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EVALUATION OF IMMEDIATELY PLACED ULTRA WIDE DIAMETER IMPLANT PLACED IN MANDIBULAR MOLARS.

Abdelrahman karam gad.

Faculty of Dentistry
Department of Oral and Maxillofacial Surgery

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Name of Candidate: Abdelrahman Karam Gad

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Keywords: Dental implant, Immediate placement, Ultra-wide.

Supervision Committee:

1- Prof. Dr. Ragab Shaaban Hassan
Professor of Oral and Maxillofacial Surgery
Oral and Maxillofacial Surgery Department
Faculty of Dentistry
Alexandria University

2- Dr. Gaafar Nabil Ahmed El Halawani
Lecturer of Oral and Maxillofacial Surgery
Oral and Maxillofacial Surgery Department
Faculty of Dentistry
Alexandria University

Role of Supervisors

1- Prof. Dr. Ragab Shaaban Hassan

Supervise the clinical work.

Manage an accurate case selection.

Help the student in interpreting results and revising the thesis.

2- Dr. Gaafar Nabil Ahmed El Halawani

Supervise the clinical work.

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ABSTRACT

Background: Ultra-wide-diameter implants (7 mm to 9 mm diameter) are gaining favor for immediate placement in the posterior area because they allow for increased engagement of molar socket walls, reduce the need to bone graft and provide better stress distribution under the high occlusal loads in the posterior area.

Aim of this study: To evaluate both the clinical and radiographical outcome on osteointegration and peri-implant bone density when using ultra wide diameter implant placed immediately in molar extraction socket.

Plan of the study: 12 implants for 12 patients will be immediately placed in fresh extracted molar sockets without flap or bone grafts. After six months, cement retained crown will be loaded to the implant. Clinical and radiographic parameters will be evaluated.

Results: Will be statistically analyzed using the Statistical Package for Social Science (SPSS) software version 20.0.

Keywords: dental implant, immediate placement, ultra-wide.

INTRODUCTION

Alveolar bone undergoes dimensional changes vertically and horizontally after tooth extraction as a result of periodontal loss and bundle bone resorption in the tooth socket leading to reduction of bone volume that affects negatively the dental implant placement and the restorative treatment functionally and esthetically.[1]

The first year following tooth loss in premolar and molar area, up to 50% ridge width reduction occurs, where two-thirds of the total reduction occur within the first three months' post extraction.[2]

To overcome these unfavorable changes, immediate implant placement is recommended at the time of tooth removal for less buccolingual bone reduction and wider crest compared to the delayed implant placement.[3]

However, Immediate implant placement in molar extraction socket is more critical unlike in single root sockets, this is due to many factors such as complex anatomy of molar roots with larger socket dimensions and also the high mechanical forces exerted on molar sites.[4]

Immediate implant as a single surgical procedure has many advantages. These advantages include ideal implant positioning,[5, 6] preservation of socket bone[7, 8] and shortened treatment time.[9] Furthermore, studies reported less amount of bone loss when the implant is placed immediately after tooth extraction.[10, 11]

The final outcome of immediate placement depends on many important factors. These factors include the preservation of the walls of alveolar bone during extraction especially the buccal plate, the oral health and hygiene

conditions, the surgical and prosthetic protocol followed, the surgical technique used, the implant position in the socket, the use of bone grafts and the elevation approach either flapless or with a flap.[12]

Successful immediate implant placement is determined by primary stability which is an essential factor[13] which is also very challenging in molar sockets due to many reasons such as the presence of multiple roots with large socket voids, and the anatomical limitations due to presence of maxillary sinus and inferior alveolar nerve.[14]

Implant design including "pitch, width, depth, shape of the thread, and crestal module" is an important factor in determining the stress distribution and primary stability during osteointegration in immediate loading implants.[15-17]

Using conventional implant in one of the molar root sockets leads to many prosthetic and maintenance complications, it compromises the emergence profile which could be avoided by placing the implant into the interradicular septum for more prosthetic improvement and long term maintenance, However, engaging to the socket septum can lead to inaccurate implant site preparation[18] and requires additional bone augmentation to fill the residual socket spaces.[19]

Wider diameter implants in immediate molar implant placement have many advantages over the narrow conventional implant. These advantages are increasing the contact area engaged the implant with the socket walls and interradicular area for better osteointegration and more favorable occlusal forces distribution[20] it also enhances the emergence profile and permits using wider and stronger prosthetic components.[21]

Ultra wide dental implants increase primary stability, permit greater bone contact and reduce the residual space in molar socket[22] so reduce the need to bone graft with a predictable outcome and very little bone loss.[23]

This technique requires high clinical experience in teeth removal atraumatically for bone preservation and site preparation, and also requires a careful case selection for a successful treatement.[20]

Hattingh et al.,[23] concluded that the immediate placement of ultrawide diameter dental implant in fresh extracted molar socket following atraumatic extraction without any flaps has a predictable outcome esthetically with minimal contour changes and accepted stability over time.

