Clinical, Radiographic and Histologic Evaluation of Tenting the Schneiderian Membrane Using Titanium Mesh for Maxillary Sinus Lift Procedure: A Randomized Controlled Clinical Trial

A Thesis Protocol
Submitted for partial fulfillment of the requirements of the
Master Degree in dental science
In
Oral and Maxillofacial Surgery
Research code**: HE-12**

Submitted By

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B.D.S, Suez Canal University, 2017

Free lance dentist

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Faculty of Dentistry
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"Thesis Research Protocol"

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Degree: ☒ **M.D.Sc.** ☐ **D.D.Sc** ☐ **PH.D.**

Department: Oral and maxillofacial surgery

Thesis Title in English: **Clinical, Radiographic and Histologic Evaluation of Tenting the Schneiderian Membrane Using Titanium Mesh for Maxillary Sinus Lift Procedure: A Randomized Controlled Clinical Trial**

Thesis Title in Arabic **التقييم الإكلينيكي و الشعاعي و الهيستولوجي لتخييم غشاء شنايدر بإستخدام شبكة التيتانيوم لإجراء رفع غشاء الجيب الأنفي الفكي: تجربة سريرية عشوائية محكمة.**

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1. Abstract:

Introduction: Atrophic maxillary ridge following long-standing extractions together with maxillary sinus pneumatization presents a challenge when an implant supported prosthesis is intended to be done.A variety of techniques and materials have been put forth to enhance the atrophic maxillary bone in order to receive an endosseous implant. **Aim**: the aim of this study is to evaluate the use of titanium mesh in tenting the Schneiderian membrane both clinically and radiographically while augmenting the Maxillary sinus. **Methodology**: Twenty posterior maxillary edentulous sites requiring open sinus augmentation for staged dental implant placement will be studied. Patients will be randomly allocated into two groups using random group generator (random.org): Group I (study group) the Schneiderian membrane will be elevated using titanium mesh fixed by bone screws. Group II (control group) will have stainless steel screws/pins placed bucco-palatally to maintain the elevated membrane and stabilize the formed blood clot. Platelet rich fibrin (PRF) will be placed at the site of elevated membrane in both groups. Surgeries will be evaluated clinically in terms of pain, edema and tissue response during the follow up period. Radiographic assessment will be performed during the surgical follow-up period and after 6 months, to evaluate the formed bone height and density using CBCT. At the time of implant placement (6 months post-sinus lift), bone core biopsies will be harvested from the grafted sinus area using a trephine bur under sterile conditions. The samples will be fixed in 10% buffered formalin, decalcified, embedded in paraffin, sectioned, and stained with Hematoxylin and Eosin (H&E) stain.

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2. Introduction and Background

The paired maxillary sinuses are air-filled spaces lying within the bilateral maxillae, lateral to the nasal cavity, superior to the maxillary teeth, inferior to the orbital floors, and anterior to the infratemporal fossa. These sinuses are the largest of the paranasal sinuses, measuring an average of 12.5 mL in volume.[2] The maxillary sinuses are lined with a thin bilaminar mucoperiosteal membrane known as the Schneiderian membrane. **(Avichai Stern and James Green.,2012).**

Within the 4 paranasal sinuses, the maxillary sinuses are the most important for dentistry due to its proximity to teeth. As the maxillary bone develops, the sinuses cavities are formed and filled by air, a physiological process called pneumatization. The pneumatization itself causes the maxillary sinuses to expand into the adjacent anatomical structures, being the alveolar process the anatomical region with the highest prevalence rate. **(Del Fabro M and Testori T.,2009).**

It is still a poorly understood process. There are reports in literature of some factors that may influence maxillary sinuses pneumatization, such as heredity, nasal mucous membrane pneumatization, craniofacial configuration, bone density, sinus surgeries, growth hormones, air pressure within the cavity of the sinus and an age-related process. **(Sánchez-Pérez A et al.,2016).**

Tooth loss promotes local dimensional changes of hard and soft tissues. In posterior regions of the upper jaw, maxillary sinus approximation may be present and such event, in combination with bone loss, can difficult implant installation in these sites. **(Misawa M et al.,2016).**

