

Effect of osteotomy technique on peri-implant bone loss and bone density: piezoelectric inserts versus twist drills—a randomized controlled trial

Abstract

Purpose

To evaluate the effect of Piezoelectric inserts vs. conventional twist drills in osteotomy site preparation on the crestal bone loss (CBL) & Peri implant Bone Density (PIBD) around dental implants.

Methodology

Prospective randomized controlled trial included 20 patients requiring replacement of a single missing posterior tooth. Patients were randomly allocated into two groups: in one group, the osteotomy site was prepared using Piezosurgery (test group), and in the second group, the osteotomy site was prepared by conventional drilling (control group), followed by i-Fix® implant placement. The prosthesis was delivered after 3 months. A CBL and bone den-

sity evaluation was done after 9 months of implant placement using cone-beam computed tomography (CBCT).

Result

Reduced amount of CBL was observed in the osteotomy site prepared by the piezoelectric device. However, intergroup comparison revealed no statistically significant CBL or PIBD between the two osteotomy techniques.

Conclusion

Within the limitations of this randomized controlled clinical trial, implant site preparation using piezoelectric inserts did not show statistically significant superiority over conventional twist drills in preserving crestal bone or enhancing PIBD.

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INTRODUCTION

Oral rehabilitation seeks to restore both the appearance and functionality of the mouth and speech systems, thereby improving the quality of life for patients. Dental implants have been notably effective in achieving this objective. The goal of implant dentistry is to replace missing or extracted teeth by strategically placing implants in anatomically, aesthetically, and functionally optimal positions. This approach preserves healthy adjacent teeth and facilitates the placement of dental prostheses over the long term (1). The process where the implant locks and attaches itself to the bone is termed as osseointegration (2).

Successful osseointegration is described as the direct, functional connection between living bone and the surface of an implant that bears functional loads. It is well known that implant stability (lack of mobility) during the bone healing period is a fundamental prerequisite to achieve osseointegration (3). In the past two decades, there has been rapid development in dental surgical techniques. One notable advancement involves the use of piezoelectric ultrasonic vibration principles, which have found extensive application across various fields of dentistry and periodontics. Osseous surgery has been conducted using either manual or motorised instruments. Manual tools provide excellent control for removing small amounts of bone in less densely mineralised areas. However, they can be challenging to manoeuvre in cortical bone, especially in situations requiring precise osteotomies.

Piezoelectric surgery has emerged as a beneficial alternative to traditional rotating instruments, addressing their drawbacks. This method is recommended for making precise, safe, and less traumatic incisions, which enhances osteogenic potential, reduces oedema, improves wound healing, and minimises microfractures and smear layer formation compared to rotating instruments. Its selective cutting mechanism also prevents damage to surrounding soft tissues (4).

Thus, the purpose of this study was to compare and evaluate the effect of Piezoelectric inserts versus conventional twist drills on CBL with the help of clinical, radiographic and Cone Beam Computed Tomography (CBCT) evaluation.

MATERIALS AND METHODS

Ethical Considerations and Informed Consent

The study was conducted after the approval of the University Ethics Committee Medical (UECM), SVSU, before conducting the research. The Ethics Committee verified that the study adhered to established ethical standards. Before participation, all participants signed a comprehensive informed consent form detailing the treatment protocol, including its benefits, procedures, and potential side effects. All participants were informed about

the study's purpose, nature, and design, and written consent was obtained before their participation.

Sample Size Estimation

The sample size was calculated based on the results of the pilot study, which was conducted on two patients for the follow-up period of nine months using the satisfaction scores of patients from two study groups and keeping the power of the study at 80%, confidence interval at 95% and level of significance at 5%, the sample size calculated was 10 per group.

