"A COMPARATIVE EVALUATION OF IMPLANT STABILITY IN IMPLANTS PLACED WITH OSTEOTOMY AND OSSEODENSIFICATION TECHNIQUE"

DISSERTATION

Submitted to

BABU BANARASI DAS UNIVERSITY,

LUCKNOW, UTTAR PRADESH

In the partial fulfillment of the requirements for the degree

Of

MASTER OF DENTAL SURGERY

In

PROSTHODONTICS, CROWN & BRIDGE

By

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Under the guidance of

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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

(Faculty of Babu Banarasi Das University)

BATCH: 2020-2023 **Enrollment No.: 12003290347**

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"A COMPARATIVE EVALUATION OF IMPLANT STABILITY IN IMPLANTS PLACED WITH OSTEOTOMY AND OSSEODENSIFICATION TECHNIQUE"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. AMRIT TANDAN,** Professor, Department of Prosthodontics, Crown & Bridge, Babu Banarasi Das College of Dental Sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

Date: 03/02/2023

Place: Lucknow

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CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled **"A COMPARATIVE EVALUATION OF IMPLANT STABILITY IN IMPLANTS PLACED WITH OSTEOTOMY AND OSSEODENSIFICATION TECHNIQUE"** is a bonafide work done by **Dr. CHARU RUKHAYA**, under my direct supervision and guidance in partial fulfilment of the requirement for the degree of Master of Dental Surgery (MDS) in Department of Prosthodontics, Crown & Bridge.

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Dr. CHARU RUKHAYA

DEDICATED TO

MY

PARENTS

for their love and endless support

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Dr. CHARU RUKHAYA

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RFA	Resonance frequency analysis
ISQ	Implant stability quotient
BIC	Bone-to-implant contact
UD	Under-drilling
OD	Osseodensification
IPS	Implant primary stability
IT	Insertion torque
SD	Standard drilling
PTV	Periotest value
CBCT	Cone beam computed tomography
ASA	American society of Anesthesiologists
BMI	Body mass index
CT	Computed tomography
HU	Hounsfield unit

AIM: The present study was done to compare and evaluate the implant stability in implants placed with osteotomy and osseodensification technique.

DESIGN: In vivo comparative study

MATERIALS AND METHODS:

The study was conducted in forty patients divided into two groups: Group A and Group B.

In Group A, twenty implants were placed in patients by osteotomy technique and in Group B; twenty implants were placed in patients by Osseodensification technique. The implant stability is evaluated and compared using Osstell device at the time of implant placement and after third month of placement.

STATISTICAL ANALYSIS USED:

The data obtained were subjected to an independent t-test (for comparing two groups) and Paired t test (for intragroup comparison)

RESULTS:

The data obtained from the intra-group comparison in the Osseo densification technique showed marked increase in dental implant stability when the same was compared between immediately placed and after three months, whereas the intra-group comparison in the Osteotomy technique showed mild variation in dental implant stability, though statistically it was insignificant due to limited time period.

CONCLUSION:

Within the limitations of this study, it was concluded that no significant difference in implant stability was seen between Osteotomy and Osseo densification technique at the first three months of implant placement when compared using an Independent t-test as $p>0.05$.

Tooth loss may be alarming when it occurs in adolescence. A loose tooth is not a normal occurrence; it may be a cause of any disease, trauma, periodontitis, poor oral hygiene, or a process of aging. Difficulty in mastication, unaesthetic appearance, and poor phonetics led to an increased demand for rehabilitation. Earlier prevalence of partial and complete edentulism has resulted in an increased demand for removable dentures or fixed partial dentures (utilizing adjacent teeth) but with the recent advancement dental implants are considered one of the most reliable treatment options for the replacement of missing teeth.

A dental implant is an artificial device resembling a tooth root anchored in the bone. This complex interaction is termed Osseointegration. The term "osseointegration" was introduced in the field of implantology by Per-Ingvar Branemark. The direct interface between the implant and the bone is a time-dependent process involving 3 different stages [1]:

- Incorporation by woven bone formation;
- Adaptation of bone mass to load;
- Adaptation of bone structure to load (bone remodeling)

The imperative requirement of osseointegration is the stability of the implant which occurs in two stages: primary and secondary. **Primary stability** is determined immediately after implant placement and therefore is a static and mechanical parameter that offers biological stability to the implant. Key factors affecting the primary stability of dental implants are bone density; implant design (macro and micro), insertion torque, surgical protocol, host factors, and operator experience. For the implant to achieve maximum stability no micro-movement is desired, undesired movement might result in a disrupted healing process which in turn would lead to implant failure. [2]

Secondary stability is achieved after the healing phase i.e. following osseointegration. This biological stability is the result of continuous bone remodeling and regeneration. [2]

Functional loading of an implant relies on implant stability. Assessment of which is categorized into 2 groups: invasive and non-invasive. The invasive method or the Destructive method is not

considered appropriate for clinical usage and therefore its usage is limited whereas the non-invasive or non-destructive method is a quantitative, repeatable, and reliable means of evaluating stability. Various clinical test methods include Surgeon's perception, Radiographical analysis, Insertion torque measurement, Percussion test, Periotest, Resonance frequency analysis (RFA), and Magnetic technology. [3]

Resonance frequency analysis (RFA) is a non-invasive diagnostic method for determining the stability of dental implants over time and thus helps to prevent any inconvenience during the treatment. It analyzes the stability via the frequency transmitting through the transducer type 42 (stainless steel or pure titanium) mounted to the implant or the abutment when the range of frequency is transferred and this resonance frequency is recorded as implant stability quotient (ISQ). The transducer or the smart peg is kept at a distance of approximately 1-3 mm from the implant or the abutment maintaining an angle of 90 degrees. The value was recorded in the buccal, lingual, mesial, and distal directions. And the process is repeated 3 to 4 times for accuracy. The ISQ ranges from zero to hundred and is dependent on the bone-to-implant contact, and rigid structure. The ISQ value and the mechanical stability are directly proportional to each other i.e.; the higher the ISQ value, the greater the stability. [3][4]

Traditionally the **osteotomies** for implant were prepared using standard drills that rely upon bone excavation. The subtractive nature and the sharpness of the drills would result in the elongated and elliptical shape of the osteotomies. The profuse heat is generated which also affects the viability of the structure surrounding it. This is due to the greater friction between the bone and the drill interface. Osteotomies prepared in narrow and short ridges may result in fenestration, and dehiscence with the greater amount of heat production.

Because of the limitation, in **2013 Dr. Salah Huwais** developed an alternative innovative approach in implantology for implant sites with deficient bone density, and was known as **Osseodensification**. The osteotomies were prepared using specially designed drills 'Densah burs' that rely on auto compaction of bone. Non-excavating action enables the biomechanical preparation of the site without producing any fenestration, or dehiscence. The sliding and rolling contact of the densifying burs results in low plastic deformation of the bone with the least amount of heat production. [5]

Osseodensifying burs (**Densah Bur**) rotate both in clockwise (bone cutting action) as well as in an anticlockwise direction allowing bone preservation by auto-compaction of bone at the peri-implant site and ensuring an increase in bone-to-implant contact percentage (BIC %) thus increasing the mechanical stability. The tapered design of the densifying burs results in the precise preparation of the site, 0.5mm less than the conventional technique. The pumping action of the burs under copious irrigation increases the plasticity of the bone. Lack of plasticity in the cortical bone is the limitation of osseodensification.

In this study, we are evaluating the implant stability placed by osteotomy and osseodensification using Resonance Frequency Analysis at 0 and 90 days intervals.

AIM:

The aim of the study is to evaluate the implant stability in implants placed with osteotomy and osseodensification technique.

OBJECTIVES:

1. To evaluate the level of implant stability at the time of implant placement with osteotomy technique.
2. To evaluate the level of implant stability after 3 months of implant placement with osteotomy technique.
3. To evaluate the level of implant stability at the time of implant placement with osseodensification technique.
4. To evaluate the level of implant stability after 3 months of implant placement with osseodensification technique.
5. To compare and evaluate the implant stability between osteotomy and osseodensification technique.

A structured review of scientific publications in English literature related to the dissertation topic **"A COMPARATIVE EVALUATION OF IMPLANT STABILITY IN IMPLANTS PLACED WITH OSTEOTOMY AND OSSEODENSIFICATION TECHNIQUE"** was done.

1. **Brånemark PI, Briene U, Adell R. Hansson O. Lindstrom and Ohlsson (1969)** [6] did an Experimental investigation on dogs to find out factors which are liable to influence the stability of anchorage of Ti implants. Arcuated implants were anchored by a screw passing transversely through the jaw. It was concluded that several factors determined the fate of implant like implants size, atraumatic restoration, primary fixture closure, loading of implant.

2. **Adell R, Lekholm U, Rockler B, Branemark PI. (1981)** [7] conducted a 15 year long longitudinal study to find out osseointegration can only be achieved by a general surgical procedure and long healing period and uniform stress distribution in functional state. Once the implants were placed the radiographic examinations were done after one week, 6 months, and 12 months postoperatively. Later the patients were observed for 5-9 years and marginal bone loss of 0.1mm and 1.5mm during the healing period was observed. The follow up period of up to 15 years was kept. It was concluded that osseointegration creates a direct and intimate contact between the vital bone and threaded Ti fixtures.

3. **N Meredith (1998)** [8] laid down various criterions to analyze the role of implant stability in the successfulness of osseointegration. He reviewed various invasive and non-invasive methods to assess implant stability which is of considerable interest in assessing early and delayed loading and in early diagnosis of implant failure.

4. **Friberg B, Sennerby L, Linden B, Gröndahl K, Lekholm U (1999)** [9] conducted a study to evaluate the extent of stability in 15 high density mandibles utilizing different designs of 75 Branemark implants with Resonance Frequency Analysis. The RFA values indicate extent of stability thus the failure rate of dental implants.

5. **Molly L (2006)** [10] the study utilizes different methods of evaluation of bone density and primary stability of dental implants and investigated the correlation between bone stability and primary stability. Further a decline in the RFA was observed after 3 weeks which later on increases with a decline in the density of bone that would significantly affect the integration of implant with the bone this showing linear increase in osseointegration.

6. **Levin L, Schwartz-Arad D (2005)** [11] in their study concluded that cigarette smoking is well known to delay wound healing, affect the periodontium and cause gingivitis and this condition could eventually lead to failure of implants.

7. **Turkyilmaz I and Edwin A McGlumphy (2008)** [12] conducted a clinical study to assess the impact of bone density on the implant success rate. CT scans of the patients were done to assess bone density and 300 implants were placed and RFA and insertion torque were considered the two main parameters to evaluate the level of implant stability. They concluded that bone density has direct influence on ISQ values and insertion torque.

