T.C.
YEDITEPE UNIVERSITY
INSTITUTE OF HEALTH SCIENCES

RETROSPECTIVE EVALUATION OF CORTICAL BONE THICKNESS IN PATIENTS WITH UNILATERAL CLEFT LIP AND PALATE

DOCTOR OF PHILOSOPHY THESIS

Dt. FEYZA NUR BULUT

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FEYZA NUR BULUT, DDS.

SUPERVISOR
Prof. Dr. Derya Çakan

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	Title, Name-Surname (Institution)
Chair of the Jury and Supervisor:	Prof. Derya Çakan (Yeditepe University, Faculty of Dentistry, Department of Orthodontics)
Member/Examiner:	Prof. Fulya Özdemir (Marmara University, Faculty of Dentistry, Department of Orthodontics)
Member/Examiner:	Prof. Gökmen Kurt (Bezmialem Vakıf University, Faculty of Dentistry, Department of Orthodontics)
Member/Examiner:	Assoc. Prof. Murat Tozlu (Gelişim University, Facuty of Dentistry, Department of Orthodontics)
Member/Examiner:	Assoc. Prof. Burcu Nur Yılmaz (Yeditepe University, Faculty of Dentistry, Department of Orthodontics)

APPROVAL

This thesis has been deemed by the jury in accordance with the relevant articles of Yeditepe University Graduate Education and Examinations Regulation and has been approved by Administrative Board of Institute with decision dated 28/01/2021 and numbered 2021/02-05.

Prof. Dr. Bayram YILMAZ

Director of Institute of Health Sciences

DECLARATION

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material which has been accepted for the award of any other degree except where due acknowledgment has been made in the text.

11/01/2021

Feyza Nur Bulut

DEDICATION

I would like to dedicate my thesis to my beloved child, Hello, who passed away on 2017. He has taught me so much and he has changed me into a better person . I love him more than anything and I miss him every single day.

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LIST of ABBREVIATIONS and SYMBOLS

ABG	: Alveolar Bone Graft
ALARA	: As Low As Reasonably Achievable
BBPE	: Bone Borne Palatal Expander
BAMP	: Bone Anchored Maxillary Protraction
BCBT	: Buccal Cortical Bone Thickness
BCLP	: Bilateral Cleft Lip and Palate
BKKK	: Bukkal Kortikal Kemik Kalınlığı
CBCT	: Cone- Beam Computed Tomography
CBT	: Cortical Bone Thickness
CEJ	: Cemento-Enamel Junction
CG	: Control Group
CS	: Cleft Side
CT	: Computed Tomography
CLP	: Cleft Lip and Palate
EDO	: Bone Borne Palatal Expansion with Differential Opening
ENT	: Ear, Nose, and Throat
FM/ MP	: Face Mask/ Maxillary Protraction
Go	: Gonion
GPP	: Gingivoperiosteoplasty
LUCLP	: Left Unilateral Cleft Lip and Palate
MASDO	: Maxillary Anterior Segmental Distraction Osteogenesis
Me	: Menton
MGJ	: Mucogingival junction
MRI	: Magnetic Resonance Imaging
N	: Nasion
NCS	: Non- Cleft Side

OL	: Orbitale Left
OMI	: Orthodontic Mini-Implant
OPT	: Orthopantomongram
OR	: Orbitale Right
PABG	: Primary Alveolar Bone Graft
PCBT	: Palatal Cortical Bone Thickness
PKKK	: Palatal Kortikal Kemik Kalınlığı
RUCLP	: Right Unilateral Cleft Lip and Palate
S	: Sella
SG	: Study Group
SABG	: Secondary Alveolar Bone Graft
TAD	: Temporary Anchorage Device
TMJ	: Temporomandibular Joint
TTDDY	: Tek Taraflı Dudak Damak Yarığı
UCLP	: Unilateral Cleft Lip and Palate
3D	: Three- Dimensional
2D	: Two- Dimensional
n	: Number of sample
mm	: Milimeter
mA	: Miliamper
kV	: Kilovoltage
µSv	: Microsieverts
SD	: Standard Deviation
%	: Percentage
i.e.	: Id est
e.g.	: Exempli gratia
=	: Equal

± : Plus- minus sign

> : Bigger

< : Smaller

ABSTRACT

Bulut, FN. (2021). Retrospective Evaluation of Cortical Bone Thickness in Patients with Unilateral Cleft Lip and Palate. Yeditepe University, Institute of Health Science, Department of Orthodontics, PhD thesis, İstanbul.

The purposes of this study were to evaluate the buccal and palatal cortical bone thickness in patients with complete unilateral cleft lip and palate (UCLP) and compare the cortical bone thicknesses at these specific locations between cleft and non-cleft sides and between subjects with and without UCLP. Fifty patients with UCLP (mean age of 14.76 ± 5.06 years) were selected for study group. The control group also contained 50 subjects (mean age of 16.54 ± 4.55 years) without any congenital deformity. Cortical bone thicknesses were evaluated using cone beam computed tomography images on 3dMD Vultus software program. Posterior buccal cortical bone thickness (BCBT) measurements were made on the cleft and non-cleft sides of UCLP patients, and on one side of the control group at maxillary interradicular areas between canine and 1st molar, at 4, 6 and 8 mm from the alveolar crest whereas palatal cortical bone thicknesses (PCBT) were also measured at 10 and 12 mm. Statistical analysis were made using NCSS software program. According to statistical evaluation, in patients with UCLP, the mean BCBT and PCBT at posterior maxilla ranged between 1.2 and 1.5 mm. There was no difference between BCBT and PCBT in UCLP group and furthermore they did not show any differences between cleft and non-cleft sides as well ($p>0.05$). On the other hand, BCBT and PCBT in UCLP group were significantly lower than that of the control group ($p<0.001$). BCBT and PCBT are generally prone to increase from anterior to posterior and from the alveolar crest to apex. In patients with UCLP, although most of the interradicular sites was found to be suitable for mini-implant insertion in terms of cortical bone thickness, less than 1 mm thicknesses may also be seen between canine and premolars, and closer to alveolar crest.

Key Words: Cortical bone thickness, cleft lip and palate, mini-implant insertion site, cone beam computed tomography

ÖZET

Bulut, FN. (2021). Tek Taraflı Dudak Damak Yarıklı Hastaların Kortikal Kemik Kalınlıklarının Retrospektif Olarak Değerlendirilmesi. Yeditepe Üniversitesi, Sağlık Bilimleri Enstitüsü, Ortodonti AD, Doktora Tezi, İstanbul.

Bu çalışmanın amaçları, tam tek taraflı dudak damak yarığı (TTDDY) olan hastaların bukkal ve palatinal kortikal kemik kalınlıklarının ölçülmesi, bu ölçümlerin TTDDY hastalarının yarık olan ve yarık olmayan tarafları arasında ve TTDDY olan hastalarla dudak damak yarığı olmayan hastalar arasında karşılaştırılmasıdır. Çalışma grubuna tam TTDDY bulunan 50 hasta (yaş ortalaması 14.76 ± 5.06 yıl), kontrol grubuna ise herhangi bir konjenital anomalisi bulunmayan 50 hasta (yaş ortalaması 16.54 ± 4.55 yıl) dahil edilmiştir. Posterior bukkal kortikal kemik kalınlığı (BKKK) ölçümleri, TTDDY hastalarının yarık olan ve yarık olmayan taraflarında, kontrol grubundaki hastaların ise tek tarafında, 1. molar ile kanin dişler arasındaki interradiküler alanlarda, alveolar krest tepesinin 4, 6 ve 8 mm apikalinde yapılmıştır. Palatal kortikal kemik kalınlığı ise (PKKK) alveolar krest tepesinin 4, 6, 8, 10 ve 12 mm apikalinde yapılmıştır. Verilerin değerlendirilmesinde NCSS istatistiksel yazılım programı kullanılmıştır. İstatistiksel değerlendirmelere göre; tek taraflı dudak damak yarıklı bireylerde posterior maksilladaki ortalama bukkal ve palatinal kortikal kemik kalınlığı 1.2 mm ile 1.5 mm arasında değişiklik göstermiştir. TTDDY grubunda, BKKK ile PKKK arasında istatistiksel olarak fark bulunmamış olup, ayrıca yarık olan taraf ile yarık olmayan taraf arasında da bir fark gözlenmemiştir ($p>0.05$). TTDDY grubunun BKKK ve PKKK değerlerinin, kontrol grubuna göre istatistiksel olarak daha düşük olduğu saptanmıştır ($p<0.001$). BKKK ve PKKK, anteriordan posteriora ve alveolar krestten apekse doğru artma eğilimi göstermiştir. TTDDY olan hastaların interradiküler alanları incelendiğinde, çoğunlukla mini vida uygulaması için yeterli kortikal kemik kalınlığı mevcut olsa da, kanin ve premolar arasında ve alveolar kreste yakın bölgelerde 1 mm'den az kortikal kemik kalınlıklarına rastlanmıştır.

Anahtar Kelimeler: Kortikal kemik kalınlığı, dudak damak yarığı, mini vida, konik ışınlı bilgisayarlı tomograf

1. INTRODUCTION and PURPOSE

The objective of an orthodontic treatment is to provide required tooth movement with minimum unwanted side effects, in other words, to eliminate anchorage loss. Conventionally, anchorage is strengthened by increasing the number of teeth bilaterally or using the muscles, extraoral devices, and the alveolar process. Avoiding unwanted tooth movement in maxillary and mandibular arches is probable with the usage of mini-implants. The use of small titanium bone screws has made the absolute anchorage possible and enhanced the range of orthodontic treatment, giving an alternative to orthognathic surgery in some cases and allowing asymmetrical three-dimensional tooth movement. Mini-implants ensure the biomechanical advantage that simplifies orthodontic treatment with the minimal need of auxiliaries and other appliances (1). Predicting resistance to tooth movement can minimize the side effects, lead to more successful treatment of complex problems, and provide efficient care in less time (2).

Mini-implants are inserted in various anatomic locations, according to the orthodontic need and the biomechanics preferred. After the placement in these anatomic sites as anchorage units, the stability of the mini-implants throughout orthodontic force application defines their success. The factors that effect mini-implant success are anatomical factors as cortical bone thickness (3), soft tissue character (4), and root proximity (5), placement related factors as insertion torque (6), placement angle (7), heat induced by predrilling (8), and clinician's experience (9), implant related factors such as mini-implant design, mini-implant system, length and diameter (10, 11), load related factors as force used (12), immediate or late loading (13), and direct or indirect anchorage (14) and lastly individual factors as age (15), sex (16), malocclusion (17, 18), and oral hygiene (19). Recently, cortical bone thickness and quality have been an element of interest in consequence of the development in orthodontic skeletal anchorage systems. Accordingly, it is reported that the cortical bone thickness and density are the primary determinants that influence implant stability rather than the ratio between the cortical and trabecular bone. Cortical bone could resist better to the deformation and carry greater forces compared to trabecular bone because of its higher modulus of elasticity. What is valid for dental implants is also valid for orthodontic mini-implants: denser and thicker cortical bone ensures better primary stability (20).

Cortical bone thickness may differ between the individuals with different facial skeletal characteristics (18, 21-25). There are studies investigating the relation between the initial stability of an orthodontic mini-implant (OMI) and cortical bone thickness in different malocclusion groups (17, 18, 22-29). However, to our knowledge, alveolar bone characteristics, particularly cortical bone thicknesses, at posterior mini-implant insertion areas of cleft lip and palate (CLP) patients have not been studied yet. The orthodontic rehabilitation of cleft lip and palate requires a complex and a relatively longer treatment period due to dental and skeletal malocclusions, and hard and soft tissue deficiencies. There is a possibility that the use of skeletal anchorage in these cases can be very beneficial because of the biomechanical advantage of mini-implants over the traditional anchorage methods, and because of various dental anomalies (i.e. hypodontia, oligodontia) seen in CLP patients. Even though temporary anchorage device (TAD) usage is becoming more popular, it has not been common in CLP treatment yet compared to non-cleft patients. The reason might be the uncertainty about the alveolar characteristics of cleft patients in possible mini-implant insertion areas. The only study which assessed palatal cortical bone thickness and density for determining the optimal sites for the insertion of an orthodontic mini-implant in CLP patients showed that this deformity was related to the decreased bone levels in comparison with non-cleft patients. However, no other study exists in the literature evaluating this significant factor affecting the mini-implant stability, the buccal and cortical bone thicknesses in patients with orofacial clefts. Thus, a guideline to determine safe and risky areas for mini-implant insertion regarding cortical bone thickness would be practical.

Therefore, the goal of this study was to quantitatively evaluate the buccal and palatal cortical bone bone thickness at interradicular areas for mini-implant insertion in the posterior maxilla of the patients with UCLP and create a map for the clinicians. The secondary aims were to compare the cortical bone thicknesses at these specific locations between the cleft and non-cleft sides and between the subjects with and without UCLP.

2. LITERATURE REVIEW

2.1. Orthodontic Mini-Implant

2.1.1. Definition

An orthodontic mini-implant is an appliance particularly designed to be inserted at certain locations in the bones of the craniofacial complex, the primary objective of which is to ensure anchorage for an orthodontic appliance (30). Mini-implants are the most commonly used temporary anchorage devices in the oral cavity (31). These temporary anchorage devices are separated from permanently placed implants in terms of insertion technique, osseointegration and size.

2.1.2. Historical Background

In 1945, the concept of skeletal anchorage was first introduced by Gainsforth and Higley (32) who inserted Vitallium screw in dogs concluding that anchorage may be obtained for orthodontic movement in the future. However, initiation of orthodontic force resulted in the failure of the screw in 16 to 31 days. This is considered to be the first published case of an implant for orthodontic anchorage.

In 1970, Leonard Linkow (33) used an implant for replacement of a missing molar. In 1964, Branemark and associates (34) had reported the use of titanium optical chambers implanted into the femur of a rabbit. The chamber was developed for *in vivo in situ* microscopic study of bone marrow. Their result showed that it was possible to secure a proper anchorage with titanium to the bone with no adverse effect. They then placed titanium endosseous implant into healed extraction site in upper and lower jaws of dogs (35). In 1969, they reported that titanium implants remained stable for 5 years without a sign of tissue injury or rejection. The implant had become firmly osseointegrated in the bone. The success has attributed to the material development and less invasive surgical procedure in which implants were loaded. In 1984, Robert and fellow researchers (36) collaborated the findings of Branemark in an extensive study of titanium implants in the rabbits. The study concluded that titanium endosseous implants provides reliable osseous anchorage for orthodontics and dentofacial orthopedics. Creekmore and Eklund (37) used Vitallium implant for anchorage for the intrusion of upper anterior teeth in 1983. Kanomi (38) first mentioned a temporarily placed mini-implant for orthodontic anchorage in 1997. Nowadays, orthodontic mini-implants vary considerably in size, in shape and in material.

