Vestibular Socket Therapy Using Acellular Dermal Matrix versus Connective Tissue Graft in Immediate Implants of Aesthetic Zone

Protocol of Thesis Submitted in Partial Fulfillment of The Requirements for Doctor Degree

in

Oral Medicine, Periodontology, Oral Diagnosis and Radiology

By

Amr Anwar Mohammed Ellithy
B.D.S (2012)
M.S.C (2021)

Oral Medicine, Periodontology,
Oral Diagnosis and Radiology
Faculty of Dentistry
Tanta University
2021

Supervisors

Dr. Maher Mohamed Mahmoud El-Tonsy

Professor of Oral medicine, Periodontology,
Oral Diagnosis & Radiology
Faculty of Dentistry
Tanta University
(Main supervisor)

Dr. Sahar Fawzy Ghoraba

Professor of Oral medicine, Periodontology,
Oral Diagnosis & Radiology
Faculty of Dentistry
Tanta University

Dr. Bassem Nabil Mohammed El Fahl

Lecturer of oral, Periodontology,
Oral Diagnosis & Radiology
Faculty of Dentistry
Tanta University

Introduction

Tooth extraction is one of the most widely performed procedures in dentistry and it may lead to significant dimensional changes of the alveolar ridge. However, loss of alveolar bone may occur prior to tooth extraction because of periapical pathology, trauma and\or advanced periodontal disease.[1]

Patients have been seeking for the optimum treatment outcomes following the replacement of missing teeth which could be achieved this by using different treatment protocols, including conventional removable prostheses, overdentures, fixed prostheses and dental implants.[2]

Dental implants have been in use for over 50 years and according to the literature are a highly successful treatment option for the long-term (10-years plus) replacement of missing teeth.[3] Considering replacing a tooth with an implant, clinician is faced to choose either delayed or immediate approach. Delayed Approach, where the hopeless tooth is extracted, and the implant is placed after completion of partial ridge healing occurs. The resultant osseous sites are often accompanied by significant vertical and horizontal changes in both hard and soft tissue dimension. These changes may subsequently require additional procedures to reconstruct the collapsed ridge and further prolong treatment duration.[4, 5]

The other approach which is immediate implant placement in the extraction socket is an attractive treatment modality that facilitates immediate tooth replacement and reduces treatment time, cost and surgical trauma as compared to delayed approaches.[6]

Elian et al.,[7] proposed a classification for the extraction sockets and the rendered treatment approach, in which sockets were divided into three types (Type I, type II and type III). Figure (1)

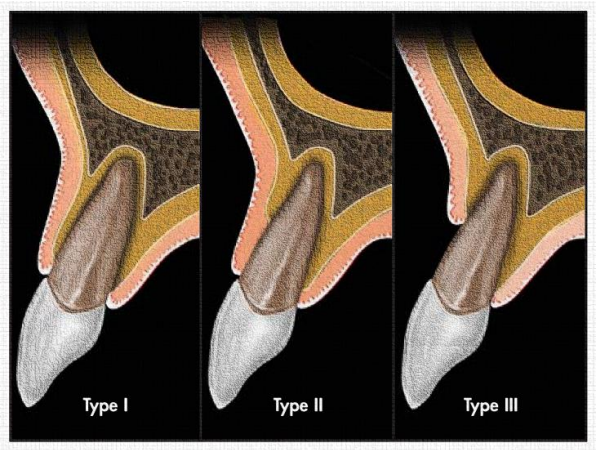

Figure (1) Illustration of the three types of extraction sockets, as defined by the facial soft tissue and buccal plate of bone present.

Type I socket, facial or buccal plate of bone and soft tissue level is normal related to the cemento-enamel junction of the extracted tooth and still intact post extraction. Type II socket, the facial soft and hard tissues are normal, but the buccal plate is partially missed after tooth extraction. Type III socket, the buccal bone plate and facial soft tissue are reduced after tooth extraction.[7]

Type II sockets are usually the most difficult to diagnose. They are very deceptive, as the inexperienced dentist may treat it as a Type I socket. This leads to less aesthetic outcomes. The major aesthetic problems arise from compromised treatment of Type II sockets because of post treatment soft tissue recession.[7]

