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Evaluation of Bone Mineral Density in Type II Diabetic and Nondiabetic Individuals in a Mandibular Load-Bearing Region: A Pilot Study

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Title: Evaluation of Bone Mineral Density in Type II Diabetic and Nondiabetic Individuals in a Mandibular Load-Bearing Region: A Pilot Study

Running title: Bone Mineral Density Evaluation in Type II Diabetics Using CBCT

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Abstract

Aim

To evaluate and compare the Bone mineral density (BMD) of the mandibular first molar area in patients with type II diabetes mellitus (T2DM) compared with nondiabetic subjects by using cone-beam computed tomography (CBCT), and its possible use in pre-implant treatment planning.

Materials and Methods

A prospective cross-sectional pilot study was conducted in 32 subjects, including 16 with T2DM and 16 systemically healthy controls. CBCT scans were obtained using standardised imaging parameters. Assessment of bone density was done by measuring greyscale values (GVs) in three regions of interest within the mandibular first molar region. These include the crestal bone, 2mm apical to the crest and basal trabecular bone. The mean grey scale values for both groups were compared using appropriate statistical tests, with $p < 0.05$ considered significant. Glycaemic status will be assessed by measuring Glycated Haemoglobin (HbA1c) levels.

Results

The diabetic group demonstrated significantly lower mean BMD than the nondiabetic group across all assessed regions ($p < 0.005$). Age-wise distribution revealed a higher proportion of diabetic patients in the 55–65 years group (62.5%) than in the nondiabetic group (43.75%), indicating a significant association with advancing age ($p < 0.005$). Statistical analysis was conducted using descriptive and inferential statistics, particularly the chi-square test and Student's unpaired t-test. The tools utilised in statistical analysis were SPSS 27.0 and GraphPad Prism 7.0. Significance level ($p<0.05$).

Conclusion

Type II diabetes mellitus is associated with reduced bone density in the mandibular first molar region, as assessed by grayscale values on cone-beam computed tomography. Site-specific evaluation of bone quality before implant placement may improve treatment planning and assist in recognising patients who require modified surgical protocols.

Clinical Significance

A comprehensive implant site assessment supports predictive treatment planning, enabling customised implant protocols that improve prosthetic stability. Ongoing monitoring of glycaemic impacts aids effective risk stratification and helps develop evidence-based guidelines.

Keywords: Bone mineral density, Cone beam computed tomography, Dental implants, grayscale values, Type II diabetes mellitus

Introduction

Type II diabetes mellitus (T2DM) is among the most common chronic metabolic disorders worldwide, with its prevalence continuing to rise and becoming a major public health challenge because of ageing populations, urbanisation, and lifestyle changes. India accounts for a substantial proportion of the global diabetic population. T2DM adversely influences skeletal metabolism by impairing bone remodelling, compromising bone quality, delaying tissue healing, and increasing susceptibility to skeletal complications. As a result, diabetic patients

require special consideration during dental implant therapy, where successful osseointegration depends largely on adequate bone quality and quantity.[1-4]

Bone is a metabolically active tissue that undergoes continuous remodelling through osteoblastic bone formation and osteoclastic bone resorption. Persistent hyperglycaemia alters normal bone remodelling by promoting the accumulation of advanced glycation end products (AGEs), which alter collagen cross-linking, reduce bone elasticity, impair osteoblast differentiation, and stimulate osteocyte apoptosis. Concurrently, increased oxidative stress and chronic inflammation enhance the expression of pro-inflammatory cytokines, including tumour necrosis factor-α (TNF-α), interleukin-1β, and interleukin-6, thereby increasing osteoclastic activity and suppressing osteoblastic bone formation. Together, these changes enhance bone resorption, suppress bone formation, impair bone turnover, reduce vascularity, compromise bone microarchitecture, and delay healing after surgical procedures.[3,5-8]

In contrast to osteoporosis, which is characterised by reduced BMD, patients with T2DM often have normal or even increased systemic BMD despite impaired bone quality and greater skeletal fragility. Recent literature evidence has emphasised that changes in trabecular microarchitecture, increased cortical porosity, collagen quality, and bone turnover have a greater influence on skeletal strength than BMD alone. Therefore, assessment of regional alveolar bone characteristics has become an important step in planning implant-supported rehabilitation for patients with T2DM.[9-12]

The alveolar process is highly responsive to metabolic changes due to its continuous remodelling and functional adaptation to occlusal loading, while remaining closely associated with the periodontal tissues. Persistent hyperglycaemia reduces angiogenesis, impairs osteogenic differentiation of mesenchymal stem cells, and limits new bone formation following tooth extraction. Both experimental and clinical studies have reported reduced trabecular connectivity, cortical thickness, and bone volume within the jaws of diabetic patients, thereby creating a biologically less favourable environment for implant placement and long-term functional loading.[1,2,13-16]

These alterations are particularly relevant in implant dentistry, where successful treatment depends on both adequate bone volume and good bone quality to achieve primary stability and long-term osseointegration. Reduced mineralisation, impaired vascularity, delayed remodelling, and compromised biomechanical properties may collectively weaken alveolar bone and reduce its ability to withstand surgical procedures and functional loading. For this reason, careful assessment of bone characteristics before implant placement is an important part of treatment planning, especially in patients with T2DM.[6,15,17]

Glycaemic control plays an important role in maintaining bone health. HbA1c is an established indicator of long-term glycaemic status and is considered useful for assessing bone healing and implant success. Poor glycaemic control prolongs inflammation, delays osteogenesis, impairs collagen maturation, and increases the risk of peri-implant complications. In contrast, patients with well-controlled diabetes often achieve implant outcomes similar to those of systemically healthy individuals. These findings suggest that both bone quality and glycaemic control should be assessed before implant treatment in patients with T2DM.[18-22]

Dental implants are a well-established treatment option for replacing missing teeth, offering functional and aesthetic outcomes. Successful implant therapy depends on stable

osseointegration, which provides a direct connection between living bone and the implant surface under functional loading. Bone quality, bone quantity, implant design, surgical technique, systemic health, and healing capacity all influence osseointegration. [7,9,23,24]

Implant stability is generally categorised into two phases: primary and secondary. Primary implant stability refers to the immediate mechanical engagement between the implant surface and the surrounding bone at the time of implant placement. It is predominantly influenced by bone density, cortical bone thickness, trabecular architecture, implant geometry, and surgical preparation. Secondary stability develops during osseointegration as new bone forms around the implant. The transition from mechanical stability to biological stability is a critical period in implant healing, during which any impairment of bone remodelling may increase the risk of implant micromotion and early implant failure.[19,23,26,27]

Dense cortical bone improves insertion torque and initial fixation, whereas porous trabecular bone provides less mechanical support and is often associated with lower implant stability quotient (ISQ) values. (Table 1) Consequently, the initial anchorage of the implant can be compromised despite a sufficient amount of bone being present on the radiograph because of structural bone changes due to diabetes. The reduction in cortical bone thickness, reduced trabecular connectivity, inadequate mineralisation, and collagen properties will adversely affect the biomechanical strength of alveolar bone.[1,2,17,28-30]

In effective implant treatment, osseointegration is achieved not only through mechanical integration but also through rapid, predictable osseointegration. Hyperglycaemia impairs this biological process through several pathways. Increased glucose concentration reduces osteoblast proliferation and differentiation, decreases alkaline phosphatase activity, reduces extracellular matrix deposition, inhibits angiogenesis, and delays mineralised bone formation around the implant surface. At the same time, increased accumulation of AGEs alters collagen fibre maturation, increases RAGE-dependent inflammation, oxidative stress, and osteocyte apoptosis, thereby disrupting bone remodelling. Diabetic bone shows delayed maturation of the bone-to-implant interface and longer recovery times than non-diabetic bone.[3,7,18,22,31,32]

It has been found through recent systematic reviews and umbrella reviews that diabetic patients who are well controlled usually obtain an implant success rate similar to that of non-diabetic subjects; however, poor glycaemic control is linked with increased chances of delayed osseointegration, peri-implant inflammation, early implant failure, and marginal bone loss. HbA1c thus serves as a significant predictive biomarker in implant dentistry, as it indicates long-term glycaemic control and relates to tissue healing potential. It has been observed in various studies that patients with acceptable HbA1c levels have good osseointegration and implant success, whereas higher HbA1c levels indicate an increased inflammatory response and poor bone formation.[7,17-19,21,22,33]

Marginal bone loss around dental implants is yet another critical determinant of implant success, as it reflects the biological response of the peri-implant tissue to mechanical stress and inflammation. Elevated blood glucose levels have been linked to increased peri-implant crestal bone turnover, slower formation of biological width, poor vascularity, and increased susceptibility to peri-implantitis. However, modern scientific studies show that proper plaque control, well-managed blood glucose, and maintenance care can significantly reduce such complications; nevertheless, people with diabetes exhibit greater marginal bone loss than healthy individuals.[8,27,28,30,31]

Recent studies have also shown that the success of implants in diabetics cannot be assessed solely by the presence or absence of diabetes, but rather by the interaction among metabolism, bone quality, implant stability, and local anatomical considerations. Recent systematic reviews consistently indicate that diabetes is not an absolute contraindication to implant placement, provided adequate glycemic control is achieved. The right patient selection, management of HbA1c levels, atraumatic surgical approach, and evaluation of implant-site bone characteristics can significantly improve outcomes.[7,8,19,21,22]

These observations highlight the importance of accurate assessment of bone quality before implant surgery, as it is a key indicator of an implant's long-term stability and predictability. As both cortical and trabecular bone types play distinct roles in the biomechanical function of dental implants, regional evaluation of bone density in the mandibular posterior region is particularly significant. Preoperative imaging that accurately assesses bone quality in a specific area may prove helpful in such cases.

Methods

Study Design

The present study was a prospective, cross-sectional, analytical pilot study using CBCT to compare mandibular alveolar bone mineral density in subjects with T2DM with that of systemically healthy subjects. This study was conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

A pilot study design was selected because there is limited published research on standardised quantitative bone density analysis using CBCT in diabetic subjects. The main goals of this pilot study included determining the feasibility of the protocol, assessing the reproducibility of standardised ROIs, estimating differences in bone density between groups, and generating initial data for further studies. This study was hypothesis-based and designed to establish the validity of the methodology before conducting the main study.