The null hypothesis is that using the ultra-wide implant placed immediately after molar extraction has no significant effect on implant stability and peri-implant bone density.

AIM OF THE STUDY

The aim of the study is to evaluate both the clinical and radiographical outcome on osteointegration and peri-implant bone density when using ultra wide diameter implant placed immediately in molar extraction socket.

PLAN OF THE STUDY

Study Design

The study is a single arm clinical trial. It will be set up and reported according to the CONSORT guidelines. [24]

The PICO question: Does the immediate placement of ultra wide diameter implant in non-restorable mandibular molar socket will enhance primary stability and peri-implant bone density?

Type of patients or population: patients with age range 20-40 years old having non-restorable mandibular molar teeth.

Type of Intervention: immediate placement of ultra wide diameter implant.

Outcomes: wound healing, socket dimensions, crestal bone loss, implant stability and bone density will be the main outcome measures of this study.

Setting and Location

Participants will be recruited from the Outpatient Clinic of Alexandria University Teaching Hospital and operated in the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University.

Summary Statement

Sample size was estimated assuming 5% alpha error and 80% study power. Tsallarico et al reported that the mean Implant Stability Quotient (ISQ) values at baseline for ultra-wide implants was 65.5 ± 7.6 and 78.8 ± 2.8 after 6 months of implant placement.[25, 26] The sample will be stratified by gender into two groups. Sample size was calculated to be 5 patients per group, increased to 6 patients to make up for loss to follow up. Total sample size = number per group × number of groups = 6 × 2 = 12 patients.

Software

Sample size was based on Rosner's method[27] calculated by Gpower 3.0.10.[28] All of the obtained data will be collected, statistically analyzed and presented in the form of tables, graphs and charts using the IBM Statistical Package for Social Science (SPSS) software version 20.0.

Eligibility Criteria

The criteria for including patients are as follows:

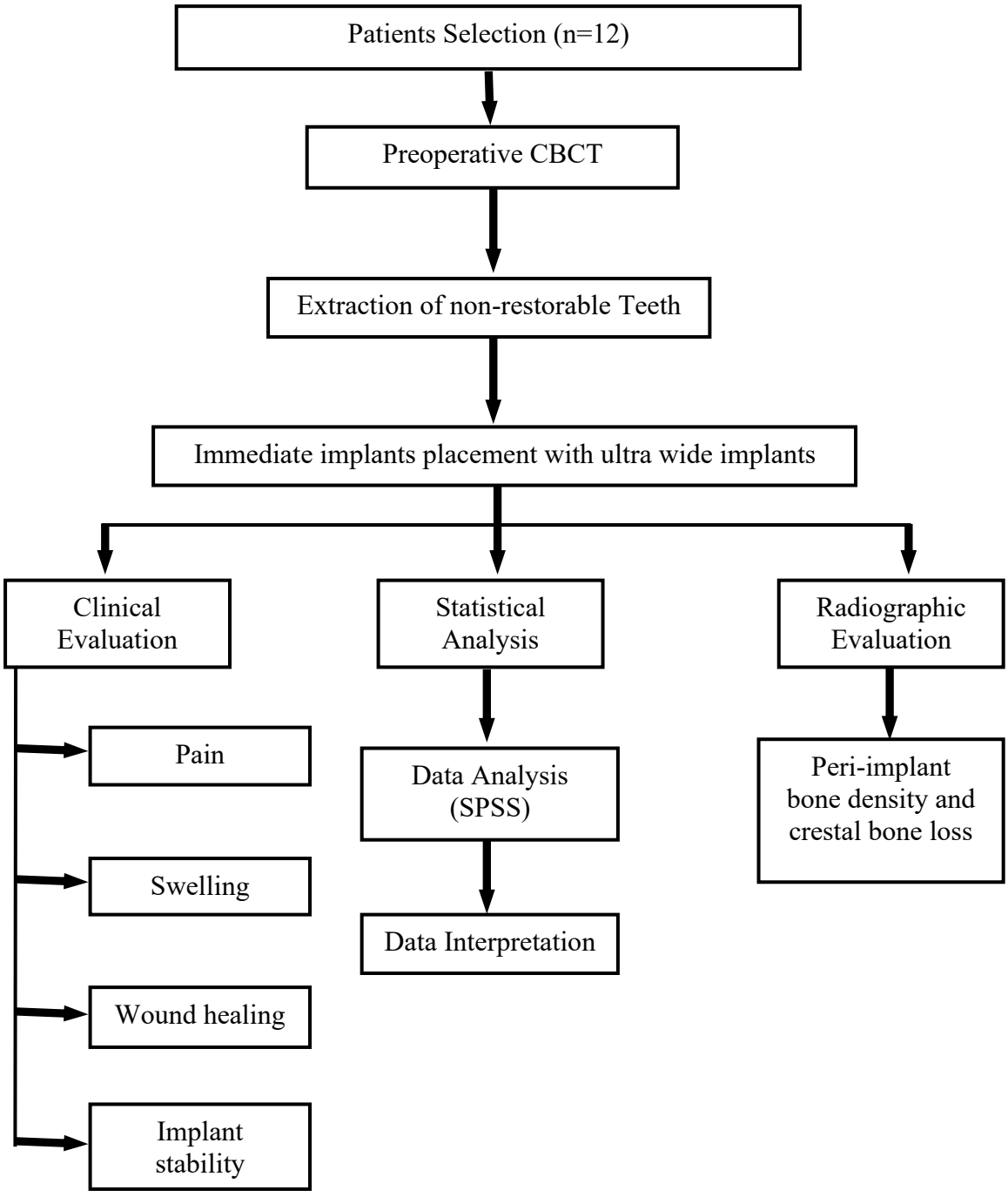
Inclusion criteria

- Adult patients ranging from 20-40 years.
- Adequate bone beyond teeth apices without jeopardizing any anatomical structure.[29]
- Non-restorable mandibular molar teeth.[23]
- Available bone with adequate width and buccolingual dimensions.
- Peri-implant bone defect should be 2mm or lesser.

Exclusion criteria

- Smokers.
- Medically compromised patients like uncontrolled diabetes and coagulation disorders.
- Tooth with periapical pathosis or bony defects.[23]

Study Design



Materials

1. (Dentium Superline implant, diameter 7mm, South Korea). *
2. Osstell.**
3. Physiodispenser***

Phases

I. Preoperative Phase

1- History

a) Personal history

Full personal data in details is required; including name, age, gender, occupation, address, telephone number. Also, the telephone number of relatives and companions.

b) Past medical history

History of any medical condition like diabetes, hypertension, drug allergy or any medications.

c) Past dental history

History of periodontal disease, badly destructed teeth, swelling, trauma, failed restorations, any oral pathology and past dental experiences.

d) Chief complaint

The patient's chief complaint, desire and expectations will be documented.

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*Superline,Dentuim Co,Doublethread,S.L.A surface (sandblasted with large grit and Acid etched),Korea

** Osstell: Osstell, Sweden

***(COXO | C-SAILOR IMPLANT MOTOR),china.

2- Clinical examination

Soft tissue will be examined for any suppuration or discharge, swelling or tooth mobility.

3- Radiographic examination

Cone-Beam Computed Tomography (CBCT) to evaluate the condition and anatomy of tooth, presence of any periapical pathology and for treatment planning.

II. Surgical Phase

1- Preoperative patient preparation

To control infection, antibiotic prophylaxis will be 1 gm amoxicillin+clavulanate sixty minutes before operation, according to the (INFECTIOUS DISEASES SOCIETY of AMERICA) guidelines. [30]

2- Operative procedure[22]

- Surgery will be performed under local anesthesia (Mepecaine-L) with 1:20000 adrenaline.
- Atraumatic tooth extraction of molar teeth without any flaps or bone removal.
- Pilot hole will be performed in inter-radicular septum following root removal.
- Osteotomy preparation will be completed up to the planned diameter of the implant, which was based on the socket dimensions, followed by implant insertion.

- The implant shoulder should be ensured to be seated 2mm below the lowest point of buccal wall and 2mm distance from the buccal wall.
- A healing abutment will be then connected to the implant and soft tissue adaptation as well as void closure will be obtained with suturing and hemostatic collagen sponge at the level of the healing abutment.