A modification to Elian's classification[7] was proposed by El Askary 2019, Each class was divided into several subdivisions based upon; buccal

bone thickness, soft tissue thickness, keratinized tissue width, palatal bone level and the degree of vertical buccal bone and soft tissue loss. This modification aimed at facilitating precise diagnosis of extraction sockets and increasing the versatility of customized treatment options for various case scenarios.[8] However, this treatment concept has been controversial in terms of implant survival , aesthetic outcomes and possible post-operative resorption of bone plates in particular, when anterior maxilla is involved.[6, 9]

Multiple approaches have been developed to overcome such drawbacks such as dual zone grafting[10] , socket shield technique[11] and more recently vestibular socket therapy. [12]

Sanz et al.,[13]studied adding bone grafts in the gap between the implant and facial bone surface in immediate implants (dual zone) and stated that the horizontal crest dimension underwent changes during healing at the facial side of the alveolar crest where this reduction estimated to 1.1mm(29%) in the cases with graft and 1.6 mm (38%) in the non-grafted case.

Another technique introduced by ***Hürzeler et al*** ., [11] which is socket shield technique that involves partial tooth extraction and intentional retention of a section of a small labio-coronal fragment at the time of immediate implant placement. This aimed at tricking the bone that the tooth is still present and preserving the blood supply reaching the facial cortical plate from the periodontal ligaments and thus reduces resorption in both buccal/proximal bone. [14]

Disadvantages of socket shield technique were reported in a systematic review by ***Gharpure and Bhatavadekar*** [15] where clinical studies showed complications as, buccal/crestal bone loss and shield exposure/failure which

were the most common. Other complications such as formation of cementum and periodontal fibers on implant surfaces, pockets , mucositis, and peri-implantitis.[15, 16] However, some clinical reports recorded stable results at one year follow up interval. It is still difficult to predict the long-term success of this technique.[17]

Most recently, a novel technique for immediate implant placement, the vestibular socket therapy (VST) was described by ***Elaskry et al.,*** [18]for treating wide variety of fresh extraction sockets , intact , thin, lost labial plate of bone and infected sockets, where a facial bone membrane shield is applied from a horizontal incision in the vestibule to cover particulate bone graft that is added in the socket in addition to placing a custom made healing abutment to seal the socket rim. It was hypothesized that this technique restore the lost osseous architecture, stabilize soft tissue margins, and allowed immediate placement compared to immediate implant placement using other techniques reported in the literature.[19, 20]

Various materials can be used to augment bone deficiency in fresh extraction socket including bone grafts and barrier membranes. One of innovative materials is the allogenic bone membranes made from demineralized cortical bone fibers that are entangled and shaped into sizes engineered to complement specific surgical applications. This unique process creates an interconnected graft material that contains BMPs and other growth factors necessary for the promotion of new bone formation. Bone membranes are flexible upon hydration and each allograft has a sterility assurance level of 10^{-6} via low-dose gamma sterilization[21, 22].

The anatomy of soft tissues around dental implants is extremely important to prevent inflammatory peri-implant diseases and ensure healthy, stable and long-term survival of a dental implant. Various methods and materials for increasing the physiological thickness of tissues have been described including connective tissue graft (CTG) which is considered the gold standard material for augmenting soft tissue around implant[23] .

Another type of membrane is freeze dried Acellular dermal matrix (Alloderm) which is a biocompatible tissue composed a structurally integrated basement membrane complex and extracellular matrix with collagen bundles and elastic fibers. The alloderm was used as an alternative to autogenous free gingival graft to increase amount of keratinized tissue around natural teeth or dental implants[24].

Given that to date, there is very little information about soft tissue around implants with vestibular socket therapy. Therefore, our study will be directed towards clinical and radiographical evaluation and comparing the Vestibular Socket Therapy (VST) technique using Alloderm versus connective tissue graft both with xenogenic bone membrane in immediate implants of anterior aesthetic zone.

Aim of The Work

The aim of this study is to evaluate and compare the Vestibular Socket Therapy (VST) technique using alloderm versus connective tissue graft both with xenogenic bone membrane in immediate implants of anterior aesthetic zone.

Materials and Methods

Study design:

A randomized controlled clinical and radiographic trial.

Study setting:

The research will be carried out in the outdoor clinic of Oral Medicine, Periodontology, Oral Diagnosis and Radiology Department, in accordance with the guidelines of human research by the Research Ethical Committee of the Faculty of Dentistry, Tanta University.

