

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: June 2, 2018

ClinicalTrials.gov ID: NCT03544580

Study Identification

Unique Protocol ID: CEBD-CU-2018-05-01

Brief Title: Soft Tissue Esthetic With Autogenous Dentin Chips and Immediate Implantation Versus Conventional Immediate Implantation With Xenograft in Thin Buccal Bone

Official Title: Soft Tissue Esthetic With Autogenous Dentin Chips and Immediate Implantation Versus Conventional Immediate Implantation With Xenograft in Thin Buccal Bone: (Randomized Controlled Clinical Trial)

Secondary IDs:

Study Status

Record Verification: June 2018

Overall Status: Not yet recruiting

Study Start: June 15, 2018 [Anticipated]

Primary Completion: August 30, 2019 [Anticipated]

Study Completion: December 30, 2019 [Anticipated]

Sponsor/Collaborators

Sponsor: Cairo University

Responsible Party: Principal Investigator

Investigator: Cherine Emad Mahmoud Mohamed Hamada [chamada]

Official Title: principal investigator

Affiliation: Cairo University

Collaborators:

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Pending

Board Name: Ethics comitty of faculty of dentistry

Board Affiliation: cairo university

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Address:

Data Monitoring: Yes

FDA Regulated Intervention: No

Study Description

Brief Summary: After tooth extraction, host bone resorption and atrophy of alveolar ridge may be observed. Bone resorption occurs specially in incisors and premolar area of jaw in region of thin buccal bone that may lead to change in contour. Total clinical bone loss height approximately 2-5 mm at first 6 months may be observed in vertical dimension , after 12 months alveolar ridge may lose up to 50 % of its width.

Detailed Description: Recently augmentation with bone grafting became one of the most common techniques surgically ; progressive bone resorption may be prevented by using augmentation procedures with use of graft materials. The gold standard in regenerative procedures is autogenous bone graft because of osteoinduction , osteoconduction and osteointegration properties required in regeneration. In autogenous bone graft there is need for a second surgical site , donor site morbidity and limited availability will lead to challenge for alternative bio-materials.

Extracted healthy non functional teeth from human are considered to be a dental waste all over the world. High proportion of extracted sockets are left untreated for physiological healing. Inadequate or failure of bone healing in sockets has been seen due to absence of bone graft material. Stem cells, matrix , trace metal ions and growth factors are rich in human tooth. Bone and dentin tissue structure are different but ratio of components is similar (mineral 70% , collagen 20% and body fluid 10% by weight). Dentin after demineralization is mainly composed of type 1 collagen 95% and non collagenous proteins as growth factors.

Conditions

Conditions: Crestal Bone Loss

Keywords: dentin
immediate implant
buccal bone resorption
crestal bone loss

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 20 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: immediate implant with dentin chips using the tooth structure presented in socket either as remaining root or as unrestorable tooth structure remove all periodontal ligaments & scraping all enamel & cementum using a stone also to cut it into slices then putting it in acid to demineralize the dentine ; then using a bone mill to transform dentine into small particles or chips to be used in jumping gap between implant & thin buccal bone	Procedure/Surgery: immediate implant with dentine chips Using dentin chips Other Names: • Conventional immediate implantation
Active Comparator: immediate implant with xenograft after surgical removal of entire badly decayed tooth we immediately put implant and in jumping gap we use xenograft	Procedure/Surgery: conventional immediate implant using xenograft Other Names: • immediate implantation with xenograft

Outcome Measures

Primary Outcome Measure:

1. Soft tissue esthetics

pink esthetic score will be taken by photos from the day of surgery till 12 months postoperatively.

The PES will evaluate the mesial papilla, distal papilla, curvature of the facial mucosa, level of the facial mucosa, and root convexity/ soft tissue color and texture at the facial aspect of the implant site as five variables. A score of 2, 1, or 0 is assigned to each of five PES parameters. Thus, in case of an implant restoration, a maximum total PES of 10 is possible

[Time Frame: 12 months]

Eligibility

Minimum Age: 20 Years

Maximum Age: 50 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

- Patient related :
 - Patient who only need to restore this single tooth.
 - Good oral hygiene
 - Systemically healthy (free from any systemic diseases)

Site related :

- Hopeless tooth (nonrestorable, badly broken, endodontically treated) indicated for extraction and immediate implant placement
- Esthetic area with thin buccal bone
- Having periapical bone more than 3mm for primary stability

Exclusion Criteria:

- Patient related :

- Smokers
- Pregnant woman

Site related

- Teeth that have to be extracted due to advanced periodontal bone loss
- Trauma in aesthetic area
- Periapical infection.

Contacts/Locations

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