8. **Quesada-García MP, Prados-Sánchez E, Olmedo-Gaya MV, Muñoz-Soto E, González-Rodríguez MP, Vallecillo-Capilla M (2009)** [13] conducted a study to reflect the viability of non-invasive technique, Resonance Frequency Analysis, in assessing the level of implant stability. RFA gives relevant information about the interface of implant-bone at the time of loading.

9. **Moon SH, Um HS, Lee JK, Chang BS, Lee MK (2010)** [14] conducted a study on sixty bovine rib blocks to find the difference in the primary stability with straight and tapered screw type of implant fixtures. The ISQ values were assessed using quantitative method, RFA, and no considerable difference was observed in the ISQ values and bone density.

10. **Javed, Khalid Almas, Roberto Crespi, George E. Romanos, Dr Med Dent (2011)** [15] reviewed clinical and experimental studies performed to evaluate correlation between implant surface roughness and primary stability after 4 weeks of placement where they

concluded that increase in the surface roughness will contribute in an increase in Osseointegration.

11. **F. Marchand et al (2012)** [16] performed a study to determine the success rate of implants placed in diabetic patients. Chronicity of the disease should be assessed before selecting the patient, elimination of the patients with poor oral hygiene status as well chronic smokers are the absolute contraindication for the dental implants. Therefore, patient selection is of utmost importance.

12. **Fawad Javed, Hameeda Bashir Ahmed, Roberto Crespi, Georgios E. Romanos (2013)** [17] conducted a study to determine the significance of factors regulating implant stability to attain successful implant integration.

13. **Manzano-Moreno, Herrera-Briones, Tala Bassam, Vallecillo-Capilla, Reyes-Botella (2015)** [18] conducted a study to evaluate the impact of various factors including placement technique, macro and microstructure designing of implant, bone regeneration on implant stability measured through Ostell Mentor Device. They concluded a significant difference in implant stability with any alteration of the parameters.

14. **Trisi P, Berardini M, Falco A, Vulpiani MP (2016)** [19] evaluated an increase in implant secondary stability by osseodensification. 10 implants were placed in left and right side of the iliac crest of sheep using conventional technique (control group) and osseodensification (test group) respectively. An increase in % bone volume and ridge width resulted in improved stability in low-density bone placed via osseodensification.

15. **Huwais S, Meyer EG (2017)** [20] conducted an experimental study to evaluate an increase in primary implant stability, bone mineral density and bone to implant contact in porcine tibia using 3 techniques: standard drilling, osseous extraction drilling using multifluted bur design, osseous drilling with same burs rotating in reverse direction.

Increased bone mineral density was documented by imaging method and 3 times increase in bone to implant contact was noticed when compared with standard drilling.

16. **Degidi M, Daprile G, Piattelli A (2017)** [21] performed a study on low-density humid bovine bone to evaluate an increase in implant stability by stepped osteotomy. The study was categorized into 3 groups: a test group and two control group, one of the control group receives implant without the underpreparation of the apical portion while the other follows the protocol and concluded an improved implant primary stability with a statistical significant difference between test group and second control group by analyzing resonance frequency values.

17. **Bhargava D, Thomas S, Pandey A, Deshpande A, Mishra SK (2018)** [22] conducted a prospective study on hemimandibles of 10 goats to compare the three osteotomy sites prepared using standard drills, bone trephine and alveolar expanders. Minimum amount of bone loss was obtained with the use of alveolar expander and resulted in enhanced primary stability by osseodensification.

18. **Monje A, Ravida A, hom-lay Wang, Jill A Helms, John B Brunski (2019)** [23] conducted a study to assess the interrelationship between mechanical and biological stability. Through implant stability quotient and marginal bone loss. A positive relation was found between insertion torque and marginal bone loss and suggested that highly efficient secondary stability is achieved with a good primary stability.

19. **Barbera-Millan J, Larrazabal-Moron C, Enciso-Ripoll JJ, PerezPevida E, Chavarri-Pardo D, Gomez-Adrain MD (2020)** [24] conducted an experimental study in low density sections of pig tibia which simulate maxillary bone by placing 55 implants each by different techniques: under drilling (UD) and osseodensification (OD). Implant stability index was determined by recording implant stability quotient (ISQ) using Penguin RFA system and an increase in the implant primary stability was noticed in OD compared to UD.

20. **Hindi AR, Bede SY (2020)** [25] conducted an observational study to access changes in bone density and implant stability on 24 patients with low bone density receiving 46 implants using osseodensification. Implant stability analyzed immediately then after 6 and 12 weeks of placement using Periotest resulted in an increase in primary stability but a significant drop in implant stability was noticed after 6 weeks of insertion.

21. **Ruiz RD, Gold J, Marquez YS, Romanos G (2020)** [26] conducted a study to evaluate the effects of two implant bed preparation techniques, under-drilling (UD) and osseodensification (OD) on the implant primary stability (IPS) and the bone density. The samples were divided into 3 groups, UD + OD (test group A), UD technique alone (test group B) and the control group. IPS was measured with 3 methods: insertion torque (IT), periotest (PTV), and resonance frequency analysis (RFA) and micro-computed tomography was used to evaluate bone density and concluded an improved IPS and bone density in test group A when compared to the control group.

22. **Ibrahim AM, Ayad SS, ElAshwah A (2020)** [27] conducted a clinical trial to evaluate the effect of osseodensification on implant stability. 20 Implants were placed in posterior maxillary ridge, each patient recieved one implant by conventional drilling other by osseodensification technique. Osstell device was used to determine increase in both primary and secondary implant stability.

23. **Sultana A, Makkar S, Saxena D, Wadhwan A, Kusum CK (2020)** [28] conducted a comparative study to evaluate the stability in implants placed with OD and traditional drilling. Placement of implants was categorized into two groups: group 1- implants placed by traditional method, group 2- implants placed by osseodensification. Implant primary stability was measured by RFA immediately and after six months. Increased primary stability resulted in group 2 when compared with group 1.

24. **Staedt, H., Kämmerer, P.W., Goetze, E. et al (2020)** [29] conducted a study on porcine mandible where the implants were placed either manually or machine-driven. The insertion torque, torque out and RFA values assess the implant stability. They concluded

an increase in the implant stability placed by standard protocol over over-dimensioned protocol.

25. **Bergamo ETP, Zahoui A, Barrera RB et al. (2021)** [30] conducted a controlled clinical trial to compare the implant stability between osseodensification and osteotomy in 56 patients. Implant stability quotient (ISQ) was recorded immediately after placement of implant and after 3 and 6 weeks and concluded higher ISQ values in osseodensification group irrespective of the area of surgery.

26. **Yeh YT, Chu TMG, Blanchard SB, Hamada Y (2021)** [31] experimented on bovine rib bones to assess the amount of changes in bone density and implant primary stability with osseodensification and osteotomy technique. Histomorphometric analysis was done to evaluate bone-to-implant contact (BIC) percentage. A significant increase in peripheral and apical bone mineral density and significant high peripheral BIC% was found in OD group.

27. **Bergamo ETP, Zahoui A, Barrera RB et al (2021)** [32] conducted a study on anterior as well as posterior aspect of maxilla and mandible where the implants were placed using standard drills and densah burs. A relative increase in implant stability quotient during the 6^{th} week of placement was observed using densah burs i.e. osseodensification.

28. **Amit M. Gaikwad, Amruta A. Joshi, Jyoti B. Nadgere (2022)** [33] investigated on endosteal implants placed via non-excavation technique and standard drills. Difference between the insertion torque values and implant stability of the samples were estimated which resulted in prevailing influence of non-excavation technique, osseodensification, over conventional.

29. **Mercier F, Bartala M, Ella B (2022)** [34] conducted a study on cadavers where 29 osteotomies were made in each group i.e., conventional and osseodensification group. Comparison of ISQ and IT values were made using Mann-Whitney U test and resulted in

a significant increase of IT in OD group. But a non-significant difference was seen in ISQ values in OD and SD group.

ARMAMENTARIUM

Materials and Equipments used in the study with specifications and Company

- Mouth mirror [API, India]
- Explorer [API, India]
- Tweezer [API, India]
- Local anesthesia [2% Lignocaine hydrochloride with adrenaline 1:80000]
- Surgical handle and blade
- Periosteal elevators [GDC]
- Disposable syringe
- Needle holder [GDC]
- Surgical needle [ETHICON^{TM}]
- Surgical scissors [Dean's]
- Normal saline (0.9%)
- Sterile gauze
- Disposable suction tip
- Physiodispenser with handpiece [NSK]
- Dental Implant [Adin, Taiwan/ bioline implants]
- Densah burs [Versah, Jackson MI USA, 1 size less than the implant size used]
- Osstell device
- CBCT

- Sutures [Vicryl # 3-0, 4-0 absorbable sutures]

Place of the study where it is conducted

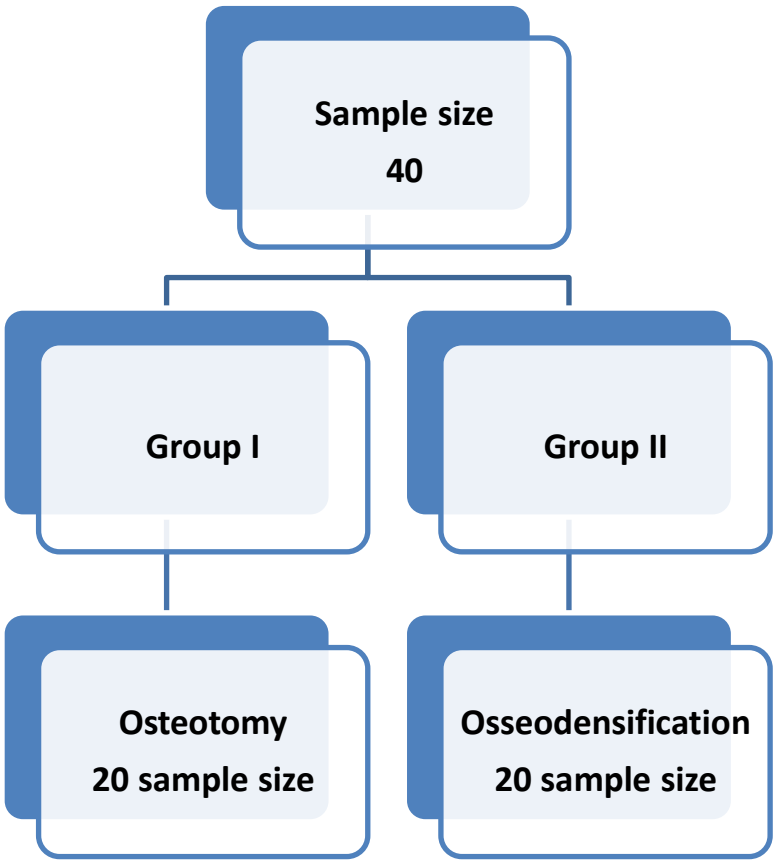
The study was conducted in the Department of Prosthodontics and Crown and Bridge, Babu Banarasi Das College of Dental Sciences, Lucknow, Uttar Pradesh.