2.1.3. Indications

The orthodontic indications of OMIs are determined by the required movement and biomechanics that will be used. The orthodontic treatment objectives that can be provided by OMIs are as following (39);

1) Antero-posterior control
    - Anterior retraction
    - Distalization
    - Molar protraction
2) Vertical control
    - Anterior intrusion and extrusion
    - Posterior intrusion and extrusion
3) Transverse control
    - Symmetric expansion
    - Asymmetric expansion

2.1.4. Contraindications

Absolut contraindications for OMI use are (40);

- Severe systemic disorders
- Specific psychiatric conditions
- Alcoholic drug abuser
- Patients with circulatory diseases or latent infections
- Patients with allergies to certain materials
- Acute infection

Relative contraindications for OMI use are (40);

- Insufficient bone volume
- Poor bone quality
- Patients having radiation therapy
- Insulin-dependent diabetes

- Heavy smokers
- Patients suffering from recurring diseases of the oral mucosa and poor oral hygiene

2.1.5. Mini-Implant Placement Sites

The mostly preferred mini-implant placement locations are cited as the buccal and palatal interradicular alveolar areas in maxillary and mandibular jaw, the palate, and the retromolar pad in the mandible (20, 41, 42). The important factors that should be taken into account when deciding on where to insert mini-implants are soft-tissue and sinus anatomy, buccolingual bone depth, nerve location, root proximity, buccal cortical bone thickness, and palatal/ lingual cortical bone thickness (42).

Implant placement locations in the maxilla are infrazygomatic crest area, tuberosity area, interradicular areas (between first and second molars, first molar and second premolar, both premolars, canine and premolar, and between incisors), and lastly midpalatal area. Implant placement sites in mandible are retromolar area, buccal interradicular areas (between first and second molars, first molar and second premolar, both premolars, canine and premolar), facial side of the symphysis , edentulous areas, and mandibular tori (43).

2.1.6. Orthodontic Mini-Implant Success and Primary Stability

Several factors are mentioned regarding the success rates of mini-implants. Anatomical factors that are investigated are soft tissue characteristics, placement sites, cortical bone thickness, and root proximity. Individual factors can be listed as sex, age, and oral hygiene. Placement related factors are placement angle (7), insertion torque, heat induced by predrilling (44), and clinician's experience (9). Implant related factors are the design, length and diameter of the mini-implant and the implant system used. In addition, loading related factors such as the magnitude of the force, immediate or late loading and, direct or indirect anchorage loading are considered (12). Amongst these factors, the anatomical features of the mini-implant site, the cortical bone thickness in particular, appear to have a direct influence on success (3, 45, 46) because primary stability of an OMI, which is the primary stability right after placement, is mostly achieved by the mechanical locking with the cortical bone, not by osseointegration.

The process causing to unsuccessful mini-implants starts with bone resorption occuring from a superior to an inferior direction in trabecular bone, causing the reduction in trabecular bone support. Therefore, bone resorption takes place at the upper and lower borders of the cortical bone. At last, the mini-implant cannot withstand the orthodontic load anymore, and it fails (45). If mini-implants stays more than 4 months bearing the orthodontic load, they can be regarded as stable and successful.

2.1.6.1. Sex

The influence of sex on the success of mini-implants is still debatable. Many articles stated no correlation between the sex and the OMI success (47, 48). Studies by Ono *et al.* (49), Fayed *et al*. (42), Vakil and Sable (50) and Kang *et al.* (51) have shown that the cortical bone thickness was greater in males than in females. Ono et *al.* (49) conducted a computed tomography study to analyze posterior buccal cortical bone thickness on 43 subjects that included 32 females and 11 males with a mean age of 24 ± 8.2 years. The measurements were made at 1-15 mm from the alveolar crest within 1 mm intervals both in maxilla and mandible. They reported that cortical bone thickness was more in males than in females at 1 to 2 mm and 5 to 9 mm apical from the alveolar crest in the maxilla. At other levels, they did not find any important difference considering gender. Also, their results showed that cortical bone thickness was less in females mesial to the maxillary first molar. Similarly, Fayed *et al.* (42) did a CBCT study to investigate buccal cortical bone thickness on 100 patients of which 54 subjects were female and 46 subjects were male with two different age subgroups, 13-18 years and 18-27 years. The analysis was made at 2 mm, 4 mm and 6 mm from the CEJ at the interradicular areas between second molars and centrals. According to their results, in the anterior maxilla at 2 mm and 4 mm, and in the posterior maxilla at 4 mm and 6 mm, female subjects had thinner cortical bone compared to male subjects. Vakil and Sable (50), on their CBCT study, evaluated buccal and palatal cortical bone thickness in a group of 27 Indian subjects whose age interval was 18-35 years. They measured cortical bone thickness at 2 mm, 4 mm, 6 mm, 8 mm, and 10 mm from the alveolar crest at every interradicular area from second molar to central incisor. Overall, they found that cortical bone thickness was more in males than in females. Kang *et al.* (51) included 9 females and 9 males with a mean age of 26.8 ± 4 years in their CT study to evaluate the palatal cortical bone thickness. Male subjects showed greater palatal cortical bone thickness values than female subjects.

On the other hand, Ohiomoba et *al*. (52) did a study to evaluate buccal and palatal maxillary cortical bone thickness on 30 female and 30 male subjects older than 12 years. They measured the interradicular areas in posterior, middle and anterior maxilla at 2 mm, 4 mm, 6 mm and 8 mm from the alveolar crest. They found that sex was not an important determinant on cortical bone thickness. On the other hand, they argued that the cortical bone of females was denser than of males. Likely, Schneider *et al.* (53) conducted a CBCT study on 290 subjects to find out the correlation between the host variants such as age, sex, growth pattern and the maxillary and mandibular cortical bone thickness. Their measurement areas were interradicular areas between second molar and canines at 2 mm, 6 mm and 10 mm from the alveolar crest both on buccal and palatal sides. They concluded that gender has no significant effect on thickness. Also, Farnsworth et *al.* (48) assessed the cortical bone thickness in maxilla and mandible on CBCT between the interdental areas from lateral incisor to second molar at 4 mm from the alveolar crest. Their group consisted of 52 patients with two subgroups with different age intervals; adolescents and adults. They found no gender related differences regarding cortical bone thickness nor in the maxilla neither in the mandible. Chun and Lim (54) investigated the bone density at the interradicular areas between the second molar to the central at 0, 2, 4, and 6 mm from the alveolar crest on CT. 14 Korean females and 14 Korean males with 27 years of mean age were included to their study. They found no relationship regarding sex and bone density.

2.1.6.2. Age

In the literature, there are conflicting views on the association between the cortical bone thickness and age. The reason it is still unknown is simply because the variations in cortical bone thickness regarding age have not been systematically investigated yet. Farnsworth et *al.* (48) divided their group as adolescents between 11 and 16 years, and adults between 20 and 45 years in their study and they measured cortical bone thickness at OMI insertion areas. The measurements were made at 4 mm from the alveolar crest for the anterior and posterior maxilla. They reported no age-dependent variation distal to the mandibular first molar but showed a significant age-dependent variation in the maxillary buccal cortical bone thickness. They concluded that the cortical bone at frequently used interdental areas for OMI insertion in both jaws was remarkably thicker in adult patients than in adolescent patients. Similar to their findings, Fayed *et al.* (42) reported that in the anterior maxilla, there were greater buccal cortical bone thickness at 6 mm from cemento-enamel junction (CEJ), and greater palatal cortical bone thickness at 2 mm from CEJ in older subjects. They formed two subgroups of late adolescents between 13 and 18 years, and young adults between 19 and 27 years. However, they did not mention any differences for buccal cortical bone thickness at 2 mm and 4 mm and palatal cortical bone thickness at 4 mm and 6 mm. Motoyoshi et *al.* (3) conducted a clinical research on mini-implant stability rate in adolescent patients. They included 57 patients of which 30 subjects were adolescents with an age interval changing from 11.7 to 18.9 years, and 27 subjects were adults with an age interval changing from 20.4 to 36.1 years. Their criteria of mini-implant success was a 6 months of stability. They correlated the age with early or late loading and with placement torque. They found out that there were no differences between the adult and adolescent patients if the adolescent group would have received late loading with 5-10 N of placement torque. The success rate was lowest in adolescents who had early loading. Schneider *et al.* (53) compared the buccal and palatal cortical bone thickness at 2, 6 and 10 mm from the alveolar crest at posterior maxilla between 141 growing patients (14.7 ± 1.6 years) and 149 adult patients (29.0 ± 9.1 years). They observed no significant variation of cortical bone thickness regarding the growth stage. Cheng et *al.* (46) conducted a prospective study on 44 patients with an age interval of 13 to 55 years. They reported that not only age but gender and magnitude of the orthodontic load had no significant influence on the primary stability of the orthodontic mini-implants. Miyawaki et *al.* (55) evaluated mini-implant and mini-plate success with a clinical study. 51 patients with a mean age of 21.8 years were collected for this study. They found no significant relation between the success rate and age variable.

Sathapana *et al.* (56) had similar findings on their sample of 11 to 50 years old except maxillary buccal incisor region and maxillary palatal incisor and premolar region. They concluded that age had comparatively minimal impact on the cortical bone thickness based on their statistically significant negative relationship between age and cortical bone thickness.

2.1.6.3. Root Proximity

The proximity of mini-implants to the neighboring tooth root is considered to be a large risk agent for the unsuccessful OMI anchorage (5, 57, 58). Nowadays, in many clinical situations, OMIs are inserted between the roots to obtain more horizontal vector of the orthodontic force. This insertion is, anyhow, not always probable because of the anatomical limitations. Kuroda et *al.* (58) conducted a clinical study on 110 patients. Root proximity was found to be a critical factor for mini-implant success. They reported that if the mini-implant had no contact with the roots, the success ratio was 90% in a one year follow-up. 2.5 mm of distance between the roots and OMI seems to be optimal to avoid damage to the adjacent structures for mini-implants do not stay still when orthodontic forces applied (59). Thereupon, these limitations demand a careful selection of the mini-implant insertion site. This risk factor is more dominant in the mandible. Overall, during mini-implant insertion, avoiding root proximity is significant for the OMI stability and orthodontic anchorage (57). It is essential to insert OMIs distant from the roots by choosing implants with appropriate size (10).

2.1.6.4. Length and Diameter

The optimal design in terms of size and shape of OMIs for orthodontic purposes stays unclear and limited advance has been made to determine the optimal design criteria. There are several controversial records regarding the impact of OMI length and diameter on primary stability and success (9, 10, 55).

So far, the available diameters for OMIs are varying from 1.2 to 1.6 mm. Among them, tapered OMIs with 1.2- or 1.3-mm diameter are preferred due to the anatomical limitations. This, of course, differs based on the insertion site and the availability of the interradicular area. Deguchi et *al.* (45) recommended that mini-implants smaller than 1.5 mm in diameter could lower the failure ratio at the posterior maxilla and mandible in situations where there was not enough distance between the roots of the subjected teeth. Therefore, OMI diameter is limited to the available interradicular space. If we are to take the width of the periodental membrane into consideration, it is essential to provide root proximity of at least 2.5 mm (57). The root proximity decreases towards the apex, so sufficient root proximity can be found at a point around the root apex (45). If a placement is obligatory below the apical area, enough root proximity can be found in between lateral and canine, between premolars, and between second premolar and first molar. Because there is less interdental space in areas between central and lateral incisors, canine and first premolar, and first and second molars, an extra attention is necessary regarding the contact between the OMI and the tooth root when inserting OMIs at previously mentioned areas (45). According to Miyawaki et *al*. (55) implants with a diameter of 1.5 mm should be used in low angle patients, and implants with a diameter of more than 2.3 mm should be used in high angle patients. High angle growth pattern, which is usually associated with thinner cortical bone, is found to be related to the failure of OMIs (18, 55).

The recommended mini-implant length in use varies from 6 to 8 mm (60). There are studies reported that the success rate of OMIs increases in proportion to the length of the OMI (45). However, Cheng et *al.* (46) proposed that the length of mini implants had zero impact on implant survival. So, longer implants do not necessarily provide a better bone support. The implant length is usually determined according to the transmucosal depth, which is the distance between the bone surface and the mucosa, rather than by the extent of bone available for anchorage (46). The width of the alveolar process in maxila is 6 mm or more at most of the sites. At regions above the alveolar process and in the molar area, 8 mm of width may be provided for the alveolar process and longer OMIs may be preferred (61).

Based on the findings of the width of the maxillary alveolar process and the root proximity, 6 mm of length with a diameter of 1.3 mm is the optimal OMI size. Besides, in lingual orthodontics, the suggested site is the mesial of the first molar at 30° of angulation, and 8 to 10 mm in length (46). Kuroda et *al.*'s (58) 3D-CT scanning recommends that OMIs with diameters of 1.3 to 1.5 mm and lengths of 6 to 8 mm are suggested for orthodontic anchorage in interdental sites.

2.1.6.5. Soft Tissue Characteristics and Anatomical Location

Soft tissue characteristics and placement site were identified as factors that were significantly related to peri-implant infection and mini-implant failure. The requirement of keratinized gingiva for keeping the mini-implant healthy has been discussed for a long time. Retrospective clinical surveys were not capable of revealing the exact differences in the maintanence of mini-implants inserted in keratinized or non-keratinized mucosa. Conversely, in a study on monkeys, Warrer *et al.* (62) realized that if there was not keratinized mucosa around the dental implants, the risk of tissue harm at peri-implant region increased. There are other studies (4, 46, 63) that also report that the presence of keratinized mucosa decreases the risk of soft tissue infection, thus OMI failure. OMIs at the posterior of the mandible are usually more open to infection, primarily because there is less attached gingiva in this area (45, 46).

The most suitable area is located in the keratinized mucosa, considering the decreased possibility of infection, and is nearly 4 to 6 mm from the alveolar crest or the cemento-enamel junction (4, 16, 42, 46, 64, 65). The soft tissue thickness is less in the mid-root area and relatively more in the coronal and apical regions of the interdental areas (4). Ono et *al.* (49) claimed that the gap from the alveolar crest to the mucogingival junction (MGJ) could be 2 to 4 mm in the maxilla, and it must be the margin to avoid the irritation of the non-keratinized tissue and the infection around the OMI. The length of attached gingiva ranges from 4.3 to 5.4 mm in the maxilla, with the most constricted site of keratinized tissue being at the first premolar region. Interdental soft tissue thickness between the first and second premolars does not significantly change in the coronoapical aspect (64).

