

# Piezoelectric drills for dental implants

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<b>Registration date</b> 09/04/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 10/09/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Traditional dental implant site preparation methods pose challenges including tissue damage and compromised appearance. Piesosurgery offers a minimally invasive alternative, but its effectiveness is underexplored. This study aims to compare piesosurgery and conventional surgery for dental implant site preparation, focusing on bone density, implant stability, and bone loss.

### Who can participate?

Patients aged 18-50 years who are missing at least two teeth, at least one of which is in the back region of the lower jaw

### What does the study involve?

Patients are treated sequentially at the two sites where they are missing teeth: at one site implant placement is conducted using piezoelectric surgery and at the other site conventional surgery is used. Post-surgical evaluations were conducted at 6 and 9 months.

### What are the possible benefits and risks of participating?

Participants may benefit from receiving dental implants. Possible risks are post-operative complications including pain and swelling.

### Where is the study run from?

Army Hospital Research and Referral (India)

### When is the study starting and how long is it expected to run for?

December 2016 to October 2023

### Who is funding the study?

Army Hospital Research and Referral (India)

### Who is the main contact?

Manish Rathi, manishrathi.077h@gov.in

## Contact information

**Type(s)**

Public, Scientific, Principal Investigator

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

16CNAHMMDS000002

## Study information

**Scientific Title**

Comparative evaluation of piezosurgery versus conventional surgery in dental implants

**Study objectives**

Implant sites prepared with piezoelectric drills are better in terms of implant stability, bone density around implants and patient post-operative recovery.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 29/09/2016, Army Dental Centre (R&R) Institutional Committee (Dhaura Kuan, New Delhi, 110010, India; +91 (0)9862157110; dental.oc86-ar@gov.in), ref: 16CNAHMMDS000002

**Study design**

Single-centre split-mouth interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Dental clinic, University/medical school/dental school

**Study type(s)**

Treatment

**Participant information sheet**

Not applicable

**Health condition(s) or problem(s) studied**

Dental implant

**Interventions**

Thirty patients with two edentulous sites, at least one of which was in the posterior mandibular region, were treated sequentially at two sites: Site A, where implant placement was conducted using piezoelectric surgery, and Site B, where conventional surgery was employed. Post-surgical evaluations were conducted at 6 and 9 months.

**Intervention Type**

Procedure/Surgery

**Primary outcome measure**

1. Bone density measured using dual-energy x-ray absorptiometry (DEXA) scan at baseline, 6 and 9 months
2. Implant stability measured using resonance frequency analysis (RFA) scan at baseline and 6 months

**Secondary outcome measures**

Patient's perception of surgery by measuring postoperative pain using a visual analogue scale (VAS) at 7 days postoperative

**Overall study start date**

25/12/2016

**Completion date**

31/10/2023

**Eligibility****Key inclusion criteria**

1. Aged 18 - 50 years
2. Edentulous site in posterior mandibular region
3. Availability of adequate bone volume without any surgical modification

**Participant type(s)**

Patient

**Age group**

Other

**Lower age limit**

18 Years

**Upper age limit**

50 Years

**Sex**

Both

**Target number of participants**

30

**Total final enrolment**

30

**Key exclusion criteria**

1. H/o extraction <6 months prior to placement of implant
2. Immunocompromised individual
3. Previous irradiation treatment in head and neck area
4. H/o periodontal disease (active/treated)
5. H/o bone metabolic disorders

**Date of first enrolment**

16/12/2016

**Date of final enrolment**

26/01/2022

**Locations****Countries of recruitment**

India

**Study participating centre**

ADC (R&R)

Dhaura Kuan

New Delhi

India

110010

**Sponsor information**

**Organisation**

Army Hospital Research and Referral

**Sponsor details**

Dhaura Kuan

New Delhi

India

110010

+91 (0)9862157110

dental.oc86-ar@gov.in

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/04zh7mt66>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Army Hospital Research and Referral

**Results and Publications****Publication and dissemination plan**

Planned publication in high impact peer-reviewed journals

**Intention to publish date**

01/08/2024

**Individual participant data (IPD) sharing plan**

Data is saved in a non-publicly available repository: the institutional repository of the University of Delhi.

The type of data stored: tables, figures, photographs.

The process for requesting access (if non-publicly available): contact the corresponding author Manish Rathi (manishrathi.077h@gov.in).

**IPD sharing plan summary**

Stored in non-publicly available repository