Study subjects

Study was conducted in complete or partially edentulous patients desiring for the replacement of missing teeth, in Lucknow, Uttar Pradesh.

Study Sample and size

A total of 40 implants were placed in patients fulfilling the eligibility criteria of the study.



Eligibility Criteria:

Inclusion criteria

- Good oral hygiene
- Healthy patients with no systemic manifestations [ASA I]
- Both males and females
- Age group >18 yr
- Short or long span edentulous area of maxillary and mandibular arch
- Jaw region with low bone density (D3 & D4)
- Sufficient regenerate gingiva
- Proper interocclusal space

Exclusion Criteria

- Presence of infections
- Jaw region with high bone density (D1 & D2)
- Parafunctional habits
- Uncontrolled systemic disease
- Inadequate inter-ridge distance
- Heavy smokers
- Patient going through radiotherapy
- Poor oral hygiene
- Poor periodontal condition

Sampling Method

Convenience sampling

Study was conducted on selected patients reporting to the Department of Prosthodontics & Crown and Bridge Babu Banarasi Das College of Dental Sciences, Lucknow.

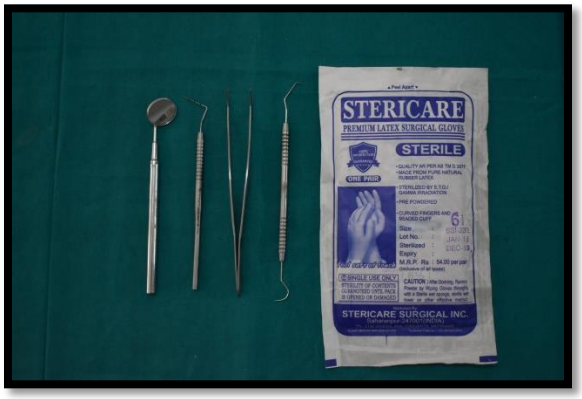


Figure 1: Diagnostics

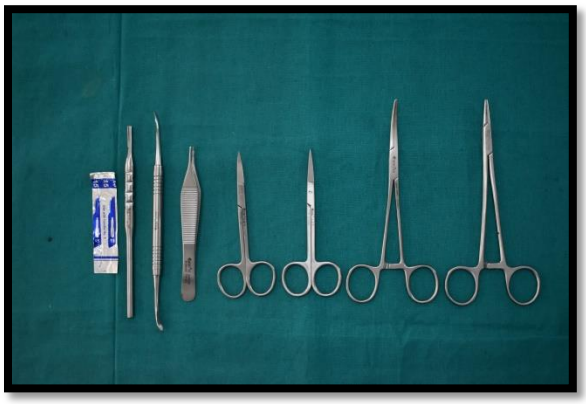


Figure 2: Surgical instruments

Figure 3: Miscellaneous items

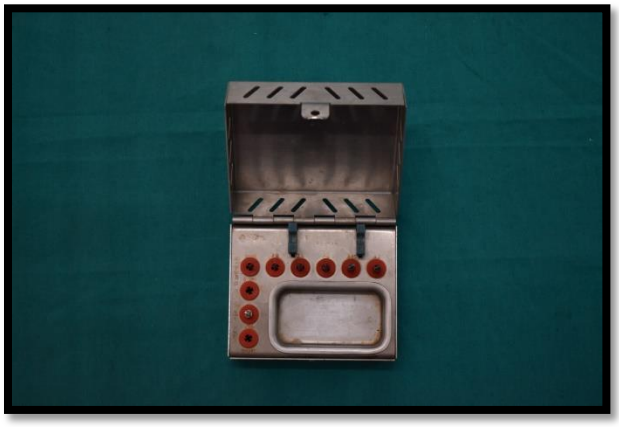


Figure 4: Implant kit (Osseodensification)

Figure 5: Densah burs

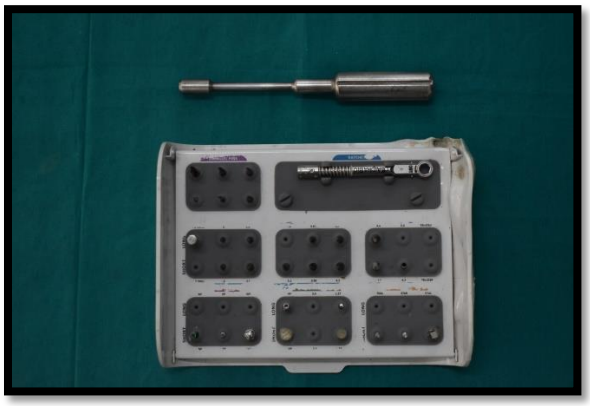


Figure 6: Implant kit (Conventional Osteotomy)

Figure 7: Physiodispenser with handpiece

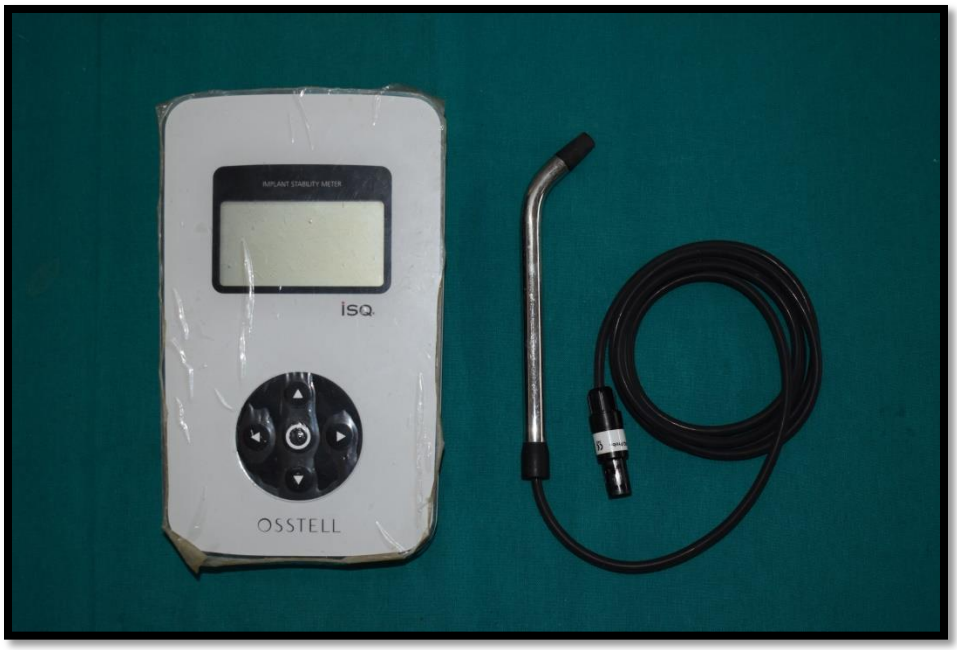


Figure 8: Osstell ISQ device

Methodology

Pre-Surgical Assessment: irreversible hydrocolloid impression material was used to obtain impression of the dental arches.

Case History:

Detailed information obtained from the patients including personal, medical, and dental history was recorded. This includes the general health of the patient, systemic diseases, oral hygiene index, and parafunctional habits such as bruxism.

Clinical examination:

The patient was clinically examined both extraorally and intraorally.

Intraoral diagnosis includes the examination of the oral mucosa, inter-ridge distance, and presence of adjacent teeth, periodontal condition of adjacent teeth, number and location of missing teeth, edentulous ridge span [size and proportion of missing teeth (mesiodistal dimension)], occlusion, retained root stumps, pathologic condition

Extraoral diagnosis includes facial symmetry, profile, form, clicking or popping sound of temporomandibular joint, cervical lymph nodes

Radiographic examination:

Implant sites were evaluated radiographically using the following radiographs:

- Orthopantomograph
- Periapical radiograph
- Panoramic radiographs
- Cone beam computed tomography (CBCT) was obtained to evaluate bone width, and height at the site of interest to ensure bone density.

Intra-oral peri-apical radiographs:

- Pre-operative

- Immediately post-operative
- Three months after implant placement

Procedure:

Analysis of the space where implants are to be installed was done, this involves:

A dental impression of both the arch was made for the evaluation of the **mesiodistal dimension** of the involved site and the desired dimension of the implant is selected.

Inter-arch distance is measured by placing the cast in occlusion to obtain an idea about the space available for the placement of the clinical crown.

Selected cases were first advised to undergo thorough oral prophylaxis.

Oral antibiotic prophylaxis

Antibiotic: Augmentin (625 mg) was recommended 1hr before the surgical procedure

Surgical phase:

Before surgery, patients were asked to rinse their mouths with 0.2% chlorhexidine digluconate solution for 2 minutes.

Preparation of the implant bed

- The surgical preparation was done under local anesthesia, 2% lidocaine with adrenaline (1:80,000).
- A crestal incision at the implant site was given followed by a reflection of a full thickness mucoperiosteal flap.
- The osteotomies were performed under copious saline irrigation at 800 rpm in a sequential manner as recommended by the protocols mentioned in the guide booklet as per the drilling technique used.

Group I (control group): the implant site was prepared with a conventional osteotomy technique in a clockwise direction using the first pilot drill followed by standard drills in a

subtractive manner at 800-1500 rpm under saline irrigation. Angulation of the preparation was checked.

Group II (test group): the implant site was prepared with an osseodensification technique using a pilot drill thereafter; densifying burs were used in a non-subtractive manner in an anti-clock wise direction at 800-1500 rpm along the length of the implant under copious irrigation.
The final drill used in the preparation was one size smaller than the diameter of the implant used.

Implant insertion

The implant was carried to the site using an implant mount without touching the implant and inserted into the osteotomy site.
The implant was then tightened using a ratchet to the desired depth with a minimum torque of 35Nm - 45Nm.

Evaluation of implant stability

Immediately after implant placement: Osstell ISQ device using Resonance frequency analyzer (RFA) was used to evaluate micro-mobility at the implant-bone junction by implants placed with both the techniques under lateral load with a vibrating transducer attached to the implant that vibrates by a sinusoidal signal. The results obtained as implant stability quotient (ISQ) depending upon the interface between the bone and implant from the buccal and lingual aspects.
Three – four repeated readings were recorded for each implant site, a cover screw was placed. Post-insertion periapical radiograph was taken to assure correct implant placement.