Participants & Study Design

This investigation was conducted as a prospective, parallel-arm, randomised controlled clinical trial at the Department of Periodontology and Implantology, Subharti Dental College and Hospital, Meerut. The conduct and reporting of this study adhered to the CONSORT guidelines. (Fig. 1)

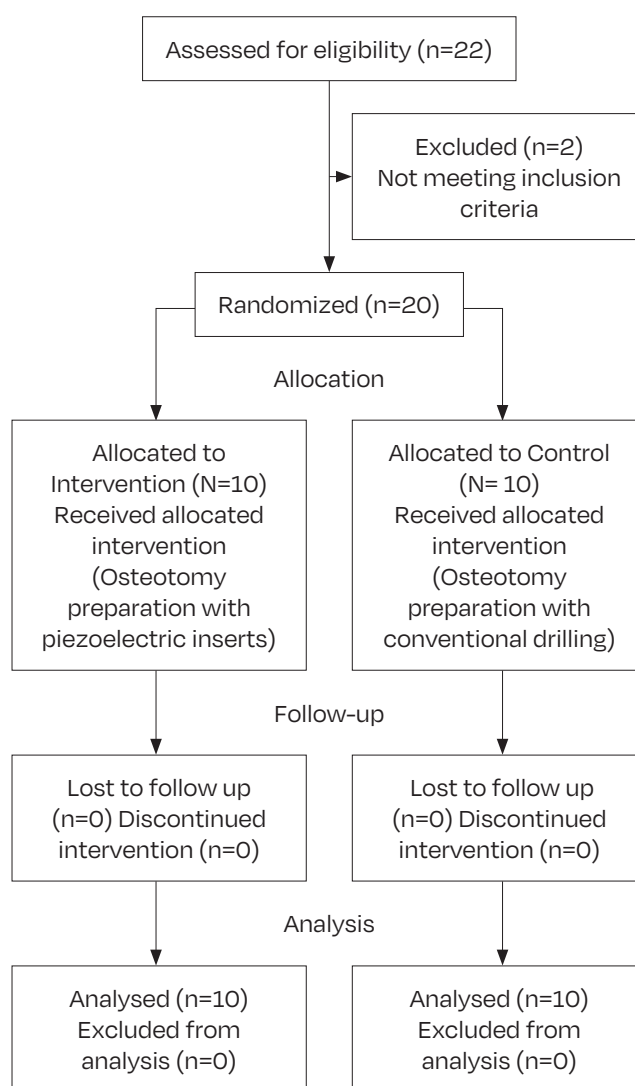


Fig. 1 Consort flow diagram

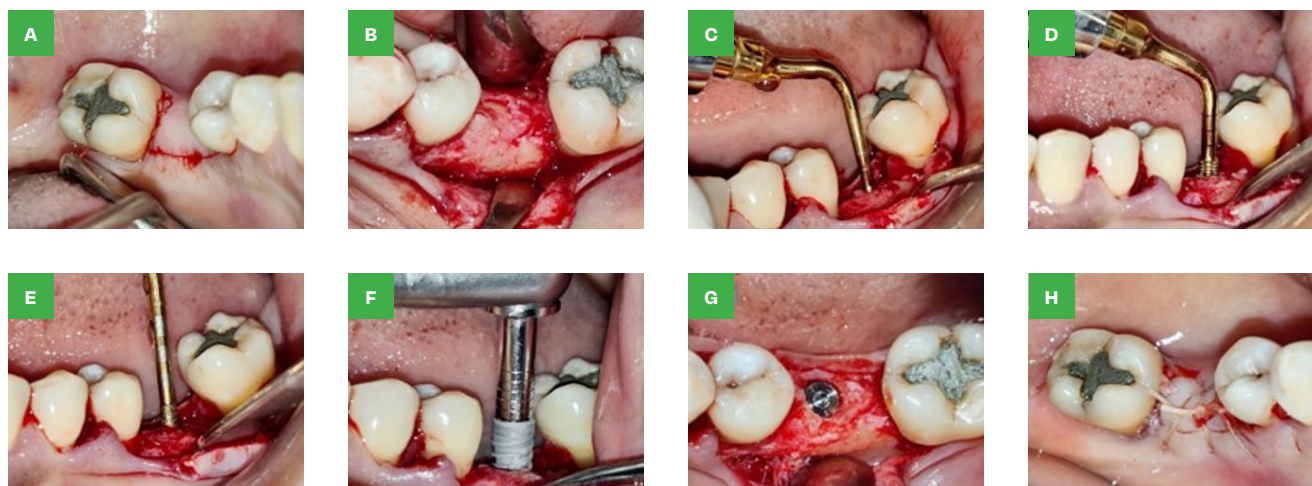


Fig. 2A-2H Osteotomy Preparation using piezoelectric inserts **Fig. 2A** Subcrestal incision **Fig. 2B** Mucoperiosteal flap reflected **Fig. 2C** Osteotomy being prepared using #ui-1 **Fig. 2D** Osteotomy being prepared using #ui-2 **Fig. 2E** Osteotomy being prepared using #ui-9 **Fig. 2F** Implant being placed using beam type torque ratchet **Fig. 2G** Implant with cover screw placed **Fig. 2H** Suture placed

Study Population

Twenty systemically healthy patients aged between 18 and 50 years requiring replacement of a single missing posterior tooth were included.

Inclusion Criteria

Patients having single missing posterior tooth with an adequate width and height of edentulous space available for placement of implant, Edentulous sites in mandibular & maxillary posterior regions, Adjacent teeth intact; restored with functionally & esthetically good restorations, restored with prosthesis precluding the addition of the missing tooth and patients with good periodontal and general health.

