TCTR ID: TCTR20230826014

Overall Recruitment Status: Completed (Has Results)

Prospective registration

This protocol was registered before enrollment of the first participant.

#### **Tracking Information**

OTHER ID:

First Submitted Date: 20 August 2023
First Posted Date: 26 August 2023
Last Update Posted Date: 01 October 2024

Title

Public Title: Effect of Dental Implant Design on Stability During Early Healing: A Randomised Controlled Trial.

Acronym: EISS

Scientific Title: Effect of Dental Implant Design on Stability During Early Healing: A Randomised Controlled Trial

Sponsor ID/ IRB ID/ EC ID: HREC-DCU 2023-051 Registration Site: Thai Clinical Trials Registry

URL: https://www.thaiclinicaltrials.org/show/TCTR20230826014

Secondary ID: No Secondary ID

**Ethics Review** 

Board Approval : Submitted, approved
 Approval Number : HREC-DCU 2023-051
 Date of Approval : 11 August 2023

Board Name: Human Research Ethics Committee

Board Affiliation: Faculty of Dentistry, Chulalongkorn University

Board Contact: Business Phone: 022188866 Ext. No Data

Business Email: ethics.dent.chula@gmail.com

Business Address: 34 Henri Dunant Road, Wang Mai, Pathumwan, Bangkok, 10330

Sponsor

 $Source(s) \ of \ Monetary \ or \ Material \ Supports: \ International \ Team \ for \ Implantology \ (ITI)$ 

Study Primary Sponsor: Chulalongkorn University

Responsible Party: Name/Official Title: Faculty of Dentistry, Chulalongkorn University

Organization : Chulalongkorn University Phone : 022188635 Ext. No Data

Email : cudentpr@gmail.com Study Secondary Sponsor : No Study Secondary Sponsor

**Protocol Synopsis** 

Protocol Synopsis: Currently, there are many studies on macrodesign and osseointegration processes, but there are no

comparative studies on osseointegration processes that indicate secondary stability between aggressive thread design titanium zirconia implant with SLActive surface (BLX) versus nonaggressive thread design

titanium zirconia implant with SLActive surface (BL) implant.

Therefore, this study aims to investigate the difference in the changing secondary stability of aggressive thread design titanium zirconia implant with SLActive surface (BLX) versus nonaggressive thread design titanium zirconia implant with SLActive surface (BL) implants using the implant stability quotient (ISQ)

and Implant stability test (IST).

URL not available

**Health Conditions** 

Health Condition(s) or Problem(s) Studied: Patient with at least one lost tooth who requires an implant for dental replacement.

Keywords: Implant thread, implant designs, secondary stability, BLX implant, BL implant

Eligibility

Inclusion Criteria: 1. Healthy patients aged more than 20 years (ASA class I, II)

2. Patients have edentulous that was extracted/lost more than 2 months before operation day.

3. Adequate bone quality and quantity to place an implant and no history of acute infection at implant site.

4. Adequate good oral hygiene and can follow up post-op instruction.

Gender: Both

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

Exclusion Criteria: 1. Patients who have jaw pathology.

2. Patients who wear orthodontic appliances.

3. Patients who have parafunctional habits (bruxism and clenching)4. Patients who are smoking > 5 cigarettes per day or chewing tobacco.

5. Patients who have uncontrolled systemic diseases which compromise the bone healing process including

Diabetes Mellitus and Osteoporosis.

6. Patients who have history of antiresorptive drug use and irradiation in head and neck area.

Accept Healthy Volunteers: Yes

Status

Overall Recruitment Status: Completed

Key Trial Dates Study Start Date (First enrollment): 10 September 2023 Indicate Type: Actual

Completion Date (Last subject, Last visit): 30 August 2024 Indicate Type: Actual

Study Completion Date: 27 September 2024 Indicate Type: Actual

Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: Phase 2
Intervention Model: Parallel

Number of Arms: 2

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

Allocation: Randomized

Control: No treatment / Standard of care

Study Endpoint Classification: Efficacy Study

Sample size

Planned sample size: 70

Actual sample size at study completion: 90

Intervantion Arm 1

Intervention name : BLX implant
Intervention Type : Experimental
Intervention Classification : Device

Intervention Description: The operation will be performed. After BLX implant insertion, the insertion torque will be noted. The implant stability quotient (ISQ) and implant stability test (IST) values will be

measured.