Study Setting

The study was carried out in the Department of Oral Medicine and Radiology, Sharad Pawar Dental College and Hospital, Datta Meghe Institute of Higher Education and Research (Deemed to be University), Sawangi (Meghe), Wardha, Maharashtra, India. The institution serves as a tertiary referral dental teaching hospital that treats patients coming from both urban and rural populations of Central India.

All clinical examinations, laboratory investigations, CBCT image acquisition, image processing, and radiographic evaluation were performed at the same Institute using consistent methods to minimise operator bias in the study.

Study Duration

Recruitment of participants, clinical assessment, laboratory investigations, CBCT scans, radiographic analysis, and statistical analysis were conducted over 1 year, from April 2025 to April 2026.

Participants were recruited in sequence throughout the research until the desired number was reached.

Ethical Approval

The protocol of this research was approved by the Institutional Ethics Committee of Datta Meghe Institute of Higher Education and Research, Sawangi (Meghe), Wardha (IEC No. DMIHER(DU)/IEC/2025/695). Prospective registration of the trial was made with the Clinical Trials Registry-India (CTRI No. CTRI/2025/05/087725). This study was carried out in accordance with the Declaration of Helsinki (2013 version) and Good Clinical Practice guidelines.

Each subject was provided with both verbal and written information about the purpose of the study, the imaging techniques used, radiation exposure, possible benefits, and the voluntary nature of participation before recruitment. Written informed consent was obtained from each patient before any procedure was performed. It was made clear to all subjects that non-participation would not affect their treatment and that they had the opportunity to withdraw from the study at any time. Participants' confidentiality was ensured using unique numbers, and all personally identifiable information was removed before statistical analysis.

Sample Size Calculation

As this investigation is a pilot study, the sample size was calculated based on data from previous research on CBCT assessment of mandibular bone density among diabetic subjects. Sample size determination was done based on the following formula for comparing two independent means:

[

n=\frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2(\sigma_1^2+\sigma_2^2)}{(\mu_1-\mu_2)^2}

]

where

- $\alpha = 0.05$
- statistical power = 80%
- $Z\alpha/2 = 1.96$
- $Z\beta = 0.84$

Expected means and standard deviations of the bone densities were calculated based on the previously conducted CBCT studies of diabetic and non-diabetic patients. Based on the aforementioned assumptions, the minimum required number of participants was set to 32 per group. However, due to the exploratory purpose of the current pilot study, recruitment feasibility, and limited resources, along with the need to calculate effect sizes rather than generate definitive clinical results, 16 subjects per group (a total of 32 subjects) were recruited.

The number of participants is deemed adequate for a pilot observational study aimed at feasibility assessment, image protocol optimisation, variance estimation, and calculation of the future sample size for the multicentre trial. (Figure 4)

Participant Recruitment

Participants were consecutively recruited from patients who visited the outpatient clinic of the Department of Oral Medicine and Radiology for CBCT scanning of the mandibular first molar region.

The details of recruitment were documented in the screening log as follows:

I. Patients screened for eligibility

Ii. Excluded patients

Iii. Reasons for exclusion

Iv. Consenting participants

V. Consenting participants who completed the study

Participants were first subjected to medical history and oral examination. Patients known to have T2DM diagnosed by their doctor for more than two years were deemed eligible for the diabetic group after confirmation of glycaemia by HbA1c. Participants who were systemically healthy, non-diabetic, and visiting for implant-site assessment were included as controls. Eligible patients were recruited consecutively until the sample size was reached, minimising selection bias. No patient withdrew after CBCT scanning, and complete data sets were available for statistical analysis.

Eligibility Criteria

Inclusion Criteria

All participants meeting the following inclusion criteria were included:

Study Group

1. Age between 35 and 60 years old.
2. Physically diagnosed Type 2 Diabetes Mellitus of more than 2 years' duration.
3. Absence of HbA1c determination within the protocol of the study.
4. Presence of edentulism at the mandibular first molar area for implant evaluation.
5. Ability to perform a CBCT scan.
6. Informed consent.

Control Group

1. Age between 35 and 60 years old.
2. Systemically healthy patients without any history of diabetes mellitus.
3. Systemically free from any illness affecting bone metabolism.
4. Appropriate candidate for the implant site evaluation at the mandibular first molar area.
5. Informed consent.

Exclusion Criteria

Patients were excluded if they were:

a. Suffering from Type 1 Diabetes Mellitus.

b. Suffering from gestational diabetes.

c. Medical history of suffering from osteoporosis, osteomalacia, Paget'sPaget's disease, hyperparathyroidism or any metabolic bone disease.

d. Diagnosed with chronic kidney disease or endocrine diseases that affect bone metabolism.

e. Undergoing treatment with bisphosphonates.

f. Taking long-term steroids.

g. Receiving any hormonal treatment that changes bone metabolism.

h. Previous experience with radiotherapy in the head and neck regions.

i. Having a history of previous chemotherapy.

j. Smokers and users of tobacco products.

k. Having an alcohol addiction.

l. Being pregnant or lactating.

m. Any active disease in the periodontium in the region where implants are placed.

n. Any history of implantation in the region of interest.

o. Any local diseases in the mandibular first molar region?

p. Any history of bone grafting.

q. Motion artefacts make images unusable for ROI analysis.

r. CBCT images are not suitable for ROI analysis.

Participant Flow

All patients who visited the department during the recruitment period were screened for inclusion. Patients who met the previously determined inclusion criteria underwent thorough clinical examinations, followed by laboratory tests to assess their glycaemic status. Participants who met the inclusion criteria underwent standardised CBCT scans of the mandibular first molar region. CBCT images were checked for image quality, followed by quantification. CBCT images with artefacts due to motion, metallic streaks, and poor visualisation of the area of interest were not quantified.

Clinical Examination

All subjects received comprehensive clinical evaluations done by a calibrated Oral Medicine and Radiology specialist under standardised clinical conditions post-enrolment. A structured case record form was used to gather demographic, medical, and dental data.

The following parameters were obtained from each subject:

1. Age
2. Sex
3. Medical History
4. Duration of T2DM (study subjects)
5. Antidiabetic drug usage
6. Systemic diseases that influence bone metabolism
7. Past treatment with implants
8. Tobacco and alcohol use
9. History of radiotherapy/chemotherapy to the head and neck regions

An intraoral examination was done afterwards to assess the proposed implant site, and it involved:

I. Mandibular edentulous first molar region
II. Ridge width and ridge form
III. Soft tissue condition
IV. Periodontal diseases
V. Local inflammatory conditions
VI. Residual root remnants
VII. Apical diseases
VIII. Past surgeries
IX. Any signs of infection

The implant site was clinically examined to determine the absence of local pathologies that might affect alveolar bone quality. Patients exhibiting active periodontitis, odontogenic infection, cysts, tumours, or excessive bone destruction in the proposed implant site were excluded from participation. Variations between examiners were controlled by using a single examiner who conducted all examinations with identical instruments under identical lighting conditions.

Glycaemic Assessment

Glycaemia of all participants was assessed before CBCT investigation. In the case of people belonging to the diabetic group, the diagnosis of T2DM had already been made based on ADA criteria by a doctor. This diagnosis was also confirmed with the help of medical history and existing antidiabetics. Venous blood samples were collected aseptically to measure HbA1c levels, which indicate the mean blood glucose level over the last 8-12 weeks. The HbA1c test was conducted at the institutional NABL-accredited laboratory by high-performance liquid chromatography (HPLC). The following information was documented:

a. HbA1c concentration (%)

b. Years since onset of diabetes

c. Class of antidiabeticantidiabeticantidiabeticantidiabeticantidiabetic drugs

d. Method of treatment (oral hypoglycaemic drugs/insulin therapy)

These HbA1c concentrations were correlated with CBCT-derived bone density measurements to assess the effects of glycaemic control on bone quality. For the control group, patients had no prior diagnosis of diabetes mellitus and had normal HbA1c concentrations.

CBCT Image Acquisition Protocol

Following the clinical examination, a CBCT scan of the patient was performed using a Planmeca ProMax® 3D Mid Cone Beam Computed Tomography System (Planmeca Oy, Helsinki, Finland) available in the Department of Oral Medicine and Radiology.

All CBCT images were obtained from a trained radiographic technologist under the direct supervision of an Oral and Maxillofacial Radiologist using identical acquisition parameters throughout the experiment.

The acquisition parameters were as follows:

- Tube voltage 90 kVp
- Tube current 6.3 mA
- Exposure time ~12 seconds
- Field of View (FOV) 5 × 5 cm
- Voxel size 200 µm
- Reconstruction slice thickness 0.2 mm
- Image matrix according to the manufacturer's specification

The field of view was chosen to include the mandibular first molar to minimise unnecessary irradiation while still providing adequate visualisation of the implant location.CBCT images were reconstructed using Planmeca Romexis® software (Version 3.9.6.152) according to the same reconstruction parameters. No post-processing filters that could alter the grey value distribution were applied before image analysis. (Figure 2)

Radiation Safety and ALARA Principle

A radiograph would be ordered only when clinically indicated in preparation for dental implants. Radiography followed the ALARA (As Low As Reasonably Achievable) principle, keeping radiation exposure at the lowest level required for diagnosis.

Radiation minimisation was achieved by:

- Use of a restricted 5 × 5 cm field size
- Consistent exposure settings
- Use of a single-shot procedure
- Prevention of multiple scans

- Appropriate patient positioning to avoid any movement

Lead apron and thyroid shield were employed without hindering image acquisition. All procedures followed institutional guidelines on radiation protection.

Standardisation of Patient Positioning

Patient positioning was thoroughly standardised before all scans to allow for reproducibility of bone density measurements. Participant positioning was done in a standing upright position with relaxed shoulders and a straight spine.

Standardisation of the following anatomical planes was done:

- Frankfort Horizontal Plane horizontal to the floor plane
- Midsagittal Plane perpendicular to the floor
- Transverse line horizontal to the floor

A disposable bite block was utilised to immobilise the maxillary and mandibular dental arches. Head immobilisation was performed using the manufacturer's craniostat, which utilised bilateral temporal and chin supports.

Participants were instructed to:

- Maintain maximum intercuspation on the bite block.
- Tongue to be lightly pressed against the palate.
- Avoid swallowing.
- Eyes to remain closed.
- Completely motionless throughout the image acquisition process.

