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Research Protocol

Dentistry Section

Determination of Palatal Soft-tissue Thickness and Safe Zone for Soft-tissue Harvest using CBCT: A Study Protocol

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ABSTRACT

Introduction: Palatal soft-tissue grafts have become popular in periodontal and peri-implant plastic surgeries because of their predictability of the results along with favourable tissue parameters. Traditional methods are either invasive or lack precision, whereas Cone-Beam Computed Tomography (CBCT) offers a reliable, non invasive and three-dimensional evaluation.

Need of the study: The studies have evaluated Palatal Mucosal Thickness (PMT) using different techniques, most have focused on isolated measurements without correlating PMT with anatomical factors such as palatal vault angle and position of greater palatine groove. There is limited data using standardised CBCT protocols. Therefore, the present study provides a comprehensive CBCT-based evaluation of PMT in relation to palatal anatomy to define a clinically relevant safe zone for soft-tissue harvesting, thereby enhancing surgical predictability and minimising complications.

Aim: To evaluate PMT at different tooth sites and to determine the safe zone for palatal soft-tissue harvest with the help of CBCT.

Materials and Methods: The retrospective cross-sectional study will be conducted in the Department of Oral Medicine and Radiology at Sharad Pawar Dental College, Wardha, Maharashtra, India, from January 2026 to December 2026. A total of 30 subjects will be included in the study. CBCT images will be retrieved retrospectively from departmental archives and analysed. The parameters to be evaluated will include PMT, palatal vault angle and distance from Cemento-Enamel Junction (CEJ) to greater palatine groove. PMT will be measured at 3 mm, 6 mm and 9 mm from the CEJ in the region extending from canine to second molar. Palatal vault angle will be classified as shallow, moderate, or deep based on predefined criteria. The distance between the palatal CEJ and the greater palatine groove will be assessed to determine the surgical safe zone for soft-tissue harvesting. The collected data will be tabulated and analysed using Chi-square test, Student's paired, unpaired t-test, One-way Analysis of Variance (ANOVA) Tukey's test to evaluate statistical significance regarding PMT and safe zone for tissue harvesting and $p<0.05$ will be considered statistically significant.

Keywords: Anatomical landmarks, Cone-beam computed tomography, Gingiva, Oral surgical procedures, Palate

INTRODUCTION

The procedures for palatal soft-tissue harvesting are commonly performed in periodontal and peri-implant plastic procedures [1]. Various methods of soft-tissue grafts harvesting have been suggested. The soft-tissue graft is considered as gold standard method of managing gingival or mucosal recessions around teeth and implants [1] due to its potential to increase marginal soft-tissue thickness, assist in healing by the primary intention and preserve the natural soft-tissue quality as that of adjacent teeth or implants. However, the location of the donor site can influence the graft dimension and its constituents [2].

The maxillary tuberosity and lateral aspect of the palate are most common donor sites for harvesting sub-epithelial connective tissue grafts and free gingival grafts, especially in the area between the first premolar to the second molar, because of their favourable tissue thickness and anatomical characteristics [3]. Palatal soft-tissue grafts are rich in connective tissue matrix with fibroblasts and collagen, provide adequate structural support and lead to predictable clinical outcomes for gingival recession treatment and soft-tissue augmentation. Owing to their ability to enhance tissue thickness and achieve superior functional and aesthetic results, it is considered as the gold standard for root coverage procedures [4].

However, variations in PMT and anatomy necessitate careful assessment to minimise complications such as neurovascular injury, bleeding or paresthesia. The relationship between PMT in relation to each tooth, palatal vault angle, and the greater palatine groove should be evaluated during grafting procedure. There is variation in PMT based on age, gender and tooth site [5].

Accurate assessment of PMT is essential to ensure optimal graft size and donor site safety. Traditional methods like bone sounding or transgingival probing are widely used but require anesthesia. Non invasive alternatives include ultrasonography, Magnetic Resonance Imaging (MRI) and CBCT. While ultrasound poses challenges in probe size and calibration, MRI offers accurate, radiation-free 3D imaging but is costly, time-consuming, and may cause claustrophobia. Each method has its trade-offs in precision, comfort, and practicality [6].

The CBCT scans can provide crucial information to ensure preservation of the neurovascular bundle and ensure optimum graft quantity when planning palatal soft-tissue grafting procedures. CBCT provides several benefits like less radiation exposure, improved image quality, increased patient comfort, and cost effective [7]. Considering all these benefits of CBCT, the aim of the present study is to comprehensively analyse the PMT and indicate the safety zone for palatal soft-tissue harvesting using CBCT.