Cone-beam computed tomography (CBCT) is currently a complementary diagnostic tool that provide three-dimensional (3D) images. It significantly reduces the overlapping of anatomical structures and enable a better evaluation of the alveolar bone and the maxillary sinus floor status. **(Hamdy RM and Abdel-Wahed N. .,2013)**

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In addition, the CBCT study can also reveal whether there are septa within the planned sinus surgical site. Normally, septa with low height (less than 2 mm) do not require further attention because the membrane can usually be elevated without difficulty. However, high septa with partial or complete separation of the sinus cavity may involve the preparation of 2 windows during sinus lift surgery. Finally, the clinician can observe possible sinus mucosal thickening, sinus polyps, and air fluid levels. **(Kao DW., 2020).**

A maxillary sinus augmentation is recommended when there is less than 10 mm of space available from the alveolar crest to the maxillary sinus, and the clinician and patient wish not to use small implants to reconstruct the area. **(Carrao V and DeMatteis I. .,2015).**

Different surgical techniques are used with maxillary sinus augmentation. A lateral maxillary window sinus lift is generally performed on patients who require more than 3 mm of augmentation. Generally, when a large amount of bone is required to place an implant, the lateral window sinus lift is recommended2 rather than a trans crestal sinus lift. **(Kao DW., 2020).**

A less invasive procedure, often referred to as the trans-crestal osteotome sinus floor elevation technique, was first presented by Dr Summers in 1994 and is a viable alternative in certain clinical settings to the lateral window sinus lift procedure. **(Summers R. .,1994).**

Osseodensification is a technique that involves plastic deformation of bone that is created by rolling and sliding contact using a densifying bur that is fluted in such a manner that it densifies and compacts the bone with minimal heat elevation. A rather new implant site/osteotomy preparation technique was developed in 2013, which densifies the bone as it prepares the implant site by means of a non-substractive drilling technique referred to as by its innovator Dr Huwais as osseodensification. This is a surgical technique that uses specialized designed fluted burs (DENSAHburs) that help densify the bone as they prepare the osteotomy site. **(Huwais S., 2018).**

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There has been a wide variety of materials suggested for augmentation of the maxillary sinus cavity in order to gain bone height and overall volume. These materials have been subject to several modifications along the years to achieve a more predictable outcome within an expected time frame. Graft materials have also varied in origin according to the desired role as osteoconductive, osteoinductive and osteogenic (**Yip et al., 2015**).

A recently adopted idea when augmenting the maxillary sinus is using the established blood clot created beneath the elevated Shneiderian membrane and its later development into bone, as a graftless technique. This reduces the overall cost of the procedure eliminating the additional costs needed for a graft material. (**Wang et al., 2024**).

Stabilization of the membrane at the new elevated level and maintaining the void created remains necessary. This may be performed using the implants placed when the residual bone height allows primary implant stability (**Zabalbu et al., 2024**).

Or it may require the use of an appliance as a space maintainer during a staged approach for augmentation of the sinus prior to implant placement (**Cricchio et al., 2011**) (**Johansson et al., 2012**) (**Kaneko et al., 2012**) (**Atef et al., 2014)** (**Ghanem et al., 2020**).

The principle governing bone formation by simply elevating the sinus membrane could also be applied in cases where insufficient bone anchorage hinders simultaneous implant placement. Thereafter evolved the idea of maxillary sinus membrane lifting without the use of any bone grafts, this was first introduced by Lundgren and colleagues. **(Lundgren S. et al., 2004).**

Histologic analysis allows clinicians to assess the quality, maturity, and composition of newly formed bone in sinus lift sites, often revealing the proportion of vital bone, residual graft particles, and connective tissue within the regenerated area **(Scarano et al., 2008)**

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Tissue biopsies obtained during implant placement enable a detailed histologic evaluation of bone healing dynamics, providing critical data on graft biocompatibility and osteoconductive capacity in maxillary sinus augmentation cases **(Testori et al., 2002).**

Histologic sections stained with specific dyes, such as hematoxylin and eosin or Masson's trichrome, facilitate the differentiation between mineralized bone, marrow spaces, and remaining graft particles, offering a comprehensive view of the healing process **(Zitzmann et al., 2001).**

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3. Research Question (RQ):

In patients with atrophied edentulous posterior maxillary ridges indicated for implant placement, what is the difference between using titanium mesh versus bone screws in tenting the Schneiderian membrane in terms of:
- Clinical ease of application, reducing the operation cost and duration.
- Radiographical gained bone height.
- Histologic structure of the newly formed bone.