Flap closure

The flap was repositioned once the operated field was cleared away and stabilized with an interrupted suture.

Post-surgical instructions:

- Avoid rinsing and spitting for 24 hours after the procedure.
- Keep tongue away from the site
- Advised soft diet
- Warm saline rinses for one week to flush away debris accumulated at the surgical site.

Antibiotics

- Chlorhexidine gluconate 0.12% oral mouthwash was prescribed for 7 days.
- Antibiotic: Augmentin (625 mg) was recommended every 12 hourly for 5 days or ibuprofen (Advil) 400-600mg 6-8 hourly for 5 days.
- NSAIDs: Cataflam tablet (Diclofenac potassium) – 50mg, eight hourly for 5 days.

Wound healing:

Follow-up visit 7-10 days postoperatively:

- The sutured wound was examined for any infection and inflammation.
- In the absence of infection, sutures were removed.

Second stage surgery

After 3 months the patient was recalled for Stage II where the flap was reflected to expose the implant and the cover screw was removed followed by an evaluation of biological stability.

Evaluation of implant secondary stability after 3 months:

A cover screw was removed and the smart peg was connected using an Osstell device to evaluate micro-mobility in both groups. The readings were obtained as implant stability quotient (ISQ) from the buccal and lingual aspects.

Three – four repeated readings were recorded for each implant site and the mean of these readings was obtained and compared.

A comparative evaluation between the groups was done immediately and after 3 months to evaluate the implant stability.

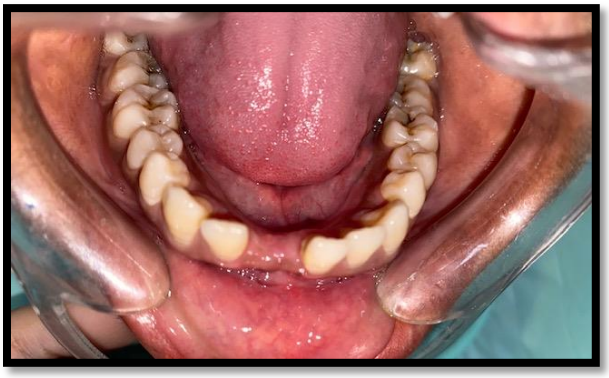


Figure 9: Pre-sugical

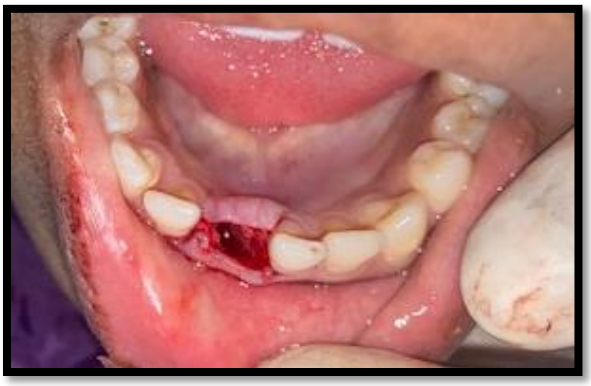


Figure 10: Incision and flap reflection

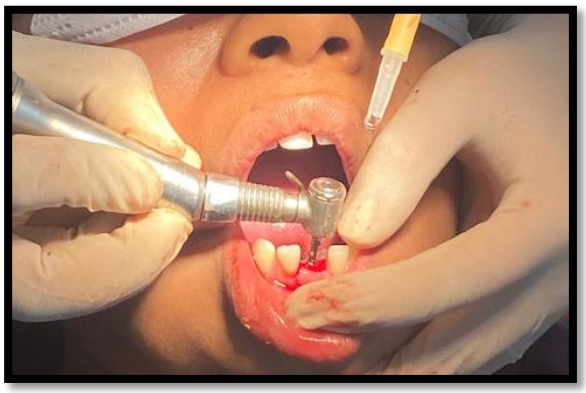


Figure 11: Drilling with Densah bur under saline irrigation

Figure 12: Primary stability measurement using Osstell ISQ device

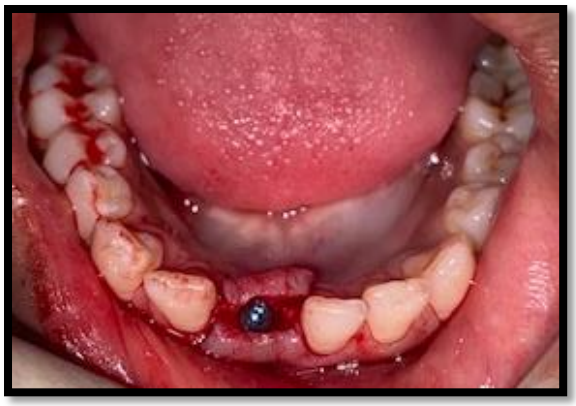


Figure 13: Implant with cover screw

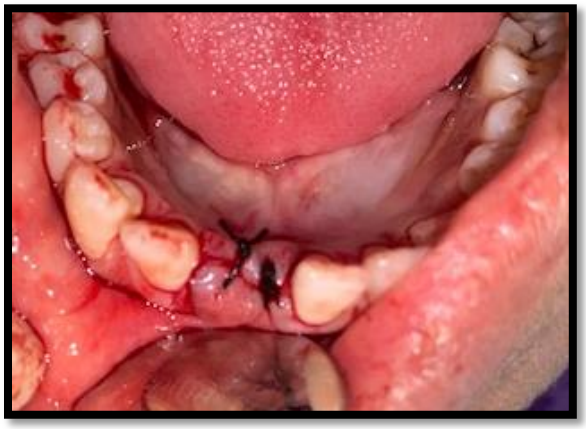


Figure 14: Flap repositioned and sutured

After 3 months of Implant placement

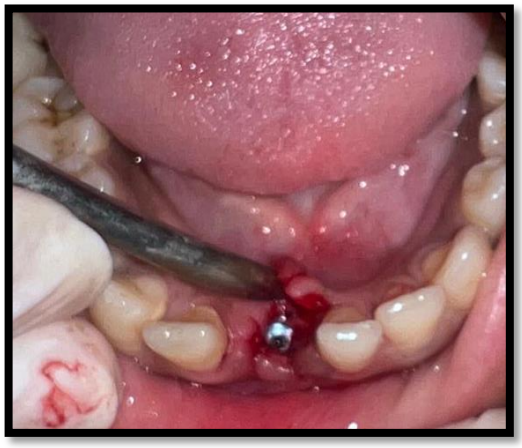


Figure 15: Incision to expose implant

Figure 16: Placement of Transducer

Figure 17: Secondary stability measurement using Osstell ISQ device

The data was entered in Microsoft excel and was analysed by SPSS (21.0 version) and further summarized and presented using Tables and Graphs.

Descriptive data was reported for each variable. Descriptive statistics such as mean and standard deviation for continuous variables was calculated.

Shapiro Wilk test was used to check the normality of the data. Distribution of data was found to be normal in a randomly selected sample. Bivariate analyses were performed using paired t-test and unpaired t-test comparing two different groups.

No significant difference was seen in implant stability in both the groups, i.e.; Group A and Group B when compared at baseline and after 3 months using independent t-test as $p>0.05$.

Table 1 showed Intergroup comparison of primary stability at the time of implant placement. No significant differences were seen in the primary stability of Group A and Group B subjects when compared using Independent t test as p>0.05.

	Group	N	Mean	Std. Deviation	Std. Error Mean
Primary stability	A	20	64.450	8.8227	1.9728
	B	20	64.600	13.0441	2.9167
P VALUE					0.966, ns

TABLE 1: Intergroup comparison of primary stability at the time of implant placement

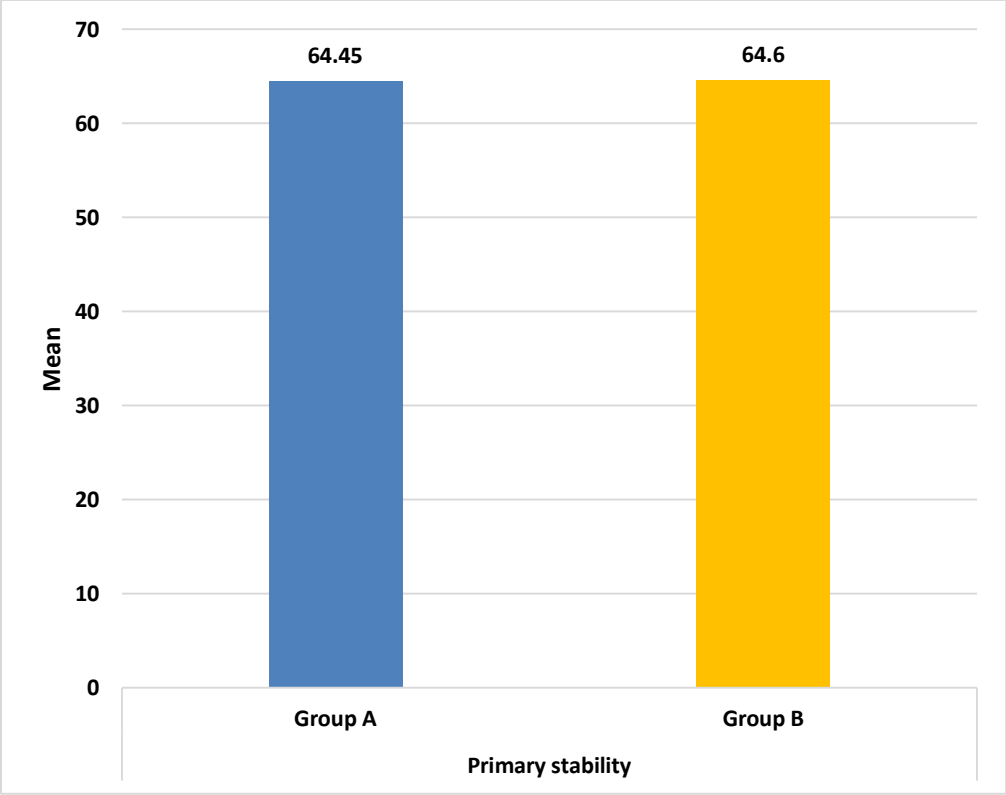


Figure 1: Intergroup comparison of primary stability at the time of implant placement

Table 2 showed intergroup comparison of secondary stability at 3 months. No significant differences were seen in the secondary stability of Group A and Group B subjects when compared using Independent t test as p>0.05.