REVIEW OF LITERATURE

Primary objective: To quantitatively assess PMT at different tooth regions (canine to second molar) and at varying distance from CEJ using CBCT.

Secondary objective:

- To determine the safe zone for palatal soft-tissue harvesting by evaluating the position of the greater palatine groove.
- To assess the relationship between palatal vault angle and PMT.

- To evaluate variations in PMT with respect to age, gender and tooth site.

Null hypothesis: There is no significant difference in PMT across different tooth regions, measurement levels, palatal vault angle, age groups and genders. However, no significant relationship exists between PMT and position of greater palatine groove.

Alternative hypothesis: There is significant difference in PMT across different tooth regions, measurement levels, palatal vault angle, age groups and gender, and a significant relationship exists between PMT and position of greater palatine groove.

Accurate assessment of PMT using techniques such as CBCT is essential for safe tissue harvesting. Previous studies have shown PMT varies with factors like age, gender, tooth position and palatal anatomy influencing clinical outcomes.

Barriviera M et al., (2009) conducted a study of new method to assess and measure Palatal Masticatory Mucosa (PMM) by CBCT. The study concluded that CBCT is a reliable, non invasive method for assessing PMT, which varies across different locations on palate by using lip and cheek retractors and wooden spatulas. They reported that mean PMT varied across different tooth regions. However, the study was limited by relatively all sample size, lack of extensive clinical validation and lack of population diversity, which may restrict the generalisability of the findings [8].

Said KN et al., (2020) carried out an examination of anatomic factors influencing dimensions of soft-tissue graft from the hard palate, a clinical study. They evaluated PMT using CBCT and reported significant variations across different tooth regions, emphasising the influence of anatomical landmarks on PMT distribution. The canine-premolar region (8-13 mm from the mid-palatal aspect) was the best location for graft harvesting [9]. However, limitation included a cross-sectional design, limited sample representation and population specificity, which may restrict broader applicability.

Yilmaz HG et al., (2015) used CBCT to assess thickness of the palatal soft-tissue and to identify the location of greater palatine foramen in the palate in 345 patients. They concluded that average PMT from the second molar to the canine was 3.7, 3.3, 3.7, 3, and 3 mm, respectively. The greater palatine foramen was most commonly located between the second and third molars. Based on mucosal thickness, the region from second premolar to second molar zone was identified as the best location for graft harvesting [10].

Seidel A et al., (2022) investigated the palatal soft-tissue volume: a 3D virtual analysis for digital workflows and pre-surgical planning. This study includes 20 participants CBCT scans and converted into 3D Standard Tessellation Language (STL) model of bone surface. The region between central incisors and palate divided into five regions of interest. The average gingival surface area of the palate was 19.1 cm^2 and mean volume was 58.2 cm^3, showing gradual decrease from posterior to anterior region. Thus, posterior palate is a more favourable donor site. The 3D method improves volumetric and linear measurements for anatomical and oral applications by providing precise pre-surgical planning data [11].

Yaman D et al., (2014) compared thickness of PMM and its relationship with different parameters in Turkish subjects. They explored mucosal alterations in hard palate areas for soft-tissue harvesting in there were no differences according to age, gender, or BMI. The study reinforces the role of variation in palatal thickness during graft planning and suggests transmucosal probing can help to assess donor site suitability. However, its limitations include population specificity and absence of clinical correlation with surgical outcomes [12].

Although several studies have evaluated PMT using various techniques, limited literature exists that integrates CBCT-based quantitative assessment of PMT with simultaneous evaluation of palatal vault angle and its relation to the greater palatine groove for defining a precise surgical safe zone. Additionally, most previous studies have been conducted in different populations with limited standardisation. Therefore, the present study aims to provide a comprehensive CBCT-based evaluation to establish clinically relevant safe zones for soft-tissues harvesting, thereby improving surgical predictability and minimising complications.

MATERIALS AND METHODS

This retrospective cross-sectional study will be conducted in the Department of Oral Medicine and Radiology at Sharad Pawar Dental College, Wardha, Maharastra, India, during the period from January 2026 to December 2026. Ethical clearance will be obtained from the Institutional Ethics Committee (IEC) of Datta Meghe Institute of Higher Education and Research (DMIHER), Deemed to be University IEC/2025/63. The study will be conducted in accordance with ethical guidelines. The study is registered with the Clinical Trials Registry of India (CTRI No.: CTRI/2026/02/103463). CBCT images of patients meeting the inclusion criteria will be retrieved from departmental archives and analysed.