4. Research Hypothesis, Aim, Objectives & Expected Outcomesss

a. Hypothesis

Null Hypothesis: There is no significant difference in ease of application and the formed bone quantity and quality between both tenting techniques.

Alternative Hypothesis: There is a significant difference in ease of application and the formed bone quantity and quality between both tenting techniques.

b. Aim

The aim of this study is to evaluate using titanium mesh versus bone screws in tenting the Schneiderian membrane clinically, radiographically and histologically.

c. Objectives:

Assessment of both tenting techniques of the Schneiderian membrane in terms of:
- Clinical intra-operative ease of application and post-operative pain and edema through Visual Analogue Scale (V.A.S.) and edema scale.
- Radiographical evaluation of formed bone through measurements on the CBCT.
- Histologic structure of the newly formed bone using hematoxylin and eosin stains.

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d. Expected Outcomes

Using stainless steel screws as a tenting barrier may be easier in application than using a titanium mesh while achieving the same clinical and radiographic results as a graftless approach for the maxillary sinus.

5. Research Design and Methods

I-Materials:

The following materials will be used in the study:

Item	Composition	Trade name
Resorbable suture	Vicryl	Egysorb Cairo, Cairo governorate, Egypt
Surgical Lancet No.15	Carbon steel	Kiato Kanpur, India
Local anesthesia	Articaine with epinephrine (1:100,000)	Artpharma Cairo, Cairo governorate, Egypt
Surgical titanium mesh	Titanium type V	Riton Guangdong, China

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Surgical stainless steel screws 1.5 mm.	Stianless steel	Haenaem Gyeonggi-do, Korea
Collagen membrane	Collagen	Matrix graft Friedrich, Germany

II-Methods:

a) **Study design:** Randomized controlled clinical study, randomization will be done using random group generator (random.org).

b) **Study setting:** The study will be conducted in the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry,Suez Canal University.

c) **Study population and samples:** Participants enrolled in this study will be selected from a group of patients seeking implant supported dental restorations in an atrophic posterior maxilla requiring staged augmentation.

d) Patient selection: 20 edentulous sites indicated for an implant supported restoration in severely atrophic posterior maxilla. Patients could be partially edentulous receiving a single implant restoration or fully edentulous receiving an implant supported overdenture.

Patient will be selected based on eligibility criteria:

Inclusion criteria: (**Testori et al., 2024**)
- Adult male/female patients with age interval 18:60 years old.
- Patients with one or more teeth requiring implant supported dental restoration in atrophic maxilla.
- Alveolar bone height less than 5 mm at the defective site.
- Good oral hygiene.
- Patient's consensual agreement to be enrolled in the study.

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Exclusion criteria: (**Wimalarathna., 2021**).
- Medically compromised patients with conditions contraindicating surgery (eg. uncontrolled diabetics, bisphosphonate intake, radio or chemotherapy).
- Patients with active infection at or related to the site of surgery (eg. acute sinusitis).
- Heavy smokers.
-Patients not indicated for an implant supported restoration at the time of enrollement (eg. active/untreated periodontal disease).
(Patients developing any medical condition that interferes with the outcomes after enrolment in the study will be excluded).

e) Clinical examination and radiographic evaluation:
- Thorough clinical examination of the oral cavity, mucosal thickness, inter-arch distance as well as dental history taking and whether previous complications occurred with local anesthesia and compliance to given treatments and instructions.
- Each patient will have a CBCT for evaluation and measurement of bone height at the defected site requiring restoration. This will dictate the exact location of the osteotomy and the desired height and width of augmentation as well as help in planning for implant placement. CBCTs will be done using the following exposure parameters for standardization: 6x8 cm field of view, 90 KV, 10 mA, an exposure time of 6.1 seconds and a voxel size of 0.2 mm.

f) Random allocation: Patients will be randomly allocated in the two groups of the study.

g) Surgical Procedure:

1) For the study group: Administration of local anesthesia to the surgical field will be followed by reflection of a full-thickness trapezoid mucoperiosteal flap with a crestal incision and two releasing incisions mesially and distally to expose the lateral wall of the sinus at the site to be augmented. A round diamond bur will be used to outline the lateral antrostomy window predetermined radiographically preserving a trap door to support and protect the membrane during procedure. The membrane will be elevated across the floor latero-medially with mesial and distal freeing to

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avoid potential tearing or perforation. The superior border of the lateral antrostomy will be prepared with holes/osteotomies to receive stainless steel fixation screws to fix the titanium mesh in place. This will be followed by resting the trap door supporting the membrane on the titanium mesh to maintain the elevated level and stabilize the blood clot formed underneath.

2) For the control group: Administration of local anesthesia to the surgical field will be followed by reflection of a full-thickness trapezoid mucoperiosteal flap with a crestal incision and two releasing incisions mesially and distally to expose the lateral wall of the sinus at the site to be augmented. A round diamond bur will be used to outline the lateral antrostomy window predetermined radiographically preserving a trap door to support and protect the membrane during procedure. The membrane will be elevated across the floor latero-medially with mesial and distal freeing to avoid potential tearing or perforation. The superior border of the lateral antrostomy will be prepared with holes/osteotomies to receive stainless steel screws/pins to be placed buccopalatally. This will be followed by resting the trap door supporting the membrane on the stainless steel screws to maintain the elevated level and stabilize the blood clot formed underneath.

3) The lateral antrostomy will be covered with a collagen membrane followed by flap re-adaptation and suturing for primary closure.

4) The titanium mesh and screws will be retrieved through a second intervention after the 6-month follow up period.

h) Post-operative care: Patients will be advised a list of instructions to follow firmly and given medication appropriate with the procedure.

- Sutures will be removed 7-10 days after the surgery (in case of emergency, flap dehiscence, severe pain, bleeding or developing sinus related signs or symptoms patients will present to the clinic for examination).

i) Clinical examination and assessment:

Post operative edema and pain will be assessed during the post-operative follow up phase using edema scale and VAS pain scores respectively.

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- Signs of inflammation, tissue reaction or local irritation will be assessed and recorded.

j) Radiographic examination and assessment:

- CBCT will be obtained during the follow-up period for evaluation of the elevated membrane at the desired height through the location of the mesh/screws.

- CBCT will be obtained after 6 months to evaluate the formed bone in terms of height.

- CBCT images will be compared for evaluation of the amount of formed bone at the surgical site using OnDemand3D ®App software (Cybermed, Seoul, Korea).

k) Histologic Assessment:

At the time of implant placement (6 months post-sinus lift), bone core biopsies will be harvested from the grafted sinus area using a trephine bur under sterile conditions. The samples will be fixed in 10% buffered formalin, decalcified, embedded in paraffin, sectioned, and stained with Hematoxylin and Eosin (H&E) stain.

The histologic evaluation will include:

- Assessment of new bone formation.
- Inflammatory response or foreign body reaction.

The goal of the histologic assessment is to determine the quality of the newly formed bone and evaluate tissue compatibility. This process will help correlate histological findings with the clinical and radiographic outcomes.

The histologic analysis will be performed following the standard protocols approved and commonly used in public universities and research centers in Egypt, ensuring reproducibility and consistency.

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6. Statistical plan

a) Sample size calculation:

To evaluate the difference between the two proposed groups;
Group I: control group and Group II: study group. A **Paired T Test** is proposed. A minimum total sample size of 14 samples will be sufficient to detect the effect size of 1 mm change in bone height and a power (1-β=0.80) of 80% at a significance probability level of $p<0.05$ partial eta squared of 0.14. (**M. Ahmed et al, 2017**)