Exclusion Criteria

Patients who were unable to perform routine oral hygiene procedures, Patients with history of smoking, Patients with TMJ disorders, Patients with dental history

of bruxism and parafunctional habits or deep bite cases, A history of substance abuse, Insufficient vertical inter-arch space to accommodate the prosthodontic components available, together with a proposed pontic and occasional gingival analog designs, Patients with uncontrolled diabetes and Absence of opposing occlusion.

Patient preparation

After the initial examination and treatment planning, the patients underwent Phase I therapy. Detailed instructions regarding self-performed plaque control measures were given to signify its importance on the success of the implant therapy. After two weeks, only patients who maintained optimal oral hygiene were included in the study and subsequently randomized into 2 groups. This was considered as baseline.

Randomization and blinding

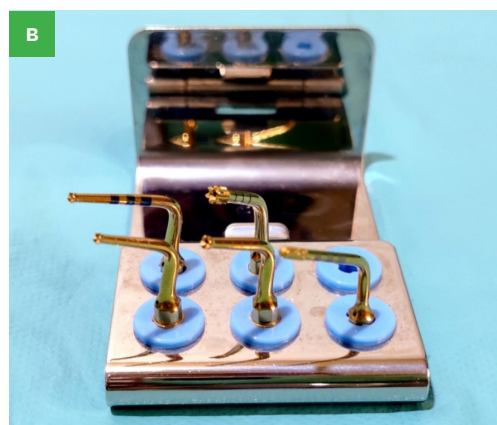
Participants were randomly allocated to either the test or control group in a 1:1 ratio using a computer-generated random number sequence. Allocation concealment was achieved using sequentially numbered, opaque,



Fig. 3A, 3B

Fig. 3A
Piezosurgery unit/
device used in the
study.

Fig. 3B
Piezosurgery inserts
used for osteotomy
preparation.