	Group	N	Mean	Std. Deviation	Std. Error Mean
Secondary stability	A	20	82.650	2.8335	.6336
	B	20	84.550	7.2219	1.6149
P VALUE					0.280, ns

TABLE 2: Intergroup comparison of secondary stability at 3 months

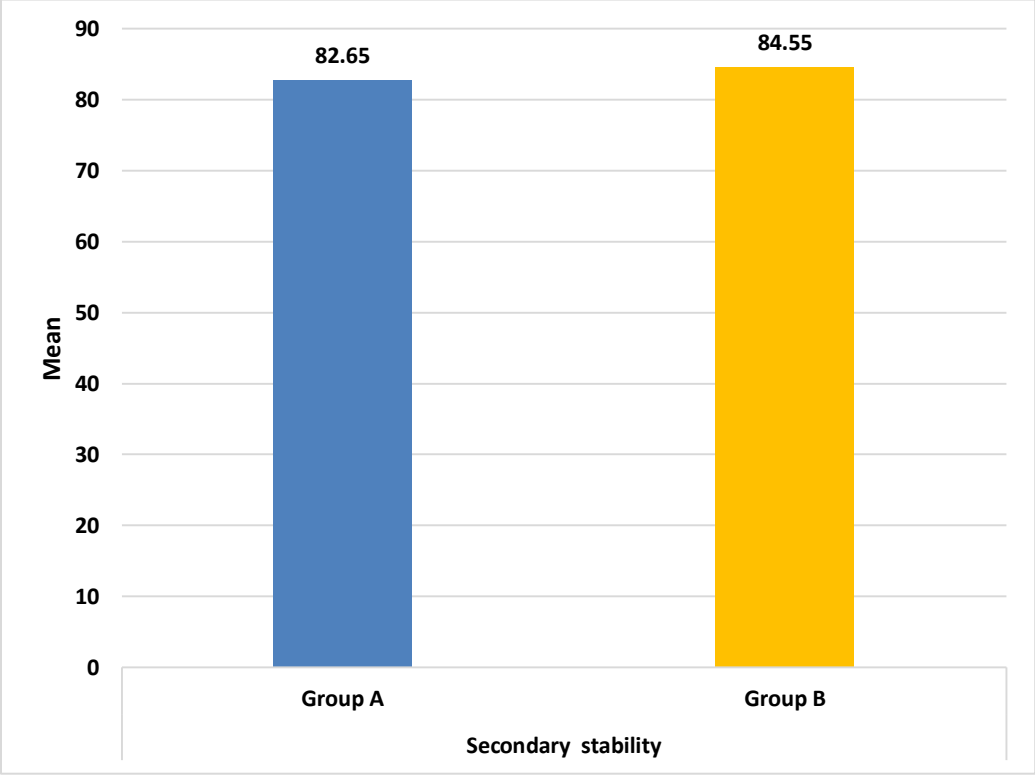


Figure 2: Intergroup comparison of secondary stability at 3 months

Table 3: Stability of the implant was found to be significantly increased in Group A subjects from the time of implant placement to 3 months as $p<0.05$ when compared using Paired t test.

		Paired Differences					T	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
GROUP A	STABILITY 0-3 MONTHS	-18.2000	8.0694	1.8044	-21.9766	-14.4234	-10.087	19	.001*

Table 3: Intragroup comparison of stability in Group A

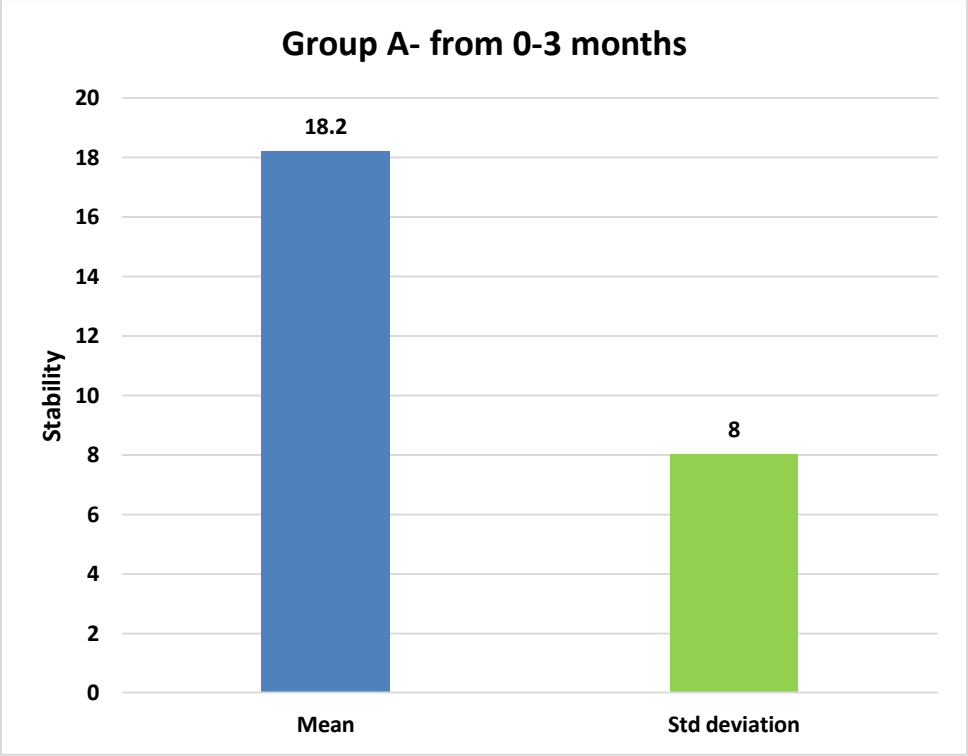


Figure 3: Intragroup comparison of stability in Group A

Table 4: Stability of the implant was found to be significantly increased in Group B subjects from the time of implant placement to 3 months as $p<0.05$ when compared using Paired t test.

GROUP B		Paired Differences					T	Df	P VALUE
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
GROUP B	STABILITY 0-3 MONTHS	-19.9500	14.8695	3.3249	-26.9091	-12.9909	-6.000	19	.000

Table 4: Intragroup comparison of implant stability in Group B

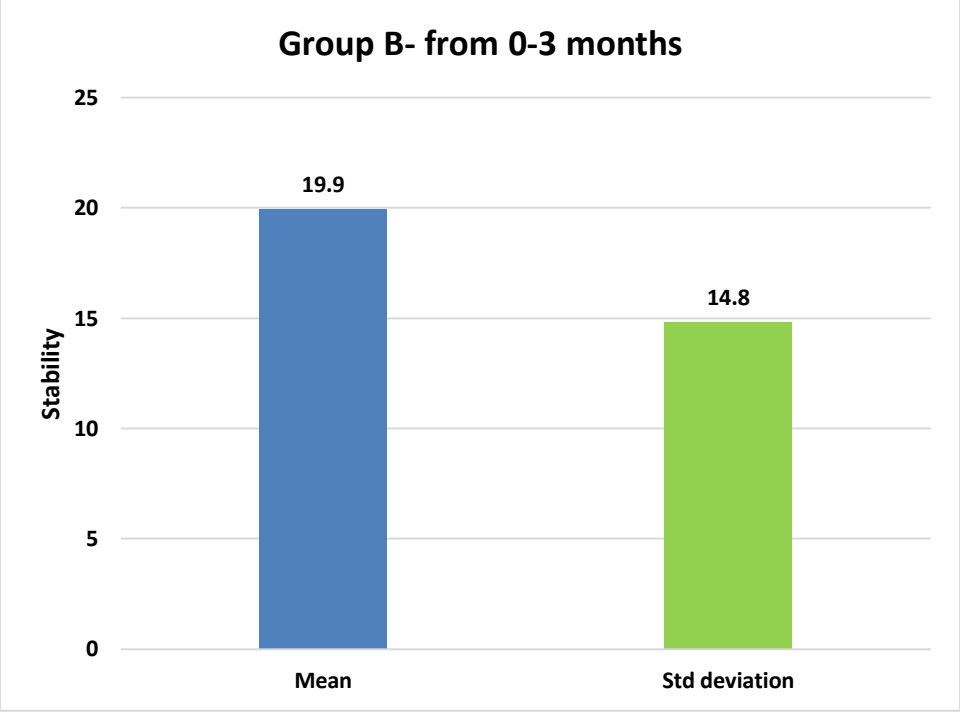


Figure 4: Intragroup comparison of stability in Group B

Oral rehabilitation of a patient with loss of single or multiple teeth either due to dental caries or periodontitis or trauma, and/or the restoration of the completely or the partially edentulous patients with a conventional complete denture or removable partial denture (RPD) has multiple drawbacks. Restoring the missing teeth with implant-supported fixed prosthesis overcomes the downsides of RPD such as retention, stability, and support. Dental implants are alloplastic biomaterials made up of Ti alloys, substantially Ti_6Al_4V with its excellent biocompatibility and mechanical properties. There have been different types of implants designed, out of which endosseous implants are extensively used in clinical practice.

The relationship between dental implants and implant stability (mechanical and biological) is influenced by a sturdy, long-lasting integration of the titanium fixtures with the surrounding vital bony structure. Numbers of factors affecting osseointegration are low bone density, implant material, implant stability, peri-apical infections, and systemic diseases. [35]

During the past decades, conventional drilling was only considered as one of the surgical procedures employed in the preparation of the implant site. This technique facilitates the removal of bone and is therefore considered as a subtractive procedure. The burs rotate in a clockwise direction under copious irrigation. But with the advancements, various other surgical techniques have been discovered to ameliorate osseointegration associated with low-density bone. Friberg et al. proposed the use of undersized drilling (UD) to produce the osteotomy a size smaller than the selected implant to improve the primary implant stability. But the increased amount of compressive forces induced by UD may lead to microfractures, resulting in delayed healing or resorption of the surrounding bone, and, overheating can lead to necrosis. In the late 70s Dr. Hilt Tatum introduced the Osteotome technique latterly, Summer's in 1994 modified Osteotomes for a sinus lift, and over time its use has been expanded in terms of bone expansion thereby increasing the density by compaction of bone. In cases of reduced mouth opening its use is not indicated. [36][37]

On the other hand, introduction of the concept of "Osseodensification" for low-density bone is an alternative novel approach for osteotomy preparation as proposed by Salah Huwais in 2013. The rationale behind this approach is to increase osseointegration by its nature of bone preservation and lateral compaction into the trabecular bone with distinctly characterized burs the "Densah Burs" with maintained ridge integrity. These burs with multiple flutes and large

negative rake angles expand the implant site. It significantly results in increased insertion torque (IT) value of 49 Ncm, improved bone density at the coronal and apical portion of the osteotomy, and an increase in % bone-implant contact (BIC) compared to the conventional drilling. It creates an environment where the bone itself acts as an autogenous graft and this close proximity of the osteoblasts with the implant body will promote bone emergence that enhances primary implant stability through under-preparation. [5]