Sample size:

Sample size was estimated assuming 5% alpha error and 80% study power. After one year, the mean thickness of labial plate was 2.18±0.73 mm using VST with bone membrane shield [18]. By assuming that VST with alloderm membrane will have similar effect as collagen membrane, according to Sarnachiaro et al., [25], the mean thickness of labial plate was estimated after 12 months to be 3.3 mm. Based on difference between two independent means using SD of 0.73, the minimum sample size was calculated to be 8 sockets per group. This was increased to 10 sockets to make up for lost to follow up cases. Total sample size = Number per group x Number of groups = 10 x 2 =20 sockets.

Software:

Sample size was based on Rosner's method [26] calculated by G-power 3.0.10. (4)

Patient and site selection:

Twenty surgical sites with remaining roots or non-restorable teeth in the maxillary anterior region from canine to canine with sockets type II

confirmed with CBCT will be selected from the Periodontology Clinic, Faculty of Dentistry, Tanta University who fulfill the inclusion criteria. The purpose of the present study will be explained to patients and informed consents will be obtained according to guidelines adopted by Research Ethics Committee, Faculty of Dentistry, Tanta University.

Inclusion criteria:

1) Adults (20-50) years old.
2) Class II socket according to ***Elian et al,*** [7]described as facial soft tissue is present but the buccal plate is partially missing following extraction of the tooth in the maxillary anterior region.
3) Thin gingival phenotype.
4) Bone quality ranges from D2-D3 as gained from preoperative cone beam computed tomography.
5) Presence of at least 3 mm of keratinized gingiva.
6) Optimal compliance as evidenced by no missing treatment appointments and positive attitude towards oral hygiene.

Exclusion criteria:

1. Medically compromised patients and systemic conditions precluding implant and periodontal surgery.
2. Smokers, diabetics, pregnant or lactating women.
4. History of chemotherapy, radiotherapy in head and/or neck region.
5. Bisphosphonate therapy.

Materials:

1) Implant*
2) Computer assisted surgical guide for implant†

* biohorizons implant, the pro,platform switching design,USA

3) Xenogenic bone membrane shield‡
4) Alloderm§
5) Xenograft **
6) Connective tissue graft

The clinical study design:

1- Phase I therapy

All patients will receive a comprehensive periodontal examination, oral hygiene instructions and they will be subjected to full mouth scaling and root planning (SRP) and polishing.

2- Patient grouping:

Twenty surgical sites will be divided into two groups; each of which has 10 surgical sites. Grouping will be done randomly sequentially numbered, opaque, sealed envelopes (SNOSE)

The groups will be treated as follow:

- Group I: Ten sites will be treated by immediate implant and VST with Alloderm + allogenic bone membrane and xenograft.
- Group II: Ten sites will be treated by immediate implant and VST with connective tissue graft + allogenic bone membrane and xenograft.

3- Surgical protocol:

– Sulcular incision will be made under local anesthesia, and then hopeless teeth will be extracted atraumatically. Socket lavage and curettage, the socket type will be assessed and confirm the presence of adequate interproximal bone level.

---

† Specially designed for every case according to biohorizons guided surgical kit
‡ Osteobiol ,flexible xenograft cortical sheet from Technoss,USA
§ AlloDerm SELECT™ RTM,biohorizons
** Deproteinized bovine bone minerals (DBBM), Min Oss X from biohorizons,USA

- A vestibular access horizontal incision will be made at the socket site, 3 to 4 mm apical to the mucogingival junction and extending 5 to 10 mm horizontally.
- A sub mucoperiosteal tunnel will be created starting from the facial aspect of the socket orifice and extending apically until the vestibular access incision.
- A computer guided surgical template will be used to deliver the implant (Biohorizons implant) in the optimum prosthetically guided position with the implant shoulder placed 3 to 4 mm apical to the labial gingival margin.
- Connective tissue graft of sufficient size will be harvested from the patient palate opposite to the area from canine region to first molar region and then trimmed to fit the facial wall

Group I: Implant will be placed through the surgical guide in the extraction socket then xenogenic bone membrane will be trimmed to fit the facial wall of the socket and introduced through the tunnel lying over the facial bone plate and stabilized by bone tacks then Alloderm membrane will be trimmed to be placed through the tunnel lying over allogenic bone membrane. The facial gap will be filled with xengogenic bone graft.

Group II: Implant will be placed through the surgical guide in the extraction socket then xenogenic bone membrane will be trimmed to fit the facial wall of the socket and introduced through the tunnel lying over the facial bone plate and stabilized by bone tacks then connective tissue graft will be placed through the tunnel lying over allogenic bone membrane. The facial gap will be filled with xengogenic bone graft.