2.1.6.6. Insertion Angle and Placement Torque

Implant stability just after placement is called primary stability. Insertion angle and torque are considered to be a relevant factor concerning primary stability (7, 66). Maxillary cortical bone density is reduced compared to the mandible (18, 20, 66, 67). Thus, it is wise to avoid higher insertion torques to avoid tissue damage and mini-implant breakage (7). The importance of insertion angle is shown in Wilmes *et al.'*s study (7). They concluded that inserting mini-implants at an oblique angle between 60° and 70° caused the greatest insertion torque measurements which was not recommended for the less dense maxilla. Instead, they advised a placement angle of 30-40°. They argued that the mini-implant could acquire a longer space inside the cortical bone with a more oblique insertion and achieve a higher initial stability. According to their results, OMI diameter had a significant effect on the placement torque but was dependant on the available space. OMIs with a diameter of 2 mm displayed significantly greater placement torque when compared with the OMIs with a diameter of 1.6 mm.

In Moon et *al.*'s study (68) they recommended a 30-40° of angulation along with the long axis of the maxillary teeth as well, in both buccal and palatal side, to improve the contact area between OMI and the bone. For the same reasons, Park (69) also suggested 30° to 40° of angulation parallel to the long axis of the maxillary teeth and 20° to 60° of angulation for the mandibular teeth. However, intense angulation through the cortical bone surface in the course of OMI placement may cause soft tissue inflammation and OMI slippage at its contact with cortical bone. Apart from the insertion angle, the insertion depth should also be considered regarding insertion torque. Several studies have presumed that the decreased stability and inadequate anchorage amount were not only related to the obliquely placed OMI but with the minimal insertion depth as well (10, 65, 70). OMIs should be placed as deep as possible to have an appropriate insertion torque (70). To succeed this in a case of transgingival insertion, a site with a thin, 1 mm to 1.5 mm, attached gingiva is usually suggested (71). This could be assessed with ease before the placement of OMI. Furthermore, a high insertion depth is suggested to both obtain a successful stability and to prevent increased tipping moments which could cause an OMI failure as well because of the greater stresses in the cortical bone (72). In addition, major placement torques could result in increased failure ratio because of the extreme bone compression in the surrounding tissues which may lead to a trauma that inhibits the healing response around the implant (7, 73). Motoyoshi *et al*. (66) suggested the insertion torque values to be between 8 Ncm and 10 Ncm. They found that the values below or above that showed less success rate in patients.

2.1.6.7. Predrilling and the Use of Pilot Holes

Heavy compression of the bone around OMI can create osteonecrosis and lead to a resorption rather than a requested healing stage (70). Predrilling may decrease the placement torque at areas with overabundant cortical bone thickness (74). Some of the researchers claimed that there could be an advantage of predrilling in particular cases. Baumgaertel (8) suggested predrilling at sites where CBT was more than 1.5 mm. Predrilling is not usually needed considering Baumgaertel's (8) guidelines to reach appropriate placement torque values. Bone that consists of thicker cortical bone, like the mandible and infrazygomatic crest, could be anticipated to face more tissue harm as crushing and to generate heat throughout insertion because of the high insertion torque. For this reason, pilot holes can be needed to diminish this injury risk on condition that the proper ratio between OMI and predrilling diameter is ensured (7).

2.1.6.8. Orthodontic Load

Several studies reported that OMIs were convenient for the force load and provided constant anchorage for orthodontic needs (12, 23, 36, 75, 76). Wehrbein and Diedrich (77) claimed that the orthodontic loading improved the bone situation located around the OMIs. In terms of the magnitude of force, a load in the range of 100 to 200 g could be well tolerated by the OMIs. It is reported that when horizontal forces that are usually used for orthodontic tooth movement applied to the OMIs, the implant stability was not impaired (76). Thus, in several reports, no difference is mentioned in the magnitude of force when compared stable and failed OMIs (45, 49).

2.1.6.9. Cortical Bone Thickness

Assessment of cortical bone thickness is essential for it is the most significant factor for primary stability of an OMI which is the key component to the entire success of orthodontic anchorage (78). The modulus of elasticity of cortical bone is greater in comparison with the trabecular bone (42). This makes cortical bone superior to the trabecular bone in terms of resistance to the deformation (42). This might be the factor for the better anchorage quality. Therefore, a correlation is proposed between the cortical bone thickness and OMI success. (52, 55, 79). At this point, it is crucial to comprehend and distinguish the two stages of the mini-implant stability: Primary (initial) and secondary (late). Primary stability is arised from a solid mechanical locking between the OMI and the bone during insertion (9). This is a significant factor that should be regarded in OMI planning, because a sufficient late stability cannot be obtained without initial stability (59). Considering bone properties, cortical bone thickness is the most significant element of primary stability (9).

Both in the maxillary and the mandibular jaw, the thickness of buccal cortical bone increases in proportion to the distance from the alveolar crest towards apex (4, 20, 48, 61, 78). In their cadaver study, Kim *et al.* (4) looked into cortical bone and soft tissue thickness between premolars, second premolar and first molar, and molars at 2, 4, 6, 8, 10 and 12 mm from the CEJ. They claimed that between premolars, and second premolar and first molar cortical bone thickness was greatest at the closest and farthest levels from the CEJ. They followed the same pattern for soft tissue thickness. In palate, between the second premolar and first molar, the CBT was highest at 2 mm apical to the CEJ while between premolars, the thickest point was at 6 mm apical to the CEJ. They showed that buccal cortical bone thickness and density were greatest between the first molar and second molar, followed by between the second premolar and first molar. Baumgaertel and Hans (20) measured the buccal cortical bone thickness at 2, 4, and 6 mm from the alveolar crest on 30 dry skulls. They concluded that in the maxillary posterior region, the thickness was greatest at 6 mm and lowest at 4 mm. The cortical bone is thickest closest to and farthest from the alveolar crest and thinnest in the middle. In the maxillary anterior site, however, the thickness increased towards the apical region. They also claimed that the buccal cortical bone thickness was increasing from anterior towards posterior. Buccal cortical bone was thinnest in the anterior region of both maxillary and mandibular jaw. Thus, it was recommended to avoid insertion in the anterior site because it is mentioned that this area provided less cortical bone for OMI anchorage and minimal keratinized tissue, and it lacked enough root proximity. Farnsworth *et al.* (48) investigated the cortical bone thickness at 4 mm from the alveolar crest on CBCT images of 52 patients. They measured the interradicular spaces from second molar to central incisor on one side of the patient. Similar to previously mentioned literatures, they also showed that the cortical bone thickness was increasing from anterior to posterior both on buccal and palatal side. These findings are compatible with the expectancy of thicker and denser cortical bone when ascending from the alveolar crest towards apical region and moving from the anterior region towards the posterior region. Therefore, to ensure maximum primary stability and cortical bone anchorage, the mini-implant should be inserted as high as possible, at least more than 4 mm apically from the CEJ, close to mucogingival junction in the attached gingiva. Ohiomoba *et al.* (52) evaluated the maxillary buccal and palatal cortical bone thickness and density on CT images of 60 patients with various ethnicity who were older than 12 years. They measured the interradicular areas at 2, 4, 6, and 8 mm from the alveolar crest from right third molar to left third molar for each patient. They found that the thickness of palatal cortical bone was greater than buccal cortical bone between the interradicular areas from the centrals to the first molars. Looking at the buccal aspect, unlike the previously mentioned studies (4, 20) who claimed that the thinnest bone was found at 4 mm, they showed that the cortical bone thickness and density decreased from 8 mm to 2 mm. They also showed that the thickness of the buccal cortical bone increased from anterior towards posterior at 8 mm. At the palatal site, at 8 mm, the bone was thickest and densest between the first premolar and canine, followed by between the premolars. The least thickest and densest palatal cortical bone was found between the centrals. Overall, they reported that the palatal cortical bone was thicker and denser in comparison with the buccal cortical bone. This variation was more remarkable in the anterior maxilla than posterior maxilla. In 2006, Deguchi *et al.* (45) quantitatively evaluated the buccal and palatal cortical bone thickness on CT images on the regions used for posterior intrusion, mesial and distal to the first molar and distal to second molar at alveolar crest and apex level, and for anterior intrusion, A-point and near the anterior nasal spine. At alveolar crest level, the buccal cortical bone thicknesses were measured as1.8 ± 0.6 mm, 1.5 ± 0.5 mm, and 1.3 ± 0.5 mm, mesial and distal to the first molar and distal to the second molar, respectively. This difference between mesial and distal region of first molar and distal region of second molar was found to be statistically significant. At the apex level, the mean buccal cortical bone thickness was 1.6 ± 0.6 mm mesial to the first molar and 1.6 ± 0.5 mm distal to the first molar. The mean palatal cortical bone thicknesses were 1.7 ± 0.9 mm, 1.7 ± 0.7 mm, and 1.7 ± 0.6 mm mesial and distal to the first molar and distal to the second molar, respectively. They reported significantly thicker cortical bone on the palate compared to the buccal side at the distal of the second molar but this difference did not apply to the mesial region of the second molar. In the anterior, they found significantly thicker cortical bone at anterior nasal spine region (3.6 ± 0.6 mm) compared to A-point (1.4 ± 0.5 mm). Similarly, Park and Cho (80) did a CT study to assess cortical bone thickness at the interradicular spaces between canine and second molar on buccal side at 5, 7, and 9 mm from CEJ on 60 adult patients (27.1 years). Their results showed that the maxillary cortical bone thickness varied from 1.17 to 1.31 mm. They observed that the cortical bone thickness was prone to decrease from the apex towards CEJ. They claimed that in the alveolar process, it was expected to measure about 1 mm or more of cortical bone thickness in the posterior maxilla. Also, according to their results, in the palate, the thickest cortical bone was found at the midpalatal region while the thinnest bone was found at the paramedian region of the posterior palate. In their study that bone evalution had been made on CT images prior to implant surgery and the implant stability was observed with resonance frequency analysis, Miyamoto *et al.* (78) suggested a significant relationship between bone thickness and primary stability. They included 50 edentulous Japanese patients between 24 and 76 years and evaluated 28 maxillary sites. They found that the mean maxillary bone thickness was 1.49 ± 0.34 mm. Kumar *et al.* (81) did a cadaver study for which they measured soft and hard tissue thickness at insertion areas. Their measurement areas were the interradicular areas between the premolars, the second premolar and the first molar, and the first molar and the second molar at 2, 4, 6, 8 and 10 mm from CEJ. Between the premolars, they found that the bone and soft tissue were thickest at 10 mm (1.43733 and 1. 73742 mm, respectively) and thinnest at 4 mm (1.28233 and 1.50317 mm, respectively) on buccal side whereas on palatal site the bone was thickest at 2 mm (1.55575 mm) and thinnest at 10 mm (1.36567 mm), and soft tissue was thickest at 8 mm (3.14033 mm) and thinnest at 2 mm (2.44308 mm). Between the second premolar and the first molar, the thickest buccal cortical bone was seen at 8 mm (1.58342 mm) while the thinnest was seen at 6 mm (1.49608 mm). The buccal soft tissue thickness at this area was greatest at 10 mm (2.04292 mm) and least at 4 mm (1.85242 mm). On palatal side, however, the cortical bone was thickest at 4 mm (1.70542 mm) and thinnest at 2 mm (1.53958 mm) while the soft tissue thickness was greatest at 10 mm (3.37350 mm) and minimal at 2 mm (2.75925 mm). According to their conclusions, the buccal cortical bone was thinnest at the middle (4 mm from CEJ) and thickest closest to and farthest from the CEJ. They claimed that in general, the thin soft tissue with the less possibility of infection and thick cortical bone to increase primary stability were advantageous. The thickness of palatal soft tissue decreased from the apex towards CEJ. Throughout the midpalatal suture, the palatal tissue showed 1 mm of uniform thickness behind the incisive papilla. They concluded that the best mini-implant insertion sites were 6 mm from CEJ on buccal side and 2 mm from CEJ on palatal side between the premolars, and 8 mm from CEJ on buccal side and 4 mm from CEJ on palatal side between the second premolar and the first molar. In addition, in the maxilla, anatomical structures like the nasal cavity and maxillary sinus need to be regarded, as well as the anatomical limitations caused by the passage from the keratinized tissue to the alveolar mucosa (82).

Overall, abovementioned studies propose that there are small dissimilarities in hard and soft tissue thickness between and within interradicular areas with the exception of a few points. It is concluded that the treatment ought be planned in a site with a cortical bone thickness of more than 1.0 mm (3, 66). Motoyoshi et *al.* (66) showed that the odds failure were 6.9 times greater when cortical bone was less than 1 mm thick. Computerized tomographic mapping of alveolar bone characteristics such as cortical bone thickness, bone density, and soft tissue thickness, the appropriate mini-implant use with the right length and diameter choice, and the orthodontic considerations such as site-specific placement technique, optimal insertion torque and orthodontic load would help the improvement of the success rate.

2.2. Cleft Lip and Palate

Cleft lip and palate (CLP) is the most frequently seen congenital deformity of the craniofacial region and is characterized by its complex etiology and the extensive multidisciplinary treatment requirements that may start at birth and continue throughout adulthood (83-85). It is represented by the interruption of the lip, palate, or lip and palate integrity. It could be seen at varying locations with different extensions. Appropriate treatment of a CLP patient should include a multidisciplinary team, consisted of plastic and reconstructive surgeons, pediatricians, orthodontists, dentists, speech and language pathologists, psychologists, and dietitians.

2.2.1. The Orthodontic Treatment Protocol of Cleft Patients

Patients with CLP frequently undergo several surgical repairs that vary according to the type and extent of the defect. The timeline of the procedures also relies on the severity of the defect and the general condition of the patient (83, 86, 87). Orthodontic treatment is usually required to normalize the function and the esthetics (88).

Treatment provided for children with CLP might differ considerably between different approaches and treatment centers, because of the diverse characteristics of each CLP defect, and also because of the absence of a sound evidence for determining the eligibility and appropriate patient selection for each surgical protocol (83). The treatment protocol of cleft patients requires lip and palate reconstruction in the first months and up to 1 year old, respectively (89). Gingivoperiosteoplasty (GPP) is a surgical technique that requires the arrangement of gingivoperiosteal flaps to provide the unification of cleft parts and provide bone regeneration in the alveolar cleft (57, 69), owing to the inherent capability of mesenchymal stem cells to promote bone in a fast and dynamic manner in the periosteal area (70).

Throughout the late mixed dentition, an alveolar bone graft is required to repair the alveolar cleft which includes closing the oronasal passage and providing sufficient bone support for the roots of the teeth neighboring to the cleft (90-92). To achieve a successful alveolar cleft rehabilitation, full closure of the oronasal fistula, bone integrity or arch stability, formation of cortical or trabecular bone, sufficient alveolar bone for canine eruption, stability of the canine or lateral incisor, and lastly clinically acceptable healthy attached gingiva should be acquired (93). Adequate alveolar bone support is required to orthodontically align tipped, rotated, and crowded teeth, particularly in the area of the cleft (94-96).