According to sample size calculations, each group would be represented by a minimum of 7 samples and a total sample size 14 samples will be selected for the study as shown in tables 1 and figure 1. The sample size was calculated according to G*Power software version 3.1.9.6. **(Cohen, 1988, Faul et al., 2007, 2013)**.
Where;
f: is the effect size; α= 0.05; β= 0.20; Power= 1- β = 0.80

$$f = \frac{\sigma_\mu}{\sigma}$$

$$\sigma_\mu^2 = \frac{\sum_{i=1}^{k} n_j (\mu_i - \mu)^2}{N}$$

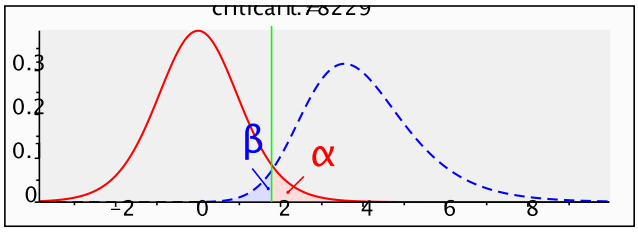

Figure 1. Sample size calculations

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Table 1: Variables of the study

Variable	Symbol	Donates	Number of samples
G	G1	Group I Study group	10
	G2	Group II Control group	10
Total Sample Size			20

b) Statistical analysis

All data will be subjected to statistical analysis. The statistical analysis will be performed using SPSS version X software (IBM SPSS Statistics version X (IBM Corp., Armonk, NY, USA). Data will be presented as the mean ± SD. The one-sample Kolmogorov–Smirnov test will be used to examine the normality of data distribution. Repeated measures analysis of variance (ANOVA) will be used to compare variables within each study group, and a post hoc test will be performed if the ANOVA is significant. The paired samples t-test will be used to compare each pair of studied variables within each study group. The independent samples t-test will be used to compare variables between the two groups studied. For all tests, the result will be considered statistically significant if the P-value is equal to or less than 0.05.

7. Ethics consideration:

The present research will be conducted after the approval of the Research Ethics Committee (REC) of the faculty of Dentistry, Suez Canal University. It will be conducted on sixteen samples of patients ethical considerations regarding patient well-being and confidentiality will be undertaken by the researcher and an informed written consent will be signed by the subjects/ patients before commencing the study explaining all clinical examinations, procedures and follow up.

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8. Time Plan

Include Grant Chart as following example:

Starting: After approval of ethical committee and faculty council

Ending: after 12 months

Activity/Month	1	2	3	4	5	6	7	8	9	10	11	12
Patient selection/Surgery	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐
Collecting data and Statistical Analysis	☐	☐	☐	☒	☒	☒	☒	☒	☒	☐	☐	☐
Writing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☒	☒

9.Research Estimated Budget in Egyptian Pound

CBCT	2250/case			36,000
Materials	3200/membrane x16	500/Screws X64	Titanium mesh, cost determined per case with average (2000/case)	99,200
Others (Miscallenous)	250 disposables /case			4,000
Statistics	5000			
Publications	25,000			
Histopathology	900/case X 16			
Total	183,600			

Sponsored by the researcher himself.

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11. Appendices

Informed consent

-1-

Suez Canal University

Faculty of Dentistry

Research Ethics Committee (REC)

Investigator Application Form

1-Name of researcher: **Hedra Sherif Kamel Michael**
2-Name of Department: **Oral and maxillofacial surgery.**

3-Adress of researcher: **Ismailia,Egypt**

a- Email: **hedra_sherif@dent.suez.edu.eg**
b- Phone number **+20 1226182970**
c- Fax number: **none**

4- Name (s) of Co-investigator (s):

5- Grade of protocol:

*M.D.Sc. (√) *Ph.D. ( ) *Doctorate degree (D.D.Sc.) ( ) *Other ( )

*Domestic ( ) *Multi-Centre within Egypt ( ) *International( )

6-Title of the research:
Clinical, Radiographic and Histologic Evaluation of Tenting the Schneiderian Membrane Using Titanium Mesh for Maxillary Sinus Lift Procedure: A Randomized Controlled Clinical Trial

7-Type of the research:
*Drug trial ( ) *Surgical technique (√) *Investigative technique (√)
*Devise study ( ) *Survey study ( )*Blood sampling ( )
*Review of old records ( )

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8-Subjects of research:

* Children (< 18 years): ( ) *Adults (>18 years) (√)

* Vulnerable groups (no)

9- Request is being made to waive (give-up) informed consent:Yes: ()No:(√)

10- The research is for the good of society: Yes: (√) No: ( )

11-Study design:

a-Phase type I: ( ) II: ( ) III: ( )

b-Randomization: Yes: (√) No: ( )

c-Placebo: Yes: ( ) No: (√)

d-Genetic sampling: Yes: ( ) No: (√)

e-Other: Yes: ( ) No: (√)

12-Facilities for the research are available: Yes: (√) No: ( )

13- List the risks of the study: pain, edema, wound infection, sinusitis, temporary epistaxis.