The socket orifice will be sealed using a customized healing abutment screwed to the implant, adequately finished, and polished to ensure a proper soft tissue emergence profile, while the vestibular access horizontal incision will be sutured.

4-Postoperative Phase

-All subjects will receive postoperative instructions including [27]

a) Rinsing with 0.1% Chlorhexidine mouth rinse twice daily for two weeks.

b) Antibiotics combination of 500 mg Metronidazole along with Amoxicillin Clavulanate (Augmentin 100 mg) every 12 hours one day preoperatively and continuing for 5 days after extraction.[18]

c) Non-steroidal anti-inflammatory (NSAID) medication of Ibuprofen 400 mg twice daily for one week.

5-Clinical Assessment:

Each group will be subjected to intraoral scanning at baseline, 6 months and 12 months. The changes in peri-implant mucosal level will be assessed by superimposition of scanning files of different intervals to monitor the changes in surface area calculated by software.

The changes in gingival phenotype could be assessed at 6 months and 12 months intervals by superimposition of DICOM files on CBCT software.

6-Radiographic Assessment:

Each group will be subjected to: Cone Beam Computed Tomography (CBCT) at baseline, 6 months and 12months to asses both thickness and height of labial (facial) plate of bone and implant survival.

7-Statistical analysis:

Results will be collected, tabulated and analyzed using computer software. Data will be presented as mean and standard deviation (SD) values and the significance level will be set at $p < 0.05$. The differences of the clinical parameters within the time intervals in each group will be determined. Statistical analysis will be carried out blindly such that the assigned groups should not be revealed during the analysis.

Rules and Responsibilities:

Study chair: Dr**.** Abd El-Salam El-Askary is the inventor of the technique will be overlooking the whole procedures to ensure the accurate delivery of the procedure as it was described.

References

1. Schropp L, Wenzel A, Kostopoulos L, Karring T. Bone healing and soft tissue contour changes following single-tooth extraction: a clinical and radiographic 12-month prospective study. International Journal of Periodontics & Restorative Dentistry. 2003;23(4).
2. AL-Omiri M, Hantash ReA, AL-Wahadni A. Satisfaction with Dental Implants: A Literature Review. Implant Dentistry. 2005;14(4):399-408.
3. Howe M-S, Keys W, Richards D. Long-term (10-year) dental implant survival: A systematic review and sensitivity meta-analysis. Journal of dentistry. 2019;84:9-21.
4. Hansson S, Halldin A. Alveolar ridge resorption after tooth extraction: A consequence of a fundamental principle of bone physiology. Journal of dental biomechanics. 2012;3.
5. Tan WL, Wong TL, Wong MC, Lang NP. A systematic review of post-extractional alveolar hard and soft tissue dimensional changes in humans. Clinical oral implants research. 2012;23:1-21.
6. Jiang X, Di P, Ren S, Zhang Y, Lin Y. Hard and soft tissue alterations during the healing stage of immediate implant placement and provisionalization with or without connective tissue graft: A randomized clinical trial. Journal of Clinical Periodontology. 2020;47(8):1006-15.
7. Elian N, Cho S, Froum S, Smith RB, Tarnow DP. A simplified socket classification and repair technique. Practical Procedures and Aesthetic Dentistry. 2007;19(2):99.
8. Elaskary A. Advances in Esthetic Implant Dentistry: John Wiley & Sons; 2019.
9. Araújo MG, Sukekava F, Wennström JL, Lindhe J. Ridge alterations following implant placement in fresh extraction sockets: an experimental study in the dog. Journal of clinical periodontology. 2005;32(6):645-52.
10. Tan-Chu J, Tuminelli FJ, Kurtz KS, Tarnow DP. Analysis of buccolingual dimensional changes of the extraction socket using the “ice cream cone” flapless grafting technique. Int J Periodontics Restorative Dent. 2014;34(3):399-403.
11. Hürzeler MB, Zuhr O, Schupbach P, Rebele SF, Emmanouilidis N, Fickl S. The socket-shield technique: a proof-of-principle report. Journal of clinical periodontology. 2010;37(9):855-62.
12. Th Elaskary A, Gaweesh YY, El Tantawi M, Maebed MA. Vestibular Socket Therapy: A Novel Approach for Implant Placement in Defective Fresh Extraction Sockets With or Without Active Socket Infection (One-Arm Cohort Study). International Journal of Oral & Maxillofacial Implants. 2021;36(1).
13. Sanz M, Lindhe J, Alcaraz J, Sanz-Sanchez I, Cecchinato D. The effect of placing a bone replacement graft in the gap at immediately placed implants: a randomized clinical trial. Clinical Oral Implants Research. 2017;28(8):902-10.