The most common options for bone grafting are either 'primary' or 'secondary' alveolar bone grafting; the timing is either at the first year of life about the time of lip reconstruction and during the formation of the primary incisors or during the mixed dentition stage, respectively (94-96). Primary alveolar bone grafting (PABG) lost its popularity because of its proven negative aspects on the development of maxilla (97). The secondary bone grafting has become the treatment of choice for CLP patients by many cleft palate groups for minimizing the effect on the maxillofacial development. It is preferrably done at the late or final stage of mixed dentition, between the nine and twelve years of age before the final orthodontic and restorative/rehabilitative treatment. Some authors claim that primary alveolar grafts (PAGs) provide better bone support that enhances the potential to develop normal dentition, whereas others suggest that secondary alveolar bone grafts (SABGs) are superior in providing adequate bone support for the eruption of the canines and teeth next to the cleft before the patient is referred for comprehensive dental and orthodontic management (98, 99). Following the secondary alveolar grafting, the spontaneous eruption of the cleft side canines through the grafted region in most patients is expected (94, 95, 100). It is claimed that the functional stimulant on the grafted bone as a result of postsurgical orthodontic treatment could provide alveolar bone remodeling and better SABG results (88). Even though the first outcomes of SABG showed better bone generation in comparison with other methods, long-term results of the patients who had SABG showed a distinctive resorption of alveolar bone grafts in the long run (93, 101, 102). Collapse of alveolar grafts could be partially because of the extent of the bone deformation, physiological streching, oral hygiene habits, oral infections, donor bone area, or insufficient mucosa support of the graft causing the exposure of the grafted tissue to the oral mucosa.

Dental anomalies usually accompany cleft lip and palate. The absence of maxillary lateral incisor is the most commonly seen dental anomaly in CLP patients

(103), and a multidisciplinary treatment approach is the best option. Alveolar bone graft (ABG) is one of the most essential procedures in the treatment protocol of CLP. The optimal rehabilitative option for CLP patients includes mesialization of posterior teeth right after SABG procedure to replace the missing tooth (104-106). The mesialization of posterior teeth, also known as canine substitution in this particular case, demands a critical anchorage control which can be provided by mini-implants. This option assures better esthetic results, spare a prosthetic treatment in an esthetic/anterior region, and improves the periodontal health and the maintanence of the SABG at the cleft side (107). After moving canine into the place of absent maxillary lateral incisors, restorative and esthetic dental treatment is performed to finish the treatment as in non-cleft patients with missing maxillary lateral incisor (105, 106, 108-115).

2.2.2. Alveolar Bone Morphology at the Cleft Side

The most affected patients show insufficient alveolar bone and soft tissue support as well as missing or abnormally formed teeth next to the cleft. They also suffer from esthetic complications in consequence of midline deviation, deficient maxillary growth, or collapsed dental arch (116).

Orthodontic treatment of CLP patients depends on the stability of the SABG after the surgery. However, it has been shown that grafted bone happens to have an inevitable partial resorption. In fact, Oberoi et *al.* (117) and Garib et *al.* (88) stated that resorption of the graft was not mainly related to the extent of the alveolar cleft, classification of cleft, developmental phase of the canine root, absence or presence of a maxillary lateral incisor, or plastic and reconstructive surgeon. Van der Meij et *al.* (100), conducted their CT study 1 year after the SABG procedure and claimed that 30% resorption of grafted bone in UCLP patients and 45% resorption in BCLP patients were seen. Feichtinger et *al.* (118) defined the critical stage of graft corruption which was 3–12 months following surgery. They also showed a strong relationship between the presence of adjacent teeth at the cleft side and the lost bone volume after SABG; if there was a missing tooth, 95% of the grafted bone was lost (97, 118). Similarly, when comparing patients who had and had not a permanent lateral incisor at the cleft side, it was seen that bone regeneration was 17.28% less in case of a permanent lateral incisor absence (119, 120). On contrary, Kim et *al.* (121) showed no relationship between the lateral incisor agenesis and the graft height or volume. In addition, maxillary canines erupted into the grafted area displayed a buccolingual constriction in the alveolar bridge at the mesial, apical, and middle root thirds (115).

The aim of bone reconstruction surgeries for CLP is functional rehabilitation of the maxillary dentoalveolar structure (122, 123). These procedures aim to fixate the maxillary arch and periodontal area, facilitate the eruption of teeth, promote full closure of oronasal fistula, correct the nasal asymmetry, and assure a solid bone structure for the orthodontic tratment or OMI placement (117). The results of these procedures regarding bone quality, bone height and bone thickness determine the biomechanics preferred in an orthodontic treatment. As noted in the OMI section, the use of mini-implants is mainly related to the bone characteristics. Therefore, it is important to consider possible deficient cortical bone areas post-operatively in CLP patients before using OMIs.

2.2.3. The Use of Orthodontic Mini-Implants in Cleft Patients

Clefts of lip and palate do not indicate any contraindication to treatment with mini-implants considering absolut or relative contraindications (124).

Indications for using skeletal anchorage in CLP patients can be examined in three parts. First, mini-implants may be used to support required orthodontic movements and the anchorage area according to tooth movement direction, and the forces that needed (125). The position and placement of any orthodontic appliance to the oral cavity should be decided to produce minimal disturbance for the patient (126). Secondly, mini-implants can be used for orthopedic purposes as an auxillary for maxillary protraction or expansion appliances. Lastly, they can be beneficial to support intermaxillary fixation needed for surgical procedures and to provide anchorage for appliances used. Also, mini-plates can be used for orthopedic purposes that mostly include maxillary protraction.

Skeletal manifestations in CLP are (127);

- Maxillary retrognathism due to sagittal maxillary deficiency
- Maxillary constriction and posterior crossbite due to transversal maxillary deficiency
- Openbite due to vertical maxillary deficiency

Dental anomalies seen in CLP are (128);

- Agenesis
- Size anomalies
- Shape anomalies
- Problems regarding eruption
- Enamel defects
- Malpositions, e.g. impaction, transposed teeth

Dental anomaly frequency is higher in CLP patients in comparison with the non-cleft individuals (129). The differences in number, size, and shape of teeth can be seen along with the developmental and positional anomalies (128, 130, 131). In patients with cleft, the most common dental anomaly is the tooth agenesis (103, 132).

2.2.3.1. The Treatment Options for Maxillary Constriction in Cleft Patients

During corrective interceptive orthopedics before SABG, maxillary expansion of the maxilla is required due to the alveolar ridge collapse and anteriorly progressive constriction. The treatment objectives include;

- Correction of crossbite
- Alignment of maxillary segments
- Accommodation for erupting maxillary teeth
- Creating room for ABG by increasing the alveolar cleft width
- Enhancement in occlusion and speech
- Providing esthetic appearance

The conventional treatment modality includes using rapid maxillary expansion appliance such as hyrax with protraction facemask. It provides an expansion in the transversal dimensions, the extension of the alveolar arch perimeter, and improvement in dental crowding, nasal air flow and buccal grooves. However, there are limitations within this protocol. The risk of overexpanding molar region to correct extreme constriction in intercanine distance and high resistance due to scarred cleft palate led the researchers to find new treatment modalities which are bone-borne palatal expansion appliances.

1) Bone-borne Palatal Expander (BBPE)

BBPE is a custom made modified hyrax expander that requires a mini-implant placement to the palatal region. Ideally two mini-implants with 1.8 mm of diameter and 8.5 mm of length are inserted between canines and first premolars and two OMIs are inserted between second premolars and molars (133). In a recent CBCT study (133), it has been shown that the force was directed to the alveolar and basal bones, circummaxillary sutures and mid-palatal suture in bone-anchored palatal expansion group. Maximum total dislocation was seen in the mid-palatal section of the cleft side These findings indicated a proper skeletal expansion without any dental movement as tipping of the teeth, unlike hyrax.

2) BBPE with Differential Opening (EDO)

One of the modifications of this technique is BBPE with differential opening. As stated before, maxillary constriction in CLP is more dominant in canine region. Garib *et al.* (134) introduced EDO appliance which was created principally to accomplish different expansion amounts in the anterior and posterior maxilla. The appliance has two mini-implants both at anterior, between canines and first premolars, and posterior palatal regions, between second premolars and molars. According to the results, there were no differences in terms of skeletal changes compared to hyrax but EDO produced 4 mm of greater increase in the intercanine width.

3) Bone-borne Palatal Distraction

Bone-borne palatal distraction is a treatment option for skeletally mature patients. The technique consists of LeFort I osteotomy without down fracture. Following the osteotomy, a bone-borne expander with mini-implants is inserted to the anterior and posterior maxilla (135).

2.2.3.2. The Treatment Options for Maxillary Hypoplasia in Cleft Patients

To solve maxillary hypoplasia in CLP patients, the maxillary protraction with facemask has been preferred to promote sutural activation at the circummaxillary sutures in growing patients. It provides forward and downward growth of the maxilla with a counter clockwise rotation, and limitation and redirection of mandibular growth with a clockwise rotation. These rotational effects are undesirable side effects in hyperdivergent patients. It is reported (136) that favorable results have been achieved during early mixed dentition. The use of facemask is recommended before 10 years old. The long term results are still controversial. The use of the maxillary teeth as anchorage cause undesirable tooth movements as increased labial tipping of maxillary incisors, extrusion of maxillary molars, increase in facial height and bite opening. Also, due to discomfort caused by extraoral appliance wear, patient compliance is sometimes difficult to obtain. The force is not continuous because of the limited wear time. In addition, it is reported many times that there is a gradual return to initial growth pattern in a long-term period. Therefore, the goal is to get more protraction and the possibility of late treatment to avoid long retention period along with an efficient method.

1) Face Mask with Mini-Plate Anchorage (FM/MP)

The technique consists of mini-plate insertion at infrazygomatic area on both sides with three mini-implants. Zygomatic buttress is used as the mini-plate placement site because it has adequate thickness and good bone properties and also a proximity to the center of resistance of nasomaxillary complex. Mini-plates have the advantages of transmitting the orthopedic force directly to the maxilla and minimizing the rotational effect. Compared to conventional facemask treatment, orthopedic maxillary protraction with minimum side effects has been achieved (137). In a study, this therapy found to be effective for protracting the maxilla in all cleft groups but the maxilla of the bilateral cleft lip and palate (BCLP) group was less advanced. It is believed that this difference is due to more scar tissue in BCLP patients (51). The most important advantage of this treatment is that it allows orthodontic treatment and maxillary protraction at the same time since mini-plates are independent from dentition. Also, late protraction is possible with less retention phase. In addition, since this technique minimizes clockwise rotation of mandible, it is more favorable in hyperdivergent patients.

2) Bone Anchored Maxillary Protraction (BAMP)

In BAMP technique, mini-plates are placed on the infrazyomatic crests and between the mandibular canine and premolar on both sides and are secured with mini-implants. Since the ideal timing is considered between ten and thirteen years of age, this technique requires mini-plate and mini-implant insertion to the late mixed dentition patients (138). Ren *et al.* (139) reported an enhancement in the midface that was justified by the forward and outward dislocation of the zygomatic arches in all subjects beside the fact that skeletal changes were only significant in two thirds of the subjects using BAMP. This finding reveals a distinctive benefit of this treatment that a LeFort I surgery cannot offer which is midface support but based on studies done on non-cleft groups, it is reported that the treatment has better soft tissue results in non-cleft patients. It also means that sutural activation without rapid maxillary expansion and potential suture opening at a later age might be possible with this technique. Compared to conventional facemask treatment, bone-anchored protraction provides more maxillary advancement, less dental compensations and a decrease in hyperdivergency.

3) Alt-RAMEC and Maxillary Protraction

The goal of rapid maxillary expansion in protraction protocols is in fact to anteriorly relocate the maxilla and to disarticulate maxillary sutures rather than expansion solely. Alt-RAMEC technique is aimed to disarticulate the circummaxillary sutures without overexpansion. The rapid maxillary expander has 2-hinges. It has a jackscrew in the center, two bolts that hold the screw, a body that holds the bolts at anterior, and two hinges of rotation at posterior. The maxillary advancement appliance consists of two consolidated, tooth-supported, intraoral maxillary protraction springs. Liou *et al.* (140) claimed that with this technique, maxilla showed an upward and forward rotation while mandible showed a posterior and inferior rotation. Also, it has been shown that the double hinged expander provided two times more expansion and three times more maxillary advancement compared to the rapid maxillary expander. As for long term results, maxilla remained stable. Whereas mandible continued to grow with a slight increase in lower facial height. There were not any periodontal or temporomandibular joint problems. The nasal structures were also dislocated and protracted anteriorly with the Alt-RAMEC technique in addition to maxilla. The nasomaxillary complex was protracted as one piece three times more compared to rapid maxillary expansion protocol. Including TADs that are placed in alignment with molar and premolar bands to this technique provides a direct force distribution to the bones with minimal dentoalveolar compensations. This might lead to a greater advancement (140).

4) Distraction Osteogenesis

Distraction osteogenesis is a technique of regenerating a new bone following a corticotomy or an osteotomy and gradual distraction without the need of bone grafts. It also has the distinctive ability to regenerate bone and soft tissues simultaneously (141).

The devices can be classified as internal and external or as tooth-borne, bone-borne, bone-tooth borne. Internal distraction can be used in patients with mild or non-cleft maxillary deficiency cases. The removable adjustable intraoral maxillary distractor consists of maxillary buttress plate to fix the plate to the anterior zygomatic wall with mini-implants, a vertical part to adjust the vector and the distractor (142).

Another intraoral technique is maxillary anterior segmental distraction osteogenesis (MASDO). This system contains a single palatal distractor or two bilateral distractors that are inserted prior to surgery. The position of the distraction device is determined on the basis of the required movement of the transport segment. An osteotomy on the level of the piriform recess and a vertical osteotomy lateral to transport segment teeth are performed. Mini-implants are suggested to be added on the anterior region, between premolars, when the orthodontic arch is smaller than 17x25 stainless steel. Since the distractors are placed below the center of resistance of the anterior segment, counter clockwise rotation of the maxilla is seen but the side effects are less severe when bilateral distractors are used (143).

2.3. The Use of Cone Beam Computed Tomography in Cleft Patients

2.3.1. Definition of Cone Beam Computed Tomography

Cone-beam computed tomography systems (CBCT) are a variety of computed tomography systems. The CBCT systems make a rotation around the patient and get the data using a cone-shaped X-ray beam. These images are to construct a three-dimensional (3D) image of dental arch, dentofacial complex, and ear, nose and throat (ENT).

The most important step to determine orthodontic diagnose, treatment design, growth estimation, and outcome evaluation is clinical examination and documentation. Orthodontic diagnostic data of a patient are dental models, intra- and extra-oral photos, a panoramic X-ray, and a lateral cephalometric radiograph, assisted with additional analysis if needed. Recently, CBCT has been a part of the diagnostic tools especially to examine the craniofacial complex in three dimensions.