A scout image was obtained first to assess patient positioning. Any corrections were made before volumetric acquisition. Only images that were correctly positioned and free from motion artefacts were considered.

Image Reconstruction and Processing

Image acquisition was followed by reconstruction of the volume dataset using Planmeca Romexis® software.

Multiplanar reconstruction images were made in the following planes:

I. Axial plane

II. Coronal plane

III. Sagittal plane

IV. Cross-sectional images

Cross-sectional images, which were perpendicular to the alveolar ridge, were obtained at the mandibular first molar region. Image brightness, contrast, and magnification were normalised

for all datasets before ROI measurement. All measurements were conducted with the same monitor resolution and lighting conditions.

Region of Interest (ROI) Selection

A standardised ROI methodology was used to ensure reproducibility of bone density analysis results. The edentulous mandibular first molar area was chosen as the region of interest since this is one of the most common load-bearing implant sites and is subjected to maximum occlusal forces. Cross-sectional slices that included the centre of the intended implant site were identified for each individual.

Three anatomically standardised ROIs were selected:

ROI 1 – Crestal Bone

The first ROI was placed directly below the alveolar crest, while the cortical crest was excluded from the analysis to ensure that artificially increased density was not obtained. The first ROI was the cancellous bone, providing the primary stability to the implant during osseointegration.

ROI 2 – Subcrestal Bone

The second ROI was taken precisely 2mm below the alveolar crest. The 2-mm level was selected since it is the level at which the coronal implant threads are engaged.

ROI 3 – Trabecular (Basal) Bone

ROI number three was located in the middle part of the central trabecular bone of the mandibular body.

It was important to eliminate:

- The inferior border of the cortex
- The buccal cortical plate
- The lingual cortical plate
- The mandibular canal
- The nutrient canals
- Residual extraction sockets

The ROI was mature cancellous bone that supported dental implants.

ROI Standardisation

For uniformity in measuring, the same ROI dimensions were kept for all subjects. The ROI was situated in the central portion of the cancellous bone, not on cortical plates or anatomical areas that could affect the density measurements. Identical slices were used to select each ROI, and anatomical landmarks were applied uniformly. Wherever bilateral edentulous mandibular first molars were available, both sides were measured, and the average measure was taken into consideration. In cases where only one side satisfied the inclusion criteria, that side alone was considered.

Bone Density Measurement Protocol

The quantitative evaluation of bone density was conducted using measurement tools built into the Planmeca Romexis® software. Since CBCT cannot produce real Hounsfield Units similar to those produced with the use of traditional multislice computed tomography, the measurement of bone density in the current study should be regarded as the result of CBCT measurements in terms of grey values (GVs) produced by the proprietary software. Thus, the results obtained should be treated as relative BMD values rather than Hounsfield Units. This should be taken into account, since the grey values of CBCT depend on the scanner properties, exposure, reconstruction, scatter radiation, and field of view. However, when image acquisition and ROI selection are standardised, CBCT-based grey values enable reliable local comparison of BMD within the same imaging system. Quantitative bone density was measured for each participant at three anatomical levels (crestal, subcrestal, and trabecular). The ROI was measured three times, and the arithmetic mean of these measurements was calculated for further statistical analysis.

Examiner Calibration and Image Analysis

To reduce observer bias and improve the reproducibility of CBCT image evaluation, all radiographic analyses were independently performed by two Oral and Maxillofacial Radiologists (Radiologist A and Radiologist B) with more than 5 years of experience in CBCT image evaluation and implant site assessment. Before conducting the study, the two radiologists participated in a calibration exercise that involved standardization of image orientation, multiplanar reconstruction, cross-sectional slice selection, region-of-interest (ROI) selection, identification of anatomical landmarks, and analysis of CBCT grayscale values. This was done using 10 CBCT images that were not part of the study. During calibration, both radiologists independently evaluated the crestal, subcrestal (2mm apical to the alveolar crest), and trabecular bone. (Figure)The ROI size, anatomical landmarks, image orientation, and image magnification were standardized during measurement. After two weeks, the same calibration images were independently evaluated again under the same viewing conditions but without reference to the previous measurements.

Reliability Assessment

The reliability of CBCT image interpretation was assessed by evaluating both interobserver and intraobserver agreement.

Interobserver Reliability

The datasets from all CBCT scans were independently analyzed by Radiologist A and Radiologist B, and both radiologists were blinded to each other's findings and to the subjects' clinical data. (Figure 3) Cohen's kappa coefficient (κ) was utilised to determine the agreement of both radiologists on the localisation of the ROI and the identification of the anatomic landmarks.

Interpretation of the kappa coefficient was based on the scale presented by Landis and Koch:

- $\kappa < 0.20$ - poor agreement
- $\kappa = 0.21\text{-}0.40$ – fair agreement
- $\kappa = 0.41\text{-}0.60$ – moderate agreement
- $\kappa = 0.61\text{-}0.80$ – substantial agreement

- $\kappa = 0.81\text{-}1.00$ – almost perfect agreement

When the Cohen's kappa coefficient exceeded 0.80, excellent agreement was assumed between the two observers. Once the agreement was confirmed, the average measurement from the two radiologists was used in subsequent statistical analysis.

Intraobserver Reliability

Reproducibility was tested on 20% of the CBCT datasets, which were randomised to the whole set by a computer-generated randomisation list and independently analysed by radiologists after a two-week gap. During a two-week analysis, both radiologists were blinded to the results obtained during the first assessment.

Reproducibility of continuous CBCT-based grayscale measurements was assessed using the Intraclass Correlation Coefficient (ICC) calculated with a two-way random-effects model for absolute agreement.

ICC values were categorized as follows:

- ICC < 0.50 - Poor reliability
- ICC = 0.50–0.74 – Moderate reliability
- ICC = 0.75–0.89 – Good reliability
- ICC ≥ 0.90 – Excellent reliability

High ICC values demonstrated excellent repeatability and reproducibility of quantitative bone density assessments.

Image Interpretation and Blinding

All datasets were anonymized before image analysis, during which a unique study number was assigned to each patient. All patient details, such as names, hospital numbers, diabetes status, HbA1c levels, duration of diabetes, and other clinical details, were removed to allow unbiased image analysis. The images were then analysed in a specialised reporting room under standardised viewing conditions, on the same high-resolution diagnostic monitor, with the same brightness, contrast, and magnification. The two radiologists (Radiologist A & Radiologist B) independently analyzed the CBCT dataset on Planmeca Romexis® software (Version 3.9.6.152). This was done through axial, coronal, sagittal, and cross-sectional image analysis before deciding on the right cross-sectional image through the centre of the mandibular first molar implant site.

The CBCT-generated grey-scale Hounsfield Unit equivalent values of each of the participants were noted at the following three anatomical levels:

- Crestal cancellous bone
- Subcrestal cancellous bone (2mm below the alveolar crest)
- Trabecular (basal) cancellous bone

All measurements were repeated 3 times by each radiologist, and the arithmetic means were calculated. After confirming the interobserver agreement, the mean of the two radiologists' values was taken as the final value.

Outcome Measures

Primary Outcome

The primary outcome was the evaluation of mean grayscale values obtained using CBCT in patients with T2DM and systemically healthy subjects at the mandibular first molar crestal, subcrestal, and trabecular sites.

Secondary Outcomes

Secondary outcome measures consisted of:

1. Bone density comparison at the three different anatomical sites for each study group.
2. HbA1c level versus CBCT-based grayscale values correlation.
3. Duration of T2DM versus mandibular bone density correlation.
4. Age and gender differences between diabetic and nondiabetic subjects.
5. Interobserver agreement calculation by means of Cohen's kappa.
6. Measurement reproducibility assessment using Intraclass Correlation Coefficient (ICC).

Data Recording and Quality Assurance

Findings from clinical examinations, laboratory investigations and radiographic measurements were prospectively documented on designed case record forms. The data generated were then entered into a password-protected electronic database. To avoid data entry errors, data were entered twice independently by two researchers. After data entry, datasets were compared for correctness. Any discrepancies were rectified using the original records and CBCT datasets.

Data quality control measures included:

- Checking the eligibility of participants before enrolment.
- Use of uniform imaging protocols in all participants.
- Daily calibration of CBCT according to guidelines issued by manufacturers.
- Standardization of patient positions.
- Uniform choice of ROI.
- Blinded interpretation of images.
- Measurement of reliability through repeat measurements.
- Verification of statistical data independently before analysis.

Only datasets that fulfilled all eligibility criteria were included in the final statistical analysis.

Statistical Analysis

All statistical analyses were performed using SPSS version 27.0 (SPSS Inc., IBM Corp., Armonk, NY, USA). All graphical presentations were done using GraphPad Prism version 7.0 (GraphPad Software Inc, San Diego, CA, USA). Continuous data were reported as mean ± SD, while categorical data were expressed in frequency and percentages. The Shapiro-Wilk test was used to check the normality of continuous data. The distribution of age and sex between the diabetic and nondiabetic groups was compared using the Chi-square test.

Intergroup comparison of CBCT-derived grayscale value at the crestal, subcrestal, and trabecular regions was done using Student's independent (unpaired) t-test. Intergroup comparisons within the same group across the three anatomical levels were performed using a paired Student's t-test.

Correlation of HbA1C level, duration of diabetes and CBCT-derived grayscale value was done using Pearson's correlation coefficient. Cohen's kappa coefficient (κ) was used to test interobserver agreement for ROI localization and anatomical landmark detection between Radiologist A and Radiologist B. The ICC, using a two-way mixed-effects model and absolute agreement, was applied to test intraobserver agreement for continuous grayscale value measurements. A two-tailed p-value less than 0.05 was considered to be statistically significant for all analyses.

Pilot Study Justification

The present study was conducted as a pilot to assess the feasibility of a protocol that utilizes quantitative analysis of alveolar bone density via CBCT in patients with Type II Diabetes Mellitus. The purpose of this study was to quantify variations in CBCT grey-scale measurements, obtain initial estimates of the effects, and assess the reproducibility of this protocol before conducting a larger study involving many participants across several locations. Conducting a pilot study when introducing a new imaging technique is very useful, as it helps improve recruitment, scanning, ROI standardization, examiner training, and statistical planning.

Reporting Guideline

The methodology, performance, statistics, and reporting of the current observational study were conducted in accordance with the STROBE guidelines. The intention in doing this was to improve the quality of the report by adhering to the guidelines.