14. Cornelini R, Cangini F, Martuscelli G, Wennström J. Deproteinized bovine bone and biodegradable barrier membranes to support healing following immediate placement of transmucosal implants: a short-term controlled clinical trial. International Journal of Periodontics & Restorative Dentistry. 2004;24(6).
15. Gharpure AS, Bhatavadekar NB. Current evidence on the socket-shield technique: a systematic review. Journal of Oral Implantology. 2017;43(5):395-403.
16. Nevins ML, Langer L, Schupbach P. Late Dental Implant Failures Associated with Retained Root Fragments: Case Reports with Histologic and SEM Analysis. International Journal of Periodontics & Restorative Dentistry. 2018;38(1).
17. Saeidi Pour R, Zuhr O, Hürzeler M, Prandtner O, Rafael CF, Edelhoff D, et al. Clinical benefits of the immediate implant socket shield technique. Journal of Esthetic and Restorative Dentistry. 2017;29(2):93-101.
18. Elaskary AT, Gaweesh YY, Maebed MA, Cho S-C, El Tantawi M. A Novel Method for Immediate Implant Placement in Defective Fresh Extraction Sites. International Journal of Oral & Maxillofacial Implants. 2020;35(4).
19. Spray JR, Black CG, Morris HF, Ochi S. The influence of bone thickness on facial marginal bone response: stage 1 placement through stage 2 uncovering. Annals of periodontology. 2000;5(1):119-28.
20. Grunder U, Gracis S, Capelli M. Influence of the 3-D bone-to-implant relationship on esthetics. International Journal of Periodontics & Restorative Dentistry. 2005;25(2).
21. Dias FJ, Arias A, Borie E, Lezcano MF, Arellano-Villalón M, Fuentes R. Comparison of morphological quantitative characteristics of the newly formed alveolar bone after the application of demineralized bone matrix and cortical bone allografts. 2019.
22. Charde P, Thakare KS, Bhongade ML, Markovic A, Deshpande AM. Reconstruction of Interimplant Papilla by Demineralized Freeze-dried Bone Allograft Block Fixed by Titanium Screw in Maxillary Esthetic Zone. J Contemp Dent Pract. 2020;21:1205-9.
23. Puzio M, Hadzik J, Błaszczyszyn A, Gedrange T, Dominiak M. Soft tissue augmentation around dental implants with connective tissue graft (CTG) and xenogenic collagen matrix (XCM). 1-year randomized control trail. Annals of Anatomy-Anatomischer Anzeiger. 2020;230:151484.
24. Yan J-J, Tsai AY-M, Wong M-Y, Hou L-T. Comparison of acellular dermal graft and palatal autograft in the reconstruction of keratinized gingiva around dental implants: a case report. International Journal of Periodontics & Restorative Dentistry. 2006;26(3).
25. Sarnachiaro GO, Chu SJ, Sarnachiaro E, Gotta SL, Tarnow DP. Immediate implant placement into extraction sockets with labial plate dehiscence

defects: a clinical case series. Clinical implant dentistry and related research. 2016;18(4):821-9.
26. Rosner B. Fundamentals of biostatistics: Nelson Education. 2015.
27. Resnik RR, Misch C. Prophylactic antibiotic regimens in oral implantology: rationale and protocol. Implant dentistry. 2008;17(2):142-50.

دراسة مقارنة لتقييم تقنية العلاج من الجهه الدهليزية لتجاويف الخلع بإستخدام كلا من الأدمه الخلويه وطعم النسيج الضام في الزراعه الفوريه ف المناطق الأماميه الجماليه

خطة بحث للإستيفاء الجزئي للحصول علي درجة الدكتوراه

في

طب الفم وأمراض اللثه وطرق التشخيص والأشعه

مقدمه من الطبيب

عمرو أنور محمد الليثي

بكالوريوس (2012)

ماجيستير (2021)

قسم طب الفم وأمراض اللثه

وطرق التشخيص والأشعه

كلية طب الاسنان

جامعة طنطا

2021

المشرفين

ا.د. ماهر محمد محمود التونسي

استاذ طب الفم وامراض اللثة ، وطرق التشخيص و الاشعة

كلية طب الأسنان - جامعة طنطا

(المشرف الرئيسي)

