed and adapted into the jumping gap as well as over the implants. Further, it will be covered with PRF membrane

□ In intervention group: Sticky bone will be inserted into the pouch by a mean of a small periosteal elevator. Additional graft material will be added and compressed until adequate filling of the pouch is achieved without overstretching the soft tissues.

□ The healing abutment will be screwed into the implant body.

Postoperative Care:

Administration of:

• Amoxicillin 500 mg (Misr Co. for Pharmaceutical Industries, Egypt) three times a day for seven days, or doxycycline 100 mg (Nile Co. for Pharmaceuticals and Chemical Industries, Egypt) twice a day if they are penicillin sensitive.

• Ibuprofen 400 mg (Brufen, Kahira Pharmaceuticals, Egypt) will be provided for severe pain.

• 0.12% Chlorhexidine mouthwash twice daily for two weeks.

Postoperative Radiographs:

• A standardized periapical parallel radiograph will be taken on the same day after implant placement to assess crestal bone level then after 3 and 6 months. CBCT scan will be scheduled for six months postoperative.

Number of visits & follow up period: Data collection will be done at 3 time points for each patient after diagnosis and patient preparation. These time points are:

Visit 1: surgical procedure.

Visit 2: 3month post-operative (first follow-up),

Visit 3: 6 months post-operative (second follow-up).

Direct benefit of the research to the human volunteer:

- Enhance the esthetic result after immediate implant placement.

- To preserve Crestal bone level after immediate implant placement.

- To preserve thickness of labial plate of bone after immediate implant placement.

- Enhance the Soft tissue profile /contour.

The scientific interest and the desired public benefit of the research:

In order to enhance the aesthetic outcome and increase the success rates of anterior dental implants, this research may not have a significant positive impact on the general population. However, research on Buccal Plate Augmentation using Sticky Bone may lead to enhancing patients' oral health, appearance, and overall quality of life.

Side effects and the degree of risk and expected to occur and how to deal with them:

-There are no major risks after immediate dental implantation.

Postoperative infection is a common minor risk and will be treated with antibiotics.

- Analgesics (non-steroidal anti-inflammatory drugs) will be used to treat discomfort after the operation.

Patient's full knowledge of the research steps: Reading [yes] Oral explanation [yes] other [ ]

1. I have carefully reviewed and understood the purpose of conducting the research and the nature of this study, and I understand what is necessary to accomplish these procedures.

2. The researcher has informed me of the possible therapeutic alternatives for this research.

3. The researcher has informed me of all the possible risks of this research and how to deal with it.

4. I agree to the imaging, recording, and all types of radiology to be performed in this study, on condition of anonymity.

5. I have made an accurate report on my health history and informed the doctor of all kinds of health reactions or unusual allergies to medicines, food, insect bites, anesthetics, dust or any reactions that have occurred to me from any other substances, abnormal bleeding or any other related conditions. For my health

6. I acknowledge that I am not involved in any other research from the beginning of this research until the end of this research and that I will inform the researcher physician if I enter any other research throughout the period of this research.

7. I undertake to return the medical devices (instruments) used in the research in case of discontinuation or when the research is completed.

After knowing the available information related to the research, the volunteer or the person in charge will be able to choose freely whether or not to subscribe. In case of approval, kindly fill out the data shown. The volunteer has the right to withdraw from the research without giving reasons.

The physician in charge of the research undertakes to keep the information of the volunteer person confidential by participating in the research, stating the methods used, such as .replacing names with code numbers or hiding facial features when photographing (etc.)

33. Biological specimens

N/A

VI. References

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