2.3.2. Historical Background

CBCT was introduced to overcome the limitations of computed tomography (CT), presenting good quality 3D images at a relatively lower radiation dose and cost. CBCT was first described in 1978 by Smith *et al.* (144), but it has been easily accesible in the late 1990s (145, 146). The first CBCT scanner for the dentofacial complex was described in 1998 by Mozzo (145) for implant planning. Continuing development in technology has provided lower radiation doses and comparatively lower costs of CBCT systems which assured the success of the CBCT. Nowadays, CBCT is widely used for orthodontic purposes.

2.3.3. Comparison with Other Imaging Methods

Three-dimensional cephalometry has become popular due to the limitations of lateral cephalometric radiograph that offers a two-dimensional (2D) presentation of a 3D object. CBCT enables the specification of the size, shape, and volumetric differences in bilateral structures as well as growth changes in 3D.

Chien et *al.* (147) has shown that the mean error when determining the landmarks was less on CBCT images in comparison with lateral cephalometric radiographs. There are advantages and disadvantages of CBCT over 2D radiographs. By minimizing the magnification, overlapping and distortion of the data, CBCT provides more accurate images. It also offers more reliable diagnosis and treatment planning through the possibility of 3D assessment. One of the main advantage of CBCT is being able to access different types of radiographic images to construct study models and to orientate the images from a single scan. These qualities make CBCT more reliable. On the other hand, the amount of radiation dose of CBCT remains controversial. Within the enhancement of technology, the radiation dose has been decreased but it is still higher than that of a cephalometric radiograph. Nevertheless, radiation dose of CBCT is relatively minimal considering the total amount of radiation doses of panoramic X-ray, cephalometric radiograph and the full set of periapical radiographs (148).

2.3.4. The Use of CBCT in Orthodontic Treatment

1) Localization of Unerupted Teeth and External Root Resorption

In orthodontic field, CBCT is pioneered as one of the diagnostic methods for investigation of impacted teeth and external root resorption of neighboring teeth. It is usually preferred if maxillary canines are impacted and root resorption of the lateral or central incisors is suspected (149). However, conventional radiographs also have a diagnostic value. Thus, before acknowledging CBCT as a first diagnostic tool in cases with impacted teeth, which cases CBCT method has been truly a necessity should be considered.

2) Evaluation of the Airways

The airway area has been evaluated by orthodontists on lateral cephalometric radiographs until recently. For patients with facial asymmetries, craniofacial deformities, or obstructive sleep apnea, the airway assessment becomes very essential for the diagnosis. Nevertheless, on 2D radiographs, only the area of the airway can be seen but in fact it is a volumetric and complex 3D structure. The relationship between the 2D airway area on lateral cephalometric radiographs and the 3D volume assessed on CBCT has been shown: if the area is larger, the volume is also larger. Yet, the area of a particular section evaluated in conventional radiographs did not match with the volume of the same section measured on CBCT; meaning the airway area on conventional radiographs did not comply with the airway volume on CBCT. This indicates that a 3D volumetric evaluation is a better option for airway assessment.

3) Trauma

Root fractures happened during a trauma may be easily overseen on 2D radiograph because of the direction of the X-ray beam. In many studies, it has been indicated that CBCT is superior in detecting root fracture and in providing more precise evaluation (150-152).

4) Orthognatic Surgery Treatment

3D design of an orthognathic case treatment is now widely preferred. The orthodontic and orthognatic treatment planning and/or outcome of the treatment may be evaluated on CBCT imaging. Evaluation of surgical interventions such as surgically assisted rapid maxillary expansion, orthognatic surgeries, distraction osteogenesis; superimposition of pre- and post-operative volumetric CBCT-derived models and observing the differences in condylar position are possible with CBCT (153).

5) The Use of Temporary Anchorage Devices

CBTC imaging in conjunction with TADs is a topic in demand as mini-implants and mini-plates improve anchorage throughout treatment and are commonly used. CBCT is not a must for TAD placement but it has given a better comprehension into various useful locations for mini-implant placement. Owing to many researches on TADs using CBCT (154, 155), there are guidelines of safe placement sites for TAD usage. However, there is limited knowledge about suitability of certain mini-implant insertion sites in CLP patients.

6) Cleft Lip and/or Palate

Cleft lip and palate (CLP) is a 3D facial defect and it might be presumed that 3D methods would assure a thorough look into the anatomical situation and the treatment possibilites. In CLP patients, CBCT is being used to evaluate the anatomy of the maxilla and the limits of the alveolar cleft, the assessment of the regenerated bone after alveolar bone grafting, and the movement of the cleft side canine. Also, it is useful for evaluating root morphology, development of the teeth adjacent to the cleft area, and the amount of soft-tissue depth (156-158). CBCT images are reproducible which is helpful to evaluate the success of secondary alveolar bone grafting (117, 159, 160). CBCT is superior compared to CT as it demands 8–10 times lower radiation dose with standard protocol (161). Nonetheless, CBCT imaging should be carefully indicated at the right time for cleft patients, especially for pediatric patients, to minimize the side effects.

7) Congenital Dental Anomalies

Even though there is limited knowledge, the superiority of CBCT over 2D radiographs for evaluation and surgical planning of impacted, persisted or supernumerary teeth that are usually joined by delayed eruption of adjacent teeth is supported by studies. Also, in cases with fusion, invaginatus, or gemination, CBCT may be helpful for endodontic treatment planning (162). Still, CBCT must be preferred only if conventional radiographs are not enough to give proper data.

8) Congenital Facial Anomalies and Syndromes

Since congenital deformities are not very commonly seen, studies consisted of big samples are not available as far as we can tell. Although several case studies have been done on congenital anomalies; there is not much information concerning the superiority of CBCT. Hence, CBCT must only be indicated in cases where conventional radiographs are not enough to give satisfactory information, and it should not be preferred as the first diagnostic method.

9) Temporomandibular Joint Abnormalities

To evaluate the temporomandibular joint (TMJ) abnormalities, CBCT is preferred over magnetic resonance imaging (MRI) and conventional radiographs. Nevertheless, MRI is the chosen tool for the investigation of inflammatory activity and soft-tissue abnormalities (163). There are many studies in literature that preferred CBCT as a first imaging method for diagnostic purposes and surgical reasons instead of conventional radiographs. Therefore, it may be assumed that CBCT may play an advantageous role in the evaluation of bone pathologies of TMJ.

10) Incidental Findings

Incidental findings are more frequently seen on a CBCT in comparison with a lateral cephalometric radiograph or an orthopantomogram (OPT) (164). This caused a controversy whether incidental findings legitimize indicating a CBCT in each orthodontic patient. First, experienced orthodontists in interpreting CBCT images are more prone to recognize incidental findings. In addition, most of the incidental findings are usually anatomical variations that could be seen on 2D radiographs, or that could be false-positive findings. So, it is still arguable if the incidental findings would cause any change in the orthodontic treatment planning or not.

2.3.5. Radiation Dose

Ever since CBCT became one of the diagnostic tools in dental field, there has been considerable debate and ambiguity about the radiation dose given to the patients. Due to the possible side effects of radiation, a patient should only be exposed to a radiation dose As Low As Reasonably Achievable (ALARA). According to the 2007 recommendations of the International Commission on Radiological Protection's (165), the recommended and reasonable dose for panoramic X-rays preferred in orthodontics changes between 14.2 to 24.3 microsieverts (μSv), and between 5.1 to 5.6 μSv for a cephalometric radiograph (166). It is hard to specify the precise amount of the radiation dose for CBCT, as there are many different variations of CBCT systems, and it relies on the field of view, voxel size, scan time, peak kilovoltage, milli-ampere setting, sensor sensitivity, and the amount of images taken. The interval of radiation dose of CBCT for a craniofacial field of view, which is larger than 10 cm to allow maxillofacial imaging, varies between 30 to 1073 μSv (166-168).

CBCT is not a standard diagnostic tool in orthodontics. To date, there is not a consensus on optimization and rationale for the use of CBCT in the orthodontic patients. If the potential advantages for diagnosis and treatment planning overbalance the probable side effects of an increased radiation dose, CBCT can be indicated. It can be seen as a safe diagnostic method in CLP cases where 3D evaluation is compulsory for planning the most suitable treatment plan (148, 153).

3. MATERIALS and METHODS

This retrospective study was approved by the Ethics Committee of Yeditepe University, Faculty of Medicine (Doc. No: 1185). Consent forms were submitted to the patients and parents with a detailed information about the usage of their CBCT data and were signed by the individuals or the guardians of the subjects included to this study.

3.1. Subjects

Our study was conducted on CBCT images of 50 patients with operated complete unilateral cleft lip and palate and 50 indivuduals without any craniofacial anomalies that have been referred to Orthodontic Department of Yeditepe University. The archives of the Department of Oral Radiology were screened, 56 patients with cleft and 68 without cleft were reviewed and CBCT images were collected according to following criteria.

Inclusion criteria for the UCLP group are as below;

- Non-syndromic UCLP patients who have undergone orthodontic treatment at Yeditepe University and had CBCT taken between January 2017 and January 2020,
- Patients older than 8 years of age in mixed or permanent dentition,
- Patients with CBCT scan taken for specific reasons such as alveolar bone grafting, orthognatic surgery, distraction osteogenesis, etc.

Inclusion criteria for control group are as below;

- Patients without any craniofacial deformity who have undergone orthodontic treatment at Yeditepe University and had CBCT taken between January 2017 and January 2020,
- Patients older than 8 years of age in mixed or permanent dentition,
- Patients with CBCT scan for specific reasons such as facial asymmetry, orthognatic surgery, temporomandibular joint disorders, trauma, impacted teeth, etc.
- No tooth agenesis or impaction on the measurement side

Exclusion criteria for UCLP group are as below;

- Syndromic UCLP patients
- Bilateral cleft lip and palate patients
- Isolated cleft lip or palate patients
- Patients younger than 8 years old

Exclusion criteria for control group are as below;

- Patients with craniofacial deformity or syndrome
- Patients younger than 8 years old

Regarding the inclusion and extrusion criterias, study and control groups were composed (Table 3.1.1.)

Table 3.1.1. Mean ages and sex distributions of UCLP and control groups

Groups	n	Female	Male	Age (year) Ort ± SS
UCLP Group	50	19	31	14.76 ± 5.06
Control Group	50	25	25	16.54 ± 4.55

3.2. Methods

All CBCT scans of the subjects were taken according to the protocols of the Department of Oral Radiology at Yeditepe University, with i-CAT FLX V17 (Imaging Sciences International LLC, Hatfield, PA, USA) at these settings: 5 mA, 120 kV, exposure time of 17.8 seconds, voxel size of 0.3 mm, axial slice thickness of 1 mm, and scanning area of 17x23 cm (Fig.3.2.1.). The protocols of the Department of Oral Radiology at Yeditepe University for taking CBCT scans are as follows: The natural head position and centric occlusion of the patient are obtained before the CBCT scan. The adjustment of the seat is made. In order to avoid the movements of the head during scanning, the soft tissue pogonion or the forehead is fixed. The patient is warned about not to shift their jaw and not to swallow.

Fig.3.2.1. i-CAT FLX V-17

3.2.1 The Evaluation of the Images

Orientation

The scans of all the patients included to this study were collected in DICOM format. Then, the DICOM data was transferred to 3dMD Vultus Software (3dMD LLC, Atlanta, Georgia, USA) (Fig. 3.2.1.1.). 3dMD Vultus software allows the orientation of CBCT scans. In the program, there is an orientation tool to determine the directions of axial, sagittal and coronal slices with right, left, anterior, posterior, superior and inferior indicators. In this way, it is possible to make the orientation of the images. On the software imaging, the head position on coronal, sagittal and axial planes was oriented using the following anatomical landmarks and planes.

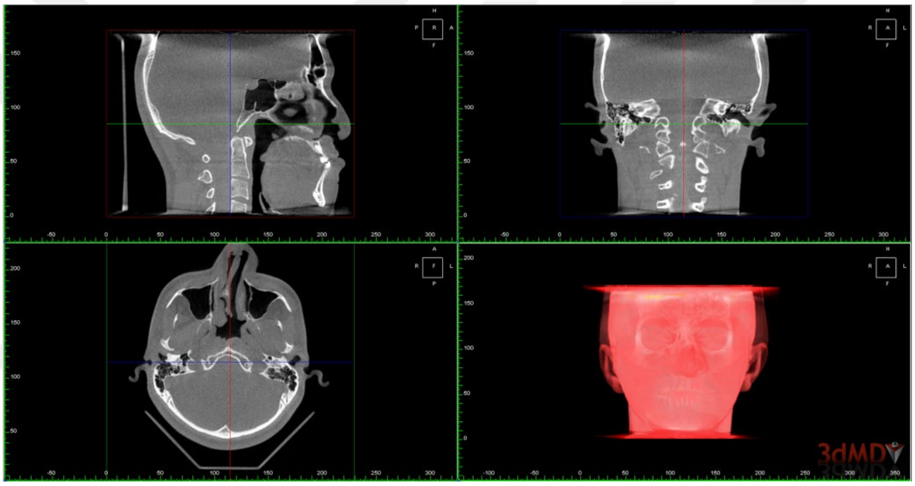

Fig. 3.2.1.1. 3dMD Vultus Software

The anatomical landmarks used in orientation:

1) Sella (S): Sella is the center of sella turcica that is above the sphenoid bone. S point is marked on 2D axial and sagittal slices and checked on 3D images (Fig. 3.2.1.2.).

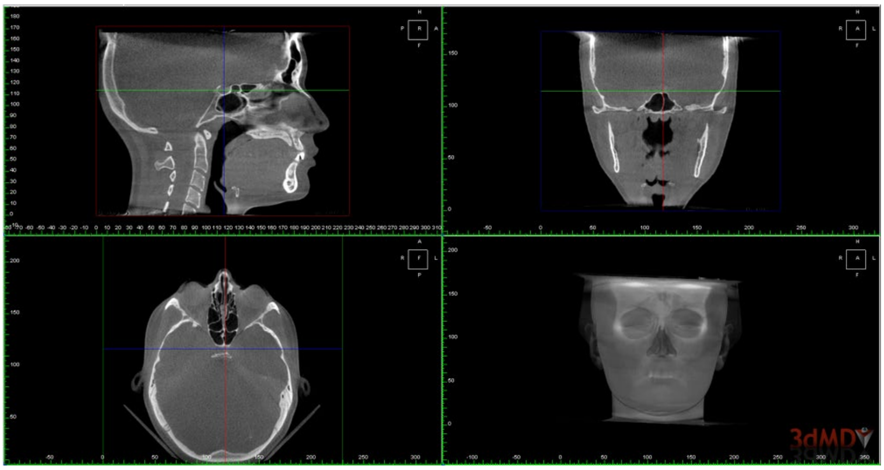

Fig. 3.2.1.2. Determination of Sella point on CBCT

2) Nasion (N): Nasion is the most anterior and superior middle point of frontonasal suture. The most anterior point of frontonasal suture is marked on 2D axial slice while the most superior point is marked on 2D sagittal slice. On 3D images, middle point is determined on the coronal view (Fig. 3.2.1.3.).

