TCTR ID: TCTR20210628006

**OTHER ID:** 

Overall Recruitment Status: Unknown

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.

 $Measurements \ of \ Implant \ Stability \ Quotient \ (ISQ) \ and \ Implant \ Stability \ test \ value \ (IST) \ will \ be \ recorded \ at \ an inplant \ Stability \ and \ an inplant \ an inplant \ an inplant \ an inplant \ and \ an inplant \ an inp$ 

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

Intervantion Arm 1

Intervention name : BLX implant SLA Intervention Type : Experimental Intervention Classification : Other

Intervention Description : Bone level X implant with SLA surface

Intervantion 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

 $\label{eq:phone:off:email:nikos@mattheos.net} Degree: Phone: 0616951610 \ Ext.: No \ Data \qquad Email: nikos@mattheos.net$ 

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

 $\label{eq:decomposition} Degree: Assoc. Prof. \\ Phone: 08913080460 \ Ext.: No \ Data \\ Email: a tiphan.p@chula.ac.th. \\ Phone: 08913080460 \ Ext.: No \ Data \\ Email: a tiphan.p@chula.ac.th. \\ Phone: 08913080460 \ Ext.: No \ Data \\ Email: a tiphan.p@chula.ac.th. \\ Phone: 08913080460 \ Ext.: No \ Data \\ Email: a tiphan.p@chula.ac.th. \\ Phone: 08913080460 \ Ext.: No \ Data \\ Email: A tiphan.p@chula.ac.th. \\ Phone: 08913080460 \ Ext.: No \ Data \\ Phone: 08913080 \ Ext.: P$ 

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

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

Official Role: Study Chair

Chulalongkorn University

Country: Thailand

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

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

Deidentified Individual Participant-level Data Sharing

Plan to share IPD: No

Reason: for ethics issues

Publication from this study

 $\begin{tabular}{ll} MEDLINE \ Identifier: & No \ Data \\ \\ URL \ link \ to \ full \ text \ publication: & No \ Data \\ \end{tabular}$