TCTR ID : TCTR20230826014

OTHER ID :

Overall Recruitment Status : Completed **(Has Results)**

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

Tracking Information

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

1. 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
	Degree : D.D.S.	Phone : 0873509075 Ext. : No Data	Email : vavavhanna@gmail.com
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

MEDLINE Identifier : No Data

URL link to full text publication : No Data