Methodological Strengths

Methodological steps have been taken to enhance internal validity in the current study, including prospective participant recruitment, appropriate participant selection criteria, standardised CBCT scanning parameters, rigorous ROI standardisation, blind image analysis, examiner calibration, measurement of intraobserver reliability, and strict quality assurance procedures. In addition, the ALARA approach was employed for optimal radiation exposure.

Results

This study included 32 participants: 16 with type 2 diabetes mellitus (diabetic group) and 16 healthy participants (non-diabetic group).

The dominant age group among participants in both groups was 55–65 years, accounting for 62.5% of the diabetic group and 43.75% of the non-diabetic group. The 45–54-year age group

accounted for 31.25% of participants in both groups, while the 35–44-year age group comprised 6.25% of the diabetic group and 25% of the non-diabetic group.

The average age of the participants was 54.87 ± 6.93 years (40 - 65 years range) in the diabetic group and 52.31 ± 8.52 years (39 - 65 years range) in the non-diabetic group. There was no significant difference in the age distribution among the two groups ($\chi^2 = 2.32$, $p = 0.31$).

Inference: The diabetic and non-diabetic groups were similar in age distribution, suggesting that age would not be a confounder in the bone mineral density comparison (Table 2, Graph 1).

The proportion of male diabetic patients was 68.75%, and that of females was 31.25%, while the proportion of males among non-diabetic patients was 43.75%, and that of females was 56.25%. Even though there were more males among people with diabetes and more females among non-diabetics, the difference between them was not statistically significant ($\chi^2 = 2.03$, $p = 0.15$).

Conclusion: In terms of gender, the two groups of participants were similar, indicating that gender did not affect the study's results (Table 3, Graph 2).

There is a statistically significant decrease in bone mineral density (BMD) in the diabetic group compared to the non-diabetic group in all analysed areas. Trabecular bone mineral density was significantly lower in diabetic patients (1000.37 ± 98.69) than in non-diabetic patients (1121.09 ± 154.94) ($t = 2.62$, $p = 0.013$). Also, there is a statistically significant decrease in crestal bone mineral density in the diabetic patients (590.96 ± 57.07) compared to non-diabetic patients (807.84 ± 126.56) ($t = 8.24$, $p = 0.0001$). Likewise, there is a statistically significant decrease in bone mineral density 2mm below the crestal level in diabetic subjects (720.12 ± 78.96) compared to healthy subjects (951.68 ± 95.35) ($t = 7.81$, $p = 0.0001$).

Inference: Patients with type 2 diabetes mellitus showed statistically significantly decreased bone mineral density in the trabecular, crestal and subcrestal regions of the mandibular first molar compared to non-diabetic subjects, indicating poor bone quality in diabetic patients (Table 4, Graph 3)

For the diabetic group, there was a statistically significant difference in all three sites tested. Trabecular BMD had significantly higher BMD values than crestal BMD ($t = 18.32$, $p = 0.0001$) and BMD of 2 mm below the crest ($t = 9.37$, $p = 0.0001$). Similarly, crestal BMD was found to have a significant difference from BMD of 2 mm below the crest ($t = 5.54$, $p = 0.0001$).

Inference: BMD in the diabetic group was not consistently high across the region studied; rather, the alveolar crest showed lower BMD, making it more prone to diabetes-related bone changes (Table 5, Graph 4).

In the diabetic group, statistically significant differences were observed among trabecular, crestal, and subcrestal BMDs in normal patients. Trabecular BMD was found to be significantly higher compared to crestal BMD ($t = 14.18$, $p = 0.0001$) and BMD 2mm subcrestal ($t = 5.60$, $p = 0.0001$). Similarly, there was a statistically significant difference between crestal BMD and BMD 2mm subcrestal ($t = 7.23$, $p = 0.0001$).

Inference: Normal patients also showed variations in bone mineral density across specific sites, with the highest at the trabecular site and the lowest at the crestal site. Absolute BMD values were higher than those observed in people with diabetes (Table 6, Graph 5).

To measure the consistency of BMD measurements, intra-observer agreement was tested using Cohen's Kappa. For all trabecular, crestal, and subcrestal BMD measurements (minimal, maximal, and average), the degree of agreement was 96.9%, with 1 disagreement out of 32 tests. The values of Cohen's Kappa were always 0.953, indicating nearly perfect agreement.

Inference: Bone mineral density measurements showed high repeatability with no significant variability between observers.

The analysis using the intraclass correlation coefficient (ICC) indicated good reliability across all bone mineral density measurements. The ICC values ranged from 0.943 to 0.956, with very narrow 95% confidence intervals, for trabecular, crestal, and subcrestal bone mineral density measurements.

Inference: High ICC values indicate high reproducibility and accuracy of CBCT-derived bone mineral density measurements, consistent with the validity of the methodology used in the current study.

As has been stated earlier, the current study showed that patients with type 2 diabetes mellitus had significantly lower CBCT-derived bone mineral density in the trabecular, crestal, and subcrestal areas of the mandibular first molar than age- and gender-matched controls. Although both patient groups exhibited normal anatomical variation in bone mineral density across alveolar bone regions, patients with type 2 diabetes mellitus had lower bone mineral density at all sites of interest. In addition, high intra-observer agreement (Cohen's Kappa = 0.953) and excellent measurement reliability (ICC = 0.943-0.956) demonstrated that the CBCT measurement protocol was highly reliable.

Discussion

The present study was conducted to analyze the bone mineral density (BMD) at the mandibular first molar implant site in patients with T2DM, compared with that in control subjects without T2DM, using CBCT measurements. In view of the rising prevalence of T2DM worldwide and the increasing number of people seeking dental implants, there is an urgent need for an accurate method to assess alveolar bone quality before implant surgery. There is widespread recognition that diabetes mellitus is a systemic metabolic disease that adversely affects bone metabolism through diminished osteoblast activity, excessive osteoclasts, inflammation, AGE deposition, and microvascular damage, all of which may affect osseointegration. While various studies have investigated implant survival rates among patients with T2DM, relatively few studies have quantitatively assessed mandibular bone mineral density at implant sites using CBCT measurements. The current study thus aims to fill this void.[1–8]

The mandibular first molar was chosen because it commonly requires implant-supported prosthetic restorations and can bear high occlusal loads. The appropriate quantity and quality of bone at this location play key roles in ensuring primary stability, osseointegration, and the implant's function. Misch pointed out that bone density is one of the main factors that affect prognosis and implant loading.[34] In addition, systematic reviews have shown consistently that low bone quality is related to poor osseointegration, marginal bone loss, and high risk of implant failure, especially in people with various medical conditions, including diabetes mellitus.[7,8,17–22]

The CBCT modality was chosen for its ability to provide three-dimensional evaluation of the alveolar bone structure with high spatial resolution and considerably lower radiation exposure than conventional multislice computed tomography. While radiographs are limited to two-dimensional images, CBCT enables high-precision localization of anatomical structures and evaluation of trabecular pattern, cortical bone thickness, and regional grey values that correlate with bone mineral density. According to the latest systematic reviews, CBCT can be successfully used as a complementary method for evaluating bone quality when a standardized acquisition protocol is used.[9],[10] Moreover, Park et al. have demonstrated that quantitative CBCT, in combination with deep-learning algorithms, correlates perfectly with traditional assessment of bone mineral density and shows high reliability.[11] Additionally, Poiană et al. found that CBCT-based mandibular indices are reliable in distinguishing patients with decreased bone mass.[12] This information made the CBCT choice justifiable for the current study.

Another significant reason for selecting CBCT was the ability to evaluate multiple anatomical regions using standardized regions of interest in a single examination. In contrast to dual-energy x-ray absorptiometry (DEXA), which assesses systemic bone mineral density, CBCT can provide local measurements at the specific location of the alveolar bone where the implants are being inserted. As Francisco et al. stated in their systematic review and meta-analysis, while DEXA remains the reference standard for the diagnosis of osteoporosis, CBCT gives additional clinically significant information regarding local bone mineral density.[9] Thus, the current research used grey value measurement based on CBCT as a measure of regional bone mineral density at mandibular first molar sites.

However, there were no statistically significant differences in age and gender distributions between the two groups. The majority of individuals were in the 55-65-year age range, characteristic of T2DM, which mainly affects middle-aged and elderly individuals. In the absence of significant differences in the demographic profile, the differences in the bone mineral density may not be attributed to age and gender. Such demographic matching will help maintain the internal validity of the research since only diabetes mellitus would influence the bone density. Similar age distribution has been noted in CBCT studies by Kammari et al., Dahihandekar et al., and Patil et al., in which age matching was performed in both the diabetic and control groups.[1],[2],[6]

Whereas males comprised a higher percentage of the group having diabetes compared to females, who formed the majority in the nondiabetic group, there was no statistically significant difference. It has been noted in various studies that there are contradictions in the results regarding the relationship between gender and mandibular bone density in people with diabetes. According to Asokan et al., there was no significant relationship between gender and mandibular bone density after adjusting for diabetes.[5] Similarly, Li et al., in their latest meta-analysis conducted in several observational studies, found that diabetes-induced skeletal changes happen regardless of gender. However, post-menopausal females might have an additional risk due to the deficiency of oestrogen.[4] Therefore, the similar demographic attributes found in the current study make it unlikely that either age or gender had any substantial effect on the differences in bone mineral density.

In conclusion, the most important result of this research is the statistically significant decrease in trabecular bone mineral density in patients with type 2 diabetes mellitus compared with the

control group. Patients with diabetes had considerably lower trabecular BMD, reflecting poor cancellous bone tissue in the first mandibular molar area. This result is consistent with those reported by Kammari et al., who showed that mandibular trabecular density in males with diabetes mellitus was significantly lower on CBCT.[1] Moreover, Dahihandekar et al. found that diabetic patients had significantly lower values of CBCT-derived bone mineral density in comparison with nondiabetic patients, which proves that diabetes negatively influences the quality of alveolar bone for implants.[2] Such decreases in mandibular bone density were also reported by Patil et al., Asokan et al., Kenawy et al., Zhang et al., and Nemtoi et al.[5,6,13–16]

The decreased density of trabecular bones in diabetic patients is attributed to various biological processes. Chronic high blood glucose levels induce the formation of advanced glycation end products that interfere with collagen matrix cross-linking, resulting in increased bone brittleness. Additionally, diabetes reduces osteoblast differentiation and bone formation, induces oxidative stress, and increases the production of inflammatory cytokines, thereby promoting bone resorption via osteoclasts. Insulin is identified by Ravindran et al. as an anabolic hormone responsible for osteoblast growth and bone remodelling. As such, defective insulin signalling leads to reduced bone formation and poorer bone quality.[3] In addition, Li et al. established that diabetes influences bone microarchitecture regardless of varying levels of bone mineral density in the body, hence implying that bone quality is more relevant than bone mass.[4] This biological phenomenon explains the significantly lower trabecular bone mineral density in the current study.

