ASSESSMENT OF MAXILLARY BONE THICKNESS AND DENSITY IN SURGICALLY REPAIRED CLEFT LIP AND PALATE PATIENTS AT DIFFERENT IMPLANT SITES- A CBCT STUDY

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In

ORTHODONTICS AND DENTOFACIAL ORTHOPAEDICS

By

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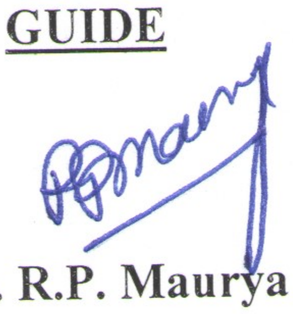

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ABSTRACT:

AIM:

Assessment of maxillary bone thickness and density in surgically repaired unilateral and bilateral cleft lip and patients at different sites for mini-screw placement on CBCT images, using i-CAT software. .

MATERIAL AND METHOD: A total 45 CBCT images were scanned, out of which 15 subjects were of unilateral cleft patients (Group I), 15 subjects were bilateral cleft patients(Group II) and15 subjects were normal subjects(control group- Group III).

Buccolingual bone thickness and density of maxilla were evaluated and compared among all the groups at four different implant sites (between two central incisors, lateral incisors and canine, first and second premolars and second premolars and first molars) at different heights from the alveolar crest (at 2, 4, 6 and 8mm respectively). Palatal bone thickness and density were also calculated in anterior (6mm behind the incisive foramen, at 3mm lateral to midpalatal suture) and the posterior region(3mm adjacent to midpalatine suture in the area adjacent to second premolar and first molar) .

RESULT: Buccolingual thickness and density was maximum in Group III > Group II >Group I except in central incisors and lateral/canine region (6, 8 mm) where the trend was III>I>II, and the difference was statistically significant among all the groups except at 6 & 8 mm between premolar and premolar-molar region. Palatal bone thickness was more in anterior region as compared to posterior region, the reverse was true for density and the difference was statistically significant among all the groups.

CONCLUSION: In cleft patients available maxillary bone thickness and density is lesser as compared to normal subjects, therefore in these cases during selection and insertion of mini implant extra precaution should be taken to ensure the success.

INTRODUCTION

Cleft lip and palate are the most common congenital deformity, may involve either only lip or palate or may involve palate and lip both . This congenital abnormality occurs in secondary palate, might be unilateral ,bilateral,complete or incomplete [1]. Cleft lip & palate occurs due to failure of fusion of maxillary process with the median nasal process and palatal process of maxilla, during 5^{th}-12^{th} week of intrauterine life [3]. Non-syndromic CLP had an incidence of 1/1258 live births [2].

Depending on the presence of isolated cleft lip and palate with their association with specific malformations, they can be classified as; syndromic and non- syndromic cleft lip and palate patients. Both the forms of cleft lip and palate patients are strongly associated with the strong genetic component [4].

Syndromic forms came into existence due to chromosomal aberrations or monogenic diseases[4]. The incidence of cleft lip and palate might be associated with many syndromes such as: Pierre Robin syndrome, Sticklers syndrome, Treacher Collins syndrome, Hemifacial microsomia and Ectodermal dysplasia [5].

Non-syndromic cleft lip and palate is the multifactorial disorder in which etiological basis of craniofacial malformation is because of interaction of genetic and environmental factors[6]. There are possible environmental risk factors involved for cleft lip and palate patients such as maternal exposure to smoke, alcohol, diet, viral infections, drugs and teratogen agents during early pregnancy[4].There are several genes involved in the susceptibility to non-syndromic cleft lip and palate; such as growth factors (TGFA, TGFb3), transcription factors like(MSX1, IRF6, TBX22), genes involved in the metabolism of xenobiotics (CYP1A1, GSTM1,NAT2),genes involved in the nutritional metabolism (MTHFR, RARA)and genes involved in immune response (PVRL1, IRF6) [4].

Various studies have concluded that adjacent to the cleft site there is decreased alveolar bone height, a long supracrestal connective tissue attachment and a higher frequency of gingival recession[l, 7,8,,9,10,11].

Dental problems of cleft lip and palate patients involve abnormalities in the size and shape of the teeth, For example, the permanent lateral incisor shows abnormalities in size and shape in the side of cleft, abnormalities in the position of teeth, delay of eruption of permanent teeth and delay of formation of permanent teeth [45].

The abnormal features associated with CLP patients are deficient mid face development resulting in class III malocclusion, maxillary transverse deficiency usually posterior cross bite, anterior cross bite and palatal and alveolar cleft. Dental abnormalities such as hypodontia, malformation and abnormal eruption pattern are also found in CLP patients [5-6]. In these patients, dental and skeletal problems require different orthodontic interventions during deciduous dentition to late permanent dentition to achieve functionally optimum occlusion and best possible aesthetics.

Complex orthodontic tooth movements and biomechanics are required for the correction of rotated teeth adjacent to cleft sites and creation of space for prosthetic replacement of the missing teeth. The complexity of the hard and soft-tissue regeneration in these sites have requisite the need for defining the preoperative morphology of the cleft areas[3].

Mini screws are widely used as temporary anchorage devices (TAD) to treat many types of malocclusion and require minimal patient compliance**.** TAD can be used to achieve absolute anchorage in maximum anchorage cases[12]. It can be also used in cases where sufficient anchorage is not available due to missing teeth or requires difficult tooth movement such as intrusion of teeth or distalization of molars. The success of a mini-implant depends upon site of placement such as interradicular distance, sinus morphology, nerve location, bucco-lingual bone depth, cortical bone thickness and density.

Mini-implants are trending now in present days because of their effectiveness, easy clinical management, and stability. Factors responsible for mini-implant stability are: alveolar bone thickness, bone density, placement angle, and location appear to be critical for successful placement. Adequate bone quantity at the placement site is important for the success of the mini-implants.

The selection of size of mini-implants varies according to the site and location of its placement. For example in maxilla, it is preferred to place a narrow implant in the interradicular areas. The stability of mini-implant depends on the strength of bone, like in the trabecular bone longer screw is needed and in case of cortical bone a shorter screw is needed. The selection of optimum site will enable the clinician to control the effective tooth movement (extrusive or intrusive movement). The placement of mini-implants requires sufficient bone depth and atleast 2.5 mm of bone width for the protection of the anatomical structures [13].

Since, implant placement sites are closure to the plane of an archwire, the force applied for the tooth movement and control of resultant counter forces are much easier. The screws for the purpose of an orthodontic anchorage must be thin (1.3mm to 1.5 mm) and should be

tapered to prevent an accidental contact of root of the tooth. In maxilla, it is preferable to use length of 8mm to 10mm and in mandible, the length should be 6mm to 8mm because of dense bone [14].

Bone density appears to be a decisive factor for the stability of mini-implants in sites with inadequate cortical bone thickness because primary retention of mini-implants during the early stages of placement is achieved by mechanical means rather than through osseointegration. Bone density influences the amount of bone in contact with the implant surface, and is responsible for distribution of mechanical stress, where bone contacts the implant surface. Hence, the stress can also be reduced by increasing the functional area over which the force is applied by increasing either the length or the diameter of the implant. The results of previous studies have concluded that bone of higher density might ensure a better biomechanical environment for mini implants **[12]**.

Bone quality of cleft patients The buccal alveolar bone for the teeth anterior to the cleft at 3 mm thinner when compared to the noncleft site.The distal alveolar bone for the teeth anterior to the cleft at 3 mm is thinner when compare to the noncleft side. The alveolar bone anterior to the cleft at buccal, palatal, and mesial surfaces of the teeth was 3 mm thinner than the noncleft site **[3].** Noncleft side having a thicker buccal alveolar bone. Radiographic alveolar bone loss was greater at the cleft site as compared with controls, due to the presence of a long supracrestal connective tissue attachment. UCLP with regard to periodontal health status and showed that bone loss was significantly higher for teeth on the cleft side as compared with the contralateral noncleft control teeth. In the cleft area there is a lower level of crestal bone**[3].**

In cases of surgically repaired patients ,it was found that the buccal bone thickness was significantly greater in the apical region (around 9mm from the alveolar crest).It was also concluded that the primary alveolar graft does not provide an additional bone width on the cleft sides as compared to the children who have not undergone alveolar grafts[16]. According to Suomalainen et al[17], the labiopalatal thickness of the grafted bone was favourable at one – third of the root length.

CBCT was developed because CT is associated with higher radiation exposure, expensive and difficulty in accessibility. CBCT generates cone-shaped beams and the images are obtained in one rotation by an image intensifier of flat panel detector, resulting in reasonably low levels of radiation dosage (Arai et al., 1999; Chan et al., 2010; Scarfe & Farman, 2008). Shorter examination time, reduced image distortion due to internal patient movements, and increased x-ray tube efficiency are the advantages of CBCT. However, limitations of CBCT

image quality are noise and contrast resolution because of the detection of large amounts of scattered radiation (Scarfe & Farman, 2008). The resolution of CBCT imaging can be measured by the individual volume elements or voxels produced from the volumetric set of data[16]. The availability of CBCT is also expanding the use of additional diagnostic and treatment software applications [18].

The optimal sites for mini-implant placement are the palatal aspect of the maxillary alveolar process, the retromolar area in the mandible and the buccal cortical plate in both maxilla and mandible [19]**.** Poggio et al [20] ranked the safest sites available in interradicular space between first molar and second premolar, 2-8mm from the alveolar crest in the posterior maxillary region.Fayed et al [17] suggested that the optimal site for mini-implant placement in the anterior region was between the central and lateral incisors in maxilla.

Motoyoshi et al [21] suggested that the cortical bone thickness of 1.0mm or more was the critical value for the success of mini screws implant. Maxilla has a thicker buccal cortical bone than on the palatal side. On buccal side, it is thickest at the site mesial to the 1st molar whereas on palatal side it is thicker at the site mesial to the second premolar.

It has been stated that a successful alveolar bone graft to repair cleft gives bony support to the tooth adjacent to the cleft, stabilizes the maxillary arch particularly in bilateral clefts, closes an oronasal fistulae and enhances the orthodontic treatment[22].Various studies have reported that there are difference in bone quality and quantity between cleft patients and normal patients.

Suomalainen et al [17] found that there was deficiency of the bone in apical and palatal areas of the defect and also recommended the careful insertion of the bone graft towards the palatal and apical direction of the cleft. Parveen S et al [2] found that the alveolar bone around the teeth adjacent to the cleft site was thinner than non cleft site. Since, maxillary bone is compromised in CLP patients, hence finding out favorable site for mini screw will provide better stability of mini screw implant and long term success of an orthodontic treatment in CLP patients, but none of the studies have evaluated the same.

In previous studies on normal patients, maxillary bone thickness and density at different implant sites were evaluated on CBCT images using various software such as i-CAT, Simplant Pro, Dolphin 3-D etc. In present study, we will use i-CAT software as it helps to create true and precise view of CBCT images. Considering this, the aim of this study was the assessment of maxillary bone thickness and density in surgically repaired cleft patients at different implant placement site on CBCT images of using i-CAT software.

AIM AND OBJECTIVES:

Aim:

Assessment of maxillary bone thickness and density in surgically repaired unilateral and bilateral cleft lip and palate patients at different sites for mini-implant placement on CBCT images using i-CAT software.

Objectives:

1. To evaluate maxillary bone thickness and density in surgically repaired unilateral and bilateral cleft lip and palate patients at different mini-implant placement sites on CBCT images, using i-CAT software.
2. To evaluate maxillary bone thickness and density in normal patients at different mini-implant placement sites on CBCT images, using i-CAT software.
3. To compare maxillary bone thickness and density of surgically repaired unilateral cleft lip and palate patients, bilateral cleft lip and palate patients with normal patients at different mini-implant placement sites on CBCT images, using i-CAT software

REVIEW OF LITERATURE

Singh M, Jawadi MH, Arya LS and Fatima 1982[23] have done a prospective study of 5276 consecutive liveborn babies, among them 291(5.5%) infants were diagnosed to have congenital malformations.They analysed that the musculoskeletal defects accounted for 41.7% of major anomalies.They also observed that the among various individual anomalies, congenital dislocation of hips, cleft lip and palate , microcephaly, club feet, polydactyly,Down syndrome and asymmetric crying facies had a frequency greater than 1 per 1000 livebirths.

Holmes .D.C et al, 1997[24] examined the influence of bone quality on the transmission of occlusal forces for endosseous dental implants.The study modeled a 3.75 ×10 mm threaded implant placed in a 12×11×8 mm section of bone and employed the finite element method.They evaluated the correlation of displacement of the implant system and the magnitude of the stress distribution in the bone(r=0.997).They predicted the implant placement in bone with greater thickness of the cortical shell and greater density of the core resulted in less microenvironment and reduced stress concentration and increases the stabilization and tissue integration.

Schlegel K.A, Kinner .F and Schlegel K.D, 2002[25] estimated that the amount of bone base is important for successful implant osseointegration. Anatomic data characterized the clinical importance of palatal midline region, trephine bur biopsies provided the material for histologic facings. An osseointegration was more favorable to the interconnecting line of first premolrs in the posterior region because anterior suture palatina mediana is less ossified than the posterior region.

Quirynen M, et al, 2003[26] compared the periodontal health as well as microbial parameters between cleft and non-cleft region.They have taken 75 patients between the age group of 8 and 20 years with unilateral cleft lip and palate and four regions of interest was selected for split mouth comparision.The area of interest are: teeth neighbouring cleft,t ooth in cleft and the corresponding contra-lateral teeth, respectively.in the unaffected quadrants.They have recorded plaque and gingival indices, pocket depth, attachment loss, bleeding on probing, tooth mobility, radiographic bone loss and gingival width at all the sites.They obtained that the difference between the teeth adjacent to cleft and the corresponding contral lateral opponents were of borderline significance($p<or=0.05$) for plaque index,the approximal probind depth and the

attachment loss.In case of tooth in the cleft was compared to the contra-lateral tooth ,the attachment loss and bone loss were significantly higher for the tooth in the cleft.They concluded that the data indicated the periodontium in unilateral cleft palate patients can cope well with a long term orthodontic treatment, even in unfavourable conditions.

Costa .A, Pasta .G and Bergamaschi .G, 2004[27] evaluated an ideal sites for the placement of TAD. They quantified bone depth by measuring volumetric computed tomography of 20 patients and quantified mucosal depth by a needle with a rubber stop.The result suggested that the bone thickness will allow 10 mm in length of temporary anchorage devices in the symphysis, retromolar and palatal premaxillary region. The length of temporary anchorage devices in the incisive fossa (in the upper and lower canine fossae) ranges from 6 to 8 mm.The result suggested while placing TAD in mobile alveolar mucosa ,transmucosal attachment is required to traverse the thickness of the soft tissue.

Kim H.J et al, 2006[28] evaluated the thickness of the soft tissue and the cortical bone for better placement of miniscrew. They have taken 23 Korean specimens of 3 maxillary midpalatal suture areas and divided into 3 groups, where group 1 included the interdental area between the first and second premolars, group 2 included the interdental area between the second and the first molar and group 3 included the interdental area between the first and second molars. They found that the buccal cortical bone thickness was closest to and farthest from the cementoenamel junction and thinnest in the middle in groups 1 and 2. The thickness of of palatal cortical bone was thickest 6mm apical to the cementoenamel junction in groups 1 and 3 and 2 mm apical to the cementoenamel junction in group 2.The miniscrew implant placement requires consideration of the placement site and angle based on anatomical characteristics for orthodontic anchorage.

Deguchi .T et al, 2006[29] studied the quantitative evaluation of cortical bone thickness with computed tomographic scanning for orthodontic implants at various locations in the maxilla and the mandible. They have taken 3-D computed tomographic images of 10 patients and thickness of cortical bone were measured in the buccal and lingual regions mesial and distal to the first molar, distal to the second molar and in the premaxillary region at two different levels. They have also measured the thickness of cortical bone at three differnt angles (30 degrees, 45 degrees and 90 degrees) and distances of the intercortical bone surface to the root surface and the root proximity were also measured. They observed significanlty less thickness of cortical bone at the

buccal region distal to the second molar in comparison of other maxillary region. The thickness of cortical bone was approximately 1.5 times at 30 degrees compared with 90 degrees. The distance from the intercortical bone surface to the root surface was significantly more at the lingual region than at the buccal region mesial to the first molar. The safest location for the placement of miniscrews ,might be mesial or distal to the first molar and optimum size of miniscrew can be approximately 1.5 mm in diameter and approximately 6 to 8 mm in length.

Kang et al ,2007[30] conducted a study to assess **the thickness of bone in a palatal region** to provide more reliable guide for the placement of mini-implant. They have taken computed tomographic images of 18 adult patients to measure thickness of bone in mid-palatal area and its vicinity posterior to incisive foramen. At regular mediolateral and anteroposterior intervals along the midpalatal suture, bone thickness was measured at 80 cooordinates. They found significant difference between male and female groups and the thickest bone available in the whole palate was the midpalatal area within 1mm of the midsagittal suture.

Chunlei X, Xianglong Z, Xing W (2007)[31]evaluated the effectiveness of miniscrew anchorage for intrusion of the posterior dentoalveolar region to correct skeletal open bite. They have taken 12 patients with class II skeletal pattern and excessive posterior growth. They used self drilling miniscrew implants, which were inserted into the posterior midpalatal area and the buccal alveolar bone between the lower molars. They applied force of 150 g to the miniscrews in each side for the intrusion of posterior teeth. Lateral cephalograms of 12 patients were taken before intrusion and immediately after intrusion, then they were measured and compared. They found out that the maxillary and mandibular first molars were intruded (1.8mm, $P<0.001$ and 1.2mm,$p<0.001$ respectively) and mandibular plane was also reduced allowing the counterclockwise rotation of mandible. They concluded that the miniscrew anchorage is minimal invasive, requires minimal patient cooperation and is being advantageous as a simple procedure.

Kravitz.N.D et al, 2007[32] evaluated complications of miniscrew placement and after orthodontic loading that affects the stability and safety of patients for optimal patients safety and success of miniscrew placement ,a thorough understanding of proper placement technique, bone density and landscape, peri-implant soft tissue, regional anatomic structures and patient home

care was taken into consideration. They reviewed the potential risk and complications of miniscrew placement in respect to insertion, orthodontic loading, peri-implant soft-tissue health and removal of miniscrew.

Aljohar.A, Ravichandran.K, and Subhani. S, 2008[34] have done a retrospective study.They have taken 807 cases of cleft lip/palate patients retrospectively from tertiary care hospital and were registered from june 1999 to December 2005.
They have divided 807 subjects into 451 boys and 356 girls.Among them 387 Cleft lip and palate was more common than isolated cleft palate (294) and isolated cleft lip (122).They also noticed boys have predominated in cleft lip and palate and cleft lip whereas girls predominated in isolated cleft palate, with boy to girl ratios of 1.6:1, 1.2:1, and 0.9:1 for cleft lip and/or palate, isolated cleft lip, and isolated cleft palate, respectively. The Riyadh region had more cases (32.0%) than the Asir (15.6%) and Eastern (14.6%) regions.They have noticed positive family history of cleft was seen in 224 cases out of which 238 cases were associated with anomalies and among them 91 had congenital heart disease.They also observed 40.5% children with isolated cleft palate patients were associated with anomalies, whereas only 23.0% of the children with isolated cleft lip or cleft lip and palate had associated malformations.They concluded that the pattern of cleft does not differ significantly from those reported in the literature for Arab populations.

Gracco .A et al, 2008[34] evaluated the 3- dimensional thickness of the palate for the determination of the location of miniscrew placement. They selected digital volumetric tomography of 162 healthy subjects and divided into 3 groups where group A included 52 subjects(ages =10-15 years, 25 boys, 24 girls); group B included 38 subjects(ages =15-20 years,18 males and 20 females) and group C has 72 subjects(age=20-40 years, 34 males and 38 women).They reconstructed 90ºparacoronal views of palatal region at 4, 8,16 and 24 mm posterior to the incisive foramen and bone height was measured laterally from the midline in each reconstruction at 0, 3and 6 mm increments. They concluded that thickest part of the palate was in the anterior region and bone thickness in the posterior region was also suitable for the placement of miniscrews as well.