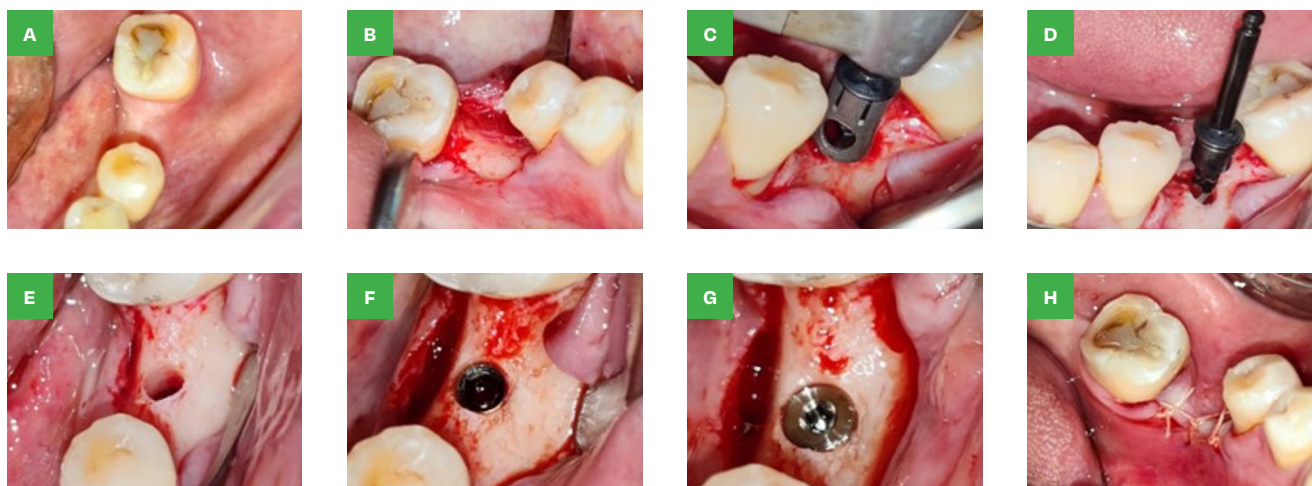


Fig. 4A-4H Osteotomy Preparation using Conventional twist drills **Fig. 4A** Sub-crestal incision **Fig. 4B** Mucoperiosteal flap reflected **Fig. 4C** Osteotomy being prepared **Fig. 4D** Angulation and depth of osteotomy verified **Fig. 4E** Osteotomy completed **Fig. 4F** Implant placed **Fig. 4G** Cover screw placed **Fig. 4H** Suture placed

sealed envelopes prepared by an independent investigator not involved in the surgical procedures. Due to the nature of the intervention, operator blinding was not feasible. However, radiographic outcome assessors and the statistician were blinded to group allocation.

Pre-surgical protocol

Patients were given one capsule of Augmentin® 625 mg

24 hrs before and one capsule of Augmentin® 625 mg 1 hr prior to the procedure.

Surgical technique

Test group (Piezoelectric Osteotomy)

After assessing the pre-treatment records and identifying vital anatomic landmarks, the selected implant site was surgically exposed by raising a mucoperiosteal



Fig. 5A-5C 2nd Stage Surgery and Prosthetic Rehabilitation in Test Group **Fig. 5A** Gingival former placed after 3 months **Fig. 5B** Elastomeric impression recorded **Fig. 5C** Crown delivered.

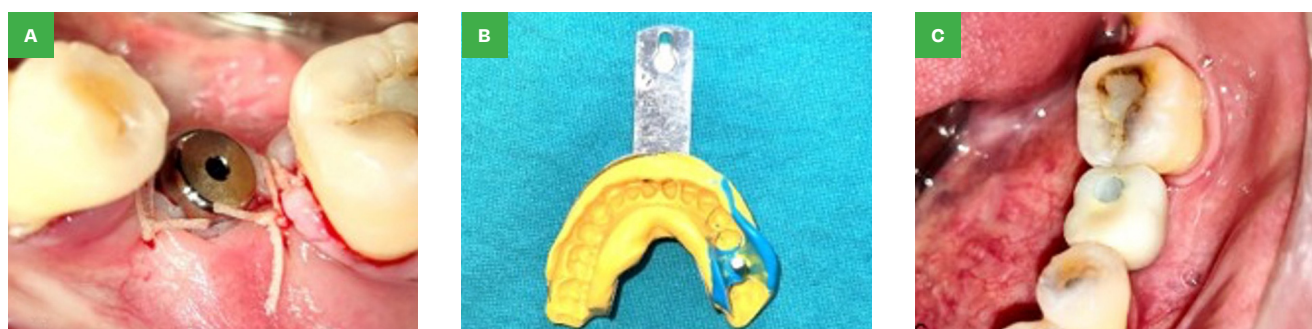


Fig. 6A-6C 2nd Stage Surgery and Prosthetic Rehabilitation in Control Group **Fig. 6A** Gingival former placed after 3 months **Fig. 6B** Elastomeric impression recorded **Fig. 6C** Crown delivered