Intervantion Arm 2

Intervention name : BL implant
Intervention Type : Experimental
Intervention Classification : Device

Intervention Description: The operation will be performed. After BL implant insertion, the insertion torque will be noted. The implant stability quotient (ISQ) and implant stability test (IST) values will be measured.

Outcome

**Primary Outcome** 

1. Outcome Name: Implant stability

Metric / Method of measurement : Implant Stability Quotient (ISQ) values

Time point: intraoperative, 2 days, 1-6 weeks, 8 weeks, 12 weeks after surgery

**Secondary Outcome** 

1. Outcome Name: Implant stability

Metric / Method of measurement: Implant stability test (IST) values

Time point: intraoperative, 2 days, 1-6 weeks, 8 weeks, 12 weeks after surgery

### Location

#### Section A: Central Contact

Central Contact First Name : Rujira Middle Name : Last Name : Charoenniwassakul

Degree: DDS Phone: 0873509075 Ext.: No Data Email: vavavhanna@gmail.com

Central Contact Backup First Name : Sureeporn Middle Name : Lastname : Tantisak

Degree: Phone: 022188866 Ext.: No Data Email: ethics.dent.chula@gmail.com

#### Section B Facility Information and Contact

1. Site Name: Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Chulalongkorn

City: Pathumwan State/Province: Bangkok Postal Code: 10330

Country: Thailand Recruitment Status: Pending (Not yet recruiting)

Facility Contact First Name : Rujira Middle Name : Last Name : Charoenniwassakul

Facility Contact Backup First Name : Sirimanas Middle Name : Last Name : Jiaranuchart

Degree: D.D.S., Ph.D. Phone: 0919289763 Ext.: No Data Email: sirimanas.som@gmail.com

Investigator Name First Name: Nikos Middle Name: Last Name: Mattheos

Degree: Role: Principal Investigator

## Section C : Contact for Public Queries (Responsible Person)

First Name : Rujira Middle Name : Last Name : Charoenniwassakul

Degree : D.D.S. Phone : 0873509075 Ext. : No Data Email : vavavhanna@gmail.com

Postal Address : Office of Research Affairs 10th floor Somdejya 93 Building Faculty of Dentistry Chulalongkorn

University

State/Province : Bangkok Postal Code : 10330

Country: Thailand Official Role: Study Principal Investigator

Organization Affiliation : Faculty of Dentistry, Chulalongkorn University

### $Section \ D: Contact \ for \ Scientific \ Queries \ (Responsible \ Person)$

First Name : Rujira Middle Name : Last Name : Charoenniwassakul

Degree : D.D.S. Phone : 0873509075 Ext. : No Data Email : vavavhanna@gmail.com

Postal Address : Office of Research Affairs 10th floor Somdejya 93 Building Faculty of Dentistry Chulalongkorn

University

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

Organization Affiliation: Human Research Ethics Committee Faculty of dentistry Chulalongkorn University

### **Summary Results**

Date of posting of results summaries: 26 September 2024

Date of first journal publication of results: Not yet published

Baseline Characteristics: The BLX group included 35 patients who received 45 taper-shaped implants, while the BL group included

33 patients who received 45 cylindrical-shaped implants. All implants were placed with clinically sufficient primary stability. Two patients in the BL implant group, with a total of 5 implants, were dropped out of the statistical analysis due to missing follow-up review at 2 days. Consequently, data from 66 patients with 85 implants was finally analysed. The patients comprised 29 males and 37 females with a mean age of 52 years. All implants were placed in the posterior regions of the maxilla (19 implants) and mandible (66 implants) without bone augmentation procedures and were connected with healing abutments. All implants osseointegrated and received the final prosthesis. No statistical differences were observed in patient characteristics, including gender, age, dental implant dimensions, and anatomic site, between the two

groups.

Participant Flow: Sixty-eight patients with 90 implants participated in this study

Adverse events: No adverse events

Outcome Measures: The BL implant has a significantly higher tendency for secondary stability compared to the BLX implant,

with statistical significance.

Brief Summary of Results: Our findings indicated that while tapered implants with cutting threads achieved significantly higher initial

insertion torque at healed posterior sites, cylindrical, non-cutting thread implants showed higher stability values at 6 weeks after placement.

# **Deidentified Individual Participant-level Data Sharing**

Plan to share IPD: No

Reason: Prohibited from regulations/contracts, Fear of inappropriate use of data, Need a consensus form colleagues,

Personal reasons

## Publication from this study

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