Ono.A, Motoyoshi and Shimizu.N, 2008[15]investigated the cortical bone thickness in the buccal posterior region mesial and distal to the first molar for the adequate placement of mini-

implants and determined the difference according to locations, age and sex. They have selected computer tomographic images of 43 patients with the mini-implants placed in the posterior region of buccal alveolar bone. The result of study was suggested that the cortical bone thickness reanged from 1.09 to 2.12 mm in the maxilla and 1.59 to 3.03 mm in the mandible, which was measured from 1 to 15 mm below the alveolar crest of bone. They found that the cortical bone was thinner in females than in males, mesial to the first molar in the region of attached gingival of the maxilla.

Wehrbein .H, 2008[35] quantitatively assessed the bone quality of the palatal bone from an implantologic standpoint. The palatal tissue blocks of autopsy material taken from 22 subjects , between the age of 18 and 63 years of age. For the placement of temporary anchorage device, 3 mm bilaterally to the midline in the different parts of palate were assessed with respect to hard tissue to total bone volume. They concluded that the hard tissue fraction in the anterior part of median palate, median part of median palate and posterior part of median palate in younger and older adults is relatively, which good for the stability of TAD.

Baumgaertel.S and Hans M.G (2009) [36]evaluated thickness of bone from CBCT scans of 30 dry skulls.He measured cortical bone thickness at 2, 4 and 6 mm from the alveolar crest. Interclass correlation and analysis of variance (ANOVA) was used to obtain the differences in cortical bone thickness. Theye concluded that the interdental buccal cortical bone thickness varies in the jaws.They found that the buccal cortical thickness increases with increasing distance from the alveolar crest in the mandible and in the maxillary anterior sextant and it varies in maxillary buccal sextants,which was thinnest at the 4mm level.

Motoyoshi M, Inaba M, Ono A,Ueno S,Shimizu N,2009[37] evaluated cortical bone thickness at mini implant placement sites in 65 orthodontic patients and was found to be directly proportional to the success rate of mini-implant.Cortical bone thickness influenced the stresses in the cancellous bone resorption but could not directly influence the stresses in the cortical bone.They observed cortical bone thickness <1mm,the cancellous bone models exhibited von Mises stresses exceeding 6 MPa and the cortical bone models without cancellous bone showed von Mises stresses exceeding 28 MPa, greater cortical bone thickness values were associated with higher mini-implant success rates.

Schneiderman.E.D, Xu.H, Salyer.K.E,2009[38] done preliminary study in which they outlined the new set of 18 CBCT measurements and apply them on 6 patients with unilateral cleft lip and palate patients and were compared with 7 normal subjects.The mean interrater reliability of 0.95 and ranged from 0.40 to 2.23 for individual measurements for 18 measurements were taken.They found that there was significant differences in palatal length, anterior palatal thickness,overall sagittal maxillary length and premaxillary height among unilateral cleft lip and palate patients and the control group(Mann-Whitney Utest,P <or = 0.037).

Fayed MMS *et al* (2010)[19] evaluated optimal sites for orthodontic mini implant placement assessed by cone beam-computed tomography, in 100 patients (46 males,54 females)and divided into two age groups(13-18 years)and(19-27 years).They found out the males and the older age group(more than 18 years) had significantly higher buccolingual, buccal and palatal cortical thickness at specific sites and levels in the maxilla and mandible.This study suggest that the optimal site for mini-implant placement in the anterior region was between the central and lateral incisors in the maxilla and between the lateral incisor and the canine in the mandible at the 6mm level from the CEJ. The optimal sites were between the second premolar and the first molar and between the first and second molars at the buccal aspect of the posterior region of both the jaws. At the palatal aspect, the optimal site was between the first and second premolars that had the highest cortical bone thickness.

Moon. S.H et al,2010[39] evaluated **palatal bone density** for the better selection of anchorage sites.They have taken computed tomographic images of 15 adult subjects(betweeen age range of 23-35 years).At regular mediolateral and anteroposterior intervals along the the midpalatal suture,80 coordinates were measured. There result suggested that there was significant difference between male and female groups and the palatal bone in the midpalatal area within 3mm of the midsagittal suture was densest bone in the entire palate.

Fransworth .D et al, 2011[40] assessed age , sex and regional differences in the cortical bone thickness which are commonly used in maxillary and mandibular miniscrew implant placement sites. They have taken cone beam computed tomography CBCT images of 52 patients, including

26 adolescents (13 girls, ages 11-13; 13 boys, ages 14-16) and 26 adults(13 men and 13 women, ages 20-45).They imported CBCT data in 3- dimensional software(version 10.5, Dolphin Imaging Systems,Chtsworth, Calif) measured the thickness of cortical bone at 16 sites representing the following regions: 3 paramedian palate sites, 1 infrazygomatic crest sites, 4 buccal interradicular sites of the mandible and 4 buccal and 4 lingual interradicular sites in the maxilla.It was found that the cortical bone was thicker in the posterior than in the anterior mandibular sites. The thickness of anterior paramedian palatal bone was significantly thicker than the posterior region of bone.The miniscrew implant placement sites are thicker in maxillary and mandibular cortical bones in adult patients.

Ludwig.B et al, 2011[41] evaluated that the anterior palate is considered to be best sites for mini-screw placement as cortical bone is thicker in the palatal region than at buccal interradicular area. According to them the treatment mechanics can be designed in any direction and can be changed during midtreatment while using the same anchorage set up. The palatal bone between the roots of second premolar and first molar is considered to be an alternative miniscrew location, with some limitations

Ryu .J.H et al, 2012[42] compared the thickness of palatal bone in early and late mixed and early permanent dentitions, according to dental age. They have selected CBCT scans of 118 subjects and divided into 38 early mixed, 40 late mixed and 40 permanent dentition subjects. They have taken measurements of 49 sites from palatal bone thickness by using in Vivo Dental 5.0 software. They have concluded that the thickness of palatal bone was lower in the early mixed dentition group than in both the late mixed and permanent dentition groups. Hence, this study was successfully useful for temporary anchorage device in the palatal region.

Garib.D.G, Yatabe.M.S, Ozawa.T.O,O.G.S Filho, 2012[11] evaluated alveolar bone thickness and level of alveolar bone around the teeth adjacent to the cleft by the help of CBCT images of patients with complete biltaeral cleft lip and palate prior to bone graft surgery and orthodontic intervention.They have taken sample of 10 patients having complete bilateral cleft lip and palate patients in mixed dentition with the mean age of 9.5 years. An axial section using **iCAT Xoran**

system was taken for the assessment of alveolar bone thickness surrounding the maxillary incisors and the maxillary canines. They evaluated thin alveolar bone plate around teeth adjacent to cleft and there was slight increase in distance between the alveolar bone crest and CEJ in the mesial and lingual aspects of canines adjacent to cleft.

Alsamak .S et al, 2013[43] investigated the potential sites for the insertion of the orthodontic mini-implants through a systematic review of studies by using computer tomography or cone beam computed tomography and assessed anatomical hard tissue parameters such as bone thickness and bone density. They concluded that the most favourable area for the mini-implant placement was in the anterior maxilla and mandible is between the canine and the first premolar. The most favourable area in the maxillary buccal region were found between the lateral incisor and the canine, while in the maxillary palatal area, it is between the central incisors or between the lateral incisor and the canine.

Sawada .K et al, 2013[44] evaluated the cortical bone thickness and proximity of root at maxillary interradicular sites for the mini implant placement in the maxillary alveolar process. They have taken 80 maxillae (right and left sides) of 40 Japanese adult skulls and measured by using a micro CT system. Buccal and palatal interradicular cortical bone thickness, alveolar width and proximity of root were measured from distal of central incisor to mesial of second molar at six interradicular sites. The buccal interradicular cortical bone thickness was greatest between canine and first premolar or between first premolar and second premolar and palatal interradicular cortical bone thickness was greater than the buccal region. The proximity of root between second premolar and first molar or first premolar and second premolar was the widest and was narrowest between central incisor and lateral incisor.

Zhao H *et al* (2013)[31] investigated the thickness of cortical bone at the inter-dental area of both jaws for orthodontic mini screw placement. The cone-beam computerized tomography (CBCT) images of 32 non-orthodontic adults with normal occlusion were taken to measure the cortical bone thickness in both the jaws. One-way analysis of variance was used to analyze the differences in cortical bone thickness. They found that the buccal cortical bone in the mandible was thicker than that in the maxilla. In the maxilla, cortical bone thickness was thicker in the buccal side than in the palatal side. Buccal cortical bone thickness in the mandible was thickest at the site distal to the first molar. In the maxilla, it was thickest at the site mesial to the first

molar, while in the palatal side of maxilla it was thickest at the site mesial to the second premolar. Hence, they concluded the changing pattern of cortical bone thickness varies at different sites.

Cassetta M, Sofen A.A.A, Altieri. F and Barbato.E (2013)[12] studied the difference in alveolar cortical bone thickness and density between interradicular sites at different levels from the alveolar crest and assessed the differences between adolescents (12-18 years of age) and adults (19-50 years of age). The result of this study showed that there was difference in thickness and density of alveolar cortical bone between male and female, adolescents and adults, upper and lower arch, anterior and posterior area of the jaws, between buccal and oral side and from crest to base of alveolar crest. They found out that the posterior region of both the jaws had higher values of thickness and density of alveolar cortical bone.
molar.

Ozdemir F, Tozlu M and Cakan D.G , (2014)[45] evaluated the cortical bone densities of the maxillary and mandibular alveolar processes in adults with different vertical facial profile using cone-beam computed tomography (CBCT) images. CBCT images of 142 adult patients with age of 20–45 years were taken and classified into hypodivergent, normodivergent and hyperdivergent groups on the basis of linear and angular S-N/Go-Me measurements. The cortical bone densities from distal aspect of the canine to the mesial aspect of the second molar at maxillary and mandibular inter dental sites were measured by the CBCT images. Female subjects in the hyperdivergent group showed significantly decreased bone density on the maxillary buccal side, while in male subjects in the hyperdivergent group displayed significantly decreased bone density on the posterior region. Furthermore, the hyperdivergent group showed significantly lower bone densities on the mandibular buccal side than hypodivergent subjects. The maxillary palatal bone density did not differ significantly among the selected groups, but female subjects showed significantly denser palatal cortical bone. Conclusion was inferred that, buccal cortical bone was denser posteriorly where as the palatal cortical bone was denser anteriorly.

Suomalainen A,Aberg T, Rautio J,Hurmerinta K(2014)[17] have done study to quantify the treatment outcome of secondary alveolar bone grafting(SABG)in 36 patients with unilateral cleft lip and palate using CBCT and to reveal the needs for improvement in surgical technique. CBCT images were obtained after 6 months of SABG.The height of the nasal floor was compared with

the unaffected site and the inter and the intraexaminer reproducibility of these evaluations was assessed.Their result showed the deficiency of the bone graft in apical and palatal areas of the defect and also asymmetry of the nasal floor was observed.They also recommended careful insertion of the bone graft towards the palatal and apical direction of the cleft.

Hourfar . J et al , 2015[46] measured vertical bone thickness on the hard palate for the adequate placement of mini-implants. They have taken 125 records of cone beam computed tomography (CBCT) scan and taken bone measurements at a 90º angle to the bone surface, on 28 predetermined and standardized points on the hard palate. They have found that the bone thickness was highest in the anterior palate ,corresponding to the region of the third palatal ruga and was decreasing significantly towards more posterior areas. Hence,they provide stable and clinically identifiable landmarks for the placement of mini-implant in the hard palate.

Ercan.E, Celikoglu.M, Buyuk S.K and Sekerci.A.E[10]**, 2015** assessed the bone support of the teeth adjacent to a cleft by using CBCT. They have taken CBCT scans of 31unilateral cleft lip and palate patients and were compared with those of contralateral noncleft teeth. For every tooth, the distance between the cementoenamel junction and the bone crest at the buccal side was measured at 0,1,2 and 4mm.They found that the thickness of bone of the central teeth at the cleft region at the crest and 2mm apically were significantly thinner than that of the central incisor at a non-cleft region. Hence, they concluded that patients with unilateral cleft lip and palate patients have reduced bone support at the teeth neighboring the cleft as compared to control group and this may cause some problems during orthodontic intervention.

Yang et al (2015)[47] conducted a study to propose a protocol for safe bicortical placement of mini-implants by measuring the interradicular spaces of the maxillary teeth and the bone quality. Cone-beam computed tomography data of 50 adults were taken. and measurements were made with SimplantPro software (Materialise, Leuven, Belgium).Bone thicknesses and interradicular distances at the planes 1.5, 3, 6, and 9 mm above the cementoenamel junction were measured. The safest interradicular

sites in the maxilla for bicortical placement of 1.5-mm-diameter mini-implants were in all planes between the first and second premolars, and between the second premolar and the first molar. He found that the safe palatal sites were between the first and second molars, and the safe labial sites of the 9-mm plane were between the central incisors, and between the lateral incisor and the canine. He also found that the safe buccal sites of the 6 and 9 mm planes were between the first

and second molars, and the safe buccal sites of the 3, 6, and 9 mm planes were between the canine and the first premolar. He concluded that cortical placement would be more stable in the maxilla. For the site between the molars, precaution should be taken at a plane higher than 6 mm to prevent maxillary sinus penetration and the most favorable interradicular area in the maxilla was between the second premolar and the first molar.

Uday NM *et al* (2016)[48] evaluated the bucco-lingual cortical bone thickness for appropriate location of implant on buccal and palatal sides in maxilla and on buccal side of mandible in 20 patients with the help of CBCT. In Group1, 10 patients of 13-17 years of age and in Group II 10 patients of 18-35years of age were taken. CBCT scans of patients were taken into 3D software for analysis. Higher cortical bone thickness was seen in adult mandibular buccal cortex region between 1st and 2nd molar and at 10 mm from CEJ, followed by maxillary buccal region and maxillary palatal region which increases from anterior to posterior sites. Maxilla along the palatal surface showed decreasing thickness from anterior towards posterior region, also the thickness decreases with increase in the distance apically. Highest reading was found in the premolar-molar site at 6mm with a mean value of 0.95mm.

Akhoon AB and Mushtaq M (2017)[49] evaluated the most suitable region of the palate for the insertion of miniscrews. Four different paracoronal sections of Digital Volumetric Tomographies of 23 patients with ages ranging between 14 and 42 years were evaluated. Thickness of the palatine bone in 20 different sites was measured. The height of the palatal bone at 0, 3 and 6 mm increments laterally from the midline was measured. The results indicated that the thickest part of the palate was found 6 mm to the left and right of the suture in the anterior part of the palate, 4 mm from the incisal foramen. In the other paracoronal sections, the thickness tend to show decrease progressively, but the highest values were always found agnate to suture. Therefore, they concluded that the thickest part of the palate was the anterior region. Although the bone was slender in the posterior region of the palate, it was also suitable for the insertion of miniscrew

Ghoneima.A, Allam.E, Kula .K,2017[16] compared the alveolar bone thickness around the teeth adjacent to the cleft using CBCT in cleft patients who have undergone primary alveolar grafting and were compared with cleft lip and palate patients waiting for secondary bone grafting and they also determined the associations with factors such as;age ,sex and type of cleft. They have taken CBCT images of 39 cleft lip and palate patients. Measurements of bone thickness was done on axial sections of each subject at 3,6 and 9mm apical to CEJ along the root length of

tooth adjacent to cleft. They have found no statistically significant associations of the factors with mesial and distal bone measurements.There was greater buccal bone thickness at 9mm in the primary alveolar graft subjects as compared to secondary bone graft. They also observed that there was greater buccal bone thickness at the level 9mm in unilateral cleft patients as compared to bilateral cleft subjects. They concluded that primary alveolar bone graft does not provide benefit to the bone width of the tooth adjacent to cleft sides as compared to children with cleft who have not undergone alveolar grafts.

Kati.F.A, 2018[5] explained in his review article clefting may involve lip only, lip and palate and palate only. He also explained that cleft lip and palate patients are affected by environmental (such as smoking, alcohol, poor nutrition) and genetic factors (such as familial factors and chromosomes). He reviewed that the treatment of clefting involves a number of specialists who decide the best treatment plan
depending on the site of defect and age of the infant.

Yadav et al 2018[50] compared the palate bone thickness and palatal bone density in the anterior, middle and posterior part of the palate in males and females.They reviewed CBCT scans of 359 patients.They have taken measurement between canine and first premolar,the first premolar and second premolar ,the second premolar and the first molar and the first molar and second molar.At the centre of palate and 4mm away from the centre another measurement were taken.They used ANOVA to analyze the palatal bone thickness and palatal bone density in different areas between 4 different groups.They concluded that the males have significantly higher palatal bone thickness than the females.

Suttapeyasri .S, Suapear .P and Narit .L(2018)[51] evaluated the accuracy of CBCT for determining cortical thickness and its correlation with micro-computed tomography(CT)and histologic analysis.They have taken 62 samples from 4 anatomic regions of the jaw were analyzed and radiographic stent was used during CBCT and bone sample harvesting.They concluded that CBCT is highly accurate in linear measurements and demonstrated correlation with genuine bone density.

Parveen S *et al* (2018)[3] conducted a retrospective study to evaluate 3-Dimensional assessment of alveolar bone thickness in individuals with non syndromic unilateral complete cleft lip and palate (NSUCCLP).They have taken 16 samples of NSUCCLP ,who have not undergone secondary bone grafting or orthodontic intervention. Alveolar bone thickness of the teeth anterior and posterior to the cleft side in the buccal, lingual, mesial and distal at 3mm, 6mm and 1mm below the apex from the CEJ was measured using Dolphin 3D software. The result of this study showed that the buccal alveolar bone for the teeth anterior to the cleft was 3mm thinner when compared to the non-cleft site. Palatal bone was the thickest of at 1mm below the apex and the mesial/distal alveolar bone on the cleft was also very thin. Towards the apex, the thickness of alveolar bone plates increases and was highest at the region 1mm prior to the apex. Hence, they concluded that the alveolar bone around the teeth adjacent to the cleft site is thinner than non-cleft site.

Moscarino.S et al , 2019[52] evaluated palatal vertical bone thickness and density in relation to soft tissue on the hard palate for the better placement of mini-implants in cleft palate patients. They have taken CBCT images of 60 patients with isolate right side cleft palate formation (n=20;6 females;14 males), left side cleft palate formation(n=20;9 females; 11 males) and without cleft formation as control group(n=20;15 females; 5 males).They have taken bone and soft tissue measurements vertically at a 90º angle to the bone surface of the hard palate. The result obtained was the highest thickness of bone was found in the anterior palate region in the control group. In case of cleft palate patients, the highest vertical bone level was found opposite to the cleft side of the patient.

Pan C.Y et al (2019)[7] evaluated effects of cortical bone thickness and trabecular bone density on primary stability of mini-implants.They have taken 3 synthetic cortical shells(thicknesses of 1,2 and 3mm) and three polyurethane foam blocks (densities of 40,20 and 10 pound/cubic foot) were used to represent jawbones of varying thicknesses and varying trabecular bone densities, 25 stainless steel OMIs(2×10 mm) were sequentially inserted into artificial bone blocks.They have divided into each 5 experimental groups of bone block and were examined by Implomates RF analyzer.They concluded that the stability of an OMI at the time of placement is influenced by both cortical bone thickness and trabecular bone density.They stated that both cortical bone thickness and trabecular bone density have strong linear correlations with resonance frequency.

Dharmadeep.G et al, 2020[53] evaluated interradicular areas and the thickness of cortical bone for the placement of miniscrew implant by using CBCT. CBCT images of 20 patients were taken and divided into three planes as axial, coronal and sagittal. They have taken measurements of mesiodistal distance and thickness of buccal cortical bone at five different heights from the cementoenamel junction towards the apical region. The safer sites for miniscrew placement in the maxilla, were between the second premolar and first molar at 10 mm height; whereas in the mandible safer sites were between first and second premolar at 6, 8 and 10 mm height; between the second premolar and first molar at 10 mm height and between first and second molar at 8 and 10 mm height.