Other key results from the present study included significantly lower bone mineral density in the crestal area of patients with type 2 diabetes mellitus compared with control subjects without diabetes. The crestal region exhibited the lowest BMD values among the analyzed regions, indicating that this part of the alveolar bone is the most vulnerable to metabolic changes associated with diabetes. From a clinical point of view, the crestal bone region is crucial since it plays an important role in the stability of the dental implant during the initial phase after its installation.[26,34]

The current study findings are in concordance with those of Kammari et al., who reported a significantly decreased crestal bone density in diabetic patients on CBCT before implant treatment and stated that diabetes mellitus adversely influences both the quantity and quality of the mandibular bone for implantation.[1] The same was observed in the study conducted by Dahihandekar et al., who observed significantly decreased density of CBCT-obtained crestal bone in patients with type 2 diabetes mellitus, which indicated that hyperglycaemia influences the structure of alveolar bone even in well-controlled patients.[2] The same has been observed in the study conducted by Patil et al., who observed decreased density of maxillary and mandibular bones in controlled diabetic patients.[6] Similar results have been reported by previous CBCT studies performed by Kenawy et al., Nemtoi et al., Jolly et al., and Zhang et al., who all noted that the bone density was lower in patients with diabetes than in their healthy counterparts.[13–16] Although these studies were different in terms of patient populations and imaging methods, they all consistently indicated that there is a deterioration in the quality of alveolar bone due to diabetes mellitus. This similarity between previous studies and the current one further confirms the effect of diabetes on mandibular bone mineral density.

The significantly reduced crestal BMD in the current study could be attributed to poor bone remodelling at the cortical and crestal alveolar bone levels. Chronic hyperglycemia leads to

microangiopathy, which reduces local blood flow, inhibits osteoblast differentiation, and prolongs inflammation, thereby impairing bone formation.[3] In addition, AGE deposition leads to stiffening of collagen and poor biomechanics of the bone, thus making the crestal bone more susceptible to mechanical loading and resorption.[3],[4] Therefore, even though the bone volume may appear normal in diabetic patients, the quality of the bone is likely to be affected.

It is worth noting that the current study further demonstrated significantly lower subcrestal bone mineral density at a distance of 2 mm from the alveolar crest in diabetic individuals than in healthy subjects. It is a significant result for clinical practice, as the subcrestal trabecular zone plays a key role in implant stabilization at a specific point following the healing period. While cortical bone provides immediate mechanical support upon implantation, long-term implant fixation largely depends on remodelling of the trabecular bone surrounding the implant.[26],[34] Therefore, diminished subcrestal bone density may adversely influence secondary implant stability and long-term implant survival.

Subcrestal low bone density noted in this research is in concordance with Patil et al.'s findings, in which there was significantly low bone density in both cortical and trabecular bone structures in the jaw bones of patients with controlled diabetes.[6] Asokan et al. also found low bone mineral density in the mandible among individuals with type 2 diabetes mellitus due to changes in metabolism caused by hyperglycemia.[5] These studies suggest that diabetes not only affects the crestal cortical bone plate, but also the cancellous bone structure that supports the implants.

Recent systematic reviews also provide additional evidence for these statements. According to Li et al., who conducted a meta-analysis of the correlation between type 2 diabetes mellitus and bone mineral density, diabetes qualitatively affects bone microstructure and the skeleton, despite the conflicting effect on systemic BMD as measured by DEXA.[4] It means that bone deterioration is more clinically meaningful than mineral bone density per se. In addition, according to Francisco et al., CBCT-based bone density analysis correlates well with traditional bone density analysis and provides valuable site-specific data for implant placement.[9] The same point was made by Poiană et al., who claimed that CBCT is a useful imaging method that helps to identify patients with decreased local bone mass.[10],[12]

One major observation from this study was the significant reduction in BMD across all three bone regions (trabecular, crestal, and subcrestal) in the presence of diabetes. The results suggest that diabetes leads to changes in bone structure throughout the entire alveolar bone, not just in one region. This is possible as the mechanism by which hyperglycaemia affects bone health involves many mechanisms, such as bone turnover, angiogenesis, collagen maturation, and inflammatory processes.[3],[4]

Intragroup analyses in the current study revealed statistically significant differences among trabecular, crestal, and subcrestal bone densities in both the diabetic and nondiabetic groups. Trabecular bone mineral density was seen to have the highest density in both groups, while the crestal bone showed the lowest density levels. The above observations suggest that regional differences in the density of the alveolar bone are an important physiological feature of the posterior mandible. Nonetheless, despite these physiological differences, the values were lower in the diabetic group across all levels.

These findings are backed up by research in implant dentistry. In a systematic review, Di Stefano et al. reported that cortical thickness and regional bone density were significant factors

in implant stability and success.[26] Misch also categorized bone quality based on regional density and found that dense cortical bone gives better primary stability compared to less dense trabecular bone.[34] The current study confirms these principles but shows that diabetes makes the regional bone density less dense.

The excellent intra-observer agreement observed in the current study enhances the validity of the results, with excellent reproducibility of the CBCT measurements, as indicated by kappa statistics close to 1.0 and ICCs greater than 0.94. A reliable measurement technique is crucial when assessing bone density differences, as interobserver variability can affect the study's results. The excellent reproducibility observed in the current study is similar to results reported in other validation studies by Park et al., which demonstrate high accuracy of quantitative CBCT measurements using image analysis.[11] Moreover, systematic reviews by Francisco et al. and Poiană et al. showed that CBCT measurement protocols are reproducible for assessing alveolar bone quality.[9],[10]

Decreased mandibular bone mineral density in diabetic patients will affect implant osseointegration. Osseointegration depends on rapid bone remodelling, blood vessel formation, and contact between the bone and the implant during the initial phase of healing. Diabetes affects all of these physiological mechanisms through its effects on osteoblastic activity, collagen production, vascularisation, and inflammation.[3] As a result, decreased bone mineral density may lead to delayed healing, instability of the implant, and bone loss during loading.

The decreased bone mineral density observed in the current study is highly significant for implant osseointegration and the long-term success of dental implants in individuals with T2DM. Initial implant stability depends on the amount and quality of bone at the recipient site, whereas secondary stability requires successful bone remodelling and osseointegration. The process of osseointegration is negatively impacted by diabetes through high levels of glucose in the body, oxidative stress, constant inflammation, poor angiogenesis, delayed osteoblastic differentiation, and excessive osteoclastic activity.[3,7,8,17–22]

The biological factors involved in these findings have been widely studied. Ravindran et al. reported that insulin is one of the main anabolic regulators of bone metabolism; it is responsible for bone cell proliferation, collagen formation, and mineralization. Consequently, insulin dysfunction in type 2 diabetes leads to decreased bone formation and, simultaneously, to osteocyte apoptosis and the production of inflammatory cytokines.[3] Moreover, advanced glycation end-products (AGEs) form in the collagen matrix and contribute to decreased elasticity of collagen, impaired mineralization, impaired trabecular architecture, and weakened mechanical properties of bones despite preserved bone mass.[3,4] This can account for poor quality of bone tissue in diabetic patients with adequate bone mineral density.

A few systematic reviews and meta-analyses have provided additional evidence of a link between diabetes and poor implant outcomes. According to Al Ansari et al., bone loss was significantly more pronounced, and the complication rate was higher in poorly controlled diabetics than in nondiabetic patients; however, in well-controlled diabetics, implant survival was satisfactory.[17] Moreover, Lv et al. found that hyperglycaemia was associated with changes in peri-implant markers, with inflammation. That osseointegration and radiological parameters around dental implants were negatively affected by it.[18] On the other hand, Wagner et al. suggested that diabetes should not be considered an absolute contraindication for implant

therapy anymore; nevertheless, careful patient selection, adequate glycaemic control, and maintenance are key for successful outcomes.[19]

Indeed, recent studies confirm these findings. In their review article, Marinelli et al. analyzed the effects of diabetes and prediabetes on implant outcomes. They found that metabolic status is more important for the prognosis of dental implants than diabetic status.[8] As James et al. found, the survival rate of implants among diabetic individuals is similar to that in nondiabetic individuals if HbA1c is controlled and surgery is properly performed.[21] According to Shahi et al., implant survival among diabetic individuals is still very high; however, delayed osseointegration and higher peri-implant bone remodelling are expected, especially in the case of long-term diabetics.[20] This further confirms the clinical significance of the decrease in bone mineral density reported in the current study.

The current results have also been found to be consistent with clinical investigations of marginal bone loss associated with implant placement in diabetic subjects. In a similar study, Ayele et al. found a significant increase in marginal bone loss in implants placed in people with diabetes compared with those in nondiabetic individuals, indicating that poor-quality bone leads to rapid peri-implant remodelling.[28] Similarly, Elserity et al. showed that there is a higher level of crestal bone changes in controlled diabetics regardless of the depth of implant placement, thus showing the need to maintain the integrity of crestal bone during implant treatment.[27],[29] It was reported by Al Zahrani and Al Mutairi that there was progressive crestal bone loss during a seven-year followup period in patients with type 2 diabetes mellitus.[30] Furthermore, it was found by Alberti et al. that there was an increased risk of peri-implant disease and implant failures in cases of poor metabolic control in diabetic patients.[31]

Experimental studies also support these findings. De Morais et al. showed that bone mineral density around osseointegrated implants was considerably lower in diabetic rats; however, insulin treatment improved bone formation around implants.[32] In a similar vein, Gómez-Moreno et al. indicated that the implant survival in patients with well-controlled type 2 diabetes mellitus over a period of three years was acceptable; however, delayed early healing and higher bone turnover were observed in comparison to healthy subjects.[33] In earlier clinical studies conducted by Kim et al. and Turkyilmaz, satisfactory results in terms of implant survival in selected diabetic patients were found with emphasis on metabolic control and maintenance therapy.[24,25] Thus, it can be concluded that decreased bone mineral density does not contraindicate implant treatment.