flap. (Fig 2a,2b) A Piezosurgery device (Surgery X, DTE Woodpecker; Guilin Woodpecker Medical Instrument Co., Ltd., Guilin, China) and inserts of increasing diameter (UI-1, UI-2, UI-7, UI-8, UI-9) were used with a power setting in Bone mode. (Fig 2c, 2d, 2e) The implant was placed into the prepared site with gentle digital pressure until resistance was met and seated into the final position with a torque ratchet, followed by the attachment of the cover screw. (Fig 2f, 2g) The procedure was completed with repositioning and suturing of the surgical flap. (Fig. 2h)

Control group (Conventional Drilling)

After exposing the selected implant site, an initial lance drill was passed to the depth corresponding to the length of implant chosen. Subsequently, the osteotomy site was prepared using sequential twist drills of increasing diameter with a physiodispenser (NSK Ltd., Tochigi, Japan). (Fig 4a, 4b, 4c). (Fig 4d) Implant was then placed into the prepared site with gentle digital pressure until resistance is met and seated into final position with a torque ratchet followed by the attachment of cover screw. (Fig 4e, 4f) The procedure was completed with repositioning and suturing the surgical flap. (Fig 4g)

2nd Stage Surgery and Prosthetic Rehabilitation

After assessing the healing period of 3-4 months, incision was placed over implant and soft tissue reflected sufficiently to permit removal of cover screw. This allowed visualization of the implant root component. A temporary healing abutment was attached to the

implant and gingival tissue was sutured around it. Healing abutment was left in situ for approximately 10 days (Fig 5a, 6a) Then impression making was done in the department of prosthodontics and a subsequent prosthetic crown was given (Fig 5b, 5c, 6b, 6c)

Outcome measures

Primary Outcome

It included CBL (mm) measured at mesial, distal, facial, and lingual aspects using CBCT

Secondary Outcomes

These included:

- a) PIBD measured in Hounsfield units
- b) Clinical peri-implant parameters
- c) Implant survival rate

The implant–abutment junction served as the reference point for all measurements.

Follow up

Patients were followed for a period of 9 months after implant placement (6 months after loading). CBCT scans were obtained at baseline and at the end of the follow-up period for assessment of CBL bone loss and PIBD.

Statistical analysis

The data regarding the clinical and radiographic parameters, recorded at baseline (implant placement) and 12 months post implant insertion was tabulated and



Fig. 7A-7C Follow up (Test Group) **Fig. 7A** Pre-op CBCT (tangential view) **Fig. 7B** Baseline CBCT **Fig. 7C** 9 months post-op CBCT

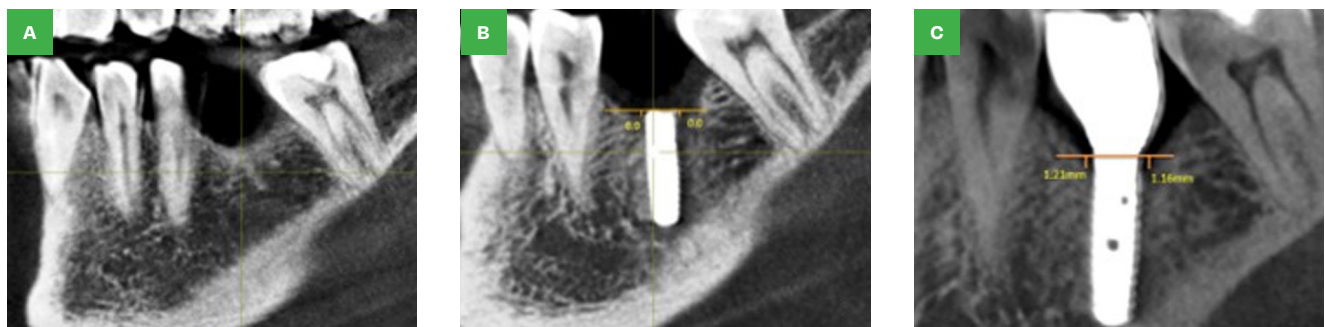


Fig. 8A-8C Follow up (Control Group) **Fig. 8A** Pre-op cbct (tangential view) **Fig. 8B** Baseline cbct **Fig. 8C** 9 months post-op cbct