Tepedino.M et al, 2020[54] investigated the available evidence in relation to the presence of sufficient interradicular space and adeuqate cortical bone thickness in patients with complete permanent dentition , in the vestibular and palatal or lingual interradicular sites (mesial to the second molar), by using 3-dimensional data sets. They included qualitative synthesis of 27 observational articles , out of which 11 articles were at lower risk of bias and 15 articles were included in the meta-analysis. The most suitable insertion sites for the mini implant placement in the maxillary region are from mesial to the first molar to distal to the first pemolar and between the canine and the lateral incisor, at the level of 6 mm from the cementoenamel junction as there was presence of adeuqate cortical bone thickness in those regions

MATERIALS AND METHODOLOGY

Materials:

This study was conducted at Babu Banarasi Das College of Dental Sciences, BBDU Lucknow, aimed for the assessment of maxillary bone thickness and density in surgically repaired cleft lip and palate patients at different sites for mini-implant placement on CBCT images using i-CAT software

Sample for this study was comprised of CBCT images of 45 subjects, of which 15 subjects were unilateral cleft lip and palate patients (surgically repaired) and 15 were bilateral cleft lip and palate (surgically repaired) and remaining 15 were normal subjects.

CBCT images of normal and surgically repaired unilateral and bilateral cleft lip and palate patients used in the study were obtained from the record file used in the previous studies done in the Department of Orthodontics and Dentofacial Orthopaedics BBDCODS, BBDU; Lucknow. CBCT images of surgically repaired cleft lip and palate patients were also taken from various Smile Train Centers of Lucknow. The approval from the Ethical and Research Committee of Babu Banarasi Das College of Dental Sciences was taken prior to start of study. A signed informed consent as per the guidelines of University was also taken from the patients.

Criteria for sample selection:

Inclusion criteria*:*

1. Non-syndromic surgically repaired unilateral and bilateral cleft lip and palate patients- study group.
2. Patients with healthy alveolar and palatal bone and periodontium (for control group).
3. Age of patients between 10-20 yrs.

Exclusion criteria:

1. Patients with hormonal and metabolic bone disorders.
2. Patients with bone pathology and on bisphosphonates medications or bone altering medications.
3. Severe facial or dental asymmetries.
4. Patients with severe crowding and spacing in the teeth.
5. Patients undergone earlier orthodontic treatment.

Materials used in this study were-

1) CBCT images of cleft lip and palate patients (surgically repaired, both unilateral and bilateral cleft lip and palate patients) and normal patients (control group) were taken.
2) i-CAT software for measurements on CBCT images.

CBCT machine

The machine used for obtaining CBCT image was i-cat Gendex CB500 **(Figure-1).** The field of view of the machine **i-cat Gendex** CB 500 was 14 × 8.5 cm, where the X-ray source current was between 10 to 15 ampere and voltage was recorded was 120 Kv and the duration of scan was 12.5 seconds with pulses exposure for the reduction of radiation.

Figure 1: CBCTmachine- i- cat Gendex CB500

Specification of CBCT Machine:

Scanning time	:	23 seconds
Tube voltage	:	250 KV
Exposure time	:	12.5 seconds
Voxel size	:	0.2 voxel
Field of view	:	8.5 cm x 8.5 cm
X-ray source current	:	10- 15 Ampere
Focal spot	:	0.5
Voltage wave safe	:	Constant potential
Tube current	:	327 Ma
Gray scale	:	14 bit
Reconstruction	:	23 seconds

Software for evaluation

i-cat software ,version 1.9.3.13 was used for the measurement of bone thickness and bone density.

Methodology:

Sample were divided into three groups, where **Group I** consisted of 15 **unilatera**l **cleft lip and palate patients (surgically repaired)** with mean age of 18 years and 2 months, **Group II** consisted of 15 **bilateral cleft lip and palate patients (surgically repaired)** with the mean age of 17 years and 1 month and **Group III**- consisted of 15 **normal patients** with the mean age of 18 years and 3 months.

For the convenient of evaluation and comparison of maxillary bone thickness and density, each group was further divided into various subgroups:

1. Subgroup a - buccolingual maxillary bone thickness at 2 mm height from the alveolar crest
2. Subgroup b – buccolingual maxillary bone thickness at 4 mm height from the alveolar crest
3. Subgroup c - buccolingual maxillary bone thickness at 6 mm height from the alveolar crest

4. Subgroup d - buccolingual maxillary bone thickness at 8 mm height from the alveolar crest
5. Subgroup e – palatal bone thickness at 3mm adjacent to midpalatal suture , 6mm behind incisive foramen
6. Subgroup f - palatal bone thickness at 3mm adjacent to midpalatal suture in the area between second premolar and first molar

Transfer of data:

CBCT scan of all the subject were taken in standing position with natural head position (Frankfort horizontal plane being parallel to the floor), with maximum intercuspal occlusion and with a relaxed tongue and passive lips posture and also instructed the patient not to move their heads or tongue. Immobilization of head has been achieved by the use of bite fork and restrainer. The thickness of slice in each plane (sagittal, coronal and axial) was 0.03 mm

The data obtained by CBCT scan was converted into the Digital Imaging and Communications in Medicine (DICOM) file format for further analysis with the i-CAT software.

Orientation of CBCT scans

Before measurements of maxillary bone thickness at different sites, DICOM file of CBCT images and were oriented as follows:

- Sagittal plane was adjusted to locate the interradicular area of interest, and
- Axial plane was oriented at different height (2, 4, 6 and 8mm) from the alveolar crest.
- Coronal plane was adjusted for the palatal region (3mm adjacent to mid-palatal suture).

Evaluation of maxillary bone thickness and density:

Bone thickness and density was measured from CBCT scan by importing the DICOM files into i-cat software. By using the software, 2-dimensional slices of 0.3mm thickness through each contact area was obtained. Left side of scan was selected for the evaluation of buccu-lingual bone thickness and density at different mini-implant placement sites i. e. at 2mm, 4mm, 6mm and 8mm height from the alveolar crest.

All the measurements were done on the computer screen in a DICOM file with the help of software measuring tool. CBCT scan were caliberated and measured for the bone quantity in the interradicular area between central incisors, between lateral incisors and canine, between first and second premolars and between second and first molars, at 2mm, 4mm, 6mm and 8mm from the alveolar crestal bone.

In palatal region, bone thickness and density were also measured at 3mm adjacent to mid-palatal suture, 6mm behind the incisive foramen and in the region between second premolar and first molar.

Method for the evaluation of buccolingual bone thickness and density

Before proceeding for the measurement, each slice was oriented in different plane of space. The sagittal slice was selected to locate the area of interest in the interradicular area. The slice was oriented so that vertical reference line bisects the interradicular space and should be parallel to the long axis of the tooth.

The axial slice was used to ensure that the four horizontal reference lines are at 2mm, 4mm, 6mm and 8mm from the alveolar crest in buccal and palatal region. A perpendicular line was taken from the crestal level of bone, interdentally and subsequently moving superiorly at every 2mm, measurements of buccolingual bone thickness and density were recorded. The buccolingual thickness was measured from the outermost point on the buccal cortical bone to the outermost point on the palatal/ lingual side of the bone, measured at 2mm, 4mm, 6mm and 8mm from the alveolar crest in the interradicular areas. The millimetric ruler was provided by the i-CAT software for measuring the distances from the alveolar crest. The line joining buccal and palatal points used for measuring the bone thickness was again selected for the measurement of density of bone in the interradicular areas.

Bone density was measured in Hounsfield units (HU), which was directly associated with tissue attenuation coefficients. An area of $1mm^2$ was selected for the measurement of the density of alveolar bone. Hounsfield unit (HU) equivalent pixel intensity value scale in the software was used for the measurement of bone density.

By this method measurement of buccolingual bone thickness and density between central incisors **(Figure-2),** between lateral incisor and canine **(Figure-3),** between 1^{st} premolars and 2^{nd} premolar **(Figure-4)** and between 2^{nd} premolar and 1^{st} molar **(Figure-5)** was done in the interradicular area at 2, 4, 6and 8mm from the alveolar crest

Figure 2: Images showing measurement of buccolingual bone thickness and density between central incisors in the interradicular area at 2, 4, 6and 8mm from the alveolar crest (axial slice on the right and sagittal slice on the left measuring buccolingual bone thickness at 4mm from the alveolar crest)

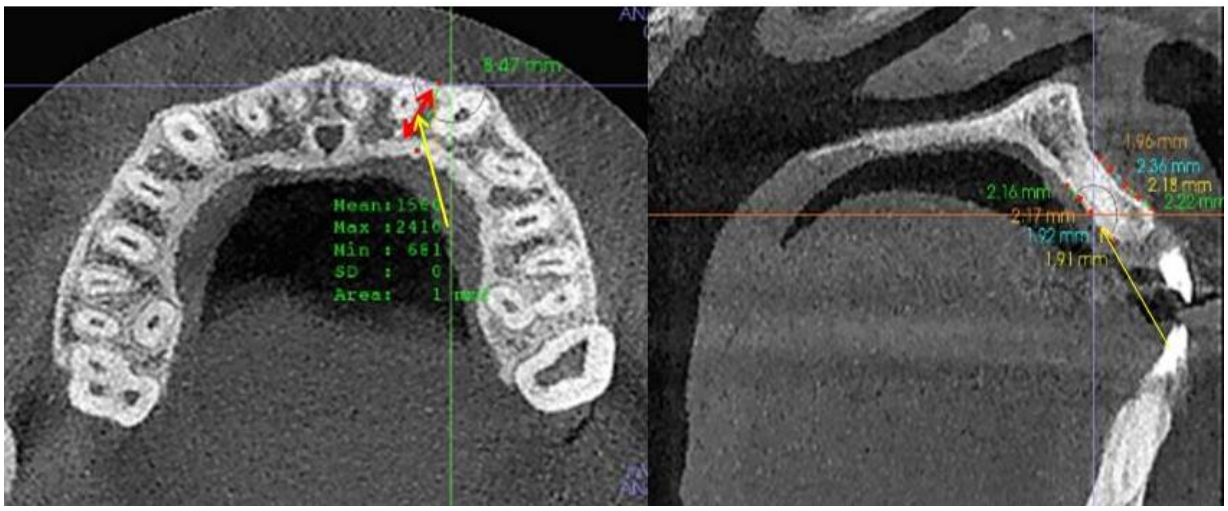

Figure 3: Images showing measurement of buccolingual bone thickness and density between lateral incisor and canine in the interradicular area at 2, 4, 6and 8mm from the alveolar crest (axial slice on right and sagittal slice on left measuring buccolingual thickness and density at 4mm from the alveolar crest)

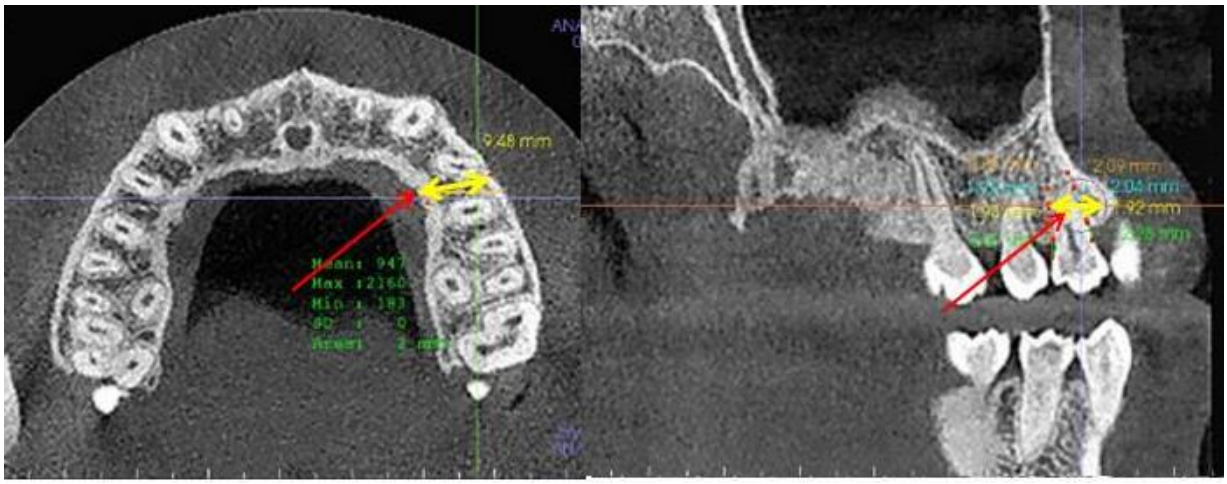

Figure 4: Images showing measurement of buccolingual bone thickness and density between first premolars and second premolars in the interradicular area at 2, 4, 6and 8mm from the alveolar crest (axial slice on the right and sagittal slice on the left measuring buccolingual thickness and density at 4mm from the alveolar crest)

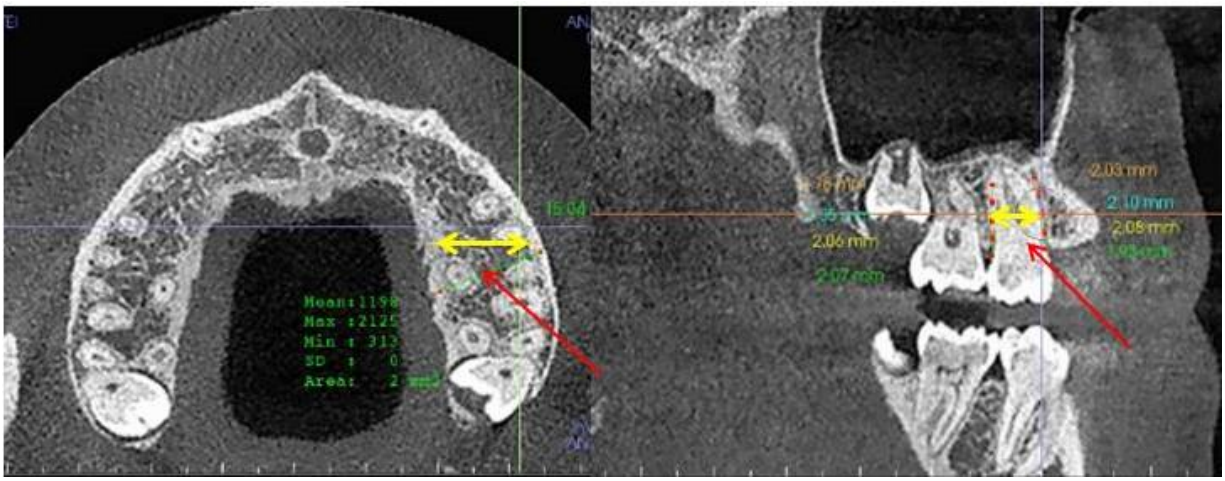

Figure 5: Images showing measurement of buccolingual bone thickness and density between second premolars and first molars in the interradicular area at 2, 4, 6and 8mm from the alveolar crest (axial slice on right and sagittal slice on left measuring buccolingual bone thickness and density at 4mm from the alveolar crest)

Evaluation of bone thickness and density in the midpalatal region:

For the measurements of palatal bone thickness and density, all the reconstructed images were oriented in the standardized position and followed by the location of incisive foramen. A reference line was constructed by taking incisive foramen as a standardized landmark for locating the center of the palate. The mid-sagittal reference

line was approached through the distal margin of incisive foramen and was established on all three planes (axial, sagittal and coronal) using toggled cross hairs in the program.

The measurements of palatal bone thickness and density in the midpalatal region of maxilla were taken at 6mm posterior to the incisive foramen and 3mm adjacent to the midpalatal suture **(Figure-6)**. In the posterior region, mid-sagittal reference line as a centre of the palate was taken again and measurement from 3mm distance from the reference line was done for the measurement of palatal bone thickness and density. The assessment of bone thickness and density in the region lateral to midpalatal suture was done on sagittal plane. In the posterior region, palatal bone thickness and density was measured between second premolar and the first molar 3mm adjacent to the midpalatine suture **(Figure-7)**.

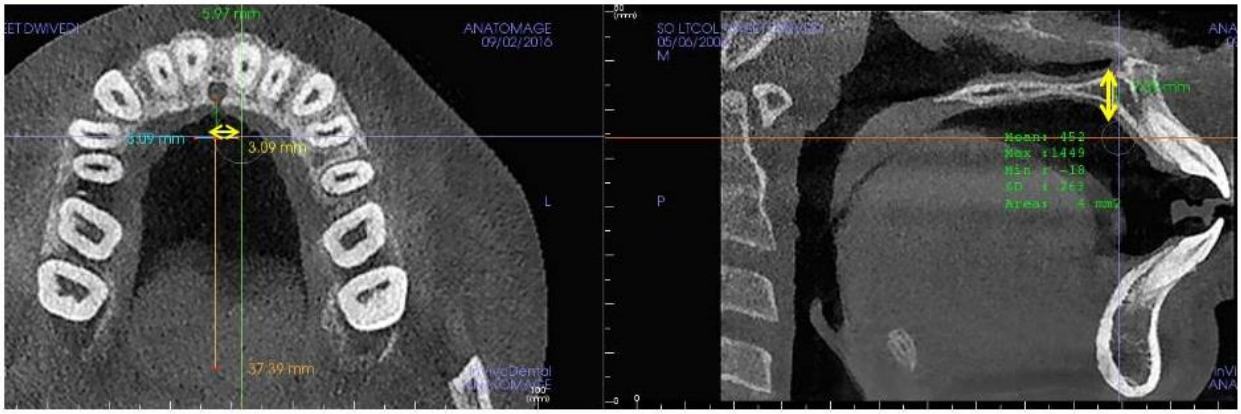

Figure 6: Images showing palatal bone thickness and density at 3mm adjacent to the midpalatine suture, taken at the distance of 6mm behind the incisive foramen (axial slice on the right and sagittal slice on the left showing measurement of palatal bone thickness and density)

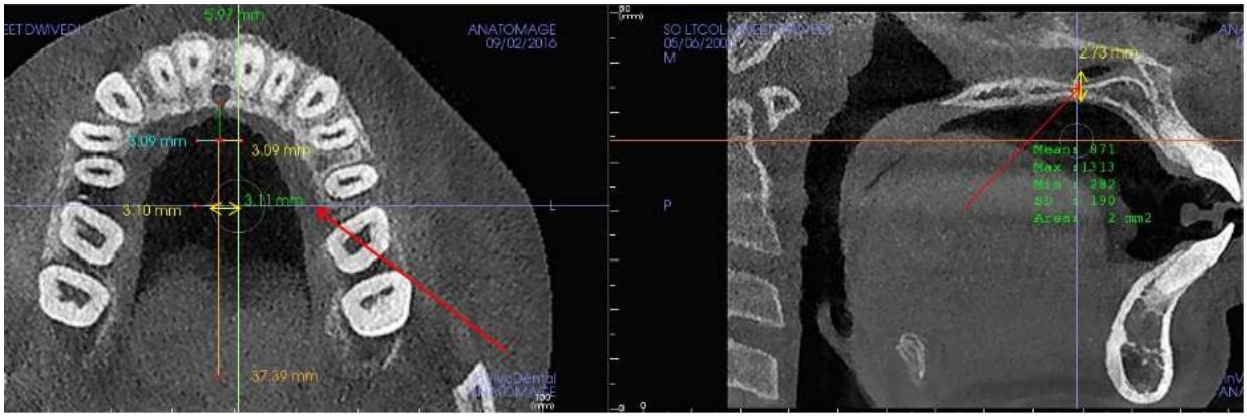

Figure 7: Images showing measurement of palatal bone thickness and density between second premolar and first molar at 3mm adjacent to the midpalatine suture, in a posterior region (axial slice on right and sagittal slice on left showing measurement of palatal bone thickness and density)

Measurement of Reliability

Measurement of reliability and repeatibity for maxillary bone thickness and density were done by repeating the measurements of 2 subjects from each group after 5 days interval from the first set of evaluation. Comparison was done by using student t-test. No statistically significant difference was observed in the readings of various study parameters taken at two time intervals as $p>0.05$ for all study groups **(Table-1)**.