As per the inclusion criteria, adult male and female patients were selected for the present study. The majority of the studies have demonstrated that the implants if placed during the adolescence phase can get displaced or submerged during jaw development. As a consequence of the age-related remodeling process implants placed after 18 years of age is known to have a better prognosis. Bone remodeling during the alveolar growth phase as stated by Percinoto, C. et al. has a negative impact on the implants if installed before the growth termination. It was also demonstrated that these interferences further restrict the transverse growth and tooth eruption which might lead to malocclusion as well resorption. [38][39]

The American Society of Anesthesiologists (ASA) classified the physical status of a patient into 5 classes to anticipate the operational pitfall. As per the classification of patients with no systemic conditions, a body mass index (BMI) of fewer than 30 was selected. [40] Several studies have shown the correlation between systemic diseases and the survival rate of the implant. Patients with bleeding disorders such as hemophilia, increased risk of fractures, delayed bone healing, peri-implantitis associated with osteoporosis and uncontrolled diabetes mellitus, and other immunosuppressive patients are at higher risk of failure. Implant surgery is an absolute contraindication for all patients with these aforementioned conditions. [41][42]

Diagnostic imaging is an integral part of pre-operative, surgical, and post-operative treatment planning. Imaging modalities include Periapical radiographs, Panoramic radiographs, computed tomography (CT), and cone beam computed tomography (CBCT). 2D radiographic imaging offers an array of obstacles such as limited coverage of area, elongation, and shortening of images, overlapping of structures, magnification, and distortion of the images over numerous advantages offered by 3D radiographic imaging such as low radiation dose, detailed and accurate scan, and reduced artifacts. Accurate evaluation of the distance between the crest of the alveolar

ridge and the surrounding vital structures, and determination of the width, and density of the alveolar bone make CBCT a reliable imaging modality. [43][44]

In the present study, the implant stability quotient (ISQ) of implants placed with two different drilling protocols in Misch type D3 & D4 bone was analyzed. Implant stability is considered an absolutely important parameter in the evolution of osseointegration. Primary dental implant stability is directly related to bone density. Lekholm and Zarb in 1985 classified residual bone obtained from radiographs as Type 1, Type 2, type 3, and type 4. In 1987, Misch and Judy classified bone quality and quantity based on its density and location into 4 grades: D1 to D4, in 1999 Misch further classified bone into 5 classes: D1, D2, D3, D4, and D5 in Hounsfield units (HU) obtained from CT examination indicates maximum density for anterior mandible whereas posterior maxilla is least dense. [45] Therefore the amount of force required to insert an implant will also be the least for the less dense bone and this required force is called insertion torque (IT). [46] An increased amount of torque will lead to greater implant primary stability which is in accordance with the study done by Trisi et al. Implants inserted with torque >35Ncm result in higher implant stability. Ottoni et al in their study demonstrated an average torque of 32 Ncm whereas; Neugebauer and associates reported an ideal insertion torque of 35Ncm.

According to various studies, the success of osseointegrated implants depends upon variable spectra such as surrounding bone level, immobilization, and absence of any radiolucency. Implant stability is considered an absolutely important parameter in the evolution of osseointegration. Clinically, several techniques are exercised to evaluate dental implant stability using the amount of torque needed during insertion, or after insertion using the resonance frequency analysis technology implemented in the Osstell device.

The objective was to corroborate the accuracy of resonance frequency analysis (RFA) with the Osstell device. The RFA was introduced by Meredith in 1996. The first-generation resonance frequency transducer was manufactured from titanium or stainless steel. It constitutes a cantilever beam with two attached piezoceramic elements that are attached to the fixture or abutment. The frequency ranges from five to fifteen kHz. Heavyweight and expensive instrumentation limits its use. The third generation comprises a battery-driven system (OsstellTM; Osstell AB, Gothenburg, Sweden). The stability values range from 1 to 100. It reduces chairside time. Evolution of newer generation of frequency analyzer the most recent

version of resonance frequency analysis is wireless, where a metal rod (a peg) is connected to the implant employing a screw connection (Osstell MentorTM; Ostell AB). The peg has a small magnet attached to its top, which is excited by magnetic pulses from a handheld computer. The peg vibrates in two directions, which are approximately perpendicular to each other. The vibration takes place in the direction that gives the highest resonance frequency (first mode) and in the direction that gives the lowest resonance frequency (second mode). Thus, two implant stability quotient values are provided, one high and one low. For instance, an implant with buccally exposed threads may show one low value, reflecting the lack of bone in the buccal–lingual direction, and one high value, reflecting good bone support in the mesial-distal direction. The RF between 3500Hz -8500Hz is produced and expressed as numbers between 1-100 ISQ. [47][48][49]

The higher the value, the higher the stability, the lesser the value greater is the instability. A successful implant typically has an ISQ value greater than 65. An ISQ <50 may indicate potential failure or an increased rate of failure.

According to a study done by Koshy et al., RFA is considered a reliable marker for stability index. In addition, Sarfaraz et al. found a drop in the ISQ values in the first 3 weeks which was significantly increased after 3 months. The wide variation in the stability may also be related to the osteoclastic and osteoblastic activity of the cells during their remodeling phase leading to decrease and an increase in the implant stability. [35]

With respect to the implant stability, this study showed an increase in the stability after 3 months of duration, though an increase is seen in both the groups, but when compared group b showed higher ISQ values. The increase in the ISQ values after 90 days of implant placement is because of the lateral compaction of bone at the peri-implant site during the healing phase. [35] According to the results of this study, there was no statistically significant difference in dental implant stability between conventional osteotomy and osseodensification technique which is in concordance with some studies that observed slightly greater stability but with no significant increase. Hindi AR also found that implant insertion torque is higher in the non-extraction techniques with an improved stability. On the contrary, some studies, however, observed a significant difference between the two approaches. Monje A et al in 2019 yielded no significant

relationship between insertion torque, primary stability, and survival rate, but with a positive relationship between mechanical and biological stability.

Intergroup comparison of primary stability at the time of implant placement is compiled in Table 1. The mean ISQ in the conventional osteotomy group and in osseodensification group is 64.450 and 64.600 respectively. Intergroup comparison of secondary stability at 3 months is compiled in Table 2. The mean ISQ in the conventional osteotomy group and in osseodensification group is 82.650 and 84.550 respectively. No significant differences were seen in the primary stability of Group A and Group B. There have been varying reports in the literature regarding the interrelationship between IT and ISQ. Mercier F et al reported a study on cadavers in whom they concluded a non-significant difference in the ISQ values of primary stability between conventional drilling and osseodensification despite higher IT values for osseodensification. Several clinical studies have also compared the use of additive and subtractive techniques to demonstrate their influence on stability. Furthermore, the results of which showed no statistically significant difference when compared via unpaired t-test.

The table shows the stability of the implant in Group A subjects from the time of implant placement to 3 months. Intragroup comparison shows standard deviation of 8.0694. A significant increase was seen as $p<0.05$ when compared using paired t-test.

The table shows the stability of the implant in Group B subjects from the time of implant placement to 3 months. Intragroup comparison shows standard deviation of 14.8695. A significant increase was seen as $p<0.05$ when compared using paired t-test. Ibrahim et al reported a clinical study which recommends the use of Densah burs over traditional ones for marked improvement in primary as well as secondary stability.

The present in-vivo study assessed the comparative evaluation of primary (baseline) and secondary (after 3 months) implant stability of implants installed via conventional and osseodensification technique. The following conclusion was drawn:

- No significant difference was seen in the implant stability quotient (ISQ) of osteotomy and osseodensification from 0 to 90 days when compared using an Independent t-test as $p>0.05$.

1. Parithimarkalaignan S, Padmanabhan TV. Osseointegration: an update. J Indian Prosthodont Soc. 2013 Mar; 13(1):2-6. doi: 10.1007/s13191-013-0252-z. Epub 2013 Jan 11. PMID: 24431699; PMCID: PMC3602536.
2. Pai UY, Rodrigues SJ, Talreja KS, Mundathaje M. Osseodensification – A novel approach in implant dentistry. J Indian Prosthodont Soc 2018; 18:196-200.
3. Swami V, Vijayaraghavan V, Swami V. Current trends to measure implant stability. J Indian Prosthodont Soc 2016; 16:124-30.
4. Singh S, Kaura S, Bansal SK, Bahl R, Singh A, Bansal S. Magnetic resonance frequency analysis (RFA) of dental implant during the osseointegration period. Baba Farid Univ Dent J 2020; 10(1):44-50.
5. Utkalika Das1, Gatha Mohanty2, Rinkee Mohanty3. Osseodensification: A New Era of Implant Osteotomy. Indian Journal of Forensic Medicine & Toxicology [Internet]. 2020 Oct. 29 [cited 2023 Jan. 26]; 14(4):8093-7. Available from: https://medicopublication.com/index.php/ijfmt/article/view/12927.
6. Brånemark PI, Adell R, Breine U, Hansson BO, Lindström J, Ohlsson A. Intra-osseous anchorage of dental prostheses. I. Experimental studies. Scand J Plast Reconstr Surg. 1969; 3(2):81-100. doi: 10.3109/02844316909036699. PMID: 4924041.
7. Adell R, Lekholm U, Rockler B, Brånemark PI. A 15-year study of osseointegrated implants in the treatment of the edentulous jaw. Int J Oral Surg. 1981 Dec; 10(6):387-416. doi: 10.1016/s0300-9785(81)80077-4. PMID: 6809663.
8. Meredith N. Assessment of implant stability as a prognostic determinant. Int J Prosthodont. 1998 Sep-Oct;11(5):491-501. PMID: 9922740.
9. Friberg B, Sennerby L, Linden B, Gröndahl K, Lekholm U. Stability measurements of one-stage Brånemark implants during healing in mandibles. A clinical resonance frequency analysis study. Int J Oral Maxillofac Surg. 1999 Aug; 28(4):266-72. PMID: 10416893.
10. Liene Molly (2006). Bone density and primary stability in implant therapy. , 17(S2), 124–135. doi:10.1111/j.1600-0501.2006.01356.x
11. Levin L, Schwartz-Arad D. The effect of cigarette smoking on dental implants and related surgery. Implant Dent. 2005 Dec; 14(4):357-61. doi: 10.1097/01.id.0000187956.59276.f8. PMID: 16361886.