أ.د. سحر فوزي غرابه

استاذ طب الفم وامراض اللثة ، وطرق التشخيص و الاشعة

كلية طب الأسنان - جامعة طنطا

د. باسم نبيل محمد الفحل

مدرس طب الفم وامراض اللثة ، وطرق التشخيص و الاشعة

كلية طب الأسنان - جامعة طنطا

الملخص العربي

المقدمة

يسعى أطباء الأسنان والمرضى للحصول على أفضل نتائج العلاج لتعويض الأسنان المفقودة. قام أطباء الأسنان بالعمل علي تحقيق ذلك باستخدام بروتوكولات العلاج المختلفة والتي من احدث أمثلتها الغرساتالمستخدمه في تعويض الأسنان لعدة عقود.

تتنوع خيارات توقيت غرس الاسنان باحدي طريقتين احدهما التقليدية والاخري الفورية حيث في الطريقة التقليدية ، يتم خلع السن ، وتوضع الغرسة بعد أن تلتئم تجاويف الخلع وفي هذه الحالة يكون شفائها مصحوبًا بتغييرات رأسية وأفقية كبيرة في كل من أبعاد الأنسجه اللينه والعظام. الأسلوب الآخر هو وضع الزرع الفوري ، حيث يمكن للطبيب أن يضع الغرسة فورًا بعد خلع السن وتتميز هذة الطريقه بتقليل وقت العلاج مع إظهار معدلات نجاح مماثلة لتلك الخاصة بالغرس التقليدي.

من اجل تحديد أفضل خيار علاجي ،أي من وضع الزرع الفوري أو المتأخر ، مع أو بدون تطعيم عظمي ، يجب أن نفهم كيفية تقييم شكل تجويف الخلع بعد خلع الأسنان ، ووجود ودرجة تراجع اللثه على السن الذي يتم خلعه ، ووجود أو عدم وجود صفيحة العظم الشدقية.

تنقسم تجاويف الخلع الي ثلاثه انواع : التجويف من النوع الاول تكون الأنسجة الرخوة المقابله للوجه وصفيحة العظم الشدقية في المستويات الطبيعية بعد الخلع اما تجويف من النوع الثاني ،تكون الأنسجة الرخوة المقابله للوجه موجودة ولكن الصفيحة الشدقية مفقودة جزئيًا بعد قلع السن اما تجويف من النوع الثالث ، يتم فقد كل من الأنسجة الرخوة للوجه ولوحة العظم بشكل ملحوظ بعد قلع الأسنان.

اثبتت التجارب ان تجاويف النوع الأول هي الأسهل والاعلي في نسب النجاح بينما يصعب علاج تجاويف النوع الثالث في خطوة واحدة وتتطلب تطعيم الأنسجة الرخوة والعظام بطعوم إضافية. في حين أنه غالبًا ما تكون تجاويف النوع الثاني هي الأكثر صعوبة في التشخيص. يمكن أن تكون خادعة للغاية ، حيث قد يتم التعامل معها على أنها من النوع الأول. هذا غالبا ما يؤدي إلى نتيجة جمالية أقل من مثالية.

من أحدث تقنيات وضع الزراعه الفوري والتي تم وصفها هوعلاج التجويف الدهليزي حيث يتم وضع شريحه داعمة من خلال شق دهليزي أفقي وتطعيم عظمي يُضاف إلى التجويف بالإضافة إلى وضع دعامة التئام مخصصة.

في هذه الدراسة الجديدة سوف يتم مقارنه و تقييم تقنية العلاج من الجهه الدهليزية لتجاويف الخلع بإستخدام كلا من الأدمه الخلويه وطعم النسيج الضام في الزراعه الفوريه ف المناطق الأماميه الجماليه.

الهدف من الدراسة:

تقييم ومقارنه تقنية العلاج من الجهه الدهليزية لتجاويف الخلع بإستخدام كلا من الأدمه الخلويه وطعم النسيج الضام في الزراعه الفوريه ف المناطق الأماميه الجماليه.

المواد والأساليب:

تصميم الدراسة:

تجربة سريرية وشعاعية.

إعداد الدراسة:

سيتم إجراء البحث في عيادة طب الفم وقسم أمراض اللثة وتشخيص الفم وقسم الأشعة ، وفقًا لإرشادات البحث البشري من قبل لجنة أخلاقيات البحث بكلية طب الأسنان جامعة طنطا.