Table- 1: Measurement of reliability for maxillary bone thickness and density

Parameter	Groups	Reading 1	Reading 2	Mean difference	P value
Buccolingual thickness (mm)	Group I	5.62±0.66	5.61±1.12	0.01	0.876
	Group II	6.60±0.76	6.59±0.89	0.01	0.877
	Group III	7.2±0.98	7.18±0.88	0.02	0.898
Buccolingual Bone density (HU)	Group I	907.22±1.1	907.19±0.65	0.03	0.921
	Group II	908.9±0.45	908.88±0.77	0.02	0.888
	Group III	910±0.33	909.89±0.56	0.11	0.789
Thickness of bone 3mm adjacent to midpalatine suture (mm)	Group I	6.65±0.77	6.64±0.65	0.01	0.865
	Group II	6.61±0.98	6.59±0.45	0.02	0.878
	Group III	6.66±0.65	6.65±0.66	0.01	0.834
Density of bone 3mm adjacent to midpalatine suture(HU)	Group I	565.87±0.71	565.86±0.65	0.01	0.866
	Group II	509±0.91	509.01±0.45	0.01	0.871
	Group III	820±0.62	820.02±0.66	0.02	0.844

Statistical analysis tool:

Data was analyzed using Statistical Package for Social Sciences (SPSS) version 21, IBM Inc. Descriptive data was reported for each variable. Descriptive statistics such as mean and standard deviation for continuous variables was calculated.

Summarized data was presented using Tables and Graphs. Shapiro Wilk test was used to check the normality of the data. As the data was found to be normally distributed bivariate analyses was performed using One way ANOVA followed by tukey's for post hoc comparison. Level of statistical significance was set at p-value less than 0.05.

ANALYSIS OF VARIANCE

Analysis of variance (ANOVA) is used when we compare more than two groups simultaneously. The purpose of one-way ANOVA is to find out whether data from several groups have a common mean. That is, to determine whether the groups are actually different in the measured characteristic. One way ANOVA is a simple special case of the linear model. For more than two independent groups, simple parametric ANOVA is used when variables under consideration follows Continuous exercise group distribution and groups variances are homogeneous otherwise non parametric alternative Kruskal-Wallis (H) ANOVA by ranks is used. The one way ANOVA form of the model is

$Y_{ij} = \alpha_{.j} + \varepsilon_{ij}$

where:

- Y_{ij} is a matrix of observations in which each column represents a different group.
- $\alpha_{.j}$ is a matrix whose columns are the group means (the "dot j" notation means that α applies to all rows of the j^{th} column i.e. the value α_{ij} is the same for all i).
- ε_{ij} is a matrix of random disturbances.

The model posits that the columns of Y are a constant plus a random disturbance. We want to know if the constants are all the same.

Assumptions are:

a) Response variable must be normally distributed (or approximately normally distributed).
b) Samples are independent.
c) •Variances of populations are equal.

d) The sample is a simple random sample (SRS).

Two-way ANOVA is used when we have one measurement variable and two nominal variables, and each value of one nominal variable is found in combination with each value of the other nominal variable. It tests three null hypotheses: that the means of the measurement variable are equal for different values of the first nominal variable; that the means are equal for different values of the second nominal variable; and that there is no interaction (the effects of one nominal variable don't depend on the value of the other nominal variable). When we have a quantitative continuous outcome and two categorical explanatory variables, we may consider two kinds of relationship between two categorical variables. In this relationship we can distinguish effect of one factor from that of the other factor. This type of model is called a main effect model or no interaction model.

Tukey Multiple Comparison Test

After performing ANOVA, Tukey HSD (honestly significant difference) post hoc test is generally used to calculate differences between group means as

where,

$$q = \frac{\bar{X}_1 - \bar{X}_2}{SE}$$

$$SE = \sqrt{\frac{S^2}{2}\left(\frac{1}{n_1} + \frac{1}{n_2}\right)}$$

S^2 is the error mean square from the analysis of variance and n_1 and n_2 are number of data in group 1 and 2 respectively.

Statistical significance:

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

$p > 0.05$ Not significant

$p \leq 0.05$ Just Significant

P<0.01 Significant

P<0.001 Highly significant

OBSERVATION AND RESULTS:

This study was conducted with an aim to assess the maxillary bone thickness and density in patients with surgically repaired unilateral and bilateral cleft lip and palate patients at different sites for mini-screw placement on CBCT image by using i-CAT software.

A total 45 CBCT images were scanned, out of which 15 subjects were of unilateral cleft patients (Group I), 15 subjects were bilateral cleft patients (Group II) and15 subjects were normal subjects (Group III).

Buccolingual maxillary bone thickness and density were evaluated among all the Groups at different heights from alveolar crest i. e. at 2 mm (Subgroup a), at 4 mm (Subgroup b), at 6 mm (Subgroup c) and at 8 mm (Subgroup d) in interradicular areas between two central incisors, between lateral incisors and canine, between first and second premolars and between second premolars and first molars. Palatal bone thickness and density were also evaluated in anterior region at 3mm distance adjacent to midpalatal suture and 6mm behind the incisive foramen (Subgroup e) and in the posterior region, 3mm adjacent to midpalatal suture in the area adjacent to second premolar and first molar (Subgroup f).

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Evaluation and Comparison of maxillary bone thickness and density in the interradicular areas in different subgroups of Group I, Group II and Group III was done by ANOVA were done in following manner:

1. Evaluation of buccolingual bone thickness and density[Table -2]
2. Comparison of buccolingual bone thickness in maxilla between two central incisors in subgroups of Group I, Group II and Group III. [Table-3]
3. Comparison of buccolingual bone thickness in maxilla between lateral incisors and canine in subgroups of Group I, Group II and Group III. [Table-4]
4. Comparison of buccolingual bone thickness in maxilla between first premolars and second premolars in subgroups of Group I, Group II and Group III. [Table- 5]

5. Comparison of buccolingual bone thickness in maxilla between second premolars and first molars in subgroups of Group I, Group II and Group III. [Table-6]
6. Evaluation of palatal bone thickness and density[Table-7]
7. Comparison of palatal bone thickness (palatal height) in maxilla in subgroup (behind 6mm incisive foramen) of Group I, Group II and Group III. [Table-8]
8. Comparison of palatal bone thickness (palatal height) in maxilla in subgroup (between second premolars and first molars) of Group I, Group II and Group III. [Table-9]
9. Comparison of buccolingual bone density in maxilla between central incisors in subgroups of Group I, Group II and Group III. [Table-10]
10. Comparison of buccolingual bone density in maxilla between lateral incisors and canine in subgroups of Group I, Group II and Group III. [Table-11]
11. Comparison of buccolingual bone density in maxilla between first premolar and second premolar in subgroups of Group I, Group II and Group III. [Table-12]
12. Comparison of buccolingual bone density in maxilla between second premolar and first molar in subgroups of Group I, Group II and Group III. [Table-13]
13. Comparison of palatal bone density (palatal height) in subgroup (behind 6mm incisive foramen) of Group I, Group II and Group III. [Table-14]
14. Comparison of palatal bone density (palatal height) in subgroup (between second premolars and first molar) of Group I, Group II and Group III. [Table-15]

Table 2 :Evaluation of buccolingual bone thickness and density

Bucco-lingual bone thickness(mm)					Density(HU)			
Groups	Between central incisors	Between lateral incisors and canine	Between First and second PM	Between second PM and first molar	Between central incisors	Between lateral incisors and canine	Between First and second PM	Between second PM and first molar
Group I a	5.709±0.576	5.907±0.868	7.600±0.763	8.044±1.141	905.867±36.672	913.333±72.397	661.600±74.638	556.133±59.351
Group II a	4.720±0.531	5.084±0.632	7.660±0.617	8.133±0.952	905.867±37.198	891.067±82.562	691.267±75.245	519.200±65.475
Group III a	7.633±0.61	7.600±1.009	9.153±0.799	9.686±1.039	905.867±36.460	1560.333±235.785	816.333±43.080	752.000±73.450
Group I b	6.340±0.644	6.527±1.10	8.400±0.969	9.000±1.099	916.333±239.55	648.400±160.241	516.533±114.370	495.533±73.125
Group II b	5.814± 0.88	6.453±1.06	8.013±0.889	8.967±1.036	908.733±63.1817	705.533±179.264	519.867±124.109	530.200±66.303
Group III b	7.712±0.879	7.800±1.07	8.933±0.87	10.353±1.271	935.933±71.482	897.600±86.698	742.267±91.067	668.333±40.367
Group I c	6.773±0.916	6.687±1.23	8.713±1.29	9.740±0.885	917.800±63.719	530.200±103.617	531.000±108.872	496.133±82.067
Group II c	6.360±0.712	6.747±0.811	8.553±0.860	9.507±0.906	881.067±83.405	553.867±162.137	472.200±108.571	415.667±102.161
Group III c	8.460±1.021	9.373±1.106	8.967±0.831	10.093±1.376	1059.267±104.866	673.267±106.551	692.733±101.748	645.400±55.769
Group I d	7.306±0.717	7.353±1.097	9.220±1.15	10.060±1.458	695.800±63.418	484.067±89.443	497.600±81.406	397.067±57.369
Group II d	6.625±0.617	6.973±1.013	9.113±0.828	9.867±1.131	654.533±43.269	447.800±91.546	452.867±118.825	361.133±75.189
Group III d	9.773±1.886	10.373±1.046	9.553±1.150	10.313±1.604	704.533±79.059	604.733±79.005	623.800±69.262	553.600±153.491

Table 2 shows evaluation of buccolingual bone thickness and density.

Buccolingual thickness and density was higher in group III followed by group II and group I

Table 3: Comparison of buccolingual bone thickness in maxilla between two central incisors in subgroups of Group I, Group II and Group III.

Group	Mean(mm)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P VALUE	Post hoc
				LowerBound	Upper Bound				
Group I a	5.7093	.57656	.14887	5.3900	6.0286	5.01	6.90	<0.001	IIIa>IIa>Ia
Group II a	4.7207	.53192	.13734	4.4261	5.0152	3.95	5.70		
Group III a	7.6333	.61140	.15786	7.2948	7.9719	6.60	8.80		
Group I b	6.3407	.64417	.16632	5.9839	6.6974	5.80	7.90	<0.001	IIIb>Ib>IIb
Group II b	5.8140	.88484	.22846	5.3240	6.3040	4.00	7.20		
Group III b	7.7120	.87938	.22705	7.2250	8.1990	6.10	9.30		
Group I c	6.773	.9161	.2365	6.266	7.281	5.1	8.3	<0.001	IIIc>Ic>IIc
Group II c	6.360	.7129	.1841	5.965	6.755	4.5	7.5		
Group III c	8.460	1.0218	.2638	7.894	9.026	6.4	10.5		
Group I d	7.3060	.71741	.18524	6.9087	7.7033	6.10	8.90	<0.001	IIIds>Id>IId
Group II d	6.6253	.61799	.15956	6.2831	6.9676	5.10	7.50		
Group III d	9.7733	1.88622	.48702	8.7288	10.8179	6.80	12.60		

<0.001 highly significant

Table 3 showing comparison of buccolingual bone thickness in maxilla between two central incisors in subgroups of Group I, Group II and Group III.

Maximum buccolingual maxillary bone thickness between central incisor at 2mm from alveolar crest was found in Group-IIIa (7.6333 $\pm$ 0.61 mm) followed by Group Ia (5.7093 $\pm$ 0.57 mm) and Group IIa (4.7207 $\pm$ 0.53 mm) and was significantly differenct from Group III ($p<0.001$)

At 4mm from alveolar crest was found in Group-IIIb (7.7120 ± 0.87 mm) followed by Group Ib (6.3407 ± 0.64 mm) and Group IIb (5.8140 ± 0.884 mm) and was significantly different from Group III ($p<0.001$)

At 6mm from alveolar crest was found in Group-IIIc (8.460 ± 1.02 mm) followed by Group Ic (6.773 ± 0.91 mm) and Group IIc (6.360 ± 0.71 mm) and was significantly different from Group III ($p<0.001$)

At 8mm from alveolar crest was found in Group-IIId (9.7733 ± 1.88 mm) followed by Group Id (7.3060 ± 0.717 mm) and Group IId (6.625 ± 0.617 mm) and was significantly different from Group III ($p<0.001$).

Table 4: Comparison of buccolingual bone thickness in maxilla between lateral incisors and canine in subgroups of Group I, Group II and Group III

Group	Mean (mm)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P VALUE	Post hoc
				Lower Bound	Upper Bound				
Group I a	5.9073	.86822	.22417	5.4265	6.3881	4.10	7.10	<0.001	IIIa>II a>Ia
Group II a	5.0847	.63298	.16344	4.7341	5.4352	3.50	6.00		
Group III a	7.6000	1.00924	.26059	7.0411	8.1589	6.30	9.30		
Group I b	6.527	1.1010	.2843	5.917	7.136	4.5	8.5	0.002	IIIb>Ib >IIb
Group II b	6.453	1.0636	.2746	5.864	7.042	4.4	7.7		
Group III b	7.800	1.0790	.2786	7.202	8.398	6.3	9.7		
Group I c	6.687	1.2357	.3191	6.002	7.371	4.7	8.9	<0.001	IIIc>Ic >IIc
Group II c	6.747	.8114	.2095	6.297	7.196	4.9	7.9		

Group III c	9.373	1.1061	.2856	8.761	9.986	7.2	11.5		
Group I d	7.353	1.0973	.2833	6.746	7.961	5.3	9.3	<0.001	IIId>Id >IId
Group II d	6.973	1.0138	.2618	6.412	7.535	5.5	8.5		
Group III d	10.373	1.0464	.2702	9.794	10.953	8.1	11.8		

<0.001 highly significant

Table 4 showing comparison of buccolingual bone thickness in maxilla between lateral incisors and canine in subgroups of Group I, Group II and Group III

Maximum buccolingual maxillary bone thickness between lateral incisors & canine at 2mm from alveolar crest was found in Group-IIIa (7.6000 ± 1.009 mm) followed by Group IIa (5.0847 ± 0.63 mm) and Group Ia (5.9073 ± 0.868 mm) and was significantly different from Group III ($p<0.001$).

At 4mm from alveolar crest was found in Group-IIIb(7.800 ± 1.07 mm) followed by Group Ib(6.527 ± 1.10 mm) and Group IIb (6.453 ± 1.063 mm) and was significantly different from Group III ($p<0.001$)

At 6mm from alveolar crest was found in Group-IIIc (9.373 ± 1.106 mm) followed by Group Ic (6.687 ± 1.23 mm) and Group IIc (6.74 ± 0.811 mm) and was significantly different from Group III ($p<0.001$)

At 8mm from alveolar crest was found in Group-IIId (10.373 ± 1.04 mm) followed by Group Id (7.35 ± 1.09 mm) and Group IId (6.973 ± 1.013 mm) and was significantly different from Group III ($p<0.001$)

Table5: Comparison of buccolingual bone thickness in maxilla between first premolars and second premolars in subgroups of Group I, Group II and Group III.

Group	Mean (mm)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P VALUE	Post hoc
				Lower Bound	Upper Bound				
Group I a	7.600	.7635	.1971	7.177	8.023	6.5	8.8	<0.001	IIIa>IIa>Ia
Group II a	7.660	.6174	.1594	7.318	8.002	6.6	8.6		
Group III a	9.153	.7999	.2065	8.710	9.596	7.5	10.9		
Group I b	8.400	.9695	.2503	7.863	8.937	6.5	9.8	0.029	IIIb>IIb>Ib
Group II b	8.013	.8895	.2297	7.521	8.506	6.4	9.8		
Group III b	8.933	.8731	.2254	8.450	9.417	7.7	10.6		
Group I c	8.713	1.2983	.3352	7.994	9.432	6.6	10.8	0.539	-

Group II c	8.553	.8601	.2221	8.077	9.030	7.4	9.9		
Group III c	8.967	.8312	.2146	8.506	9.427	7.8	10.6		
Group I d	9.220	1.1565	.2986	8.580	9.860	7.3	10.8	0.498	-
Group II d	9.113	.8280	.2138	8.655	9.572	7.4	10.1		
Group III d	9.553	1.1501	.2969	8.916	10.190	7.5	11.3		

<0.001 highly significant

Table 5 showing comparison of buccolingual bone thickness in maxilla between first premolars and second premolars in subgroups of Group I, Group II and Group III.

Maximum buccolingual maxillary bone thickness between first premolar & second premolars at 2mm from alveolar crest was found in Group-IIIa (9.513 ± 0.799 mm) followed by Group IIa (7.660 ± 0.617 mm) and Group Ia (7.600 ± 0.7635 mm) and was significantly different from Group III ($p<0.001$).

At 4mm from alveolar crest was found in Group-IIIb (8.933 ± 0.8731 mm) followed by Group IIb (8.013 ± 0.8895 mm) and Group Ib (8.400 ± 0.96 mm) and was significantly different from Group III ($p<0.001$).

At 6mm from alveolar crest was found in Group-IIIc (8.967 ± 0.831 mm), Group IIc (8.553 ± 0.86 mm) and Group Ic (8.713 ± 1.29 mm) and was significantly different from Group IIIc($p<0.001$).

At 8mm from alveolar crest was found in Group-IIId (9.553 ± 1.150 mm) Group IId (9.11 ± 0.828 mm) and Group Id (9.220 ± 1.156 mm) and was significantly different from Group IIId ($p<0.001$).

Table 6: Comparison of buccolingual bone thickness in maxilla between second premolars and first molars in subgroups of Group I, Group II and Group III

Group	Mean (mm)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P VALUE	Post hoc
				Lower Bound	Upper Bound				
Group I a	8.0447	1.14121	.29466	7.4127	8.6766	6.40	9.60	<0.001	IIIa>IIa >Ia
Group II a	8.1333	.95219	.24585	7.6060	8.6606	6.30	9.50		
Group III a	9.6867	1.03983	.26848	9.1108	10.2625	7.80	11.50		
Group I b	9.000	1.0994	.2839	8.391	9.609	6.3	10.6	0.002	IIIb>IIb >Ib
Group II b	8.967	1.0362	.2676	8.393	9.541	6.8	10.5		
Group III b	10.353	1.2716	.3283	9.649	11.058	8.0	12.1		
Group I c	9.740	.8854	.2286	9.250	10.230	8.1	10.9	0.335	-
Group II c	9.507	.9067	.2341	9.005	10.009	7.5	10.9		
Group III c	10.093	1.3766	.3554	9.331	10.856	7.8	12.3		
Group I d	10.060	1.4589	.3767	9.252	10.868	7.5	12.6	0.688	-
Group II d	9.867	1.1312	.2921		10.493	7.9	11.5		

Group III d	10.313	1.6040	.4141	9.425	11.202	7.9	13.3		

<0.001 highly significant

Table 6 showing comparison of buccolingual bone thickness in maxilla between second premolars and first molars in subgroups of Group I, Group II and Group III

Maximum buccolingual maxillary bone thickness between second premolar & first molar at 2mm from alveolar crest was found in Group-IIIa (9.6867 ± 1.039 mm) followed by Group IIa (8.133 ± 0.95 mm) and Group Ia (8.044 ± 1.14 mm)and was significantly different from Group III ($p<0.001$)

At 4mm from alveolar crest was found in Group-IIIb (10.353 ± 1.271 mm) followed by Group IIb (8.96 ± 1.03 mm) and Group Ib (9.00 ± 1.099 mm)and was significantly different from Group III ($p<0.001$)

At 6mm from alveolar crest was found in Group-IIIc (10.093 ± 1.37 mm) Group IIc (9.507 ± 0,906 mm) and Group Ic(9.74 ± 0.885 mm) and significantly different from Group III ($p<0.001$)

At 8mm from alveolar crest was found in Group-IIId (10.313 ± 1.604 mm) Group IId (9.867 ± 1.13 mm) and Group Id (10.06 ± 1.45 mm)and was significantly different from Group III ($p<0.001$).