Although most publications concur with the current results, some disagreement persists regarding the correlation between diabetes and systemic bone mineral density. According to Li et al., several epidemiologic studies have shown normal or even raised DEXA bone mineral density among people with type 2 diabetes despite their increased fracture risk.[4] Such a contradiction is explained by deterioration of bone microstructure and collagen quality instead of reduced mineral content alone. Since DEXA measures systemic bone mineral density, it might not be a very good indicator of the local bone mineral density of the jawbone where an implant will be placed. On the other hand, CBCT allows evaluation of the condition of local bone structures in the jaws.[9,10,12] The current research results confirm the aforementioned assumption by showing the decreased local mandibular bone mineral density despite no systemic skeletal evaluation.

A further strength of the current study is that it uses a standardised CBCT protocol with defined regions of interest at the trabecular, crestal, and subcrestal levels. Reproducibility of the measurements has been achieved through excellent inter-observer agreement, with Kappa values of 0.953 and intraclass correlation coefficients ranging from 0.943 to 0.956. This is in line with a validation study by Park et al., who found excellent reproducibility of quantitative CBCT-based bone density measurements.[11] The inclusion of measurement reproducibility in the methodology is another strength of the current study.

However, despite the benefits of this study, some limitations should be noted. Firstly, the study has a relatively small sample size (n = 32), which may limit the generalizability of the results. Secondly, the sample was collected in only one institution, leading to potential selection bias. Thirdly, the study used a cross-sectional design, meaning it was not possible to establish causation among the duration of diabetes, glucose control, and gradual changes in bone density. Lastly, bone mineral density was estimated from CBCT grey values rather than Hounsfield units or DEXA. While modern research supports the use of standardised CBCT grey values for this purpose, discrepancies across CBCT scanners may hinder comparison.[9–12] Also, some variables, such as HbA1c levels, duration of diabetes, antidiabetic medications, BMI, serum vitamin D levels, smoking, periodontal condition, and inflammatory factors, were not considered in the study.

Future studies should use multi-centre longitudinal designs with increased sample sizes to examine time-dependent alterations in alveolar bone mineral density resulting from improvements or deterioration in glycemic control. The correlation between bone density assessed by CBCT and HbA1c, ISQ, resonance frequency analysis, insertion torque values, and implant survival rates would go a long way toward establishing the importance of CBCT as a diagnostic tool before implant placement.

From the clinical standpoint, there are several significant implications of the results obtained from the current study. Pre-prosthetic bone assessment in patients with type 2 diabetes mellitus should go beyond measuring bone height and width and also account for regional bone quality. Bone mineral density measurement using CBCT can help clinicians identify patients predisposed to low primary stability and prolonged osseointegration, thereby enabling appropriate adjustments to the treatment plan. Such changes include proper glycaemic control before surgery, improved implant surface design, higher insertion torque whenever possible, longer healing periods before functional loading, staged loading, and better maintenance after the operation.[34] Besides, it is essential to cooperate with oral medicine specialists, radiologists, endocrinologists, and other physicians to ensure optimal systemic metabolic control before the procedure.

In conclusion, the current study demonstrated that patients with type 2 diabetes mellitus had significantly reduced trabecular, crestal, and subcrestal bone mineral density in the area of the mandibular first molar compared with age- and sex-matched nondiabetic individuals. The latest research confirms these results, with systematic reviews and biological evidence indicating that diabetes negatively affects the alveolar bone and can hinder implant integration. However, the existing literature indicates that diabetes is not an absolute contraindication to implant treatment. On the contrary, thorough CBCT evaluation before implant placement, good glycaemic control, appropriate surgical treatment planning and strict post-treatment maintenance are key factors in ensuring successful implant treatment in diabetics.[17–22,34]

Conclusion

Based on the limitations of this pilot study, it was found that patients with Type II diabetes mellitus have significantly lower bone mineral density in the first molar area of the mandible compared with nondiabetic patients, as determined by CBCT grey scale measurements. The reduction in bone density in the crestal, subcrestal, and trabecular areas indicates that diabetes negatively affects bone quality, leading to poor implant stability and osseointegration. Clinically, these findings highlight the importance of assessing regional bone quality and glycaemic control before implant placement in patients with Type II diabetes.

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Availability of data and materials

The datasets used and/or analysed in the current case report are available from the corresponding author on reasonable request.

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List of abbreviations

DM – Diabetes Mellitus

BMD – Bone mineral density

T2DM – Type 2 diabetes mellitus

GVs – Grey values

CBCT – Cone beam computed tomography

3D – Three-dimensional

ROI - Region of interest

IEC – Institutional ethical committee

CTRI - Clinical Trial Registry of India

ICC - Intraclass Correlation Coefficient

STROBE - Strengthening the Reporting of Observational Studies in Epidemiology statement.

ISQ - Implant stability quotient

HbA1c – Glycated Haemoglobin

AGEs – Advanced Glycation End Products

TNF-α – Tumour Necrosis Factor-alpha

ISQ – Implant Stability Quotient

ADA – American Diabetes Association

HPLC – High-Performance Liquid Chromatography

ICC – Intraclass Correlation Coefficient

ALARA - As Low As Reasonably Achievable

Declarations

Ethics approval and consent to participate

Ethical clearance for the study was granted by the Institutional Ethics Committee of Datta Meghe Institute of Higher Education and Research, Sawangi (Meghe), Wardha, with IEC number as DMIHER(DU)/IEC/2025/695. The study is also registered under the Clinical Trials Registry of India (CTRI No. CTRI/2025/05/087725). Declaration of Helsinki: The study was conducted in accordance with the Declaration of Helsinki; an ethics committee approved the protocol, and informed consent was obtained from patients. Informed consent from participants was mandatorily obtained before their inclusion in this study, and their confidentiality was maintained by not using any identifiable information.

Data availability

The datasets used and/or analysed during the current study are included in the published article, and the raw data are available from the corresponding author on reasonable request.

Competing interests

The authors declare no competing interests

Conflicts of Interest

None declared.

Human ethics and consent for participants:

The informed consent of all participants was obtained before including them in the experiment, and also for publishing the study results. The experiment was conducted in accordance with human ethics standards.

Funding

Not provided

Authors' contributions

MK: Conceptualisation, methodology, patient selection, data gathering, CBCT image capturing and analysis, analysis, interpretation of the results, writing and revising the manuscript. MK was the lead researcher and coordinated all the aspects of the research.

VL: Conceptualisation, designing, supervision, methodology, validation of the CBCT findings, critical and editorial review and editing of the manuscript, Project administration and overall guidance of the research process.

RK: Contributed to methodology of the study, statistical analysis, critical scientific review, and validation of the study findings.

The involvement of all authors in the process of study concept development, review and critical revision of the manuscript for intellectual content and approval of the final version of the paper is ensured.

Figure and figure legends

Table and table legends

Graph and graph legends

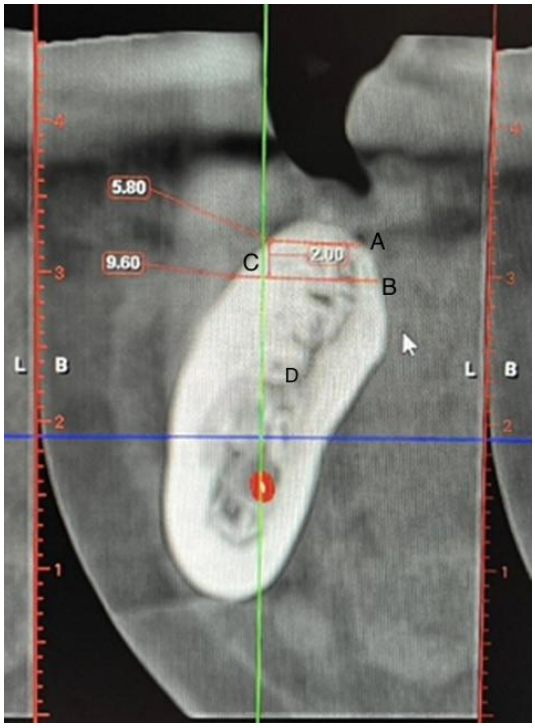


Figure 1: CBCT cross-sectional image

A: Crestal level

B: Subcrestal level (2mm below the crestal level)

C: Distance between A and B = 2mm

D: Trabecular bone

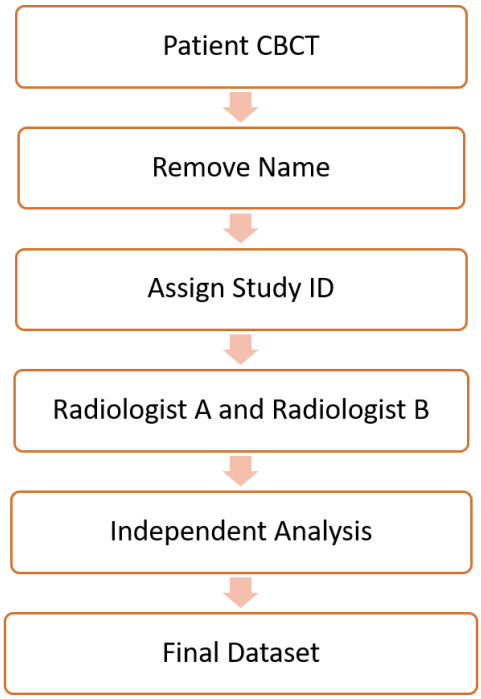


Figure 3. Workflow of CBCT image anonymisation and independent evaluation by two oral and maxillofacial radiologists.