14- Are the risks reasonable to the potential benefits to the subjects, if any, or to the knowledge to be gained? Yes: (√) No: ( )

15- Privacy and confidentiality of subjects are assured Yes: (√) No: ( )

16- The subject of the research could quit at any time without penalty or loss of any benefits to which they would otherwise be entitled Yes: (√) No: ( )

Signature of the principal investigator: Date:

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التقييم الإكلينيكي و الشعاعي و الهيستولوجي لتخييم غشاء شنايدر بإستخدام شبكة التيتانيوم لإجراء رفع غشاء الجيب الأنفي الفكي: تجربة سريرية عشوائية محكمة

خطة بحث مقدمة توطئة للإتمام الجزئي للحصول على

درجة الماجستير فى علوم طب الاسنان

في جراحة الفم والوجه والفكين

كود البحث: HE-12

مقدمة من

هدرا شريف كامل ميخائيل

بكالوريوس طب وجراحة الفم والأسنان جامعة قناة السويس 2017

طبيب أسنان حر

المشرفين

اللقب	الاسم	الوظيفة	الجامعة	التوقيع
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كلية طب الأسنان

جامعة قناة السويس

2025

الملخص العربى:

1) المقدمة :

يمثل الضمور الشديد في الفك العلوي الخلفي تحديًا عند الحاجة إلى عمل استعاضة سنية مدعومة بالزرعات. يحدث هذا مع فقدان العظام المتقدم بعد عمليات القلع طويلة الأمد بالإضافة إلى تهوية واتساع الجيب الفكي العلوي.
تم ابتكار مجموعة متنوعة من التقنيات والمواد لتعزيز عظام الفك العلوي من أجل تهيئته لتلقي غرسة أسنان.

2) الهدف من البحث :

مقارنة تقنيتين مختلفتين في رفع و تثبيت غشاء الجيب الأنفي الفكي إكلينيكيا و إشعاعيا و هيستولوجيا و ذلك لتعزيزعظام الفك العلوي.

3) أسئلة البحث :

في المرضى الذين يعانون من ضمور الفك العلوي الخلفي , ما هي تقنية الخيام التي ستكون أسهل في التطبيق وأفضل لتثبيت غشاء الجيب الأنفي الفكي لتقليل تكلفة العملية ومدتها وكذلك دراسة نتائج كلتا التقنيتين من حيث استجابة الأنسجة الرخوة وحجم العظام وبنيتها؟

4) خطة البحث ومنهجية الدراسة:

سيتم دراسة 20 موقعًا خاليًا من الأسنان في الفك العلوي الخلفي تتطلب زيادة عظم الجيوب الأنفية المفتوحة جانبيا لوضع غرسة أسنان مرحليا. سيتم إدراج المرضى بشكل عشوائي في مجموعتين باستخدام مولد المجموعة العشوائية (random.org)
- المجموعة 1 (مجموعة الدراسة) سيتم رفع غشاء شنايدر باستخدام شبكة من التيتانيوم مثبتة بواسطة مسامير عظمية للحفاظ على الغشاء المرتفع وتثبيت جلطة الدم.

- المجموعة 2 (المجموعة الضابطة) سيتم رفع غشاء شنايدر باستخدام براغي/دبابيس من الفولاذ المقاوم للصدأ موضوعة على نحو شدغي حنكي للحفاظ على الغشاء المرتفع وتثبيت جلطة الدم.

سيتم تقييم العمليات الجراحية سريريًا من حيث الألم (VAS) التورم واستجابة الأنسجة خلال فترة المتابعة. سيتم إجراء التقييم الإشعاعي خلال فترة المتابعة الجراحية وبعد ستة أشهر، لتقييم ارتفاع وكثافة العظام المتكونة باستخدام CBCT.