3- Postoperative care[23]

- Patients will be given comprehensive oral hygiene care and postoperative instructions, including;
  - Not to rinse for 24 hours after surgery.
  - Cold fomentation for 24 hours only postoperatively.
  - Soft diet, high protein, high calorie diet and fluids for 2 weeks postoperatively.

Postoperative medication

They will be advised to take the prescribed medications, which include:

- Amoxicillin 875mg + Clavulanic acid 125mg * every 12 hours for 7 days.
- Non-Steroidal Anti Inflammatory drugs** every 8 hours for 4 days.
- Chymotrypsin +Trypsin 300 E.A.U*** every 8 hours for 5 days
- 0.12% chlorhexidine mouth wash**** 3 times daily for 2 weeks.
- Sutures will be removed after one week from surgery.

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* Augmentin: GalaxoSmithKline,UK

** Cataflam: Diclofenac potassium 50mg: Novartis. Switzerland

*** Alphintern: Chemotrypsin 300 E.A.U (14microkatals) +Trypsin 300 E.A.U (5microkatals): Amoun Pharmaceutical Co. S.A.E

**** Hexitol: Chlorhexidine 125mg/100ml concentration 0.125%: Arabic drug company, ADCO

4- Clinical follow-up phase

Patients will be followed-up both clinically and radiographically for 9 months.

a) Clinical Evaluation

1- Postoperative pain.[31]
   - It will be recorded for each patient after 48 hrs postoperatively, then after one week through a 10-point Visual Analogue Scale (VAS) from 0 to 10.
   - (0-1= None, 2-4= Mild, 5-7= Moderate, 8-10= Severe).

2- Postoperative swelling.[32]
   - It will be recorded for each patient after 48 hours postoperatively, then after one week through a 10-point scale with 4 parameters will be used.
   - None (no swelling), light (intraoral, localized to the treated area), moderate (extraoral swelling localized to the treated area), and severe (extraoral swelling extending beyond the treated area).

3- Implant stability.[33]
   - It will be measured by implant stability meter (Osstell™) immediately postoperative and at 6 months.

4- Peri-implant probing depth.[34]
   - Pocket probing on dental implants should be conducted with a light force (approximately 0.25 N); peri-implant pocket depths should be ≤5 mm.

b) Radiographic Evaluation[23]

Immediately postoperative, after 6 months and after 9 months CBCT will be requested in order to evaluate:

1- Peri-implant bone density

2- Crestal bone loss

III. Prosthetic phase[22]

After 6 months of integration, the implant was restored with a cemented retained crown.

STATISTICAL ANALYSIS

All of the obtained data will be collected, statistically analyzed and presented in the form of tables, graphs and charts using the IBM Statistical Package for Social Science (SPSS) software version 20.0.

ETHICAL CONSIDERATIONS

Participant Safety

The study subjects will receive both oral and written information about the benefits and risks of the interventions, also about the gained advantages compared to the conventional method which are reduced treatment plan time, less procedure steps and placement of the implant fixture in an optimal axial position threats.

Follow Up policy

The patients will be followed up for 6 months in the outpatient clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry. All patients' personal information will be recorded, and a direct contact with the patient and his or her relatives will be established using telephone number in order to ensure ease of recall and to provide keen and up to date follow up.

Informed Consent

All patients will sign an Informed Consent Form before undergoing the operation to ensure and confirm their understanding of the outcome of the operation and the risks they might be subjected to during the intervention.

Research Ethics Committee approval

The clinical part of the study will be performed after gaining the ethical clearance from the Research Ethics Committee, Faculty of Dentistry, Alexandria University.

DURATION OF STUDY

Estimated Time: 12 months.

Tasks/Duration	1st day	1st week	1st Month	4th Month	6th Month	9th Month	9th – 12th Month
Surgical Procedure	√						
Clinical Evaluation		√	√	√	√	√	
Radiographic Evaluation	√				√	√	
Data Collection							√
Data Analysis							√
Writing Manuscript							√

ESTIMATED BUDGET

Total Budget:

Item	Quantity/patient	Cost /L.E	Total
CBCT	3x12	400	14400
Armamentarium		3000	3000
Implant	1x12	2400	28800
Total			46200

PROBLEMS ANTICIPATED

- Microbial interference with osteointegration.
- Failure to recall the patient for follow up (Follow up dropout).

PUBLICATION POLICY

The study will be submitted for either national or international journals for publication.

- Abdelrahman Karam Gad.
- Prof. Dr. Ragab Shaaban Hassan.
- Dr. Gaafar Nabil Ahmed El-Halawani.

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