	Thickness (mm)		Density (HU)	
Groups	**Thickness of bone adjacent to midpalatine**	**Thickness of bone adjacent to midpalatine**	**Density of bone adjacent to midpalatine**	**Density of bone adjacent to midpalatine**

Table 7 showing evaluation of palatal bone thickness and density

	suture 6mm behind incisive foramen(mm)	**suture between second premolar and first molar(mm)**	**suture 6mm behind incisive foramen (HU)**	**suture between second premolar and first molar(HU)**
Group I	6.6067 ± 0.66812	2.6667 ± 0.70778	563.400 ± 79.8801	676.867 ± 95.4073
Group II	6.6133 ± 0.74533	2.6533 ± 0.65560	506.200 ± 55.4375	703.400±111.4834
Group III	8.7553 ± 0.69001	3.6340 ± 0.32708	835.467 ± 86.5604	1099.000 ±147.12

Table 7 showing evaluation of palatal bone thickness and density

Palatal bone thickness and density was higher in group III followed by group II and group I

Midpalatine suture area:

Table 8: Comparison of palatal bone thickness (palatal height) in maxilla in subgroup (behind 6mm incisive foramen) of Group I, Group II and Group III.

Groups	Mean(mm)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
				Lower Bound	Upper Bound		
Group Ie	6.6067	.66812	.17251	6.2367	6.9767	5.40	7.80
Group IIe	6.6133	.74533	.19244	6.2006	7.0261	5.50	7.90
GroupIIIe	8.7553	.69001	.17816	8.3732	9.1374	7.90	9.70
P value	<0.0001						
Post hoc	3>1,2						

<0.001 highly significant <0.01 significant <0.05 just significant <0.05 not significant

Table 8 showing comparison of Palatal bone thickness of maxillary bone at 3mm from midpalatal suture (6mm behind the incisive foramen)

Palatal bone thickness at subgroup e in group I was 6.6067± 0.66mm. Palatal bone thickness at subgroup e in group II was 6.6133± 0.74 mm and in group III was 8.7553± 0.69 mm.

Significant differences were seen among all three groups, when compared using One way ANOVA as $p<0.05$. Post hoc comparison showed more thickness of bone in group III adjacent to midpalatine suture as compared to group I and group II .

Table 9: Comparison of palatal bone thickness (palatal height) in maxilla in subgroup (between second premolars and first molars) of Group I, Group II and Group III.

Groups	Mean(mm)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
				Lower Bound	Upper Bound		
Group If	2.6667	.70778	.18275	2.2747	3.0586	1.30	3.90
Group II f	2.6533	.65560	.16927	2.2903	3.0164	1.60	3.70
Group IIIf	3.6340	.32708	.08445	3.4529	3.8151	3.10	4.40
P value	<0.0001						
Post hoc	3>1,2						

<0.001 highly significant <0.01 significant <0.05 just significant <0.05 not significant

Table 9 showing comparison of Palatal bone thickness of maxillary bone between second premolars and first molars in different groups at 3mm from midpalatal suture, categorized f (between second premolars and first molars)

Palatal bone thickness in group I at subgroup f was 2.6667± 0.70mm, in group II was 2.6533± 0.65 mm and in group III was 3.6640± 0.32 mm.

Significant differences were seen among group I, group II and group III when compared using One way ANOVA as $p<0.05$. Post hoc comparison showed more thickness of bone in group III normal subjects adjacent to midpalatine suture as compared to group I and group II.

Table 10: Comparison of buccolingual bone density in maxilla between central incisors in subgroups of Group I, Group II and Group III.

Group	Mean (HU)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P VALUE	Post hoc
				Lower Bound	Upper Bound				
Group I a	909.13	36.672	9.469	888.83	929.44	839	958	0.981	-
Group II a	906.53	37.198	9.604	885.93	927.13	840	957		
Group III a	908.27	36.460	9.414	888.08	928.46	846	961		
Group I b	916.333	239.5542	61.8526	783.673	1048.994	96.0	1127.0	0.876	-
Group II b	908.733	63.1817	16.3134	873.744	943.722	824.0	998.0		
Group III b	935.933	71.4827	18.4568	896.348	975.519	868.0	1132.0		
Group I c	917.800	63.7195	16.4523	882.513	953.087	809.0	1023.0	<0.001	IIIc>IIc>Ic
Group II c	881.067	83.4056	21.5352	834.878	927.255	710.0	998.0		
Group III c	1059.267	104.8669	27.0765	1001.193	1117.340	908.0	1262.0		
Group I d	695.800	63.4183	16.3745	660.680	730.920	567.0	798.0	0.083	-
Group II d	654.533	43.2697	11.1722	630.571	678.495	599.0	733.0		
Group III d	704.533	79.0595	20.4131	660.752	748.315	533.0	876.0		

<0.001 highly significant

Table 10 showing comparison of buccolingual bone density in maxilla between central incisors in subgroups of Group I, Group II and Group III.

Maximum buccolingual maxillary bone thickness between central incisors at 2mm from alveolar crest was found in Group-IIIa (908.27 ± 36.46 mm) Group IIa (906.53 ± 37.198 mm) and Group Ia(909.13 ± 36.67 mm)was significantly different from Group III ($p<0.001$)

At 4mm from alveolar crest was found in Group-IIIb (935.93± 71.4827 mm) Group IIb (908.733 ± 63.1817 mm) and Group Ib (916.333 ± 239.5542 mm) and was significantly different from Group III ($p<0.001$)

At 6mm from alveolar crest was found in Group-IIIc (1059.2± 104.8 mm) followed by Group IIc (881.06 ± 83.4 mm) and Group Ic (917.800 ± 63.71 mm)and was significantly different from Group III ($p<0.001$)

At 6mm from alveolar crest was found in Group-IIId (704.533 ± 79.0595 mm) Group IId (654.533 ± 43.2697 mm) and Group Id (695.800 ± 63.4183 mm) and was significantly different from Group III ($p<0.001$).

Table 11: Comparison of buccolingual bone density in maxilla between lateral incisors and canine in subgroups of Group I, Group II and Group III.

Group	Mean (HU)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P VALUE	Post hoc
				Lower Bound	Upper Bound				
Group I a	913.333	72.3974	18.6929	873.241	953.426	786.0	1024.0	<0.001	IIIa>Ia >IIa
Group II a	891.067	82.5629	21.3177	845.345	936.788	784.0	999.0		
Group III a	1560.33	235.7852	60.8795	1441	1679.65	1178	1904		
Group I b	648.400	160.2412	41.3741	559.661	737.139	479.0	984.0	<0.001	IIIb>Ib >IIb
Group II b	705.533	179.2643	46.2858	606.260	804.807	458.0	995.0		
Group III b	897.600	86.6980	22.3853	849.588	945.612	709.0	1023.0		
Group I c	530.200	103.6176	26.7539	472.819	587.581	322.0	678.0	0.008	IIIc>Ic >IIc
Group II c	553.867	162.1370	41.8636	464.078	643.655	323.0	786.0		
Group III c	673.267	106.5514	27.5115	614.260	732.273	474.0	798.0		
Group I d	484.067	89.4431	23.0941	434.535	533.599	257.0	578.0	<0.001	IIId>Id >IId
Group II d	447.800	91.5464	23.6372	397.103	498.497	244.0	598.0		
Group III d	604.733	79.0058	20.3992	560.981	648.485	463.0	695.0		

<0.001 highly significant

Table 11 showing comparison of buccolingual bone density in maxilla between lateral incisors and canine in subgroups of Group I, Group II and Group III.

Maximum buccolingual maxillary bone thickness between lateral incisor & canine at 2mm from alveolar crest was found in Group-IIIa (1560.33 ± 235.78 mm) followed by Group Ia (913.33 ± 72.39 mm) and Group IIa (891.067 ± 82.56 mm) and was significantly different from Group IIIa ($p<0.001$)

At 4mm from alveolar crest was found in Group-IIIb (897.60 ± 86.69 mm) followed by Group Ib (648.400 ± 160.24 mm) and Group IIb (705.533 ± 179.26 mm) and was significantly different from Group IIIb ($p<0.001$).

At 6mm from alveolar crest was found in Group-IIIc (673.267 ± 106.55 mm) followed by Group Ic (530.200 ± 103.61 mm) and Group IIc (553.86 ± 162.13 mm) and was significantly different from Group IIIc ($p<0.001$).

At 8mm from alveolar crest was found in Group-IIId (604.733 ± 79.005 mm) followed by Group Id (484.06 ± 89.44 mm) and Group IId (447.800 ± 91.54 mm) and was significantly different from Group IIId ($p<0.001$).

Table 12: Comparison of buccolingual bone density in maxilla between first premolar and second premolar in subgroups of Group I, Group II and Group III.

Group	Mean (HU)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P VALUE	Post hoc
				Lower Bound	Upper Bound				
Group I a	661.600	74.6389	19.2717	620.266	702.934	509.0	786.0	<0.001	IIIa>Ia>IIa
Group II a	691.267	75.2458	19.4284	649.597	732.936	568.0	797.0		
Group III a	816.333	43.0808	11.1234	792.476	840.191	709.0	894.0		
Group I b	516.533	114.3709	29.5304	453.197	579.870	345.0	765.0	<0.001	IIIb>Ib>IIb
Group II b	519.867	124.1099	32.0450	451.137	588.596	287.0	673.0		
Group III b	742.267	91.0671	23.5134	691.835	792.698	540.0	820.0		
Group I c	531.000	108.8728	28.1108	470.708	591.292	309.0	698.0	<0.001	IIIc>Ic>IIc
Group II c	472.200	108.5714	28.0330	412.075	532.325	209.0	643.0		
Group III c	692.733	101.7486	26.2714	636.387	749.080	480.0	869.0		
Group I d	497.600	81.4062	21.0190	452.519	542.681	367.0	599.0	<0.001	IIId>Id>IId
Group II d	452.867	118.8257	30.6807	387.063	518.670	209.0	569.0		
Group III d	623.800	69.2626	17.8835	585.444	662.156	509.0	730.0		

<0.001 highly significant

Table 12 showing comparison of buccolingual bone density in maxilla between first premolar and second premolar in subgroups of Group I, Group II and Group III.

Maximum buccolingual maxillary bone thickness between first premolars and second premolars at 2mm from alveolar crest was found in Group-IIIa (816.33 ± 43.08 mm) followed by Group Ia (661.60 ± 74.638 mm) and Group IIa (691.26 ± 75.24 mm) and was significantly different from Group IIIa ($p<0.001$)

At 4mm from alveolar crest was found in Group-IIIb (742.267 ± 91.06 mm) followed by Group Ib (516.53 ± 114.37 mm) and Group IIb (519.86 ± 124.109 mm)and was significantly different from Group IIIB ($p<0.001$)

At 6mm from alveolar crest was found in Group-IIIc (692.733 ± 101.74 mm) followed by Group Ic (531.000 ± 108.87 mm) and Group IIc (472.20 ± 108.571 mm) and was significantly different from Group IIIc ($p<0.001$)

At 8mm from alveolar crest was found in Group-IIId (623.800 ± 69.26 mm) followed by Group Id (497.600 ± 81.406 mm) and Group IId (452.867 ± 118.825 mm) was significantly different from Group IIId ($p<0.001$)

Table 13: Comparison of buccolingual bone density in maxilla between second premolar and first molar in subgroups of Group I, Group II and Group III

Groups & Sub – groups	Mean (HU)	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum	P VALUE	Post hoc
				Lower Bound	Upper Bound				
Group I a	556.133	59.3511	15.3244	523.266	589.001	498.0	673.0	<0.001	IIIa>Ia>IIa
Group II a	519.200	65.4754	16.9057	482.941	555.459	347.0	599.0		
Group III a	752.000	73.4507	18.9649	711.324	792.676	601.0	850.0		
Group I b	495.533	73.1250	18.8808	455.038	536.029	401.0	672.0	<0.001	IIIb>Ib>IIb
Group II b	530.200	66.3036	17.1195	493.482	566.918	405.0	698.0		
Group III b	668.333	40.3674	10.4228	645.979	690.688	609.0	717.0		
Group I c	496.133	82.0678	21.1898	450.686	541.581	354.0	645.0	<0.001	IIIc>Ic>IIc
Group II c	415.667	102.1614	26.3780	359.092	472.242	234.0	576.0		
Group III c	645.400	55.7697	14.3997	614.516	676.284	567.0	790.0		
Group I d	397.067	57.3691	14.8126	365.297	428.837	309.0	511.0	<0.001	IIId>Id>IId
Group II d	361.133	75.1892	19.4138	319.495	402.772	253.0	478.0		
Group III d	553.600	153.4916	39.6314	468.599	638.601	50.0	698.0		

<0.001 highly significant

Table13 showing comparison of buccolingual bone density in maxilla between second premolar and first molar in subgroups of Group I, Group II and Group III

Maximum buccolingual maxillary bone thickness between second premolar and first molar at 2mm from alveolar crest was found in Group-IIIa (752.00 ± 73.45 mm) followed by Group Ia (556.133 ± 59.35 mm) and Group IIa (519.200 ± 65.475 mm) and was significantly different from Group IIIa ($p<0.001$)

At 4mm from alveolar crest was found in Group-IIIb (668.33 ± 40.36 mm) followed by Group Ib (495.533 ± 73.12 mm) and Group IIb (530.200 ± 66.30 mm) and was significantly different from Group IIIb ($p<0.001$)

At 6mm from alveolar crest was found in Group-IIIc (645.400 ± 55.76 mm) followed by Group Ic (496.13 ± 82.06 mm) and Group IIc (415.667 ± 102.16 mm) and was significantly different from Group IIIc ($p<0.001$)

At 8mm from alveolar crest was found in Group-IIId (553.600 ± 153.49 mm) followed by Group Id (397.067 ± 57.36 mm) and Group IId (361.133 ± 75.189 mm) and was significantly different from Group IIId ($p<0.001$)

Table 14: Comparison of palatal bone density (palatal height) in subgroup (behind 6mm incisive foramen) of Group I, Group II and Group III

Groups	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum
					Lower Bound	Upper Bound	
Group I e	15	563.400	79.8801	20.6250	519.164	607.636	409.0
Group II e	15	506.200	55.4375	14.3139	475.500	536.900	410.0
Group III e	15	835.467	86.5604	22.3498	787.531	883.402	702.0
P value	<0.0001						
Post hoc	3>1,2						

Table14 showing comparison of Palatal bone density of maxillary bone at 3mm from midpalatal suture, 6mm behind the incisive foramen

Palatal bone density in group I at 3mm from the midpalatal suture behind incisive foramen was 563.4± 79.8HU. Palatal bone density, in group II at was 506.2± 55.43 HU and at subgroups in group III was 835.467± 86.5 HU at 3mm from midpalatal suture, 6mm behind the incisive foramen**.**

Significant differences were seen among group I, II and III, when compared using One way ANOVA as $p<0.05$. Post hoc comparison showed more density of bone in group III adjacent to midpalatine suture as compared to group I and group II.

Table 15 : Comparison of palatal bone density (palatal height) in subgroup (between second premolars and first molar) of Group I, Group II and Group III

	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum
				Lower Bound	Upper Bound	
1f	676.867	95.4073	24.6341	624.032	729.701	532.0
II f	703.400	111.4834	28.7849	641.663	765.137	514.0
III f	1099.000	147.1253	37.9876	1017.525	1180.475	849.0
P value	<0.0001					
Post hoc	3>1,2					

Table 15 showing comparison of Palatal bone density of maxillary bone in different groups at 3mm from midpalatal suture (between second premolars and first molars)

Palatal bone density at subgroup f , in group I was 676.86± 95.4 HU, in group II was 703.4± 111.4 HU and in group III was 1099± 147 HU.

Significant differences were seen among group I, II and III, when compared using One way ANOVA as $p<0.05$. Post hoc comparison showed more density of bone adjacent to midpalatine suture, in group III as compared to group I and group II.

DISCUSSION

Cleft lip and palate are the most common congenital deformity , occurs due to failure of fusion of maxillary process with the median nasal process and palatal process of maxilla, during 5^{th}-12^{th} week of intrauterine life [3].

In cleft patients, developing dental and skeletal problems require orthodontic interventions during deciduous dentition to late permanent dentition to achieve functionally optimum occlusion and best possible aesthetics. Complex orthodontic tooth movements and biomechanics are required for the correction of rotated teeth adjacent to cleft sites and creation of space for prosthetic replacement of the missing teeth. The complexity of the hard and soft-tissue regeneration in cleft sites has requisite the need for defining the preoperative morphology of the cleft areas **[3].**

Wahaj and collegues [58]recommended that bone grafting after orthodontic expansion in cleft patients for implant placement because of deficient bone in the anterior maxillary region. The bone graft is important for the stability and support to the maxillary alveolar arch. They stated that the success of bone graft as well as dental implants depends upon the type of bone graft, bone quality at cleft site and severity of cleft lip and palate.

Berger et al[13] stated that the radiographic alveolar bone loss was greater at the cleft site as compared with controls, due to the presence of a long supracrestal connective tissue attachment. UCLP with regard to periodontal health status and showed that bone loss was significantly higher for teeth on the cleft side as compared with the contralateral noncleft control teeth.

Pareveen et al [2] found that the buccal and distal alveolar bone for the teeth anterior to the cleft at 3 mm was thinner when compared to the noncleft site. The alveolar bone at buccal, palatal, and mesial surfaces of the teeth anterior to the cleft was approximately 3 mm thinner when compared to the noncleft site. They suggested that it is essential to undergo secondary bone grafting before orthodontic intervention to preserve the labial/buccal bone as well as interdental bone. In their previous study, samples were taken CBCT images of nonsyndromic unilateral complete cleft lip and palate patients (NSUCCLP) were taken which have not undergone secondary bone grafting or orthodontic intervention while in the present study

nonsydromic surgically repaired unilateral and bilateral cleft lip and palate patients who have not undergone orthodontic intervention were taken.

Ghoneima et al [16] found that the buccal bone thickness was significantly greater in the apical region around 9mm from the alveolar crest in surgically repaired patients. They also found that the lingual thickness of bone was greater at 6mm and 9mm from the alveolar crest. It was also concluded that the primary alveolar graft does not provide an additional bone width on the cleft sides as compared to the children who have not undergone alveolar grafts premolars.

Considering this, it can be anticipated that buccal and palatal bone thickness varied both cleft and non-cleft side in various studies (Graccio et al,2008, Parveen et al,2018). As cleft patients have tendency for bone loss at cleft sites, use of primary , secondary, tertiary alveolar grafts are commonly used in such patients.The factors influencing mini implant stability are alveolar bone thickness, bone density , placement angle, site of implant etc.

As bone thickness varies in cleft lip and palate patients , hence it was decided to compare important factors affecting mini implant stability i.e, buccolingual and palatal bone thickness, buccolingual and palatal bone density between normal and cleft patient.

For calculating bone thickness and density use of 3-D imaging systems like CBCT are beneficial to better resolution and measurement in all three planes of space.

Alshammery [60] reported that CBCT allows the view the 2 dimensional images in either sagittal, oblique or coronal planes and numerous other inclinations at the same time.

Suutapreyasri et al[51] evaluated the accuracy of CBCT for measurement of cortical bone thickness and bone density at the implant site. They concluded that CBCT is highly accurate in linear measurements and demonstrated correlation with genuine bone density.

CBCT scans were converted into DICOM file and were oriented in all 3 plane space (sagittal, axial and coronal plane) and area of interest was selected on these planes and measurements of bone thickness and density were done.

Parsa et al[61] assessed the accuracy of CBCT in evaluation of trabecular bone density. They suggested that the measurements of bone density could be used to quantify the parameters of microstructures of bone. Hence it was decided to make the measurements on CBCT.