Surface	Group A (Mean $\pm$ SD)	Group B (Mean $\pm$ SD)	Inter-group Difference	Statistical Significance
Mesial	1.09 $\pm$ 0.10	1.05 $\pm$ 0.19	0.13 mm	NS ($p > 0.05$)
Distal	1.11 $\pm$ 0.11	1.04 $\pm$ 0.11	0.07 mm	NS ($p > 0.05$)
Facial	0.96 $\pm$ 0.10	0.84 $\pm$ 0.39	0.12 mm	NS ($p > 0.05$)
Lingual	0.90 $\pm$ 0.09	0.76 $\pm$ 0.35	0.14 mm	NS ($p > 0.05$)
NS = Not statistically significant ($p > 0.05$)				

Tab. 1 Surface-wise inter-group comparison showing no statistically significant differences between Group A and Group B ($p > 0.05$).

Aspect	Group	Mean Gain (HU)	% Improvement	Intra-group p-value (Paired t-test)	Inter-group p-value at 9 months (Unpaired t-test)
Facial	Test	+137.90	12.99%	p = 0.1004 (NS)	p = 0.0994 (NS)
	Control	+48.00	5.04%		p = 0.2174 (NS)
Lingual	Test	+107.73	11.36%	p = 0.1147 (NS)	p = 0.0946 (NS)
	Control	+76.70	9.23%		p = 0.0991 (NS)
Mesial	Test	−20.43	33.78%*	p = 0.2001 (NS)	p = 0.1215 (NS)
	Control	+188.10	3.29%		p = 0.1351 (NS)
Distal	Test	+16.30	2.72%	p = 0.1128 (NS)	p = 0.1071 (NS)
	Control	+25.60	3.44%		p = 0.1002 (NS)
NS = Not statistically significant (p > 0.05)					

Tab. 2 Surface-wise bone density changes (HU) and percentage improvement in Test and Control groups showing no statistically significant intra- or inter-group differences ($p > 0.05$).

subjected to statistical analyses. All the values were expressed in the form of mean and standard deviation. A biostatistician with expertise in dentistry analysed the data without knowing the group assignment. The statistical tests used to compare between intragroups were paired 't' test, and for intergroup comparison unpaired 't' test and a probability value (P value) ≤ 0.005 was considered statistically significant. Statistical analysis was performed with SPSS® (SPSS, Inc., an IBM Company) Statistics Version 2.0 for Windows.

RESULTS

CBL & PIBD were evaluated at 4 and 9 months for intergroup and intra-group comparison. CBL around the implant was evaluated using the sliced images to check for the middle-most aspect of the implant. A line was drawn through the IAJ was used as the reference line, and the depth of bone loss was measured. A CBCT scan (ORTHOPHOS SL, Galileos- Sirona, CS 9300 Scanner®) was done to assess the PIBD. Similarly, to measure the PIBD, images were sliced to check the middle-most aspect of the implant. The implant was divided into coronal and axial sections, each section being divided into three equal parts for recording bone density on the facial, lingual, mesial, and distal aspects of the implant in Hounsfield units (H.U.) (Tab. 1). Inter-group comparison of measurements recorded at the mesial, distal, facial, and lingual surfaces demonstrated slightly higher mean values in Group A when

compared to Group B across all evaluated sites. The observed mean differences ranged from 0.07 mm at the distal surface to 0.14 mm at the lingual surface. Despite these numerical variations, none of the inter-group differences reached statistical significance ($p > 0.05$). Additionally, Group B exhibited greater variability, particularly at the facial and lingual surfaces, as reflected by higher standard deviation values. Overall, the findings indicate that both groups performed comparably, with no statistically significant differences in outcomes across any of the assessed surfaces (Tab. 2).

