

TCTR ID : TCTR20210628006

Overall Recruitment Status : Unknown

OTHER ID :

Prospective registration
This protocol was registered before enrollment of the first participant.

Tracking Information

First Submitted Date : 27 June 2021
First Posted Date : 28 June 2021
Last Update Posted Date : 28 June 2021

Title

Public Title : Impact of various implant designs to early stability of dental implant
Acronym : BLX, Stability
Scientific Title : Impact of various implant designs to early stability of dental implant
Sponsor ID/ IRB ID/ EC ID : HREC_DCU 2021-008
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20210628006>
Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : 027/2021
Date of Approval : 04 June 2021
Board Name : The Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University
Board Affiliation : Faculty of Dentistry, Chulalongkorn University
Board Contact : Business Phone : 022188866 Ext. No Data
Business Email : ethics.dent.chula@gmail.com
Business Address : Somdet Ya 93 Building, Chulalongkorn University Dental Hospital Henri Dunant Rd, Pathum Wan, Pathum Wan District, Bangkok 10330

Sponsor

Source(s) of Monetary or Material Supports : The International Team for Implantology (ITI)
Study Primary Sponsor : The International Team for Implantology (ITI)
Responsible Party : Name/Official Title : The International Team for Implantology (ITI)
Organization : Straumann, institute AG,Switzerland
Phone : 0616951610 Ext. No Data
Email : research-screening@straumann.com
Study Secondary Sponsor : No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis : A prospective cohort study will be conducted. Subjects will be consecutively recruited at Faculty of Dentistry, Chulalongkorn at Department of Oral and Maxillofacial Surgery (OMFS). The enrolled patients will be indicated for and have consented to implant treatment, suitable for treatment within the inclusion criteria. All implants will be installed using the standard guided protocol recommended by the manufacturer and healing abutment will be placed for transmucosal healing. Demographic and clinical variables related to patient and implant characteristics will be recorded. Timing of implant placement (early, delayed) will be recorded. Measurements of Implant Stability Quotient (ISQ) and Implant Stability test value (IST) will be recorded at 9 time points (T1-T9)
T1 defined as implant placement day (T1)
T2-T9 defined as 2 days, week 1,2,3,4,5,6,8 after implant placement, respectively.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : Missing posterior tooth in healed site without need for bone augmentation (Type 4C by Gallucci et al 2018)
Keywords : BLX, Stability

Eligibility

Inclusion Criteria : 1. Subjects in need of dental implant placement for replacement of missing teeth.
2. Medically healthy (American Society of Anesthesiologists Classification I-II).
3. Age over 20 years old.
4. Healed implantation site grater than equal 2months
5. Adequate bone quality and quantity (including simultaneous bone augmentation)
6. Adequate bone height for implant length at least 8 millimeters
7. The insertion torque is equal to or more than 25 Ncm after implant placement.

Gender : Both

Age Limit : Minimum : 20 Years Maximum : N/A (No limit)

Exclusion Criteria : 1. Medically compromised subjects (ASA classification III-V).
2. General contraindications against dentoalveolar surgery or augmentation procedures
3. Active drug therapy with drugs that may significantly affect bone metabolism or host-inflammatory responses, e.g. anti-resorptive agents, corticosteroid or immunosuppressive medications and non-steroidal anti-inflammatory drugs.
4. Medium and Heavy smoker (> 10 cigarettes per day) or recent heavy smoker (history of > 20 cigarettes/day within last 5 years)
5. Pregnant or intending to conceive
6. Subjects are not able/willing to consent for participation in the study.

Accept Healthy Volunteers : Yes

Status

Overall Recruitment Status : Unknown

Key Trial Dates Study Start Date (First enrollment) : 01 July 2021 Indicate Type : Anticipated

Completion Date (Last subject, Last visit) : 03 June 2023 Indicate Type : Anticipated

Study Completion Date : 03 June 2023 Indicate Type : Anticipated

Design

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : Phase 4

Intervention Model : Parallel

Number of Arms : 2

Masking : Masked Masked Role : Allocation concealment, Subject, Statistician

Allocation : Randomized

Control : No treatment / Standard of care

Study Endpoint Classification : Efficacy Study

Sample size

Planned sample size : 60

Intervention Arm 1

Intervention name : BLX implant SLA

Intervention Type : Experimental

Intervention Classification : Other

Intervention Description : Bone level X implant with SLA surface

Intervention Arm 2

Intervention name : Bone level implant

Intervention Type : No Intervention

Intervention Classification : Other

Intervention Description : Bone level implant, SLA surface

Outcome**Primary Outcome**

1. Outcome Name : Implant Stability Quotient values

Metric / Method of measurement : Resonance frequency analysis

Time point : Implant placement day, 2 days, 1,2,3,4,5,6,8 week after implant placement

Secondary Outcome

1. Outcome Name : Implant stability test values

Metric / Method of measurement : Anycheck

Time point : Implant placement day, 2 days, 1,2,3,4,5,6,8 week after implant placement

Location

Section A : Central Contact

Central Contact	First Name : Nikos	Middle Name :	Last Name : Mattheos
	Degree :	Phone : 0616951610 Ext. : No Data	Email : nikos@mattheos.net
Central Contact Backup	First Name : Pawida	Middle Name :	Lastname : Pataraprasit
	Degree : Assoc.Prof.	Phone : 0838408222 Ext. : No Data	Email : primpawida@gmail.com

Section B Facility Information and Contact

1. Site Name : Department of Oral and Maxillofacial Surgery (OMFS) Faculty of Dentistry, Chulalongkorn University

City : Wangmai State/Province : Bangkok Postal Code : 10330
Country : Thailand Recruitment Status : Pending (Not yet recruiting)

Facility Contact First Name : Atiphan Middle Name : Last Name : Pimkhaokham
Degree : Assoc.Prof. Phone : 08913080460 Ext. : No Data Email : atiphan.p@chula.ac.th

Facility Contact Backup First Name : Pawida Middle Name : Last Name : Pataraprasit
Degree : Assoc.Prof. Phone : 0838408222 Ext. : No Data Email : primpawida@gmail.com

Investigator Name First Name : Nikos Middle Name : Last Name : Mattheos
Degree : Assoc.Prof. Role : Principal Investigator

Section C : Contact for Public Queries (Responsible Person)

First Name : Atiphan Middle Name : Last Name : Pimkhaokham
Degree : Assoc.Prof. Phone : 08913080460 Ext. : No Data Email : atiphan.p@chula.ac.th

Postal Address : Department of Oral and Maxillofacial Surgery (OMFS) Faculty of Dentistry, Chulalongkorn University 34 Henri-Dunant Road, Wangmai, Pathumwan

State/Province : Bangkok Postal Code : 10330
Country : Thailand Official Role : Study Chair

Organization Affiliation : Head of Department of Oral and Maxillofacial Surgery (OMFS) Faculty of Dentistry, Chulalongkorn University

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Atiphan Middle Name : Last Name : Pimkhaokham
Degree : Assoc.Prof. Phone : 0891308046 Ext. : No Data Email : nikos@mattheos.net

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State/Province : Bangkok Postal Code : 10330
Country : Thailand Official Role : Study Chair

Organization Affiliation : Head of Department of Oral and Maxillofacial Surgery (OMFS) Faculty of Dentistry, Chulalongkorn University

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No

Reason : for ethics issues

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data