Maxillary bone thickness and density had been measured at different sites and different height for normal individuals and variations were seen considering this , the aim of the study was assessment of maxillary bone thickness and density in surgically repaired cleft patient

(unilateral and bilateral cleft lip and palate patient) at different implant patient site on CBCT images of using i-CAT software.

A total of 45 CBCT scans were evaluated and divided into three groups. Group 1 included patient with unilateral cleft lip and palate(n=15), Group 2 included patient with bilateral cleft lip and palate(n=15) and group 3 included normal individual which served as control group(n=15).

Each of these groups were further subdivided into sub groups a,b,c,d based of different bone heights i.e., 2,4,6 and 8mm respectively. Buccolingual bone thickness and density was measured at different bone heights at four commonly used implant sites buccally i.e., between central incisors, between lateral incisor and canine, between two premolars and between second premolar and first molar. Palatal bone thickness and density was measured at 2 different sites at 3mm adjacent to mid palatine suture, 6mm behind incisive foramen and 3mm adjacent to midpalatine suture in the areas of second premolar and first molar. All the measurements were made using i-CAT software. Data was tabulated and comparisons were made statistically.

The results of the present study indicated that cleft patients had decreased buccolingual bone thickness and density, palatal bone thickness and density in comparison to normal individuals

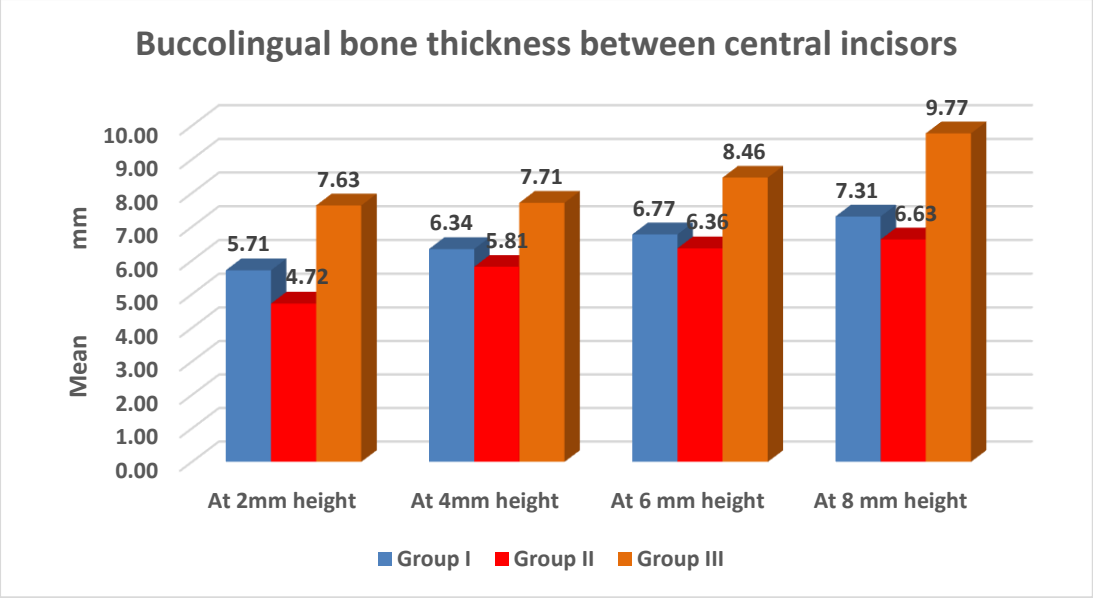
Buccolingual bone thickness showed statistically significant different for each region (between central incisors, between lateral incisors and canine , between first and second premolars , between second premolar and fist molar) at different heights in different groups except at 6 and 8mm in premolars and in premolar and molar region. (Refer to graph 1to 4 and table 2-5)

Buccolingual bone density showed statistically insignificant difference in each region except in the areas between central incisors at 6mm from the alveolar crest.(Refer to graph 5-8 and table 9-12

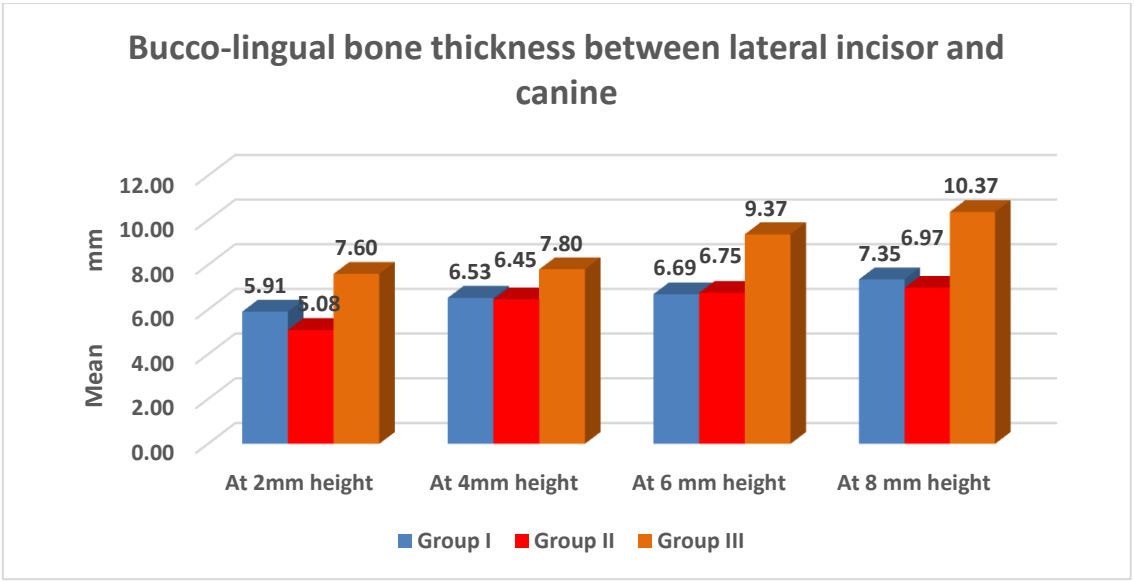
For central incisors region as well as for lateral incisors and canine, buccolingual bone thickness at 2mm showed a trend of group III> II> I, i.e, buccolingual bone thickness between central incisors was 7.63±0.61 mm in group III, 5.7± 0.57mm in group II and 4.72±0.53 mm in group I(refer to table 3, graph 1).

Buccolingual bone thickness for central incisors region as well as lateral incisors and canine, showed a trend for group III>I, II at 4, 6 and 8mm from the alveolar crest. The buccolingual

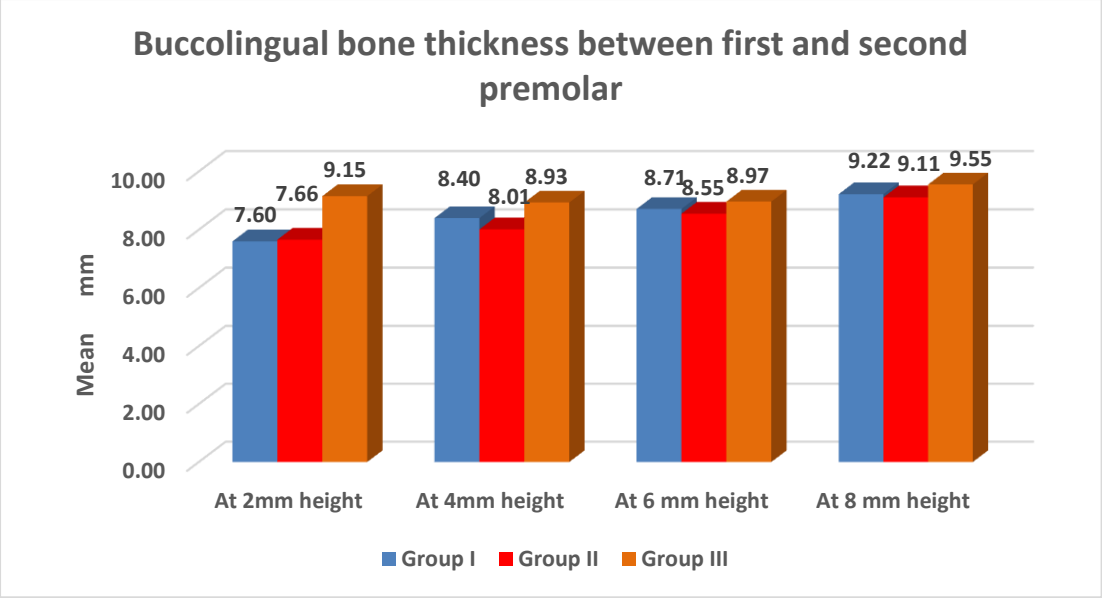
bone thickness between lateral incisors and canine at 4mm was 7.8± 1.01mm in group III, 6.5±1.10 mm in group II and 6.4±1.06 mm in group I. The buccolingual bone thickness between lateral incisors and canine at 6mm was 9.3±1.1 in group III, 6.7±0.8 mm in group II and 6.6±0.12 mm in group I (refer to table 4, graph 2) trend of group III>I>II. (Refer to graph 1-2 and table 3-4). For buccolingual density between central incisors, buccolingual density at showed a trend of group III>II>I (refer to graph 5 and table 10). The buccolingual thickness of maxillary bone at 6 and 8 mm in the interradicular areas between first and second premolars and between second premolars and first molars .The buccolingual bone thickness at 6mm in the interradicular areas between first and second premolars, group II was 8.55± 0.86mm , group I was 8.71± 1.29 mm and in group III was 8.96±0.83 mm ($p>0.05$) (as shown in table, graph 3). The buccolingual bone thickness at 6mm in the interradicular areas between second premolars and first molars in group I and II was 9.74±.88mm and 9.5± 0.90 mm differed significantly among the three groups and in group III was 10.0± 1.37mm ($p > 0.05$) (as shown in table 6, graph 4). The buccolingual bone thickness at 8mm in the interradicular areas between second premolars and first molars in group I was 9.2± 1.15mm , group II was 9.1±0.82mm and group III was 9.5± 1.15mm ($p>0.05$) (as shown in table 6, graph 3).The buccolingual bone thickness between second premolars and first molars at 8mm in group I was10.0±1.45mm ,group II was 9.86±1.13 and group III was 10.3±1.60 mm, and ($p> 0.05$)(as shown in table 6, graph 4). Buccolingual bone thickness for first and second premolar region at 2 and 4mm and for second premolar and first molar region at 6mm showed a trend of group III>II>I (refer to table 5,6,graph 3,4).



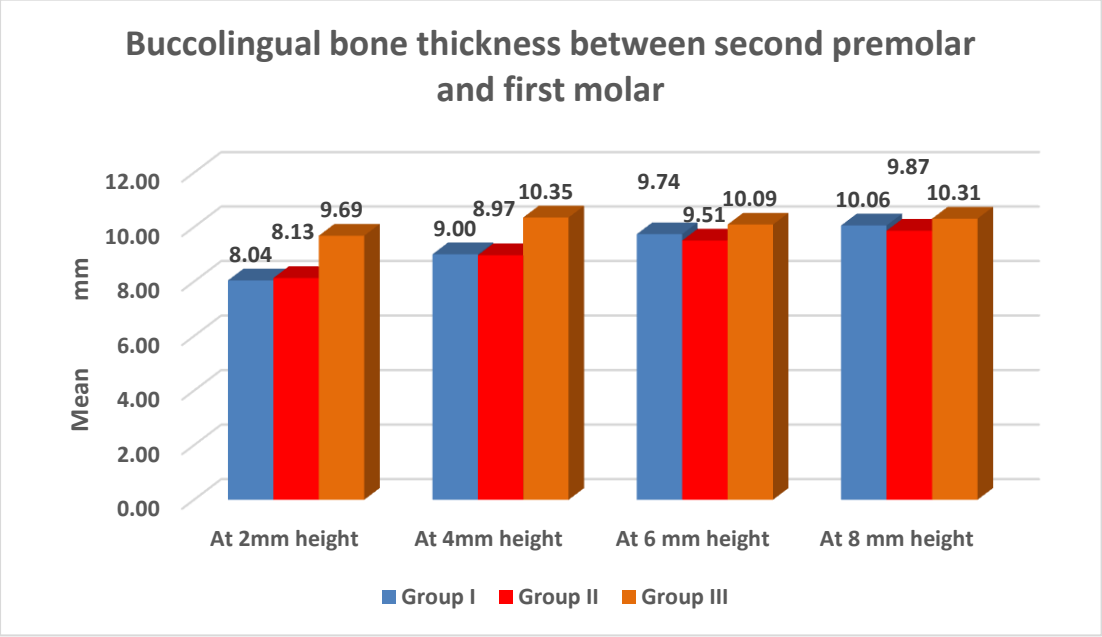
Graph 1: Buccolingual bone thickness in different groups between central incisors at 2, 4, 6 and 8 mm from the alveolar crest



Graph2: Buccolingual bone thickness in different groups between lateral incisor and canine at 2, 4, 6 and 8 mm from the alveolar crest



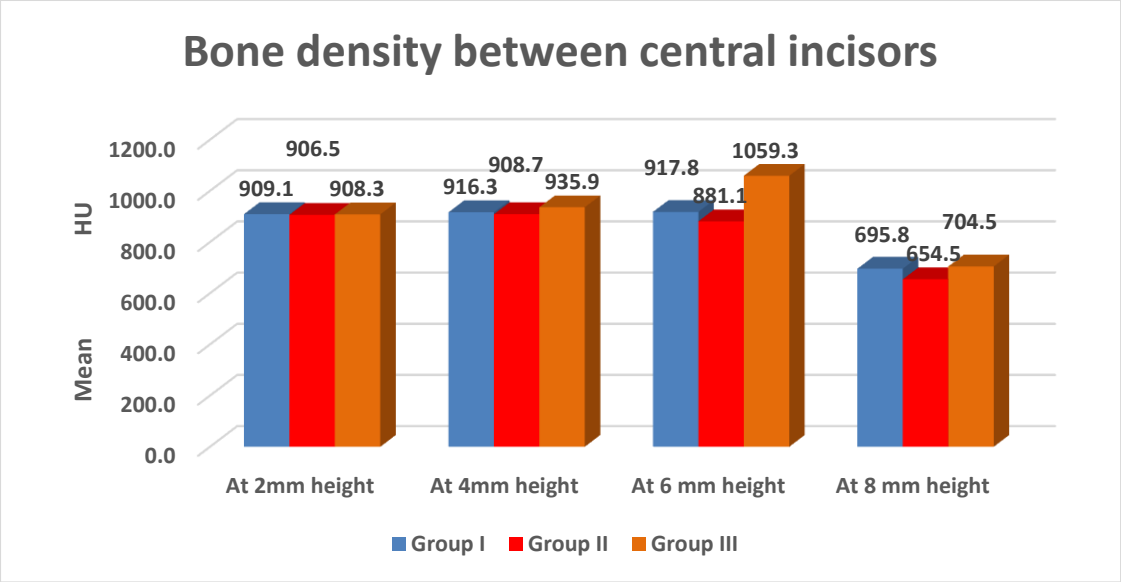
Graph 3: Buccolingual bone thickness in different groups between first and second premolar at 2, 4, 6 and 8 mm from the alveolar crest



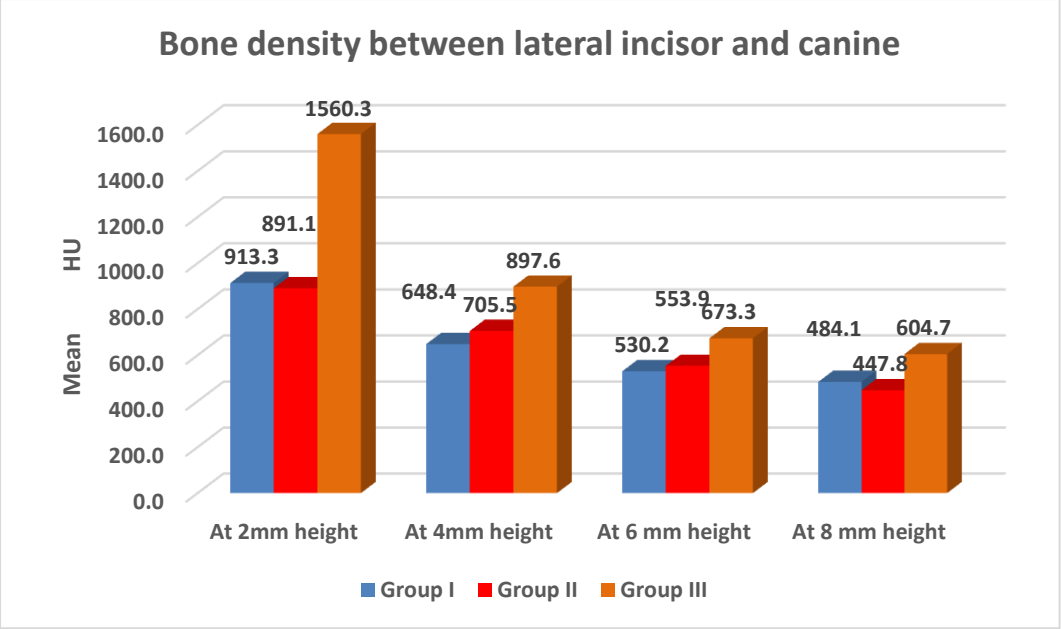
Graph 4: : Buccolingual bone thickness in different groups between second premolar and first molar at 2, 4, 6 and 8 mm from the alveolar crest

Buccolingual bone density showed statistically insignificant difference in each region except in areas between central incisors at 6mm from the alveolar crest and also showed a trend of group III> II, I. Buccolingual density in central incisors at 6mm was 1059.2± 104.8 HU in group III, 881.06 ± 83.4 HU in group II and 917.8± 63.7 HU in group I (refer to table 9, graph 4).

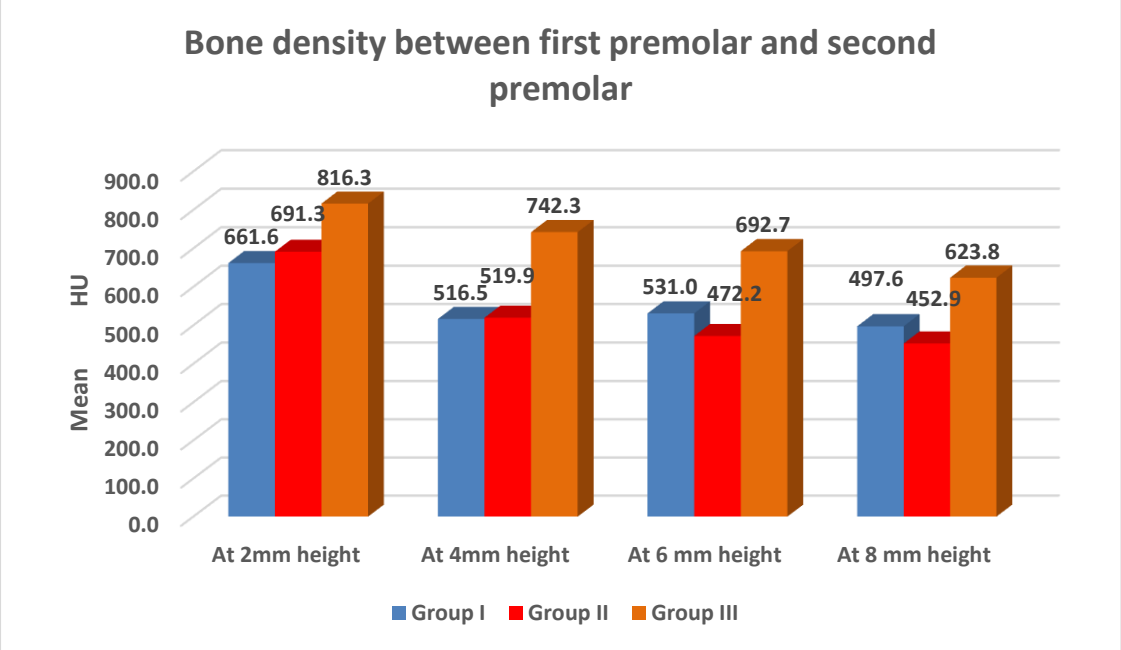
Buccolingual bone density in different groups between lateral incisor and canine at 4, 6 and 8 mm from the alveolar crest showed highly significant difference and showed a trend of group III>II, I (refer to table 10, graph 6).