12. Turkyilmaz I, McGlumphy EA. Influence of bone density on implant stability parameters and implant success: a retrospective clinical study. BMC Oral Health. 2008 Nov 24; 8:32. doi: 10.1186/1472-6831-8-32. PMID: 19025637; PMCID: PMC2614413.
13. Quesada-García MP, Prados-Sánchez E, Olmedo-Gaya MV, Muñoz-Soto E, González-Rodríguez MP, Vallecillo-Capilla M. Measurement of dental implant stability by resonance frequency analysis: A review of the literature. Med Oral Patol Oral Cir Bucal. 2009 Oct 1; 14 (10):e538-46.
14. Moon SH, Um HS, Lee JK, Chang BS, Lee MK. The effect of implant shape and bone preparation on primary stability. J Periodontal Implant Sci. 2010 Oct; 40(5):239-43. doi: 10.5051/jpis.2010.40.5.239. Epub 2010 Oct 31. PMID: 21072221; PMCID: PMC2967812.
15. Javed F, Almas K, Crespi R, Romanos GE. Implant surface morphology and primary stability: is there a connection? Implant Dent. 2011 Feb;20(1):40-6. doi: 10.1097/ID.0b013e31820867da. PMID: 21278526.
16. Marchand F, Raskin A, Dionnes-Hornes A, Barry T, Dubois N, Valéro R, Vialettes B. Dental implants and diabetes: conditions for success. Diabetes Metab. 2012 Feb; 38(1):14-9. doi: 10.1016/j.diabet.2011.10.002. Epub 2012 Jan 27. PMID: 22284547.
17. Javed F, Ahmed HB, Crespi R, Romanos GE. Role of primary stability for successful osseointegration of dental implants: Factors of influence and evaluation. Interv Med Appl Sci. 2013 Dec; 5(4):162-7. doi: 10.1556/IMAS.5.2013.4.3. Epub 2013 Dec 20. PMID: 24381734; PMCID: PMC3873594.
18. Manzano-Moreno FJ, Herrera-Briones FJ, Bassam T, Vallecillo-Capilla MF, Reyes-Botella C. Factors Affecting Dental Implant Stability Measured Using the Ostell Mentor Device: A Systematic Review. Implant Dent. 2015 Oct; 24(5):565-77. doi: 10.1097/ID.0000000000000308. PMID: 26244855.
19. Trisi P, Berardini M, Falco A, Podaliri Vulpiani M. New Osseodensification Implant Site Preparation Method to Increase Bone Density in Low-Density Bone: In Vivo Evaluation in Sheep. Implant Dent. 2016 Feb; 25(1):24-31. doi: 10.1097/ID.0000000000000358. PMID: 26584202; PMCID: PMC4770273.
20. Huwais S, Meyer EG. A Novel Osseous Densification Approach in Implant Osteotomy Preparation to Increase Biomechanical Primary Stability, Bone Mineral Density, and

Bone-to-Implant Contact. Int J Oral Maxillofac Implants. 2017 Jan/Feb; 32(1):27-36. doi: 10.11607/jomi.4817. Epub 2016 Oct 14. PMID: 27741329.

21. Degidi M, Daprile G, Piattelli A. Determination of primary stability: a comparison of the surgeon's perception and objective measurements. Int J Oral Maxillofac Implants. 2010 May-Jun; 25(3):558-61. PMID: 20556255.
22. Bhargava D, Thomas S, Pandey A, Deshpande A, Mishra SK. Comparative study to evaluate bone loss during osteotomy using standard drill, bone trephine, and alveolar expanders for implant placement. J Indian Prosthodont Soc 2018;18:226-30
23. Monje A, Ravidà A, Wang HL, Helms JA, Brunski JB. Relationship Between Primary/Mechanical and Secondary/Biological Implant Stability. Int J Oral Maxillofac Implants. 2019 Suppl; 34:s7-s23. doi: 10.11607/jomi.19suppl.g1. PMID: 31116830.
24. Barberà-Millán, Javier & Larrazábal-Morón, Carolina & Enciso-Ripoll, Juan & Pérez-Pevida, Esteban & Chávarri Prado, David & Gómez-Adrián, María. (2020). Evaluation of the primary stability in dental implants placed in low density bone with a new drilling technique, Osseodensification: an in vitro study. Medicina oral, patología oral y cirugía bucal. 26. 10.4317/medoral.24231.
25. Hindi AR, Bede SY. The effect of osseodensification on implant stability and bone density: A prospective observational study. J Clin Exp Dent. 2020 May 1; 12(5):e474-e478. doi: 10.4317/jced.56727. PMID: 32509230; PMCID: PMC7263779.
26. Delgado-Ruiz R, Gold J, Somohano Marquez T, Romanos G. Under-Drilling versus Hybrid Osseodensification Technique: Differences in Implant Primary Stability and Bone Density of the Implant Bed Walls. Materials (Basel). 2020 Jan 15; 13(2):390. doi: 10.3390/ma13020390. PMID: 31952138; PMCID: PMC7013970.
27. Ibrahim, A., Ayad, S., ElAshwah, A. THE EFFECT OF OSSEODENSIFICATION TECHNIQUE ON IMPLANT STABILITY (CLINICAL TRIAL). *Alexandria Dental Journal*, 2020; 45(2): 1-7. doi: 10.21608/adjalexu.2020.86758
28. Sultana A, Makkar S, Saxena D, Wadhawan A, Kusum CK. To compare the stability and crestal bone loss of implants placed using osseodensification and traditional drilling protocol: A clinicoradiographical study. J Indian Prosthodont Soc 2020;20:45-51

29. Staedt, H., Kämmerer, P.W., Goetze, E. *et al.* Implant primary stability depending on protocol and insertion mode — an ex vivo study. *Int J Implant Dent* **6**, 49 (2020). https://doi.org/10.1186/s40729-020-00245-3
30. Bergamo ETP, Zahoui A, Barrera RB, Huwais S, Coelho PG, Karateew ED, Bonfante EA. Osseodensification effect on implants primary and secondary stability: Multicenter controlled clinical trial. Clin Implant Dent Relat Res. 2021 Jun; 23(3):317-328. doi: 10.1111/cid.13007. Epub 2021 May 27. PMID: 34047046; PMCID: PMC8362055.
31. Yeh YT, Chu TG, Blanchard SB, Hamada Y. Effects on Ridge Dimensions, Bone Density, and Implant Primary Stability with Osseodensification Approach in Implant Osteotomy Preparation. Int J Oral Maxillofac Implants. 2021 May-Jun; 36(3):474-484. doi: 10.11607/jomi.8540. PMID: 34115061.
32. Bergamo ETP, Zahoui A, Barrera RB, Huwais S, Coelho PG, Karateew ED, Bonfante EA. Osseodensification effect on implants primary and secondary stability: Multicenter controlled clinical trial. Clin Implant Dent Relat Res. 2021 Jun; 23(3):317-328. doi: 10.1111/cid.13007. Epub 2021 May 27. PMID: 34047046; PMCID: PMC8362055
33. Joshi AA, Gaikwad AM, Padhye AM, Nadgere JB. Overview of Systematic Reviews and Meta-analyses investigating the Efficacy of Different Nonsurgical Therapies for the Treatment of Peri-implant Diseases. Int J Oral Maxillofac Implants. 2022 Jan-Feb; 37(1):e13-e27. doi: 10.11607/jomi.9088. PMID: 35235624.
34. Mercier F, Bartala M, Ella B. Evaluation of the Osseodensification Technique in Implant Primary Stability: Study on Cadavers. Int J Oral Maxillofac Implants. 2022 May-Jun; 37(3):593-600. doi: 10.11607/jomi.9144. PMID: 35727254.
35. Hiranmayi K V. Factors influencing implant stability. J Dent Implant 2018;8:69-76
36. Palaskar JN, Joshi N, Shah PM, Gullapalli P, Vinay V. Influence of different implant placement techniques to improve primary implant stability in low-density bone: A systematic review. J Indian Prosthodont Soc 2020; 20:11-6.
37. Nkem Obiechina. Osteotome technique: A Minimally Invasive Way to Increase Bone for Dental Implant Placement in The Posterior Maxilla and Prevent Sinus Membrane Perforation for Single and Multiple Teeth Replacements. J Med - Clin Res & Rev. 2019; 3(3): 1-6.

38. Cronin RJ Jr, Oesterle LJ, Ranly DM. Mandibular implants and the growing patient. Int J Oral Maxillofac Implants. 1994 Jan-Feb;9(1):55-62. PMID: 8150513.
39. Percinoto C, Vieira AE, Barbieri CM, Melhado FL, Moreira KS. Use of dental implants in children: a literature review. Quintessence Int. 2001 May;32(5):381-3. PMID: 11444071.
40. Doyle DJ, Hendrix JM, Garmon EH. American Society of Anesthesiologists Classification. [Updated 2022 Dec 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK441940/
41. Santhosh Kumar MP. Effects of Systemic Conditions on Dental Implants. International Journal of Clinical Dentistry [Internet]. 2022 Jul [cited 2023 Jan 26];15(3):529–38. Available from: https://search.ebscohost.com/login.aspx?direct=true&db=ddh&AN=159874531&site=ehost-live
42. Donos N, Calciolari E. Dental implants in patients affected by systemic diseases. Br Dent J. 2014 Oct;217(8):425-30. doi: 10.1038/sj.bdj.2014.911. PMID: 25342349.
43. Somaraj V, Ravishankar P, Sridevi A et al. Cone beam computerized tomography - a boon to dentistry. Int J Health Sci Res. 2018; 8(6):285-289.
44. Riyaz, Mohamed & Al-Ruthea, Mohammed. (2019). Cone Beam Computed Tomography in Prosthodontics. International Journal of Contemporary Medical Research. 6. A10-A14. 10.21276/ijcmr.2019.6.1.21.
45. Urmi Agrawal., et al. "Is Bone Density a Success Criterion in Dental Implants". Acta Scientific Dental Sciences 5.6 (2021): 146-150.
46. Goswami MM, Kumar M, Vats A, Bansal AS. Evaluation of dental implant insertion torque using a manual ratchet. Med J Armed Forces India. 2015 Dec;71(Suppl 2):S327-32. doi: 10.1016/j.mjafi.2013.07.010. Epub 2013 Sep 24. PMID: 26843747; PMCID: PMC4705154.
47. Meredith N, Alleyne D, Cawley P. Quantitative determination of the stability of the implant-tissue interface using resonance frequency analysis. Clin Oral Implants Res. 1996 Sep;7(3):261-7

48. Sennerby L, Meredith N. Resonance frequency analysis: measuring implant stability and osseointegration. Compend Contin Educ Dent. 1998 May; 19(5):493-8, 500, 502; quiz 504.
49. Sennerby L, Meredith N. Implant stability measurements using resonance frequency analysis: biological and biomechanical aspects and clinical implications. Periodontol 2000. 2008; 47:51-66.