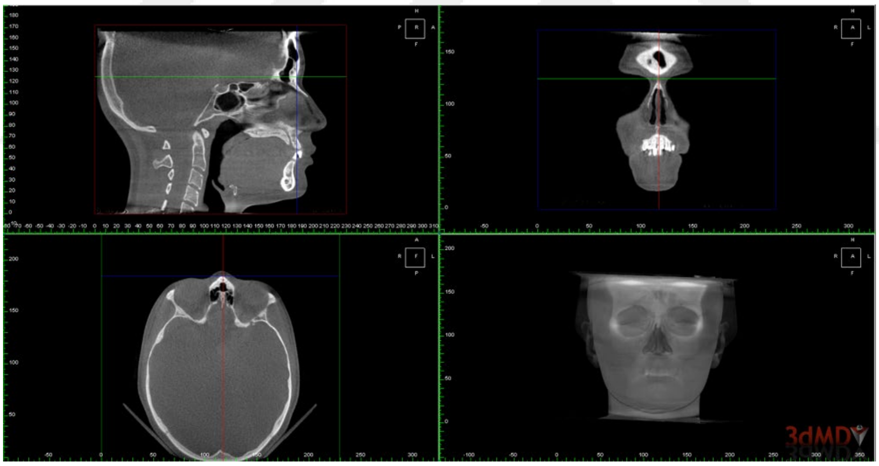

Fig. 3.2.1.3. Determination of Nasion point on CBCT

3) Crista Galli: The crista galli is the upper part of the perpendicular plate of the ethmoid bone, which rises above the cribriform plate (Fig.3.2.1.4.).

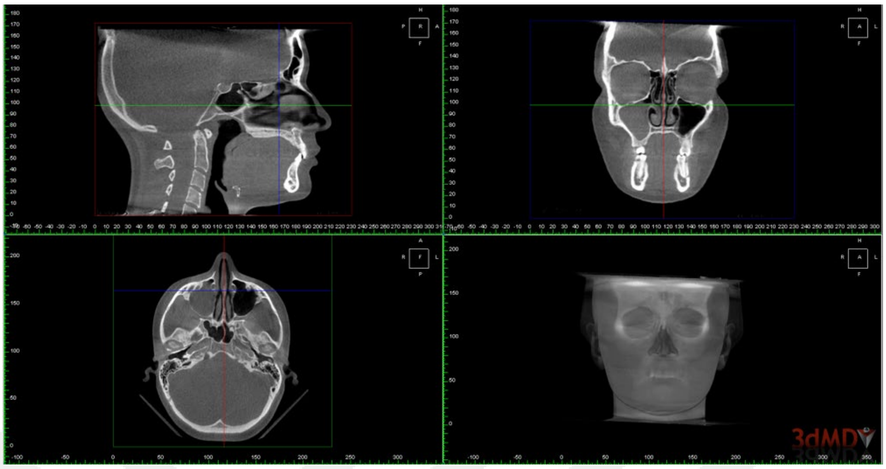

Fig. 3.2.1.4. Determination of Crista Galli on CBCT

4) Orbitale: The orbitale is defined as the lowest point on the infraorbital margin. Right and left orbitale points are marked on the sagittal slice. Then, their parallelism to the lower border of the screen is checked on the coronal section (Fig. 3.2.1.5.).

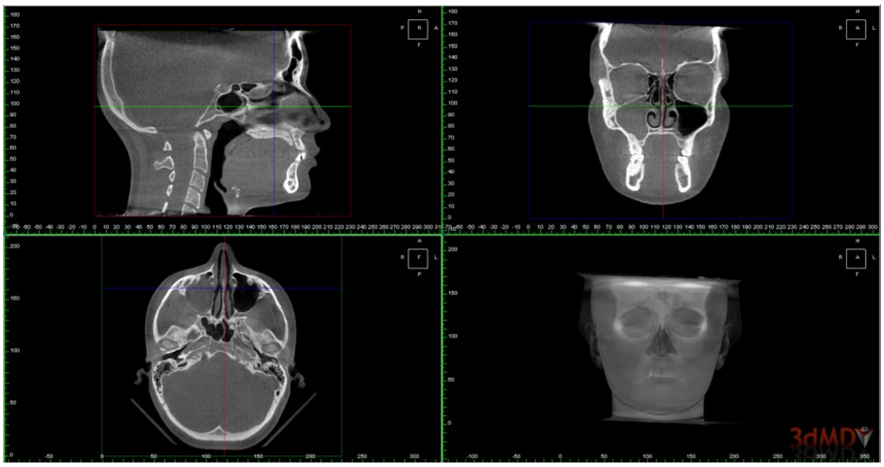

Fig. 3.2.1.5. Determination of Orbitale on CBCT

To construct a midsagittal plane, first the midline of crista galli on the coronal slice (Fig. 3.2.1.6.), then nasion and sella points on the sagittal slice were marked (Fig. 3.2.1.7.). The midsagittal plane that contained these landmarks and that is perpendicular to the lower border of the computer screen was considered to be the midline of the face. The location of the constructed midline was checked on the coronal and sagittal planes as well (Fig.3.2.1.8.). Also, on the coronal slice, as being perpendicular to the midsagittal plane, the parallelism of the right and left orbitale was obtained (Fig.3.2.1.9.). This orientation process was applied to all collected data.

Fig. 3.2.1.6. Marking of the midline of crista galli on the coronal slice

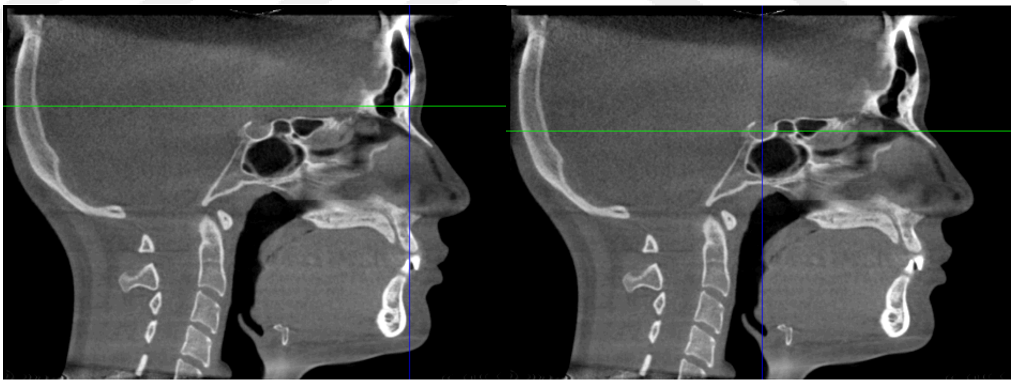

Fig. 3.2.1.7. Marking of Nasion and Sella points on sagittal slice

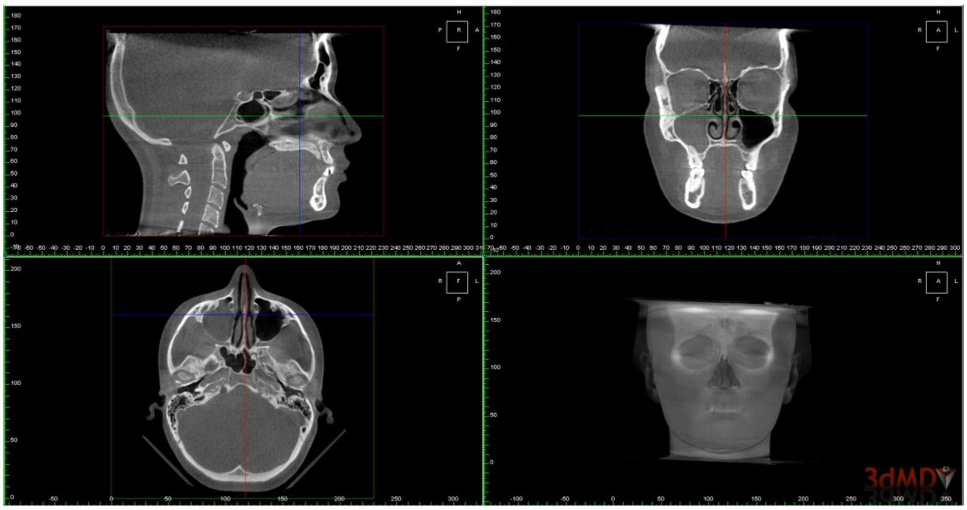

Fig. 3.2.1.8. Constructed midline

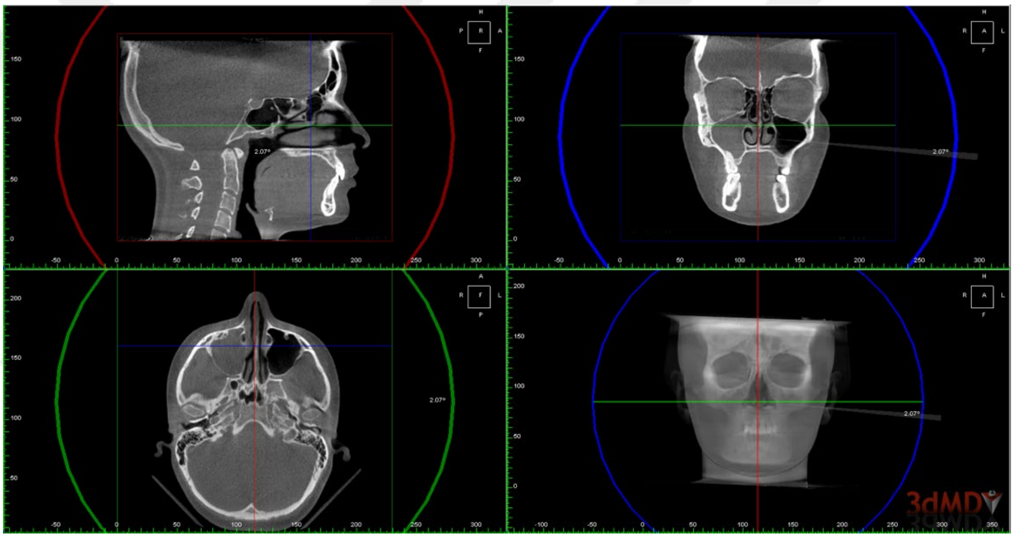

Fig. 3.2.1.9. Parallelism of the righ and left orbitale

3.2.2. Measurement

The measurements were made solely on the maxilla. Since the aim of this study is to evaluate the buccal and palatal cortical bone thicknesses at mini-implant placement sides, the measurement points were determined concordantly. On the sagittal slices, the measurement levels from the alveolar crest first determined for each interradicular area (Fig. 3.2.2.1-6). Then, the buccal and palatal cortical bone thicknesses were measured on the axial slices.