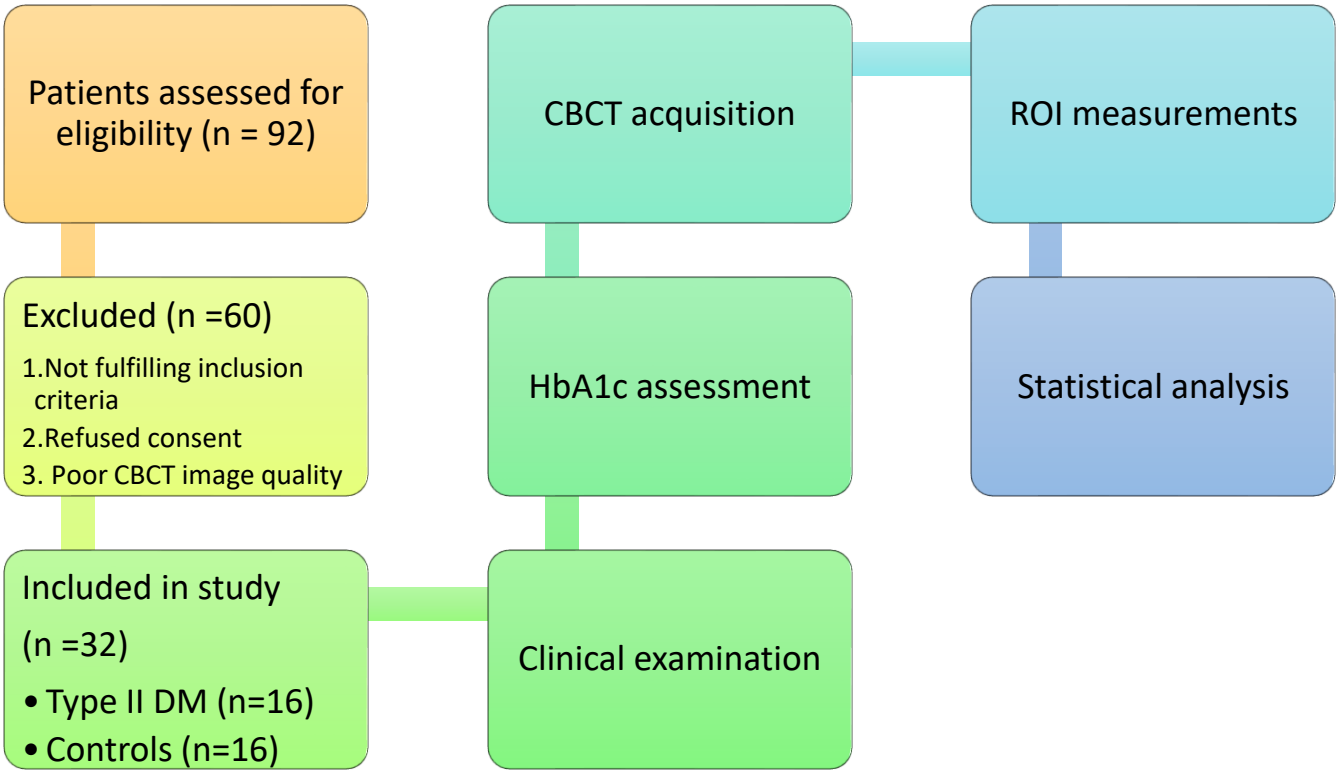


Figure 4. Diagram depicting the process of subject selection and methodology used in the study. Out of 92 patients screened for inclusion criteria, 60 subjects were excluded from the study because they did not fulfill the inclusion criteria, lacked informed consent, and had poor quality of CBCT images. The total number of participants used in the study was 32 (16 diabetic patients and 16 control group patients).

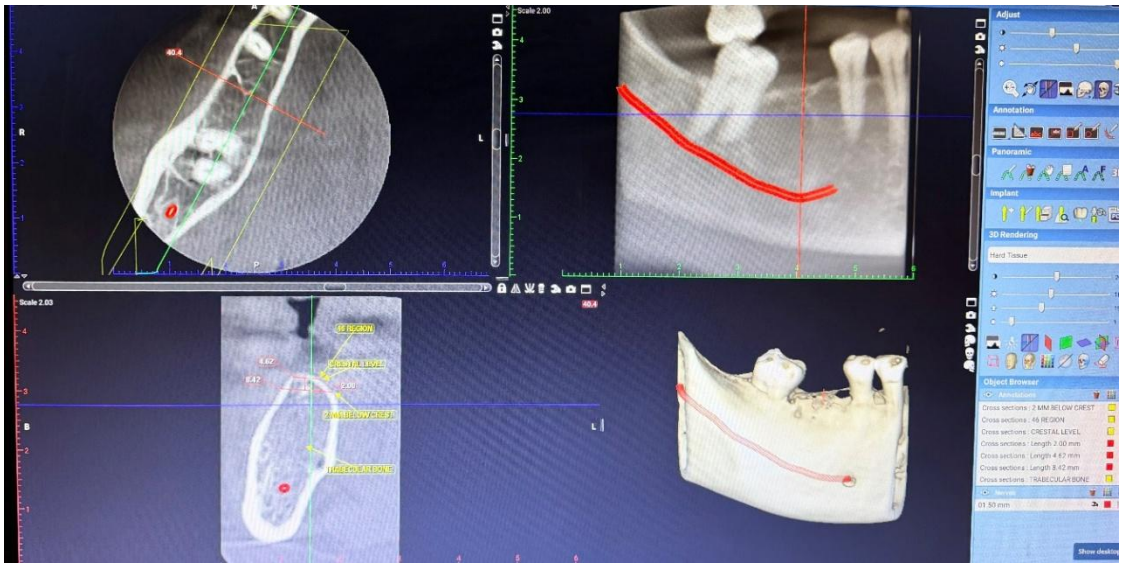


Figure 2. Multiplanar Reconstruction of Cone-Beam Computed Tomography (CBCT) Showing the Selection of Standardised Region of Interest (ROI) for Bone Density Assessment on Edentulous Mandibular First Molar Site. (A) Axial plane image showing the orientation of the cross-sectional plane at the implant site. (B) Panoramic reconstructed image showing the curve of the mandibular arch with the selected cross-section. (C) Cross-sectional image showing the points at which the bone density is measured (crestal bone, 2mm below the alveolar crest/subcrestal region, and trabecular bone with the inferior alveolar canal indicated). (D) Three-dimensional reconstruction of CBCT image showing the position of the selected cross-section plane in the mandibular first molar region.

Variable	**Low/ Moderate Cut-off**	**Moderate/ High Cut-off**	**N**	**Agreements**	**Disagreements**	**Observed Agreement**	**Expected Agreement**	**Cohen's Kappa**
Trabecular BMD - Min	261.0	301.0	32	31	1	0.969	0.334	0.953
Trabecular BMD - Max	1651.0	1891.0	32	31	1	0.969	0.333	0.953
Trabecular BMD - Mean	954.5	1086.5	32	31	1	0.969	0.333	0.953
Crestal BMD - Min	258.0	340.0	32	31	1	0.969	0.334	0.953
Crestal BMD - Max	921.0	1132.0	32	31	1	0.969	0.334	0.953
Crestal BMD - Mean	605.5	707.0	32	31	1	0.969	0.333	0.953

BMD 2 mm from crestal - Min	282.0	326.0	32	31	1	0.969	0.334	0.953
BMD 2 mm from crestal - Max	1142.0	1478.0	32	31	1	0.969	0.334	0.953
BMD 2 mm from crestal - Mean	730.0	888.0	32	31	1	0.969	0.334	0.953

Table 7. Repeatability of bone mineral density measurement results using the intra-observer agreement test (Kappa coefficient of Cohen)

Variable	**ICC**	**95% CI**	**Interpretation**
Trabecular BMD Min	0.943	0.898–0.967	Excellent
Trabecular BMD Max	0.955	0.910–0.979	Excellent
Trabecular BMD Mean	0.956	0.911–0.980	Excellent
Crestal BMD Min	0.956	0.911–0.980	Excellent
Crestal BMD Max	0.945	0.900–0.969	Excellent
Crestal BMD Mean	0.956	0.911–0.980	Excellent
2mm below crest BMD Min	0.953	0.908–0.977	Excellent
2mm below crest BMD Max	0.953	0.908–0.977	Excellent
2mm below crest BMD Mean	0.954	0.909–0.978	Excellent

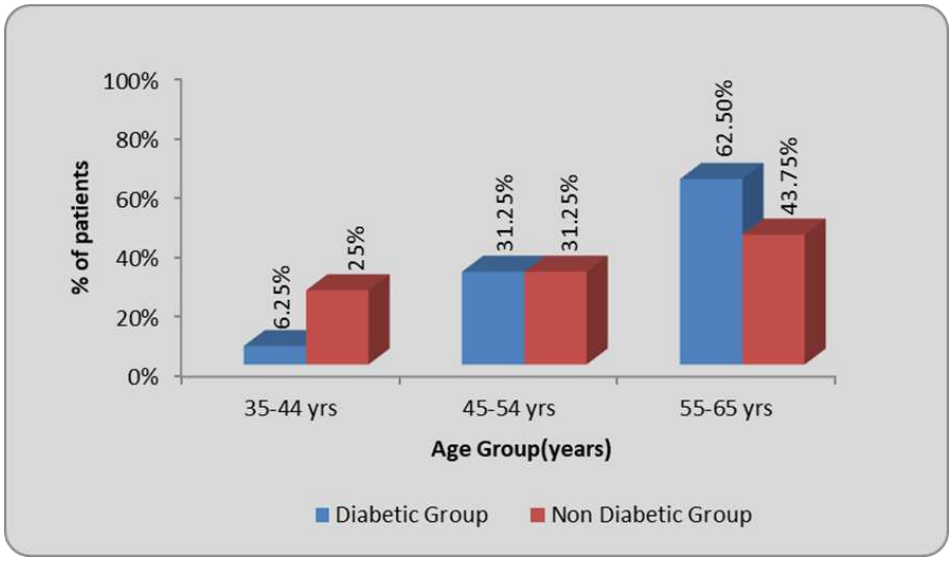
Table 8. Reliability of bone mineral density measurements – Intra-observer reliability (Intraclass Correlation Coefficient)

Bone Type	Description	Clinical characteristics
D1	Dense cortical bone	Highly dense cortical bone with minimal trabecular component
D2	Thick cortical bone with dense trabecular bone	Ideal bone quality for implant placement
D3	Thin cortical bone with dense trabecular bone	Moderate bone quality; common in the posterior mandible and anterior maxilla
D4	Very thin cortical bone with low-density trabecular bone	Poor bone quality, lower primary implant stability

Table 1. Lekholm and Zarb classification of bone quality (D1–D4) based on cortical and trabecular bone characteristics relevant to dental implant treatment planning.[34]