و ستتم دراسة الهيستولوجي بإستخدام صبغة الهيماتوكسين و الايوسين لتحديد جودة العظم المتكون حديثا و تقييم استجابة الفك لوجود مادة غريبة.

سيتم شرح كل الخطوات الخاصة بالبحث لكل المرضى المشتركين بالبحث وسيتم الحصول على موافقة مكتوبة على كافة خطوات البحث .

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الإجراء الجراحي :

المجموعة الدراسة:

- تلقي التخدير الموضعي
- سيتم رفع غشاء شنايدر باستخدام شبكة من التيتانيوم مثبتة بواسطة مسامير عظمية للحفاظ على الغشاء المرتفع وتثبيت جلطة الدم.

المجموعة الضابطة:

- تلقي التخدير الموضعي
- سيتم رفع غشاء شنايدر باستخدام براغي/دبابيس من الفولاذ المقاوم للصدأ موضوعة على نحو شدغي حنكي للحفاظ على الغشاء المرتفع وتثبيت جلطة الدم.

5) الخطة الإحصائية :

تم حساب حجم العينة وفقا لإصدار برنامج .G * power 3.1.9.6لمعرفة العدد الأمثل لإجراء التجربة وعند إجراء التجربة سيتم جمع البيانات وجدولتها طبقا للجدول الزمني المحدد وبعد الإنتهاء من إجراء التجربة وجمع البيانات كاملة سيتم إختيار التحليل **الإ**حصائي المناسب لتحديد الفروق المعنوية بين المجموعات المختلفة تحت الدراسة بإستخدام أحد البرامج الإحصائية مثل SPSS (V. 26)عند مستوى معنويه P-value ≤ 0.05 or 0.01

-سيتم عرض البيانات كمتوسطات ±الإنحراف المعياري في صورة جداول.

-عرض البيانات في صورة رسوم بيانية.

-إستخدام إختبارات للمقارنة بين مجموعتي الدراسة.

- سيتم عرض البيانات الفئوية على شكل تكرارات)ن (ونسب مئوية) ٪ إن وجدت.
- إستخدام إختبارمربع كاي لإختبار أهمية الارتباط بين المتغيرات الفئوية.

6) الجدول الزمني:

رقم المعيار	وصف المرحلة	التاريخ المتوقع للانتهاء من العمل	ملاحظات
1	الإعداد	شهر	
2	شراء الخامات المساعدة للبحث	شهران	

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	تحضير الكيماويات		
3	الجزء العملي	خمسة اشهر	
4	تجميع البيانات	شهران	
5	التحليل الإحصائي	اسبوع	
6	تغيير النتائج	اسبوع	
7	كتابة المراجعة الأدبية	اسبوع	
8	كتابة طرق البحث	اسبوع	
9	كتابة المناقشة	اسبوعين	
10	تجميع الرسالة كاملة	اسبوع	

7) مرفقات :

الإستماره المستنيرة

جامعة قناة السويس

كلية طب الاسنان

لجنة أخلاقيات البحث العلمي نموذج الموافقه المستنيرة

لإجراء بحث طبي علي مشارك متطوع

إسم المشارك المريض .....النوع .....:

السن .....:تاريخ الميلاد.....:

١ -عنوان البحث باللغة العربية:

التقييم الإكلينيكي و الشعاعي و الهيستولوجي لتخييم غشاء شنايدر بإستخدام شبكة التيتانيوم لإجراء رفع غشاء الجيب الأنفي الفكي: تجربة سريرية عشوائية محكمة

٢ - الخلفية العلمية (الموضوع البحث) والهدف من إجراء البحث:

مقارنة تقنيتين مختلفتين في رفع و تثبيت غشاء الجيب الأنفي الفكي وإكلينيكيا و إشعاعيا و ذلك لتعزيزعظام الفك العلوي.

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٣ - ما سوف يتم إجراؤه بالتفصيل:
يقتصر هذا البحث على الأفراد الذين يسعون إلى الحصول على استعاضات سنية مثبتة بواسطة غرسات في المنطقة الخلفية من الفك العلوي (منطقة الضروس/ الضواحك) بشرط ألا يكون ارتفاع العظم كافي لوضع الزرعات.

يعتمد البحث طريقتين لتخييم غشاء شنايدر لزيادة عظم الفك العلوي من خلال الجيب الأنفي الفكي كمرحلة تمهيدية لاستقبال زرعات مستقبلية.