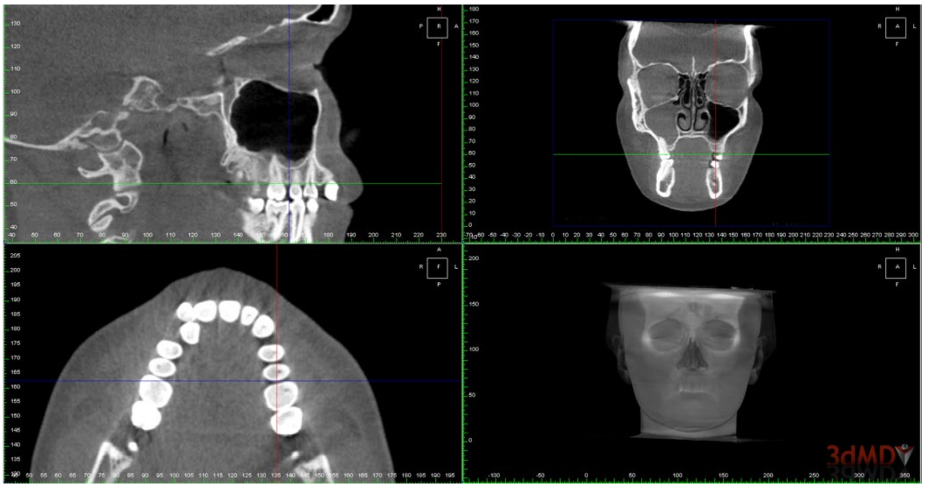

Fig. 3.2.2.1. Determination of the alveolar crest

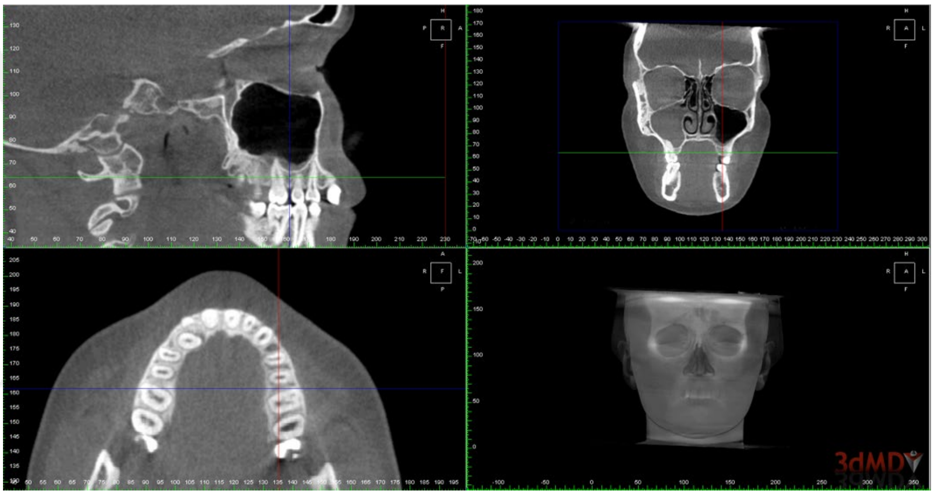

Fig. 3.2.2.2. 4 mm from the alveolar crest

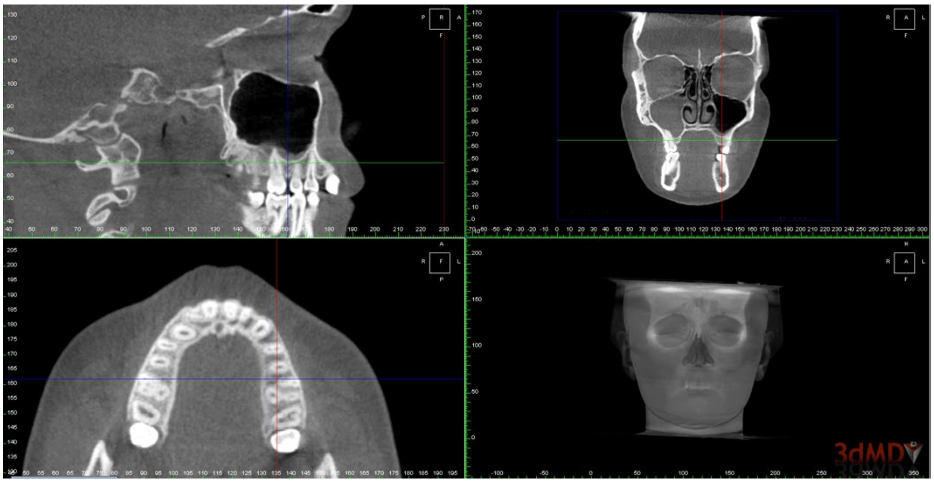

Fig. 3.2.2.3. 6 mm from the alveolar crest

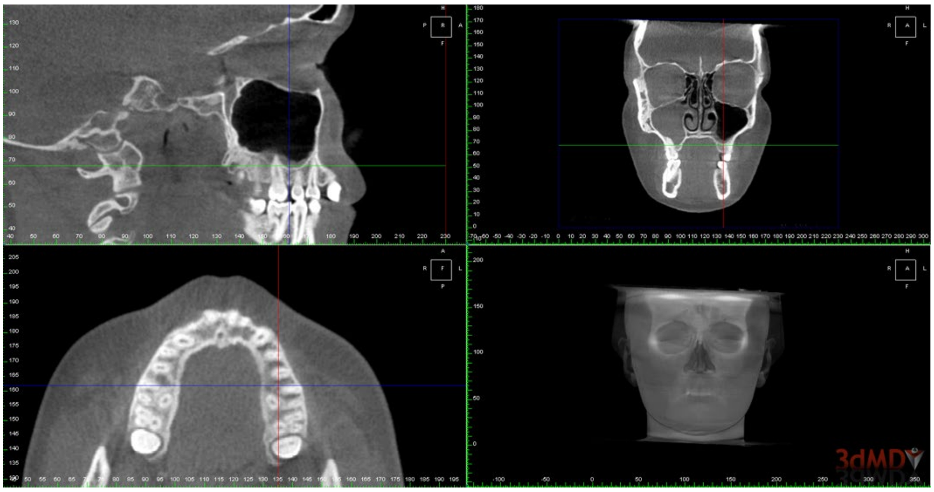

Fig. 3.2.2.4. 8 mm from the alveolar crest

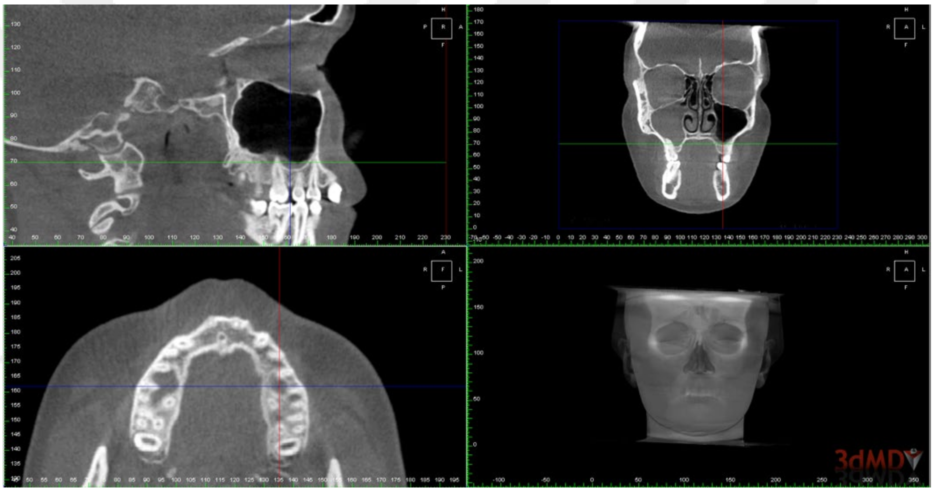

Fig. 3.2.2.5. 10 mm from the alveolar crest

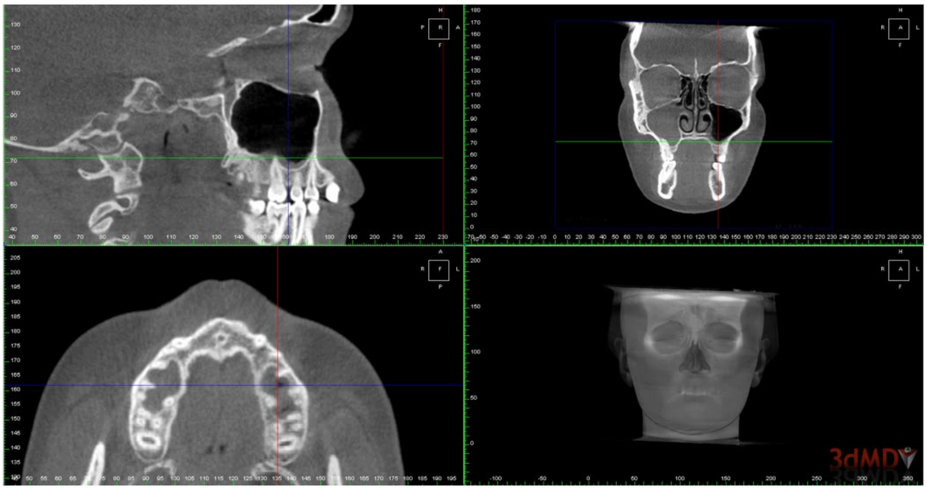

Fig. 3.2.2.6. 12 mm from the alveolar crest

In UCLP group, from the mesial of the right 1st molar to the distal of right canine, and from the mesial of the left 1st molar to the distal of left canine, the measurements were made in every interradicular area. We have not included the anterior region, between the canines, for two reasons; first, 7 out of 50 patients in study group have not had alveolar bone graft which have a direct impact on the presence of cortical bone at the cleft area (Table 3.2.2.1.), then 35 out of 50 patients had one or two missing laterals (Table 3.2.2.2.).

Among adult patients who had permanent dentition, only 11 of them had missing premolar at cleft side (Table 3.2.2.3.). When measuring young adolescent patients in mixed dentition, interdental regions of the primary teeth were used for premolar measurement areas when the permanent teeth have not erupted yet (Table 3.2.2.4.-Table 3.2.2.5.). In the presence of primary teeth, the same terminology of permanent dentition was used to avoid confusion and keep the tables as simple as possible.

Two subgroups were derived from the study group: Cleft Side (CS) and Non-Cleft Side (NCS). Therefore, the measurements were made on both sides. As for control group, only right or left side was measured since it is shown that cortical bone width is the same for both sides of the jaws (45).

Table 3.2.2.1. Patients with and without alveolar bone graft

Number of UCLP patients	Number of patients with ABG	Number of patients without ABG
50	43	7

Table 3.2.2.2. Patients with one/two missing lateral incisors

Number of UCLP patients	Number of patients with one missing lateral incisor on CS	Number of patients with one missing lateral incisor on NCS	Number of patients with two missing lateral incisors
50	31	4	4

Table 3.2.2.3. Patients with one/two missing premolars

Number of UCLP patients	Number of patients with one missing premolar on CS	Number of patients with one missing premolar on NCS	Number of patients with two missing premolars
50	5	4	6

Table 3.2.2.4. Interradicular areas with primary/permanent teeth in UCLP group

Number of interradicular areas in UCLP group	Number of interradicular areas with primary teeth in UCLP group	Number of interradicular areas with permanent teeth in UCLP group
285	96	189

Table 3.2.2.5. Interradicular areas with primary/permanent teeth in control group

Number of interradicular areas in control group	Number of interradicular areas with primary teeth in control group	Number of interradicular areas with permanent teeth in control group
150	18	132

Similar to previous studies, the buccal cortical bone thickness measurements were made at the 4 mm, 6 mm and 8 mm apical to the alveolar crest which was checked on coronal and sagittal slices (20, 52, 64, 169). Similarly, palatal cortical bone thickness measurements were made at the 4 mm, 6 mm, 8 mm, 10 mm, and 12 mm apical to the alveolar crest (3, 53) (Fig. 3.2.2.7-11.). At each level and interradicular area, cortical bone thickness was measured on the axial slice. In accordance with previous studies, the measurement sites are interradicular spaces between canine and premolar, first premolar and second premolar, and premolar and first molar.

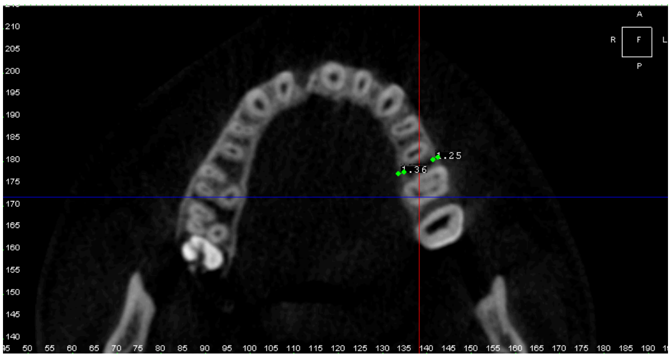

Fig. 3.2.2.7. Measurements at 4 mm from the alveolar crest on buccal and palatal side

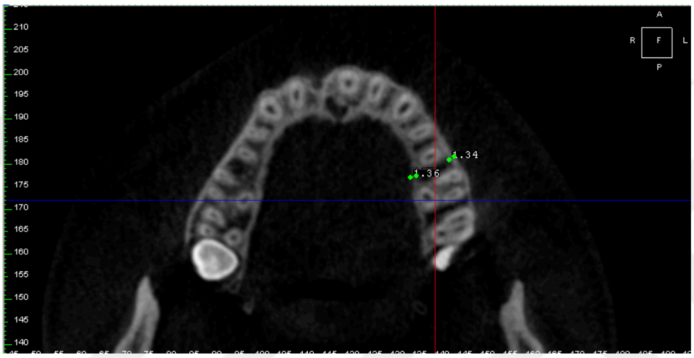

Fig. 3.2.2.8. Measurements at 6 mm from the alveolar crest on buccal and palatal side

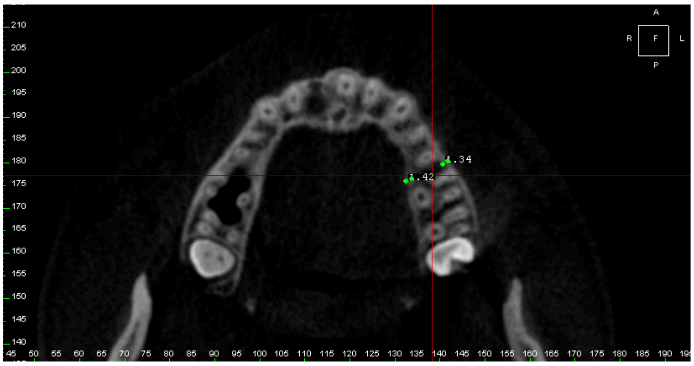

Fig. 3.2.2.9. Measurements at 8 mm from the alveolar crest on buccal and palatal side

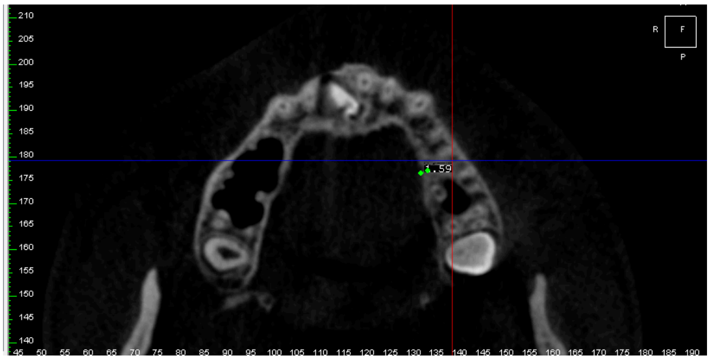

Fig. 3.2.2.10. Measurement at 10 mm from the alveolar crest on palatal side

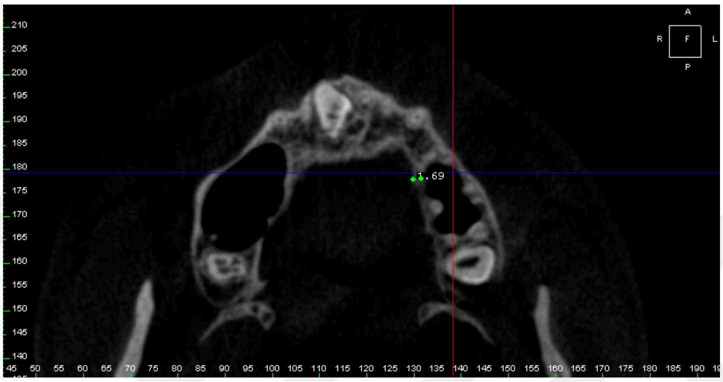

Fig. 3.2.2.11. Measurement at 12 mm from the alveolar crest on palatal side

3.2.2.1. Buccal Cortical Bone Thickness

The measurements made for the assessment of buccal cortical bone thickness are;

1) 1st Molar- Premolar
    - BCBT at 4 mm
    - BCBT at 6 mm
    - BCBT at 8 mm
2) 2nd Premolar- 1st Premolar
    - BCBT at 4 mm
    - BCBT at 6 mm
    - BCBT at 8 mm
3) Premolar- Canine
    - BCBT at 4 mm
    - BCBT at 6 mm
    - BCBT at 8 mm

3.2.2.2. Palatal Cortical Bone Thickness

1) 1st Molar- Premolar
    - PCBT at 4 mm
    - PCBT at 6 mm
    - PCBT at 8 mm
    - PCBT at 10 mm
    - PCBT at 12 mm

2) 2nd Premolar- 1st Premolar
    - PCBT at 4 mm
    - PCBT at 6 mm
    - PCBT at 8 mm
    - PCBT at 10 mm
    - PCBT at 12 mm
3) Premolar- Canine
    - PCBT at 4 mm
    - PCBT at 6 mm
    - PCBT at 8 mm
    - PCBT at 10 mm
    - PCBT at 12 mm

Apart from the cortical bone thicknesses, the vertical growth pattern of the subjects were also evaluated on lateral cephalometric radiographs. S-N/ Go-Me angle and S-Go/ N-Me ratio were measured to evaluate the vertical growth pattern of the patients. The distribution of high angle, low angle and normal patients was made based on these angular and linear measurements. For S-Go/N-Me, if the ratio was less than 61% the patient was considered as high angle. If it was between 61% and 69% the patient was included in the normal group. Finally, if the ratio was more than 69% the patient was considered as low angle (170). For the S-N/Go- Me, if the angle was less than 27° the patient was accepted as low angle. The angles between 27° - 37° indicated a normal patient. Lastly, an angle more than 37° indicated high angle group (171).