Table 2: Patient distribution in two groups based on age in years

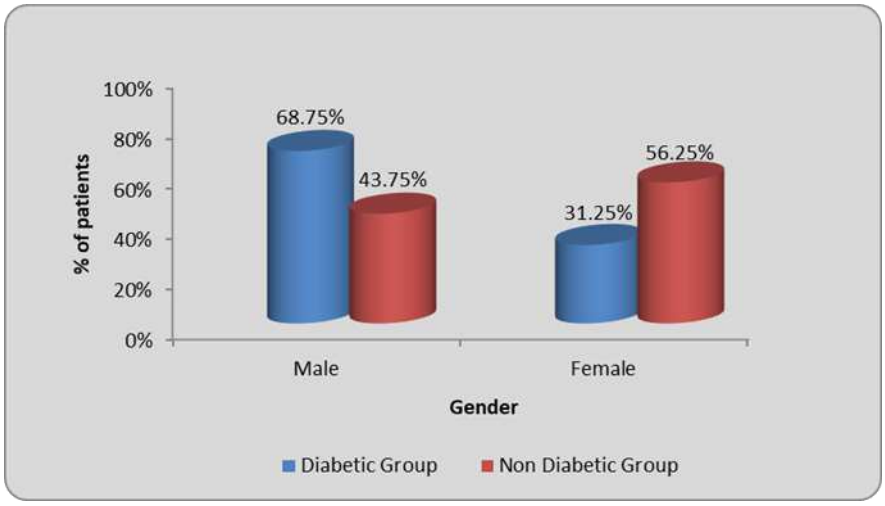
Age Group(yrs)	Diabetic Group	Non-Diabetic Group	χ2-value
35-44 yrs	1(6.25%)	4(25%)	
45-54 yrs	5(31.25%)	5(31.25%)	
55-65 yrs	10(62.5%)	7(43.75%)	2.32
Total	16(100%)	16(100%)	P=0.31, NS
Mean±SD	54.87±6.93	52.31±8.52	
Range	40-65 yrs	39-65 yrs	



Graph 1: Patient distribution in two groups based on age in years

Table 3: Patient distribution in two groups based on gender

Gender	Diabetic Group	Non-Diabetic Group	χ2-value
Male	11(68.75%)	7(43.75%)	2.03 P=0.15, NS
Female	5(31.25%)	9(56.25%)	
Total	16(100%)	16(100%)	

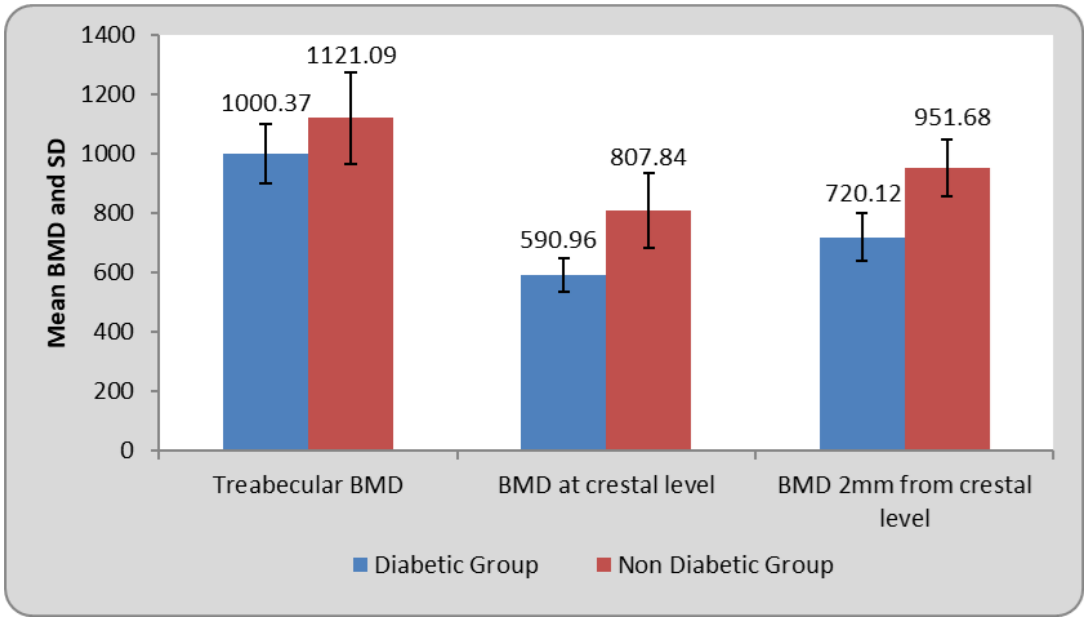


Graph 2: Patient distribution in two groups based on gender

Table 4: Comparison of BMD between two groups (Student's unpaired t-test)

(S-Significant, p <0.05)

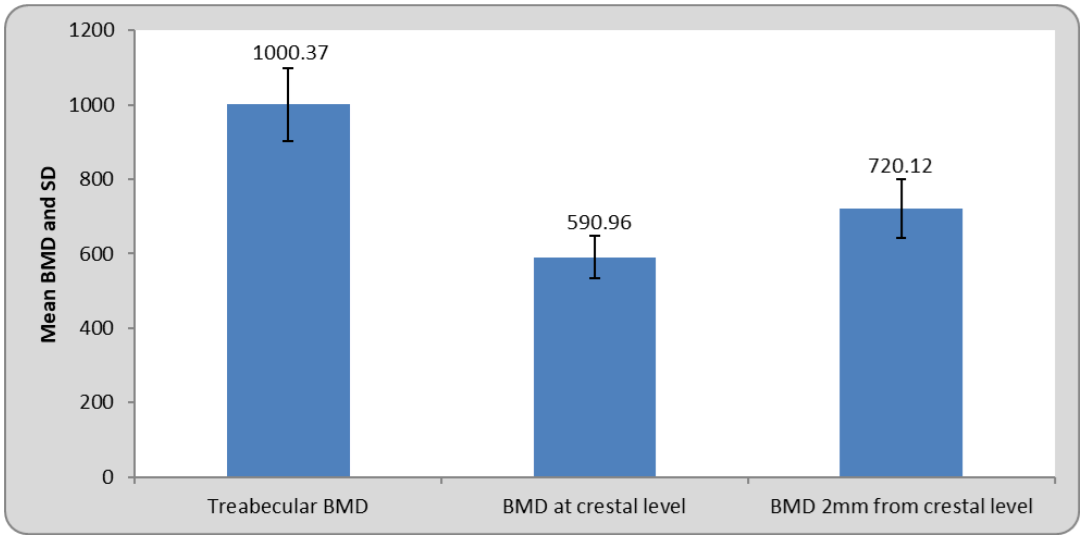
BMD	Diabetic Group	Non-Diabetic Group	t-value	p-value
Trabecular BMD	1000.37±98.69	1121.09±154.94	2.62	0.013**, S**
BMD at crestal level	590.96±57.07	807.84±126.56	8.24	0.0001**, S**
BMD 2mm from the crestal level	720.12±78.96	951.68±95.35	7.81	0.0001**, S**



Graph 3: Comparison of BMD between two groups

Table 5: Intragroup comparison of BMD in diabetic group (Student's Paired t test) (Descriptive Statistics)

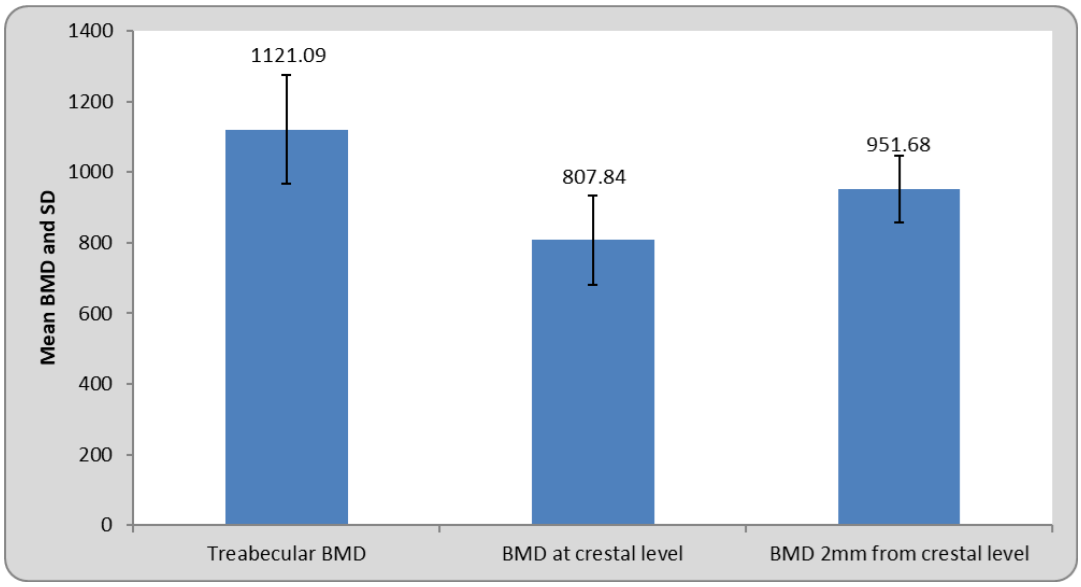
	Mean	N	Std. Deviation	Std. Error Mean	Trabecular BMD Vs BMD at the crestal level	Trabecular BMD Vs BMD 2mm from the crestal level	BMD at the crestal level Vs BMD 2mm from the crestal level
Trebecular BMD	1000.37	16	98.69	24.67	18.32 P=0.0001, S	9.37 P=0.0001, S	5.54 P=0.0001, S
BMD at crestal level	590.96	16	57.07	14.26			
BMD 2mm from the crestal level	720.12	16	78.96	19.74			



Graph 4: Intragroup comparison of BMD in the study group (Student's Paired t test)

Table 6: Intragroup comparison of BMD in non-diabetic group (Student's Paired t test) (Descriptive Statistics)

	Mean	N	Std. Deviation	Std. Error Mean	Trabecular BMD vs BMD at the crestal level	Trabecular BMD vs BMD 2mm from the crestal level	BMD at the crestal level Vs BMD 2mm from the crestal level
Trabecular BMD	1121.09	16	154.94	38.73	14.18 P=0.0001, S	5.60 P=0.0001, S	7.23 P=0.0001, S
BMD at crestal level	807.84	16	126.56	31.64			
BMD 2mm from the crestal level	951.68	16	95.35	23.83			



Graph 5: Intragroup comparison of BMD in the Control group