DISCUSSION

There has been a swift progress in dental surgical techniques. Among these advancements is a method utilising piezoelectric ultrasonic vibration principles, which has been introduced and found extensive application in dentistry and periodontics.

Osseous surgery has been performed using either manual instruments or motorized instruments. Traditional motor driven instruments include Micromotor but due to its less revolutions per minute, it couldn't be used for osseous surgeries. Airotor also had to be discarded due to no control over its torque. Physiodispenser, on the other hand, solved both these problems, as it had high revolutions per minute and control over torque, but it caused a lot of heat generation, which in turn affects the critical temperature of the bone.

Heat affects bone tissue by inducing hyperemia, necro-

sis, fibrosis, osteocytic degeneration, and increased osteoclastic activity. It was revealed by various studies that temperatures higher than 47 °C for about 1 min can result in osteonecrosis (5).

Piezoelectric surgery is promoted for its ability to create accurate, safe, and minimally traumatic incisions, thereby facilitating enhanced osteogenic potential, reduced oedema, improved wound healing, and lower occurrence of microfractures and smear layer compared to rotating instruments (4).

Additionally, Özalp et al in a cadaveric study highlighted differences in surgical dynamics between piezosurgery and conventional rotary systems, particularly in terms of aerosol generation and tissue interaction, emphasizing the biological and procedural advantages of piezoelectric techniques.

In our study, CBL (mesial, distal, facial & lingual), there were statistically significant differences seen in both the experimental and control group when compared at successive time intervals from baseline to 9 months. However, the results were statistically nonsignificant when both the control and experimental groups were compared with each other. These results were in accordance with the study done by Stacchi C et al (7) in which non-significant results were found when traditional rotary instruments or piezoelectric inserts were used to prepare the osteotomy sites in 20 patients.

Similar observations have been reported by Raj et al (8) who demonstrated comparable peri-implant soft and hard tissue outcomes between different implant placement protocols, further supporting the lack of statistically significant differences in peri-implant bone changes.

Erisksson et al (9) It was further stated in their study that 47°C is considered as the critical temperature for the success of dental implants. Therefore, controlling the amount of heat generated during the preparation phase is essential for osseointegration.

In PIBD (facial mesial lingual distal), improvement was seen from baseline to 9 months in the controlled and experimental group individually when compared at successive time intervals. However, the results were statistically non-significant when the controlled and experimental groups were compared with each other at base line and at 9 months. These results are in accordance with the study done by Maglione et al (10) and Nandal et al (11) in which the results were non-significant statistically, but there was a difference regarding buccal density.

The present study is based on the fact that the Ultrasonic osteotomy site preparation technique allows precise and effective bone cutting without damaging adjacent soft tissues. Further stating that this approach is based on micro-vibrations created by the piezoelec-

tric effect. The alternation of high-frequency vibrations with pauses at a frequency of up to 30 Hz prevents overheating while maintaining optimum cutting capacity, thereby increasing the implant stability.

However, the existing literature provides limited and inconclusive evidence regarding the influence of piezosurgical osteotomy site preparation on the bone-implant interface when compared with conventional drilling techniques. In view of this paucity of data, the present study was undertaken to contribute additional evidence in this area.

CONCLUSION

Within the limitations of this randomized controlled clinical trial, implant site preparation using piezoelectric inserts did not show statistically significant superiority over conventional twist drills in preserving crestal bone or enhancing PIBD.

Limitations

1. The sample size was limited to 20 subjects with 20 edentulous sites. Increasing the sample size would yield more significant results.
2. In relation to radiographic evaluations (CBCT) of bone density, long term observations and evaluations are required, mainly through prospective, randomized and multicenter trials.
3. The study would have been more reliable if histological evaluation was included in the study, which was avoided due to ethical concerns.

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