يجب أن تتوافر بعض الشروط في المشاركين في البحث بحيث ألا تتعارض حالتهم الصحية/ المرضية بشكل عام او موضعي مع الإجراء الجراحي المجرى أثناء فترة البحث.

مكان البحث: عيادات قسم جراحة الفم و الوجه و الفكين، كلية طب الأسنان بجامعة قناة السويس، الإسماعيلية.

مدة البحث: ستة أشهر.

عدد الحالات المشاركة: عشرون حالة (موضع عظمي ضامر بسبب اتساع و تمدد الجيب الأنفي الفكي).

تفاصيل خطوات البحث
عند التطوع للمشاركة و بعد التأكد من توافر الشروط اللازمة للإدراج في البحث سيتم توزيعك بشكل عشوائي في إحدي مجموعتين:
المجموعة الأولى: سيتم رفع غشاء شنايدر باستخدام شبكة من التيتانيوم مثبتة بواسطة مسامير عظمية للحفاظ على الغشاء المرتفع وتثبيت جلطة الدم.
المجموعة الثانية: سيتم رفع غشاء شنايدر باستخدام براغي/دبابيس من الفولاذ المقاوم للصدأ موضوعة على نحو شدغي حنكي للحفاظ على الغشاء المرتفع وتثبيت جلطة الدم.

سيخضع كل مشارك لتصوير أشعة مقطعية على الموضع المعني بالبحث قبل إدراجه وبعد الجراحة الأولى وفي نهاية مدة البحث.

4)الفوائد المتوقعه من البحث:

زيادة عظم الفك العلوي الخلفي بما يسمح باستعاضات سنية مثبتة بواسطة زرعات. و يمكن ايضا

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الاستفادة منها على المدى البعيد في تثبيت استعاضات سنية ثابته او متحركة بزرعات سنية لتعويض خلعات أكثر بالفك العلوي.

5-المخاطر المحتمل حدوثها من اجراء البحث:

تتمثل المخاطر في المضاعفات المصاحبة لأي إجراء جراحي مثل الإحساس بالألم و التورم و تلك الوارد حدوثها مثل التهاب الجرح أو التهاب بالجيب الأنفي أو النزيف المؤقت من الأنف.

6-التعويضات في حالة حدوث مخاطر:

في حالة عدم تكوين عظم كافي للزرعة عند انتهاء المدة سيتم التعامل مع الموقف في الجراحة الثانية أثناء وضع الزرعة بواسطة اضافة عظم جديد أو تغيير أجراء تثبيت الزرعة.

7- البدائل المتاحة في حالة رفضك الإشتراك في هذا البحث : التركيبات الثابتة أو المتحركة.

8- سرية معلوماتك :
سوف تعامل معلوماتك بسريه كامله ولن يطلع عليها سوي الباحث الرئيسي .بعد انتهاء الدراسه سيتم ابلاغك بالنتائج وأي نتائج خاصه تتعلق بحالتك الصحية.

9- حقك في الإنسحاب: من حقك الإنسحاب من البحث في أي وقت دون إبداء أسباب ودون أي عواقب سلبيه عليك .

10- في حالة أخذ أي عينه :فسوف لا تستخدم في أي بحث آخر .

11- عند وجود أي إستفسار لديك يمكنك الاتصال .

بالباحث الرئيسي : هدرا شريف كامل تليفون 201226182970+

من ينوب عنه تليفونيا:

مقرر لجنة الأخلاقيات :.....
تليفون.....

أقر أنني اطلعت وفهمت الأجراءات التي ستتم من خلال هذا البحث ووافقت عليها.

.المشارك في البحث :الباحث الرئيسي

الاسم .....: التوقيع .....:

البصمه..... التاريخ:.....

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**ملحوظه :من حق المتطوع الحصول على صورة من الإقرار .

هذا البحث :

توطئة لرسالة ماجستير (√)

توطئة لرسالة دكتوراه ( )

بحث غير ممول (√)

تمت الموافقه علي هذا البحث من قبل لجنة اخلاقيات البحث العلمي
بتاريخ :.....

هذه الموافقه سارية حتى :.....

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