Sample size calculation:

$n1=\{(\sigma_1^2 + \sigma_2^2/k) (Z_1-\alpha/2 + Z_1-\beta)^2\}$

Δ^2

Δ=difference in group means;

k=ratio=n_2/n_1

Z1−α/2=two-sided Z value (e.g., 1.96 for 95% confidence interval)

Z1−β=power of the Test: 80%

Level of significance: 5%(95% confidence interval)

Mean palatal soft-tissue measurement at first premolar in group S=3.19

Mean palatal soft-tissue measurement at first premolar in group D=2.71

σ1= SD of palatal soft-tissue measurement at first premolar in group S=0.66

σ2= SD of palatal soft-tissue measurement at first premolar in group D=0.50 [5]

For detecting mean difference of 0.48 i.e., Δ= 3.19-2.71=0.48

K=1

N=(0.66*0.66+0.50*0.50)(1.96+0.84) 2 =23.32 =25

0.48*0.48

25 patients needed in study, after considering 20% dropout final sample required is 30 samples

Inclusion criteria: CBCT images of patients aged 15-60 years with bilateral presence of teeth from the canine to second molar region will be included. The selected age range represents individuals with fully developed permanent dentition and relatively stable palatal anatomy, minimising the influence of growth-related changes seen in younger patients and age-related degenerative or atrophic changes observed in older adults, which may affect PMT [13].

Exclusion criteria: CBCT images showing evidence of previous palatal surgery, trauma, fracture or congenital anomalies of palate will be excluded, as these conditions may alter the normal palatal anatomy. Images with missing teeth, metallic restoration, severe crowding, local pathology, rotation or spacing in the maxilla will be excluded to avoid distortion of anatomical landmarks and ensure precise and reproducible measurements. Additionally, images with tongue interference, soft-tissue superimposition, or developmental dental anomalies in the region of interest will be excluded to maintain image clarity and measurement reliability.

Study Procedure

Patients will be retrospectively recruited based on the availability of complete records, including systematic history, clinical examination, and radiographic data.

In this, systemic history and clinical examination were not performed anew but were obtained from existing patient records and case sheets available in the department of Oral Medicine and Radiology. Only cases with complete clinical documentation along with corresponding CBCT images were included in the study. The relationship of PMT with individual tooth sites, palatal vault angle and the greater palatine groove will be evaluated. Additionally, variations in PMT based on age, gender and tooth location will be assessed.

Outcomes

Primary outcome: The primary outcome of this study will be the quantitative assessment of PMT at different teeth regions (from canine to second molar) and measurement levels using CBCT. This will enable comparison of PMT across different anatomical sites and contributing to the identification of optimal donor areas for palatal soft-tissue harvesting.

Radiographic evaluation of PMT will be carried out by measuring the distance from the mid-portion of the CEJ to the mid-palatal suture along a horizontal line. In the coronal view, reference points will be marked from the CEJ at 3 mm intervals along a line bisecting the palatal root. From each of these points, a perpendicular line will be drawn to meet the tangential line, and the palatal thickness will be recorded accordingly [3].

The CBCT images obtained from ProMax3DMid (Planmeca) and measurements will be recorded accordingly. Two examiners will evaluate the images separately to avoid bias.

The palatal vault angle will be evaluated in the coronal section at the level of maxillary first molar by forming an angle between a horizontal line at the CEJ and a line extending to the mid-palatal suture. Based on this, the palatal morphology will be categorised as shallow group (Group-S), in which the palatal vault angle is less than 30°; the moderate group (Group-M), with an angle ranging between 30° and 40°; and the deep group (Group-D), where the palatal vault angle is greater than 40° [3].

Secondary outcome: The secondary outcomes of this study include the identification of anatomically safe zones for palatal soft-tissue harvesting by evaluating the location of the greater palatine groove in relation to the palatal CEJ. This involves measuring the distance from the midpoint of the palatal CEJ at reference points as canine, first premolar, second premolar, first molar, second molar (T3-T7) to the corresponding palatine groove, helping to identify areas that are safer for surgical intervention. The study will also assess the relationship between PMT and palatal vault angle to determine its influence on tissue availability. Additionally, variations in PMT with respect to age, gender, and tooth site will be analysed to understand individual and regional differences in palatal anatomy [3].

STATISTICAL ANALYSIS

Statistical analysis will be done by using software Statistical Package for Social Sciences (SPSS) 27.0 version and GraphPad Prism 7.0 version. Statistical analysis will be done by using descriptive and inferential statistics using Chi-square test, Student's paired, unpaired t-test, One-way ANOVA, Tukey's test and $p<0.05$ is considered as level of significance.

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