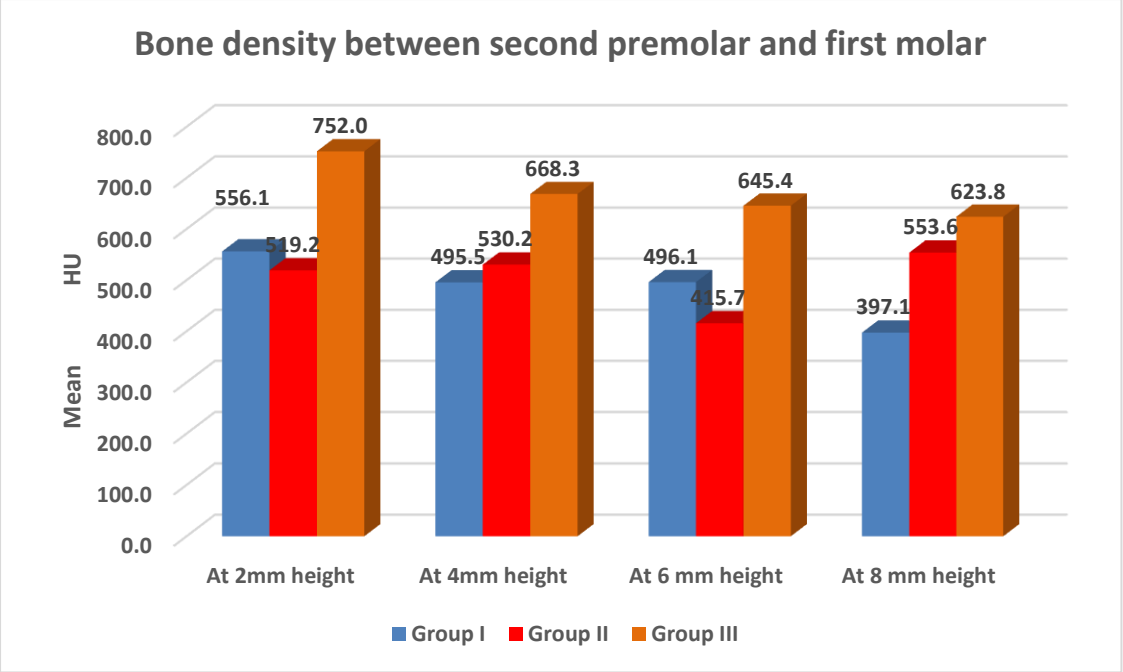
Graph 5: Buccolingual bone density in different groups between central incisors at 2, 4, 6 and 8 mm from the alveolar crest



Graph 6: Buccolingual bone density in different groups between lateral incisors and canine at 2, 4, 6 and 8 mm from the alveolar crest

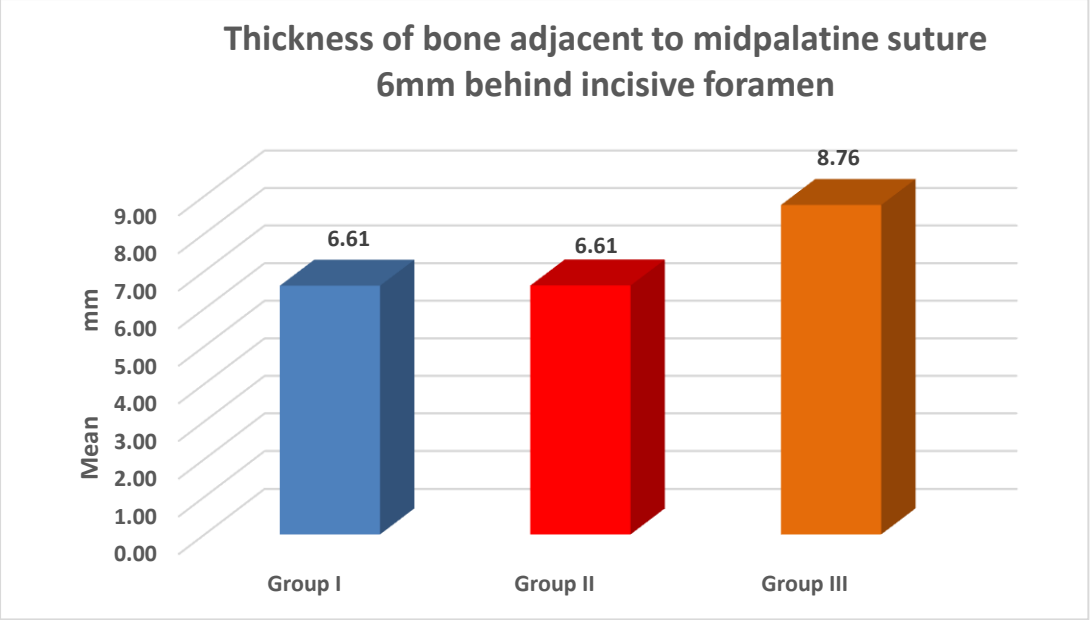


Graph 7: Buccolingual bone density in different groups between first and second premolars at 2, 4, 6 and 8 mm from the alveolar crest

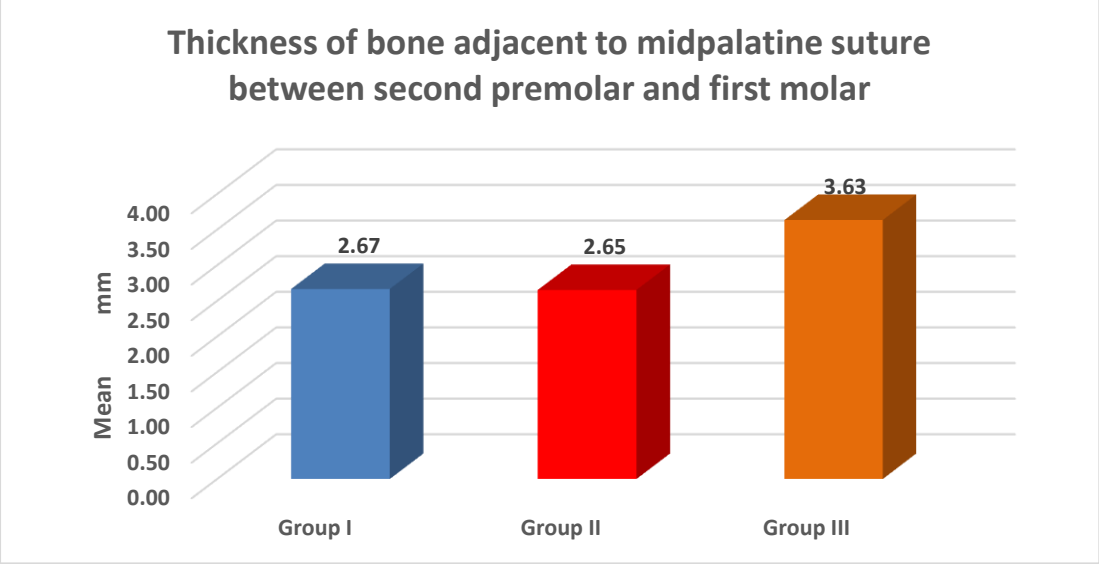


Graph 8: **Buccolingual bone density in different groups between second premolars and first moalrs at 2, 4, 6 and 8 mm from the alveolar crest**

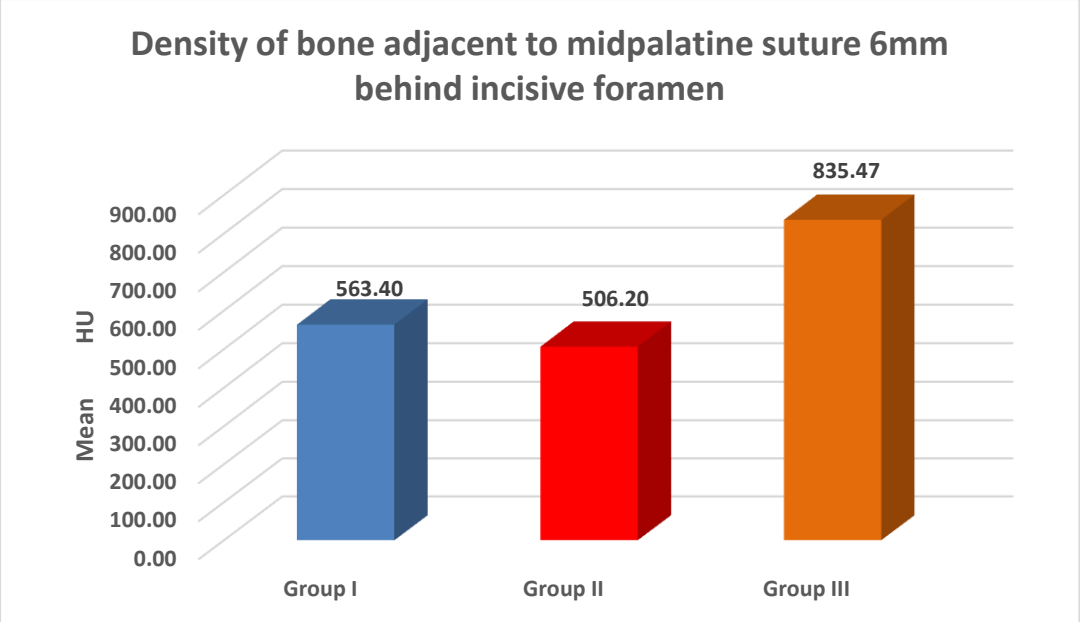
Palatal bone thickness and density showed statistically significant difference for each region (behind 6 mm distance from the incisive foramen at 3 mm adjacent to midpalatal suture and in the area between second premolar and first molar) between different group.(refer to graph 9-12 and table 8-9 and 14-15).For palatal bone thickness was same at both region selected i.e, group III> I, II. The density for palatal bone side showed a similar trend.(refer to graph 10 and 12 and table 13 and 15).



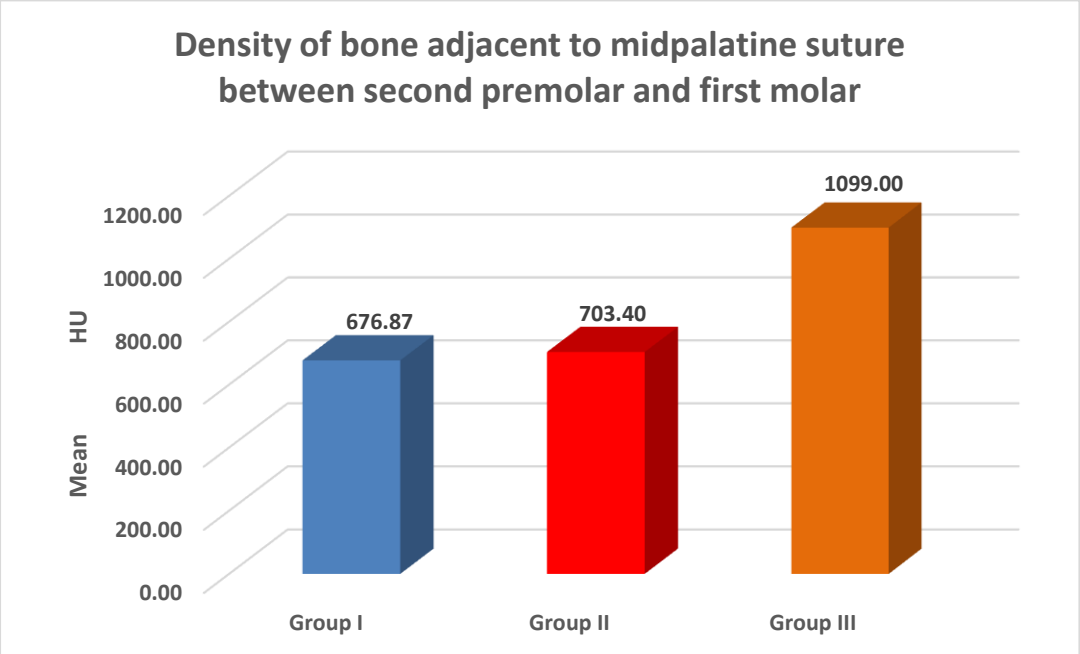
Graph 9: Palatal bone thickness in different groups at 3mm from midpalatal suture ,6 mm behind incisive foramen



Graph 10: palatal bone thickness in different groups at 3mm from midpalatal suture between second premolar and first molar



Graph 11: Palatal bone density in different groups at 3mm from midpalatal suture ,6 mm behind incisive foramen



Graph 12: Palatal bone density in different groups at 3mm from midpalatal suture between second premolar and first molar

Comparison of results was done with previous studies conducted to evaluate buccolingual bone thickness or palatal bone thickness or density at different locations and different bone heights.Factors responsible for mini-implant stability are: alveolar bone thickness, bone density, placement angle, and location appear to be critical for successful placement.

Fransworth and collegues [40] found that the interradicular bone between first premolar and second premolar and second premolar and first molar were thicker than the bone at the lateral incisor and canine and first molar and second molar sites in the maxillary region. They also found that the anterior paramedian palatal bone was significantly thicker than posterior palatal bone. Similar to this study bone thickness increased from anterior to posterior region in present study as well at different bone height.

Gracco et al [28] reported that the anterior part of the palate was thickest bone at the suture and in the paramedian areas but despite of reduced thickness in the posterior region, is also suitable for miniscrews placement. Moon.S.H[39] et al evaluated palatal bone density for the better selection of anchorage sites. They suggested that the palatal bone in the midpalatal area within 3mm of the midsagittal suture was densest bone in the entire palate. Similarly we found that the thickness of bone 3mm adjacent to mid palatal suture at 6mm from incisive foramen was more than that between second premolar and first molar for all the groups.

Matsui et al[60] emphasized on the sufficiency of bone availability for the successful implant placement in cleft patients. They stated that an implant placement requires attention to bone volume for its stability.

Balaji et al [15] stated that the most common sites used for implant placement in maxilla are interradicular areas between two central incisors (specifically for intrusion), between second premolars and first molars, between first and second permanent molars, infrazygomatic region- zygomatic buttress and midpalatal area.Poggio et al [20] assume that a minimum clearance of 1 mm of alveolar bone around the miniscrew would be sufficient for periodontal health.

Samantha Moscarino [52]et al evaluated palatal vertical bone thickness and density in potential anchorage sides in cleft palate patients. They reported that there is highest bone thickness in the anterior palate of noncleft patients and thickness decreases significantly in posterior region. They also evaluated bone density, which did not show any significant difference between cleft patients and normal control group. The present study supports the above study, the thickness of bone increases from anterior palate to posterior palate in all three groups but the quantity and quality of bone varies between group I /II and group III.

Poggio et al [20] concluded that the more anterior and the more apical region are the safest sites for miniscrew placement in maxilla. They reported that the safest sites for miniscrew placement are available in interradicular spaces in posterior maxilla are on the buccal or palatal side between first premolar and second premolar between 5 and 11mm from the alveolar crest. The interradicular space on the buccal side, between second premolar and first molar from 5 to 8mm from the alveolar crest were the safest zones for miniscrew placement. In the present study, it was found that the buucolingual bone thickness and density of maxilla was most favourable for the implant placement in the interradicular areas between first and second premolars and between second premolars and first molars at 6 and 8mm among all three groups (as shown in table5-6, 9-10, graph 3,4). However placement at such height is not always advisable in posterior segment because of close proximity to maxillary sinus in anterior segment, placement at 6, 8mm where buccolingual bone thickness and density are highest can be used for mini screw placement in cleft patients also, buccolingual bone thickness and density increased as bone height increased, hence for better stability increased bone height could be preferred in anterior region for cleft patients as well. However increased buccolingual thickness and density in posterior region at increased bone height will not always be physical.

Akhoon and Mustaq [49] also concluded that the anterior part of the palate is the thickest at the suture, about 4-8mm from the foramen and at the paramedian areas. They found the thickness of bone in the posterior region of the palate is also suitable for miniscrews with appropriate length and diameter. The present study found that the palatal bone thickness between second premolars and first molars at 3mm adjacent to midpalatal suture were 3.63± 0.32mm in group III, 2.65± 0.65mm in group II and 2.66± 0.70mm in group I (refer to table 10.12, graph10,12)and

Bernhart and collegues [62] recommended paramedian region at 3-4 mm distance from the suture and 6-9 mm distal to the incisive foramen. Alsamak .S et al [43] investigated the potential sites for the insertion of the orthodontic mini-implants through a systematic review of studies by using computer tomography or cone beam computed tomography and assessed anatomical hard tissue parameters such as bone thickness and bone density. The most favourable area in maxillary buccal region were between the lateral incisor and the canine,

while in the maxillary palatal area, it is between the central incisors or between the lateral incisor and the canine which corroborates with the present study.

In present study it was found the anterior part of palate (6mm behind the incisive foramen) was thicker and was having more density as compared to posterior region of palate in the area adjacent to second premolar and first molar and can be considered for implant placement in all three groups (refer to graph 9-12).

Bajaj et al[15] suggested that the diameter of miniscrews are 2mm or wide while microscrews are less than 2mm wide. If micro- implant are placed at 30- degree to 40 -degree angle to the long axis of the teeth in the maxilla, it will keep the screw in the widest space available between the roots in the apical region. Considering the finding of the all points in the previous studies, this study got favourable thickness and density of bone in normal (group III) as well as cleft patients (group I and II) at 6 to 8 mm height in the interradicular areas between central incisors. The interradicular areas between lateral incisors and canine, between first and second premolars and between second premolars and first molars , bone thickness and density was favourable for mini implant placement in all three groups at all the parameters taken for the measurement (at 2, 4, 6 and 8 mm from the alveolar crest) (refer to table 1-8, graph 1-8). The palatal bone thickness and density measured at 3mm adjacent to midpalatal suture (6mm behind the incisive foramen) was also favourable for microimplant placement in all three groups (refer to table 9,11, graph 9,11) but shorter length and appropriate diameter of implant should preferred in cleft patients(group I and II) with careful placement with optimum torque.

The main limitation of this study was the selection of only two regions for the assessment of palatal bone thickness and density. By involving more paramedian areas adjacent to midpalatal suture and selection of more points posterior to incisive foramen at the mid palatal suture may reveal more accurate measurement of palatal bone thickness and density.

To conclude it can be said buccal mini implant can be placed at increased height at anterior region and 2,4,6 mm in posterior region considering the location of muccogingival junction and hinderance due to buccal frenum.

Paramedian areas are suitable for mini implant placement palataly as mid palatine might not be completely calcified in normal adults and chances are there of interposition of soft tissue between screw and bone. Midpalatal suture is distorted in unilateral cleft lip and palate and bilateral cleft lip and palate patient, hence paramedian areas away from cleft site will be best sites for mini implant placement.

As bone thickness and density are reduced in cleft patient hence shorter than normally recommended mini implant will be preferred even mini implant with lesser diameter will be helpful.Locations of cleft decides values of palatal bone thickness and density should decode placement of mini implant.

CONCLUSION

The present study was conducted to assess maxillary bone thickness and density in surgically repaired unilateral and bilateral cleft lip and palate patients at different implant sites on CBCT images by using i-CAT software.