ANNEXURE-I

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the IXth Institutional Ethics Sub-Committee

IEC Code: 21 **BBDCODS/04/2022**

Title of the Project: A comparative evaluation of implant stability in implants placed with osteotomy and osseodensification technique.

Principal Investigator: Dr Charu Rukhaya **Department:** Prosthodontics and Crown & Bridge

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Charu Rukhaya,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07th April, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow
4.	Dr. Akanksha Bhatt Member	Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. Puneet Ahuja)
Principal
BBDCODS

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

ANNEXURE-II

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"A Comparative Evaluation of Implant Stability in Implants Placed with Osteotomy and Osseodensification Technique"** submitted by **Dr Charu Rukhaya** Post graduate student from the **Department of Prosthodontics and Crown & Bridge** as part of MDS Curriculum for the academic year 2020-2023 with the accompanying proforma was reviewed by the Institutional Research Committee present on **11th October 2021** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

ANNEXURE-III

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Consent Form (English)

Title of the Study: A comparative evaluation of implant stability in Implants placed with osteotomy and osseodensification Technique.

Study Number……..

Subject's Full Name…….

Date of Birth/Age ……

Address of the Subject…….

Phone no. and e-mail address……

Qualification ……

Occupation: Student / Self Employed / Service /

Housewife/ Other (Please tick as appropriate)

Annual income of the Subject……

Name and of the nominees(s) and his relation to the subject..... (For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated……..for the above study and have had the opportunity to ask questions. OR I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that the sponsor of the project, others working on the Sponsor‘s behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

5. I permit the use of stored sample (tooth/tissue/blood) for future research. Yes / No

6. I agree to participate in the above study. I have been explained about the complications and side effects, if any, and have fully understood them. I have also read and understood the participant/volunteer’s Information document given to me.

Signature (or Thumb impression) of the Subject/Legally

Acceptable Representative: ……

Signatory‘s Name……. Date …….

Signature of the Investigator…… Date……..

Study Investigator‘s Name..... Date……..

Signature of the witness…… Date……..

Name of the witness……

Received a signed copy of the PID and duly filled consent form

Signature/thumb impression of the subject or legally

Date…

Acceptable Representative

ANNEXURE-IV

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

Guidelines for Devising a Participant / Legally Acceptable Representative Information Document (PID) in English

1. Study Title

A comparative evaluation of implant stability in Implants placed with osteotomy and osseodensification Technique.

2. Invitation Paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information.

3. What is the purpose of the study?

The aim of the study is to evaluate the implant stability in implants placed with osteotomy and osseodensification technique.

4. Why have I been chosen?

You are chosen as you fulfill the criteria for the study.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

6. What will happen to me if I take part?

You will have to come four to five times, in the first visit the implant site will be prepared followed by the measurement of implant stability and in the third month. As a volunteer, your responsibility will be to arrive on time.

7. What do I have to do?

There will be certain changes made in the dietary intake with few other precautionary measures, and you will be expected to follow that.

8. What is the procedure that is being tested?

Dental implants surgery is a procedure that replaces missing teeth with screw like component that look and function much like real ones. The implant stability will be assessed once the implant is placed, which indicate the level of stability of dental implants at the time of placement. The same procedure will be followed after 3 months. Crown will be placed once the surrounding tissues are healed and the required stability is achieved. You are expected to follow all the instructions given by the doctors.

9. What are the interventions for the study?

Pre-surgical: CBCT will be obtained before starting the procedure

Surgical: implant site will be prepared under 2% lignocaine with adrenaline and full thickness of flap will be raised for either osteotomy or osseodensification technique as per the required condition. Then immediately the implant stability will be measured with a device, the same procedure of stability measurement will also be done after 3 months.

Post-surgical: medications will be prescribed such as: Antibiotics, Nsaids.

10. What are the side effects of taking part?

There are some associated side effects of dental implants placement such as pain and discomfort last not more than two weeks, minor bleeding and in case of infection or any numbness or loosening of the implants report immediately to the doctor.

11. What are the possible disadvantages and risks of taking part?

- Diabetic patients are more susceptible to infection and this could be a reason for implant failure.
- Osteoporosis a disease of decreased bone mass, increased bone weakness, and have more potential to fracture resulting in poor implant stability therefore higher chances of implant failure.
- Failure rate of implants is more in heavy smokers and is directly related to tobacco use.

12. What are the possible benefits of taking part?

By taking part in this study you will be receiving a better treatment option at a lesser discomfort. The method of placing implants yields better implants anchorage and longer implant life.

13. What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the research being studied. If this happens, you will be informed about it and the changes that can happen to the study will be informed. You are free to withdraw in the middle of the study. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

If the study finishes/stops before the stipulated time, then the reason for the same will be explained to the patients.

15. What if something goes wrong?

Volunteers will be taken care of by the doctors expertising in the field at BBDCODS opd.

16. Will my taking part in this study be kept confidential?

Your name, address or any personal or other information will not be shared outside the BBDCODS.

17. What will happen to the results of the research study?

Identity of the participants will not be disclosed in any result/ reports/ publications.

18. Who is organizing the research?

Study is organized by the researcher. Complete cost of the implant will be given by the patient.

19. Will the results of the study be made available after study is over?

If the patient wishes, the result of the study will be made available to him/ her.

20. Who has reviewed the study?

The HOD /IRC/IEC of the institution has reviewed and approved the study.

21. Contact for further information

Dr. Lakshmi Bala

Member Secretary of Ethics Committee of the institution,

Address: Babu Banarasi das University, Faizabad road, Atif Vihar, Lucknow, UP.

226028

Email: bbdcods.iec@gmail.com)

Name of patient –

Address –

Email –

Tel no. –

Signature of PI……

Name……..

Date……..

The participant will be given a copy of the information sheet and the signed consent form. Thank you for taking part in the study.

ANNEXURE-V

MASTER CHART

GROUP A

S. No.	PRIMARY STABILITY	SECONDARY STABILITY
1.	70	87
2.	55	78
3.	55	80
4.	71	87
5.	55	83
6.	72	82
7.	75	82
8.	70	87
9.	74	86
10.	75	80
11.	71	85
12.	50	83
13.	72	80
14.	57	80
15.	59	84
16.	54	80
17.	70	85
18.	72	82
19.	55	83
20.	57	79

GROUP B

S. No.	PRIMARY STABILITY	SECONDARY STABILLITY
1.	73	98
2.	72	73
3.	73	75
4.	72	85
5.	70	81
6.	57	77
7.	52	83
8.	92	93
9.	73	78
10.	73	89
11.	70	98
12.	45	79
13.	71	75
14.	43	70
15.	55	74
16.	57	80
17.	70	76
18.	75	80
19.	59	71
20.	40	75

ANNEXURE-VI

Formulas used for analysis

STATISTICAL ANALYSIS

Formula used for the analysis

A. The Arithmetic Mean

The most widely used measure of central tendency is arithmetic mean, usually referred to simply as the mean, calculated as

$$\bar{X} = \frac{\sum_{i=1}^{n} X_i}{n}$$

B. The Standard Deviation

The standard deviation (SD) is the positive square root of the variance, and calculated as

$$SD = \sqrt{\frac{\sum X_i^2 - \frac{(\sum X_i)^2}{n}}{n-1}}$$

Where, n= no. of observations

And also denoted by subtracting minimum value from maximum value as below

C. Tests of significance

Test of significance are used to estimate the probability that the relationship observed in the data occurred purely by chance was there a relationship between the variables. They are used to test the hypothesis proposed at the start of the study.

In this study parametric tests were used

a) The data was normally distributed
b) The data was obtained from the sample which is randomly selected
c) The data was quantitative data

I. T TEST

T tests are based on the t distribution which is a symmetrical, bell-shaped curve like the normal distribution, but having different area and probability properties.

T distribution is a family of curves which are differentiated by their degrees of freedom.

With increasing sample sizes, the t distribution assumes the shape of the normal distribution. 2 A sample size of 100 is often chosen as the cut-off point for deciding when to apply For t or z.

TYPES OF T-TEST INDICATIONS

a) Paired T Test

The paired t test is used to decide whether the differences between variables measured on the same or similarly matched individual are on average zero. As the data are matched there must be an equal number of observations in each sample.

Assumption: The paired t-test assumes that the differences in scores between pairs are approximately normally distributed, although the two sets of data under scrutiny do not need to be normally distributed.

b) Unpaired or two-sample t test (equal variance assumed)

The unpaired t test is used for comparing two independent groups of observations when no suitable pairing of the observations is possible. The samples do not need to be of equal sizes.

Assumptions: The test requires the populations to be normally distributed with equal variance, though the test is relatively robust to deviations from these assumptions. Unpaired t test or two-sample t test (unequal variance).

When the variances of the two groups differ and transformation does not produce equal variance, the calculation of the t test becomes more complex. Instead of using the pooled variance, estimates of the individual population variances are used

Formula:

$$t = \frac{M_x - M_y}{\sqrt{\frac{S_x^2}{n_x} + \frac{S_y^2}{n_y}}}$$

M =mean

n = number of scores per group

$$S^2 = \frac{\sum (x - M)^2}{n - 1}$$

x = individual scores

M = mean

n= number of scores in group

- Define the problem
- State null hypthesis(H_0) & alternate hypothesis(H_1)
- Find t value, Find (X_1 - X_2)
- Calculate SE of difference between two means

$$SE = \sigma\sqrt{1/n_1 + 1/n_2} \text{ or}$$

$$t = (X_1 - X_2) / SE$$

- Calculate degree of freedom = $n_1 + n_2 - 2$
- Fix the level of significance (0.05)
- Compare calculated value with table value at corresponding degrees of freedom and significance level
- If observed t value is greater than theoritical t value, t is significant, reject null hypothesis and accept alternate hypothesis

Statistical significance

Level of significance "p" is level of significance signifies as below:

$p > 0.05$ Not significant (ns)

$p < 0.05$ Significant (*)

ANNEXURE-VII

Ouriginal

Document Information

Analyzed document	sheru rukhaya.docx (D168777603)
Submitted	2023-01-24 07:23:00
Submitted by	Amrit Tandan
Submitter email	tandanamrit@bbdu.ac.in
Similarity	4%
Analysis address	tandanamrit.bbduni@analysis.urkund.com

Sources included in the report

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