# COVER PAGE

Study protocol with statistical analysis plan and informed consent form

Date: 10-06-2022 (ethical approval)

**Study title:**

A comparative study to evaluate implant stability and peri-implant marginal bone loss around two different thread and body designs of implants at specified time intervals: an in vivo study

अटल बिहारी वाजपेयी मेडिकल यूनिवर्सिटी उत्तर प्रदेश
Atal Bihari Vajpayee Medical University Uttar Pradesh

# 'A COMPARATIVE STUDY TO EVALUATE IMPLANT STABILITY AND PERI IMPLANT MARGINAL BONE LOSS AROUND TWO DIFFERENT THREAD AND BODY DESIGN OF IMPLANTS AT SPECIFIED TIME INTERVALS- AN IN VIVO STUDY'

सर्वे सन्तु निरामयाः

HE CURES
CAREER P.G. INSTITUTE OF DENTAL SCIENCES & HOSPITAL
LUCKNOW

*Dissertation Submitted to Atal Bihari Vajpayee Medical University, U.P. in partial Fulfilment of the Requirementof*

**MASTER OF DENTAL SURGERY**

In the Speciality of

DEPARTMENT OF PROSTHODONTICS CROWN & BRIDGE

Name of Guide **Dr. MARIYAM ALI**

**(PROFESSOR AND HEAD)**

Name of Candidate **Dr. SHYAMOLIMA HAZARIKA**

Batch: 2021-2022

CAREER POST GRADUATE INSTITUTE OF DENTAL SCIENCES & HOSPITAL, LUCKNOW, UTTAR PRADESH, INDIA

***Affiliating University***

**ATAL BIHARI VAJPAYEE MEDICAL UNIVERSITY, U.P.**

Career Post Graduate Institute of
Dental Sciences & Hospital
I.I.M. Road, Ghailla, Lucknow-226 013
Tel: 0522-2851001, 2960439, Fax: 0522-2851058
www.careermedicaldental.com
e-mail: careerdental@careertrust.in, careermedical@careertrust.in

No. CPGIDSH/22/385 Date 10.06.2022

# ETHICAL COMMITTEE CERTIFICATE

The duly constituted Ethical Committee for Post Graduate students of Career Post Graduate Institute of Dental Sciences & Hospital, Lucknow has approved and cleared the research project of **Dr. Shyamolima Hazarika**, Post Graduate Student of Batch **2021-22** in the speciality of **Prosthodontics and Crown & Bridge.**

The topic of the research project is as follows:

'A COMPARATIVE STUDY TO EVALUATE IMPLANT STABILITY AND PERI IMPLANT MARGINAL BONE LOSS AROUND TWO DIFFERENT THREAD AND BODY DESIGNS OF IMPLANTS AT SPECIFIED TIME INTERVALS - AN IN-VIVO STUDY'

**Dr. Shadab Mohammad**
Chairman
Ethical Committee for Post Graduate Students
Professor
Department of Oral & Maxillofacial Surgery
Faculty of Dental Sciences
King George's Medical University
Lucknow (U.P.)

Head
Dept. Oral & Maxillofacial Surgery
FODS, King George's Medical
University U.P. Lucknow.

**Dr. Balasundari Shreedhar**
Principal
Secretary Ethical Committee
Career Post Graduate Institute of
Dental Sciences & Hospital,
Lucknow (U.P.)

(Dr. BALASUNDARI SHREEDHAR)
PRINCIPAL
Career Post Graduate Institute
of Dental Sciences & Hospital
Lucknow-226013

## ENDORSEMENT BY HEAD OF THE INSTITUTION

This is to certify that **'A comparative study to evaluate implant stability and peri implant marginal bone loss around two different thread and body design of implants at specified time intervals- An in vivo study'** is a bonafide work by ***Dr. Shyamolima Hazarika*** under the guidance of ***Dr.Mariyam Ali*** in partial fulfillment of requirements for the award of Degree of Master of Dental Surgery in the speciality of Prosthodontics and Crown & Bridge. Hereby, this dissertation is being forwarded to ATAL BIHARI VAJPAYEE MEDICAL UNIVERSITY, U.P. to my good belief and knowledge.

**Dr. Balasundari Shreedhar**

PRINCIPAL
Career Post Graduate Institute of Dental Sciences & Hospital,
Lucknow
Uttar Pradesh, India

**Date: 27/3/24**
**Place: Lucknow**

**Abstract**

**Background:** Implant design plays a crucial role in achieving primary stability and maintaining peri-implant bone levels. Variations in thread geometry and implant body shape may influence biomechanical performance and osseointegration outcomes. This study aimed to evaluate and compare implant stability and peri-implant marginal bone loss between double-threaded straight-body implants and triple-threaded conical-body implants at different time intervals.

**Materials and methods:** This in vivo clinical study included 30 patients requiring implant-supported restoration in the posterior mandibular region. Participants were randomly allocated into two groups: group A received double-threaded straight-body implants, and group B received triple-threaded conical-body implants. Implant stability was assessed using resonance frequency analysis (RFA) with the Osstell Mentor device at baseline, 3 months, and 6 months. Peri-implant marginal bone levels were evaluated using standardized intraoral periapical radiographs with a grid technique. Statistical analysis included repeated measures analysis of variance (ANOVA) and independent samples t-test, with Bonferroni correction for post hoc comparisons.

**Results:** Both groups demonstrated changes in implant stability over time. Group A showed a slight decrease at 3 months followed by an increase at 6 months, whereas group B exhibited a continuous increase in implant stability quotient (ISQ) values. Intergroup comparison revealed significantly higher ISQ values in group B at all time intervals ($p < 0.05$). Marginal bone levels in both groups showed a gradual reduction over time. Although slightly greater bone loss was observed in group B, intergroup differences were not statistically significant ($p > 0.05$).