The following conclusion were drawn from the study-

- Buccolingual bone thickness showed statistically significant different for each region (between central insicors, between lateral incisors and canine , between first and second premolars , between second premolar and fist molar) at different heights in different groups except at 6 and 8mm in premolars and in premolar and molar region.
- Buccolingual bone density showed statistically insignificant difference in each region except in the areas between central incisors at 6mm from the alveolar crest.
- Palatal bone thickness and density showed statistically significant difference for each region (behind 6 mm distance from the insicive foramen at 3 mm adjacent to midpalatal suture and in the area between second premolar and first molar) between different group.
- For central incisors region as well as for lateral incisors and canine, buccolingual bone thickness at 2mm showed a trend of group III> II> I ,whereas for 4, 6,8mm ,it was group III>I>II
- For first and second premolar region as well as for second premolar and first molar region, buccolingual thickness at 2 and 4 mm showed a trend of group III >II>I.
- For density between central incisors, buccolingual density at showed a trend of group III>II>I (at 6mm from alveolar crest).
- For palatal bone thickness was same at both region selected i.e, group III> I, II. The density for palatal bone side showed a similar trend.
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BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES
(FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Assessment of Maxillary Bone Thickness and Density in Surgically Repaired Cleft Lip and Palate Patients At Different Implant Sites – A CBCT Study."** submitted by **Dr Divya Tripathi** Post graduate student from the **Department of Orthodontics & Dentofacial Orthopedics** as part of MDS Curriculum for the academic year 2018-2021 with the accompanying proforma was reviewed by the Institutional Research Committee present on **27th November 2018** at BBDCODS.

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

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

Received
Divya Tripathi
12/12/18

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

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

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

IEC Code: 17 BBDCODS/01/2019

Title of the Project: Assessment of Maxillary Bone Thickness and Density in Surgically Repaired Cleft Lip and Palate Patients At Different Implant Sites – A CBCT Study.

Principal Investigator: Dr. Divya Tripathi **Department:** Orthodontics & Dentofacial Orthopedics

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

Type of Submission: New, MDS Project Protocol

Dear Dr. Divya Tripathi,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 10th January 2019.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics & Dentofacial Orthopedics, BBDCODS, Lucknow
4.	Dr. Sumalatha M.N. Member	Reader, Department of Oral Medicine & Radiology, BBDCODS, Lucknow

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

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

Lakshmi Bala
22/01/19

(Dr. Lakshmi Bala)
Member-Secretary
IEC

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

Forwarded by:

(Dr. B. Rajkumar)
PRINCIPAL Principal
BBDCODS
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

BabuBanarasi Das College of Dental Sciences

(A constituent institution of BabuBanarasi Das University)

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

Participant Information Document (PID)

1. Study title

   Assessment of maxillary bone thickness and density in surgically repaired cleft lip and palate patients at different implant sites- A CBCT study.

2. **Invitation paragraph**

   You are being invited to take part in a research study, it is therefore important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

3. **What is the purpose of the study?**

   The purpose of this study is the assessment of maxillary bone thickness and density in cleft patients at different sites for mini-screw placement on CBCT images using i-CAT software.

4. **Why have I been chosen?**

   You have been chosen for this study as you are fulfilling the required criteria for this study.

5. **Do I have to take part?**

   Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you still are free to withdraw at any time and without giving a reason.

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

   You will have to give consent to use your CBCT image.

7. **What do I have to do?**

   You do not have to change your regular lifestyles for the investigation of the study.

8. What is the procedure that is being tested?

Maxillary bone thickness and density at various implant sites will be measured on CBCT scan using i-CAT software.

9. What are the interventions for the study?

Only your CBCT scans will be taken which you must have got it done for other reasons and you will not have any side-effects on your health.

10. What are the side effects of taking part?

There are no side effects on patients of this study.

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

There are no risk or disadvantages of taking part in this study.

12. What are the possible benefits of taking part?

This study will help in finding out favourable site for mini-screw placement ,which will ensure better stability of mini-screws and its contribution in long term success of an orthodontic treatment in such cases..

13. What if new information becomes available?

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

If the study stops/finishes before the stipulated time, this will be explained to the patient/volunteer.

15. What if something goes wrong?

If any severe adverse event occurs, or something goes wrong during the study, the complaints will be handled by reporting to the institution (s), and Institutional ethical community.

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

Yes it will be kept confidential.

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

The results of the study will be used to assess the maxillary bone thickness and density in surgically repaired cleft lip and palate patients at different sites for mini-screw placement on CBCT images using i-CAT software . Your identity will be kept confidential in case of any report/publications.

18. Who is organizing the research?

This research study is organized by the academic institution (BBDCODS).

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

Yes.

20. Who has reviewed the study?

The study has been reviewed and approved by the Head of the Dept, and the IEC/IRC of the institution.

21. Contact for further information

Dr. Divya Tripathi

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Dr. Laxmi Bala,

Member Secretary,

Babu Banarasi Das College of Dental Sciences.

Lucknow-227105

bbdcods.iec@gmail.com

Signature of PI.....

Name.....

Date .....

बाबू बनारसीदास कॉलेज आफ डेन्टल साइन्सेज
(बाबू बनारसीदास विश्वविद्यालय का एक घटक संस्थान)
बी0बी0डी0 सिटी, फैजाबाद रोड– लखनऊ 227105 (भारत)

प्रतिभागी के लिए सूचना–पत्र

1. अध्ययन शीर्षक :–

क्लेफ्ट लिप एवं पैलेट के शल्य चिकित्सा से सुधार हुए मरीजों के ऊपरी जबड़ों में इम्प्लान्ट लगने वाली जगहों पर हड्डी की मोटाई व घनत्व का आंकलन करना है (सी0बी0सी0टी अध्ययन) ।

2. **निमंत्रण अनुच्छेद :–**

आपको एक अध्ययन/शोध परीक्षण में भाग लेने के लिए आमंत्रित किया जा रहा है । यह जानना जरूरी है कि यह अध्ययन क्यों किया जा रहा है । कृपया ध्यान से आगे दी गयी जानकारी को पढ़िये । इसमें भाग लेना, न लेना आप पर निर्भर करता है ।

3. **अध्ययन का उद्देश्य क्या है ?**

अध्ययन का उद्देश्य क्लेफ्ट लिप एवं पैलेट के शल्य चिकित्सा से सुधार हुए मरीजों के ऊपरी जबड़ों में इम्प्लान्ट लगने वाली जगहों पर हड्डी की मोटाई व घनत्व सी0बी0सी0टी द्वारा आंकलन करना है ।

4. **मुझे इस अध्ययन के लिए क्यों चुना गया है ?**

आपको इस अध्ययन के लिए चुना गया है, क्योंकि आप इसके लिए आवश्यक मापदण्डों को पूरा कर रहे हैं ।

5. क्या इसमें मुझे भाग लेना चाहिए ?

अनुसंधान में आपकी भागीदारी पूरी तरह स्वैच्छिक है । यदि आप भागीदारी करते हैं तो आपको रखने के लिए सूचना पत्र दिया जायेगा और सहमति–पत्र पर हस्ताक्षर करने के

लिए कहा जायेगा । अध्ययन के दौरान आप किसी भी कारण अथवा किसी भी समय अपना नाम वापस लेने के लिए स्वतंत्र हैं ।

6. मुझे क्या होगा यदि मैं इस अध्ययन में भाग लेता हूँ ।

आपको अपनी सी0बी0सी0टी0 छवि का उपयोग करने के लिए सहमति देनी होगी ।

7. मुझे क्या करना है ?

आपको अध्ययन की जाँच के लिए नियमित जीवन शैली को बदलने की जरूरत नहीं है ।

8. किस प्रक्रिया का परीक्षण किया जा रहा है ?

विभिन्न मैक्सिलरी इम्प्लान्ट प्रत्यारोपण स्थलों पर हड्डी की मोटाई और घनत्व को आई–कैट साफ्टवेयर का उपयोग करके सी0बी0सी0टी0 स्कैन में मापा जायेगा ।

9. इस शोध में कौन से हस्तक्षेप किये जायेंगे ?

आपके ऊपरी जबड़ों में इम्प्लान्ट लगने वाली जगहों पर हड्डी की मोटाई व घनत्व का सी0बी0सी0टी0 द्वारा आंकलन किया जायेगा । केवल आपके सी0बी0सी0टी स्कैन का आंकलन किया जायेगा, जो आपने अन्य कारणों से कराया होगा । आपके स्वास्थ्य पर इसका कोई दुष्प्रभाव नहीं होगा ।

10. इस अध्ययन में भाग लेने के क्या दुष्प्रभाव है ?

इस अध्ययन के रोगियों पर कोई दुष्प्रभाव नहीं होगा ।

11. इस अध्ययन में भाग लेने के संभावित जोखिम और नुकसान क्या है ?

इस अध्ययन में भाग लेने से कोई नुकसान नहीं है ।

12. अध्ययन में भाग लेने के संभावित लाभ क्या हैं ?

यह अध्ययन मिनी–स्क्रू इम्प्लान्ट प्रत्यारोपण के लिए अनुकूल स्थानों का पता लगाने में मदद करेगा, जो मिनी–स्क्रू की बेहतर स्थिरता सुनिश्चित करेगा और इस तरह के मामलों में एक रूढ़िवादी उपचार की दीर्घकालिक सफलता में इसका योगदान होगा ।

13. **क्या होगा यदि कोई नई जानकारी उपलब्ध हो जाती है ?**

यदि अनुसंधान के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है तो आपको इनके बारे में बताया जायेगा और आप अपने शोधकर्ता के साथ इस पर चर्चा करने के लिए स्वतंत्र रहेंगे, आपका शोधकर्ता आपको बतायेगा कि क्या आप अध्ययन जारी रखना चाहते हैं । यदि वापस लेने का निर्णय लेते हैं तो आपका शोधकर्ता आपकी वापसी की व्यवस्था करेगा । यदि अध्ययन जारी रखने का निर्णय लेते हैं तो आपको एक अद्यतन सहमति–पत्र पर हस्ताक्षर करने के लिए कहा जा सकता है ।

14. **क्या होता है जब अध्ययन/शोध परीक्षण बन्द हो जाता है ?**

यदि अध्ययन निर्धारित समय से पहले बन्द हो जाता है तो यह रोगी को समझाया जायेगा ।

15. **क्या होगा अगर कुछ गलत हो जायेगा ?**

यदि अध्ययन के दौरान कोई गम्भीर प्रतिकूल घटना होती है या कुछ गलत होता है तो संस्थान और संस्थागत नैतिक समुदाय को रिपोर्ट करके शिकायतों को नियंत्रित किया जायेगा ।

16. **मेरे इस अध्ययन में भाग लेने को गोपनीय रखा जायेगा ?**

हाँ इसे गोपनीय रखा जायेगा ।

17. **अध्ययन/शोध परीक्षण के परिणाम का क्या होगा ?**

अध्ययन के परिणामों का उपयोग आई–कैट साफ्टवेयर का उपयोग करके सी०बी०सी०टी० छवियों का मिनी–स्क्रू इम्लान्ट प्रत्यारोपण के लिए अलग–अलग स्थानों पर सर्जिकल रूप से सुधार किये गये क्लेफ्ट लिप एवं पैलेट रोगियों में अधिकतम हड्डी की मोटाई और घनत्व का आंकलन करने के लिए किया जायेगा । किसी भी रिपोर्ट के मामले में आपकी पहचान गोपनीय रखी जायेगी ।

18. इस अध्ययन को कौन आयोजित किया जा रहा है और इस परीक्षण के लिए धन कहाँ से आयेगा ?

यह शोध अध्ययन शैक्षणिक संस्थान (वी0वी0डी0सी0ओ0डी0एस0) द्वारा आयोजित किया जा रहा है ।

19. क्या सेवायें शोध खत्म हो जाने के पश्चात् उपलब्ध रहेगी या नहीं ?

हाँ ।

20. इस अध्ययन का पुर्ननिरीक्षण किसने किया है ?

अध्ययन की समीक्षा की गयी है और विभाग के प्रमुख और आई0ई0सी0 द्वारा अनुमोदित किया गया है ।

21. अधिक जानकारी के लिए ?

डा0 दिव्या त्रिपाठी
डिपार्टमेन्ट आफ आर्थोडांटिक्स एवं डेन्टोफेशियल आर्थोपेडिक्स
बाबू बनारसीदास कॉलेज आफ डेन्टल साइन्सेज,
लखनऊ–227105
मो0 नं0– 9450709720

डा0 तृप्ति टिक्कु (विभाग प्रमुख)
डिपार्टमेन्ट आफ आर्थोडांटिक्स एवं डेन्टोफेशियल आर्थोपेडिक्स
बाबू बनारसीदास कॉलेज आफ डेन्टल साइन्सेज,
लखनऊ–227105
मो0 नं0– 9554832799

डा0 लक्ष्मी बाला
सदस्य सचिव,
बाबू बनारसीदास कॉलेज आफ डेन्टल साइन्सेज,
लखनऊ–227105
bbdcods.iec@gmail.com

मरीज का हस्ताक्षर .....

नाम .....

दिनांक : .....

BabuBanarasi Das College of Dental Sciences

(BabuBanarasi Das University)

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

Consent Form (English)

Title of the Study -: Assessment of maxillary bone thickness and density in surgically repaired cleft lip and palate patients at different implant sites-A CBCT Study.

Study Number.....

Subject's Full Name.....

Date of Birth/Age .....

Address of the Subject.....

Phone no. and e-mail address.....

Qualification .....

Occupation: Student / Self Employed / Service / Housewife/ Other (Please tick as appropriate)

Annual income of the Subject.....

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

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

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

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

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

5. I permit the use of stored sample (tooth/tissue/blood) for future research. Yes [ ] No [ ] Not Applicable [ ]

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

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:.....

Signatory's Name..... Date .....

Signature of the Investigator..... Date.....

Study Investigator's Name..... Date.....

Signature of the witness..... Date.....

Name of the witness.....

Received a signed copy of the PID and duly filled consent form Signature/thumb impression of the subject or legally Date.....

बाबू बनारसीदास कॉलेज आफ डेन्टल साइन्सेज
(बाबू बनारसीदास विश्वविद्यालय का एक घटक संस्थान)
बी0बी0डी0 सिटी, फैजाबाद रोड– लखनऊ 227105 (भारत)

सहमति पत्र

अध्ययन शीर्षक– क्लेफ्ट लिप एवं पैलेट के शल्य चिकित्सा से सुधार हुए मरीजों के ऊपरी जवड़ों में इम्प्लान्ट लगने वाली जगहों पर हड्डी की मोटाई व घनत्व का आंकलन करना है (सी0बी0सी0टी अध्ययन) ।

अध्ययन संख्या .....

प्रतिभागी का पूर्ण नाम.....

जन्मतिथि / आयु .....

प्रतिभागी का पता .....

फोन नं0, और ई–मेल पता .....

योग्यता.....

व्यवसाय : छात्र / स्व कार्यरत / सेवा / ग्रहिणी .....

अन्य (उचित रूप से टिक करें) .....

प्रतिभगी की वार्षिक आय .....

प्रत्याशियों के नाम और प्रतिभागी से संवंध ..... (परीक्षण से संबंधित मौत के मामले में मुआवजे के प्रयोजन के लिए)

1. मेरी पुष्टि है कि मैंने अध्ययन हेतु सूचना पत्र दिनांक ..... को पढ़ व समझ लिया तथा मुझे प्रश्न पूछने या मुझे अध्ययन अन्वेष्ज्ञक ने सभी तथ्यों को समझा दिया है तथा मुझे प्रश्न पूछने के समान अवसर प्रदान किये गये ।
2. मैंने यहॉ समझ लिया कि अध्ययन में मेरी भागीदारी पूर्णतः स्वैच्छिक है और किसी भी दबाव के विना स्वतंत्र इच्छा के साथ दिया है किसी भी समय किसी भी कारण के बिना, मेरे इलाज या कानूनी अधिकारें को प्रभावित किए विना अध्ययन में भाग न लेने के लिए स्वतंत्र हूँ ।
3. मैंने यह समझ लिया है कि अध्ययन के प्रयोजक की तरफ से काम करने वाले लोग आचार समिति और नियमाक अधिकारियों को मेरे स्वास्थ्य रिकार्ड को वर्तमान अध्ययन या आगे के अध्ययन के सन्दर्भ देखने के लिए मेरी अनुमति की जरूरत नहीं है, चाहे मैंने इस अध्ययन से नाम वापस ले लिया है । हॉलाकि मैं यह समझता हूँ कि मेरी पहचान को किसी भी तीरसरे पक्ष या प्रकाशित माध्यम में नहीं दी जायेगी ।
4. मैं इससे सहमत हूँ कि कोई भी डेटा या परिणाम जो इस अध्ययन से प्राप्त होता है उसका वैज्ञानिक उद्देश्य (ओ) के उपयोग के लिए मेरी तरफ तरफ से कोई प्रतिबंध नहीं है ।

BabuBanarasi Das College of Dental Sciences

(BabuBanarasi Das University)

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

Child Assent Form

StudyTitle -: Assessment of maxillary bone thickness and density in surgically repaired cleft lip and palate patients at different implant sites – A CBCT Study.

StudyNumber_____

Subject's FullName_____

Date of Birth/Age_____

Address_____

_____

_____

I_____, exercising my free power of choice, hereby give my consent for participation in the study entitled: "....." I have been informed, to my satisfaction, by the attending physician, about the purpose of the study and the nature of the procedure to be done. I am aware that my parents/guardians do not have to bear the expenses of the treatment if I suffer from any trial related injury, which has causal relationship with the said trial drug. I am also aware of right to opt out of the trial, at any time during the course of the trial, without having to give reasons for doing so

Signature of the study participant_____

Date:_____

Nameofthe study participant_____

Signature of the Witness _____

Date_____

Name of the Witness _____

Signature of the attending Physician_____Date:_____ Name of the attending Physician

बाबू बनारसीदास कॉलेज आफ डेन्टल साइन्सेज
(बाबू बनारसीदास विश्वविद्यालय का एक घटक संस्थान)
बी0बी0डी0 सिटी, फैजाबाद रोड– लखनऊ 227105 (भारत)

शिशु सहमति पत्र

मैं ..... अनुसंधान "क्लेफ्ट लिप एवं पैलेट के शल्य चिकित्सा से सुधार हुए मरीजों के ऊपरी जबड़ों में इम्प्लान्ट लगने वाली जगहों पर हड्डी की मोटाई व घनत्व का आंकलन करना है (सी0बी0सी0टी अध्ययन)" में भाग लेने के लिए अपनी सहमति प्रदान करता हूँ । मुझे अध्ययन के हेतु और उसमें की जाने वाली प्रतिक्रिया के बारे में चिकित्सक द्वारा बता दिया गया है । मुझे पता है कि अध्ययन सम्बन्धी किसी हानि जिसका अध्ययन की दावा से सम्बन्ध है उसका खर्च मेरे माता पिता अथवा अभिभावक को नहीं वहां करना है । मुझे यह भी पता कि मैं इस अध्ययन से किसी समय बिना कोई कारण बताये बाहर हो सकता हूँ ।

अध्ययन में भाग लेने वाले का नाम और हस्ताक्षर
..... दिनांक .....

गवाह के हस्ताक्षर ..... दिनांक .....

गवाह का नाम .....

चिकित्सक का नाम और हस्ताक्षर ..... दिनांक .....

5. भविष्य के अनुसंधान के लिए भंडारित नमूना (ऊतक/रक्त) पर अध्ययन के लिए अपनी सहमति देता हूँ ।

हाँ ( ) नहीं ( ) अनउपयुक्त ( )

6. मैं परीक्षण की अनुमति देता हूँ। मुझे इसके द्वारा यदि कोई परेशानी होती है तो इसके बारे में जानकारी दे दी गयी है । मैंने रोगी जानकारी सूचना पत्र को पढ़ तथा समझ लिया है ।

प्रतिभागी/कानूनी तौर पर स्वीकार्य प्रतिनिधि का हस्ताक्षर (या अगूँठे का निशान) .....

हस्ताक्षरकर्ता का नाम ..... दिनांक ..... अन्वेषक के हस्ताक्षर ..... दिनांक .....

अध्ययन अन्वेषक का नाम .....

गवाह के हस्ताक्षर ..... दिनांक ..... गवाह के नाम .....

मैंने पीआईइडी और विधिवत भरे सहमति फार्म का एक हस्ताक्षर की नकल प्राप्त की.

प्रतिभागी कानूनी तौर पर प्रतिनिधि का हस्ताक्षर/अंगूठे का निशान .....

दिनांक.....

Curiginal

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Sources included in the report

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