- سوف يتم شرح كل خطوات المتبعة في الدراسة قبل البدء فيها مع اخذ موافقتهم كتابيا.

حجم العينة:

تم تقدير حجم العينة بناءً على افتراض 5٪ خطأ ألفا و 80٪ قوة دراسة

إجمالي حجم العينة 20 مريض مقسمين عشوائيا علي مجموعتين .

كل المرضى المختارين لابد أن تتوافر فيهم الصفات الآتية:

1. بالغين في السن من 20 : 50 عام
2. يتم تضمين المرضى إذا كان لديهماكثر من سن واحد غير قابل للعلاج منه بدون علامات العدوى الحادة في المنطقة الأمامية للفك العلوي من النوع الثاني لتجاويف الخلع مع وجود عظام كافية في القمة والحنك للسماح بوضع الغرسة بشكل صحيح مع ثبات أولي كافٍ.

3. سمك لثه رقيق

- **ويستبعد من الدراسة كلا من:**

1. المرضى الذين يعانون من ظروف مرضية قد تؤثر على العملية الجراحية او الغرسات.
2. المدخنون .
3. الحوامل والمرضعات .

<u>المواد المستخدمة:</u>

1. الغرسات
2. دليل جراحي لوضع الغرسات بواسطة الحاسب
3. غشاء عظمي
4. الأدمه الخلويه
5. طعم النسيج الضام

تصميم الدراسة

<u>مراحل العلاج</u>

المرحلة الاولى للعلاج :

ولكل المشتركين في الدراسة تشمل :

1- إزالة الجير وتنعيم الجذور.

2- تعليمات الحفاظ على صحة الفم ونظافته.

مجموعات المرضى:

سوف يصنف المرضى عشوائيا إلى مجموعتين علاجيتين كل منهما سوف يتلقى إحدى طرق العلاج الآتية:

<u>المجموعة الاولى</u> : غرسات فوريه مع تقنية العلاج من الجهه الدهليزية لتجاويف الخلع بإستخدام الأدمه الخلويه

<u>المجموعة الثانية</u> : غرسات فوريه مع تقنية العلاج من الجهه الدهليزية لتجاويف الخلع بإستخدام طعم النسيج الضام

المرحلة الجراحية:

- كل الجراحات سوف تتم بواسطة نفس الجراح .
- ومراعاة إعطاء كل المرضى تعليمات ما قبل و بعد الجراحة.
- - يتم عمل شق جراحي تحت التخدير الموضعي ، ثم يتم قلع الأسنان والجذور المتبقية بطريقة غير رضيه. غسيل التجويف وكشطة ، سيتم تقييم نوع التجويف والتأكد من وجود مستوى عظام مناسب.
- - سيتم عمل شق أفقي للوصول إلى الدهليز في موقع التجويف ، من 3 إلى 4 مم قمي إلى الوصلة المخاطية اللثة ويمتد من 5 إلى 10 مم أفقيًا.
- - سيتم إنشاء نفق تحت الغشاء المخاطي بدءاً من الجانب الوجهي من فتحة التجويف ويمتد بشكل قمي حتى شق الوصول الدهليزي.
- - سيتم استخدام قالب جراحي موجه بالكمبيوتر لإيصال الغرسة في الوضع الأمثل
- - سيتم وضع الغشاء المناسب في مكان جدار الوجه من التجويف وإدخاله من خلال النفق الموجود فوق لوحة عظام الوجه ويتم تثبيته بواسطة دبابيس العظام.
- - سيتم ملء التجويف من الجهه الوجهيه بمواد تطعيم مختلفة وسيتم إغلاق فتحة التجويف التاجيه باستخدام دعامة التئام مخصصه .

1- التقييم الإكلينيكي :

سوف ستم تقييم سمك اللثه في البدايه وبعد 6 اشهر وبعد 12 شهر

2- التقيم الإشعاعي :

التصوير المقطعي مخروط الشعاع سوف يتم أخذها في لبدايه وبعد 6 اشهر وبعد 12 شهر لتحديد سمك وارتفاع العظم المتكون حول الغرسات وكذلك نجاح الغرسات .

التحليل الإحصائي:

كل البيانات المجمعة سوف تنظم ويتم جدولتها وتحلل إحصائيا بواسطة الكمبيوتر .