**Conclusion:** Triple-threaded conical-body implants demonstrated significantly higher implant stability, while both designs showed comparable peri-implant bone responses during early healing.

**Statistical analysis**

Statistical analysis of the data was performed using Statistical Package for the Social Sciences (SPSS) software (version 26.0; IBM Corp., Armonk, NY, USA). The data were compiled and organized using Microsoft Excel. For all continuous variables, including implant stability quotient (ISQ) values and marginal bone height, the results were expressed as mean ± standard deviation (SD).

The normality of data distribution was assessed using the Shapiro–Wilk test. A p-value greater than 0.05 was considered indicative of normal distribution. Homogeneity of variance between groups was evaluated using Levene's test.

Changes within each group over different time intervals (baseline, 3 months, and 6 months) were analysed using repeated measures analysis of variance (ANOVA). When statistically significant differences were observed, post hoc pairwise comparisons were performed using Bonferroni correction to adjust for multiple comparisons.

Comparisons between group A and group B at each time point were carried out using the independent (unpaired) Student's t-test for normally distributed data. Paired t-test was used to evaluate differences within the same group over time wherever applicable.

Marginal bone loss between different time intervals was analysed using paired t-test for intragroup comparisons and independent t-test for intergroup comparisons.

A p-value $< 0.05$ was considered statistically significant.

In addition to p-values, 95% confidence intervals (CI) were calculated for mean differences to assess the precision and clinical relevance of the results. To determine the magnitude of differences between groups, Cohen's d was calculated for intergroup comparisons, where 0.2 indicates a small effect, 0.5 a moderate effect, and ≥0.8 a large effect.

Radiographic measurements were performed twice by the same examiner to ensure consistency, and intra-examiner reliability was assessed using the intraclass correlation coefficient (ICC).

**Student's t-test**

When the sample size is small and the population standard deviation is unknown, Student's t-test is used to test the significance of the difference between two means. This test was developed by W. S. Gossett, whose pen name was "Student"; hence, it is also known as Student's t-test.

The t-value is defined as the ratio of the observed difference between two sample means to the standard error of the difference.

It is applied to determine the statistical significance of differences between two groups and is classified into:

1. Independent (unpaired) t-test
2. Paired t-test

**Criteria for applying Student's t-test**

1. The sample must be randomly selected.
2. The data should be quantitative (continuous).

3. The variable should follow a normal distribution.
4. The sample size is typically small (generally less than 30).
5. Observations should be independent.

## Unpaired (independent) 't' test:

This test is applied to unpaired data of independent observations made on individuals of two different or separate groups or samples drawn from two populations, to test if the difference between the means is real or it can be attributed to sampling variability.

**Steps**:

1. As per the null hypothesis, assume that there is no real difference between the means of two samples.
2. Find the observed difference between means of two samples $(\overline{X_1} - \overline{X_2})$
3. Calculate the standard error of difference between the two means.

$$SE = \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}$$

4. Calculate the 't' value

$$t = \frac{X_1^2 - X_2^2}{SE}$$

5. Determine the pooled degrees of freedom from the formula

   $d.f. = (n_1 - 1) + (n_2 - 1) = n_1 + n_2 - 2$

6. Compare calculated value with the table value (table of 't') at particular degrees of freedom to find the level of significance.

## Paired "t" test:

It is applied to paired data of independent observations from one sample only when each individual gives a pair of observations.

**Steps**:

1. As per the null hypothesis, assume that there is no real difference between the means of two samples.
2. Find the difference in each set of paired observations before and after ($X_1 - X_2 = X$)
3. Calculate the mean of the differences $(\overline{X})$
4. Work out the standard error of mean, SE = SD/ $\sqrt{n}$
5. Determine 't' value

$$\text{'t'} = \frac{\overline{X}}{\text{Standard error of difference}}$$

6. Find the degrees of freedom (n – 1)
7. Refer 't' table and find the probability of 't' corresponding to n- 1 degree of freedom.
8. If the probability is more than 0.05, the difference observed has no significance, because it can be due to chance.

**Annexure – II**

**Informed consent**

1. I agree to get myself/my patient …… treated, and the nature and effect of the dental procedures have been explained to me.
2. I understand that all dental and local anaesthetic procedures carry some unpredictable risks.
3. I also consent to such further or alternative dental procedures as may be found necessary during the procedure.
4. It has been explained to me that my patient/I will be operated on under local anaesthesia, and I consent to this.
5. I further consent to the use of this information and record in the future for dental research, education, and training purposes.

Date: _____ Signature of the patient/patient caretaker: _____

**ANNEXURE – III**

**PATIENT PROFORMA**

Career Post Graduate Institute of Dental Sciences and Hospital, Lucknow

| | | |
|---|---|---|
| Name: | O.P.D. No: | Date: |
| Address: | Occupation: | Age: |
| | | Sex: |

CHIEF COMPLAINT:

PRESENT DENTAL HISTORY:

PAST DENTAL HISTORY:

PAST MEDICAL HISTORY:

PERSONAL HISTORY:

ORAL HYGIENE HABITS:

**Implant placed on: _____**

1. Site of placement: _____
2. Implant system: _____
3. Dimensions of the implant: _____

**1) Evaluation of crestal bone loss (with grid)**

| Parameter | At the time of placement | After 3 months | After 6 months |
|---|---|---|---|
| **Mesial** | | | |
| **Distal** | | | |
| **Mean height** | | | |
| **Bone loss** | | | |

**2) Evaluation of implant stability**

| Parameter | At the time of placement | After 3 months | After 6 months |
|---|---|---|---|
| **Mesial** | | | |
| **Distal** | | | |
| **Mean** | | | |