3.3. Statistical Reproducibility

To evaluate the processing of CBCT images and the precision of the measurements, 25 patients from each group were randomly selected. One month after the first measurements, the measurements were repeated for these 50 patients using the exact same method.

3.4. Statistical Analysis

Statistical analysis was performed using NCSS software for Windows (Kaysville, UT, USA). Besides from descriptive statistics (mean, standard deviation) Shapiro-Wilk normality test was done to analyze the distribution of the variables. For normally distributed variables, paired one way ANOVA test was performed to compare cortical bone thicknesses at different levels and interdental areas, and Newman Keuls multiple comparison test was used for the comparison of the subgroups. To assess the qualitative data, the chi square test was used. To compare the UCLP and normal group, independent t test was used whereas CS and NCS measurements were compared with paired t test. An independent t test for comparing the age distribution of the groups and a chi square test for evaluating the distribution of sexes were performed. The correlation between the age and the cortical bone thickness was analysed using the Pearson correlation test. Results were considered significant at $p < 0.05$.

Based on the observed effect size of 0.48, experimental statistical power analyses were conducted using G*power 3.1 program (Heinrich-Heine-Universität Düsseldorf, Germany) to determine the power of the study. The sample size was calculated based on the ability to measure cortical bone thickness. The expected standard deviation of this difference was taken from Yatabe *et al.*'s (172) study. The calculation indicated that for a study with a power of 0.80 and alpha of 0.05, we required a total of 55 patients in the study group.

To determine intraexaminer agreement, intraclass correlation coefficients were calculated.

4. RESULTS

4.1. Measurement Reliability

The measurements were repeated one month after the first measurements for 25 patients from each group by the same operator to determine intra-rater agreement using intra-class correlation coefficients. Intraclass correlation coefficients of 0.75 or above are usually considered good and those above 0.9 to be excellent (173). In our study, intraclass correlation coefficients were all above 0.80 (Table 4.1.1- 2.)

Table 4.1.1. Intraclass correlation coefficients for buccal cortical bone thickness measurements

Interradicular Area	Distance from the alveolar crest	Intraclass correlation coefficients	95% (Confidence Interval)
1st Molar-Premolar	**4 mm**	0.832	(0.811-0.916)
	6 mm	0.879	(0.814-0.972)
	8 mm	0.912	(0.882-0.984)
2nd Premolar- 1st Premolar	**4 mm**	0.901	(0.864-0.994)
	6 mm	0.833	(0.809-0.937)
	8 mm	0.897	(0.843-0.975)
Premolar- Canine	**4 mm**	0.908	(0.875-0.976)
	6 mm	0.845	(0.822-0.974)
	8 mm	0.846	(0.811-0.794)

Table 4.1.2. Intraclass correlation coefficients for palatal cortical bone thickness measurements

Interradicular Area	Distance from the alveolar crest	Intraclass correlation coefficients	95% (Confidence interval)
1st Molar-Premolar	**4 mm**	0.847	(0.814-0.969)
	6 mm	0.876	(0.818-0.903)
	8 mm	0.834	(0.820-0.897)
	10 mm	0.898	(0.834-0.907)
	12 mm	0.821	(0.809-0.865)
2nd Premolar- 1st Premolar	**4 mm**	0.819	(0.804-0.881)
	6 mm	0.879	(0.814-0.972)
	8 mm	0.845	(0.832-0.974)
	10 mm	0.832	(0.811-0.916)
	12 mm	0.833	(0.809-0.937)
Premolar- Canine	**4 mm**	0.865	(0.824-0.881)
	6 mm	0.862	(0.814-0.896)
	8 mm	0.834	(0.807-0.885)
	10 mm	0.912	(0.882-0.984)
	12 mm	0.901	(0.864-0.994)

4.2. Comparison of Age and Sex Distribution of the UCLP and Control Group

The mean values and standard deviations of age and sex distributions of the groups are provided in Table 4.2.1. There was no statistically significant difference between groups with regard to gender distribution (p>0.05). Although the mean age of the control group was greater than that of the UCLP groups, no statistically significant difference was found (p>0.05). Further correlation test was performed to determine any relationship between the age and the cortical bone thickness, however, no correlation was revealed in both groups (Table 4.2.2.).

Table 4.2.1. Comparison of the mean age and sex distribution of the groups by independent t-test and chi square test

	Female n (%)	**Male n (%)**	**Age (year) Mean ± SD**
UCLP Group (n:50)	19 (38%)	31 (62%)	14.76 ± 5.06
Control Group (n:50)	25 (50%)	25 (50%)	16.54 ± 4.55
p value	0.227^{Ψ}		0.068^{ξ}

$^{\xi}$Independent t test, $^{\Psi}$Chi square test

Table 4.2.2. The correlation between age and cortical bone thickness in unilateral cleft lip and palate and control groups with independent t test

		Age (UCLP Group)	Age (Control Group)
BCBT 1st Molar- Premolar/ 4 mm	**r**	0.069	0.06
	p	0.633	0.678
BCBT 1st Molar- Premolar/ 6 mm	**r**	0.141	0.172
	p	0.33	0.233
BCBT 1st Molar- Premolar/ 8 mm	**r**	0.001	0.163
	p	0.996	0.257
BCBT 2nd Premolar- 1st Premolar/ 4 mm	**r**	0.135	0.151
	p	0.411	0.302
BCBT 2nd Premolar- 1st Premolar/ 6 mm	**r**	0.277	0.139
	p	0.088	0.342
BCBT 2nd Premolar- 1st Premolar/ 8 mm	**r**	0.268	0.155
	p	0.099	0.287
BCBT Premolar-Canine/ 4 mm	**r**	0.068	0.215
	p	0.641	0.138
BCBT Premolar-Canine/ 6 mm	**r**	0.062	0.224
	p	0.674	0.122
BCBT Premolar-Canine 8 mm	**r**	0.102	0.164
	p	0.487	0.255
PCBT 1st Molar- Premolar/ 4 mm	**r**	-0.06	-0.103
	p	0.68	0.475
PCBT 1st Molar- Premolar/ 6 mm	**r**	-0.082	0.022
	p	0.569	0.877
PCBT 1st Molar- Premolar/ 8 mm	**r**	-0.09	-0.06
	p	0.535	0.681
PCBT 1st Molar- Premolar /10 mm	**r**	-0.068	0.006
	p	0.647	0.967
PCBT 1st Molar- Premolar/ 12 mm	**r**	-0.207	-0.134
	p	0.163	0.355
PCBT 2nd Premolar- 1st Premolar/ 4 mm	**r**	0.088	-0.099
	p	0.594	0.5
PCBT 2nd Premolar- 1st Premolar/ 6 mm	**r**	0.021	-0.096
	p	0.901	0.514
PCBT 2nd Premolar- 1st Premolar/ 8 mm	**r**	-0.036	-0.133
	p	0.829	0.364
PCBT 2nd Premolar- 1st Premolar/ 10 mm	**r**	-0.072	-0.143
	p	0.664	0.326
PCBT 2nd Premolar- 1st Premolar/ 12 mm	**r**	-0.136	-0.25
	p	0.409	0.083
PCBT Premolar-Canine/ 4 mm	**r**	-0.042	-0.18
	p	0.779	0.215
PCBT Premolar-Canine/ 6 mm	**r**	0.017	-0.102
	p	0.909	0.487

Table 4.2.2. The correlation between age and cortical bone thickness in unilateral cleft lip and palate and control groups with independent t test- continued

		Age (UCLP Group)	**Age (Control Group)**
PCBT Premolar-Canine/ 8 mm	**r**	-0.071	-0.069
	p	0.637	0.635
PCBT Premolar-Canine/ 10 mm	**r**	-0.057	0.052
	p	0.706	0.723
PCBT Premolar-Canine/ 12 mm	**r**	-0.089	0.125
	p	0.566	0.385

4.3. Vertical Growth Pattern of UCLP and Control Groups

S-N/ Go-Me angle and S-Go/ N-Me ratio were measured in order to identify if the patient was in the hyperdivergent, hypodivergent, or normal groups. In UCLP group, 68% of the patients had high angle, 8% had low angle, and 24% had normal growth pattern. In the control group, 20% of the subjects had high angle, 28% had normal, and 52% had low angle growth pattern. There was a statistically significant difference between the groups regarding the distribution of the patients' growth pattern ($p<0.001$), with UCLP group showing dominance of high angle subjects whereas low angle subjects were dominant in the control group (Table 4.3.1.).

Table 4.3.1. Distribution and comparison of subjects with different vertical growth pattern of the groups with chi square test

Vertical Growth Pattern	**UCLP Group**		**Control Group**		**p**
	n	**%**	**n**	**%**	
High angle	34	68%	10	20%	**0.0001**
Low angle	4	8%	26	52%	
Normal	12	24%	14	28%	

4.4. Buccal Cortical Bone Thickness of UCLP and Control Groups

The buccal cortical bone thicknesses of the UCLP and control groups were measured at 4, 6, and 8 mm from the alveolar crest and the mean, minimum and maximum bone thickness values were obtained for the analysis (Table 4.4.1.- 4.4.3.) (Fig. 4.4.1.-4.4.3.).

Table 4.4.1. The mean, minimum and maximum values of buccal cortical bone thickness of cleft side of unilateral cleft lip and palate group

Site		Buccal Cortical Bone Thickness (mm)		
		Mean±SD	Minimum	Maximum
1st Molar-Premolar	4 mm	1.25±0.16	0.90	1.53
	6 mm	1.31±0.13	0.99	1.59
	8 mm	1.38±0.12	1.05	1.61
2nd Premolar-1st Premolar	4 mm	1.18±0.18	0.91	1.48
	6 mm	1.27±0.16	1.00	1.58
	8 mm	1.32±0.14	1.04	1.60
Premolar-Canine	4 mm	1.17±0.18	0.86	1.46
	6 mm	1.22±0.16	0.91	1.46
	8 mm	1.28±0.15	0.92	1.52

Table. 4.4.2. The mean, minimum and maximum values of buccal cortical bone thickness of non-cleft side of unilateral cleft lip and palate group

Site		Buccal Cortical Bone Thickness (mm)		
		Mean±SD	Minimum	Maximum
1st Molar-Premolar	4 mm	1.26±0.15	0.91	1.51
	6 mm	1.33±0.16	0.93	1.61
	8 mm	1.40±0.14	0.93	1.62
2nd Premolar-1st Premolar	4 mm	1.21±0.17	0.88	1.51
	6 mm	1.27±0.16	0.93	1.53
	8 mm	1.33±0.16	0.92	1.63
Premolar-Canine	4 mm	1.18±0.18	0.79	1.51
	6 mm	1.25±0.17	0.88	1.52
	8 mm	1.31±0.16	0.99	1.58

Table. 4.4.3. The mean, minimum and maximum values of buccal cortical bone thickness of control group

Site		Buccal Cortical Bone Thickness (mm)		
		Mean±SD	**Minimum**	**Maximum**
1st Molar-Premolar	**4 mm**	1.40±0.08	1.21	1.53
	6 mm	1.45±0.07	1.26	1.57
	8 mm	1.50±0.07	1.27	1.60
2nd Premolar-1st Premolar	**4 mm**	1.40±0.06	1.25	1.53
	6 mm	1.44±0.07	1.24	1.59
	8 mm	1.49±0.06	1.27	1.59
Premolar-Canine	**4 mm**	1.37±0.07	1.21	1.48
	6 mm	1.41±0.06	1.24	1.50
	8 mm	1.46±0.07	1.27	1.59

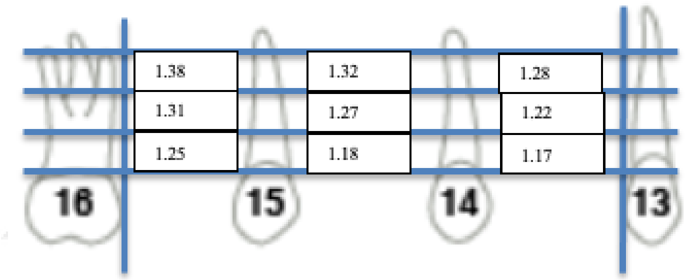

Fig. 4.4.1. The mapping of buccal cortical bone thickness of the cleft side of UCLP group given as the mean value in mm

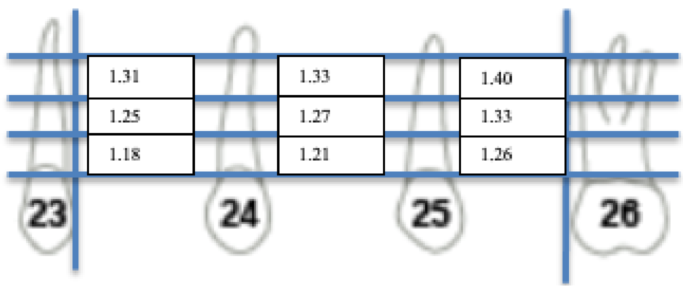

Fig. 4.4.2. The mapping of buccal cortical bone thickness of the non-cleft side of UCLP group given as the mean value in mm

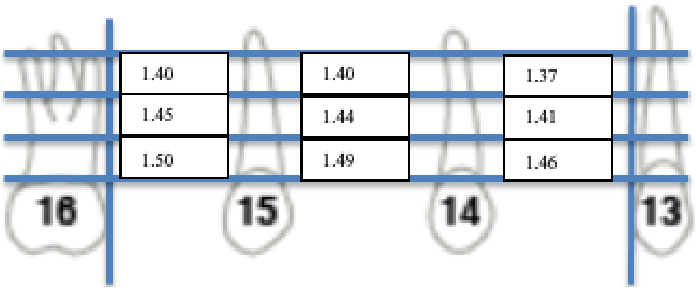

Fig. 4.4.3. The mapping of buccal cortical bone thickness of the control group given as the mean value in mm

4.5. Comparison of Buccal Cortical Bone Thicknesses of UCLP and Control Groups

4.5.1. Comparison of Buccal Cortical Bone Thicknesses between Cleft Side of UCLP and Control Group

When the buccal cortical bone thicknesses were evaluated, the control group had significantly higher values of bone thickness compared with the cleft side of the UCLP group in every interradicular areas and at all levels ($p<0.001$) (Table 4.5.1.1.).

Table 4.5.1.1. Comparison of buccal cortical bone thicknesses between cleft side of unilateral cleft lip and palate group and control group with independent t test

Site		Buccal Cortical Bone Thickness (mm) UCLP Group Cleft Side (n=50) Mean±SD	Buccal Cortical Bone Thickness (mm) Control Group (n=50) Mean±SD	p
1st Molar-Premolar	4 mm	1.246±0.156	1.403±0.076	**0.0001*** **
	6 mm	1.315±0.133	1.455±0.070	**0.0001*** **
	8 mm	1.380±0.125	1.505±0.075	**0.0001*** **
2nd Premolar-1st Premolar	4 mm	1.185±0.182	1.397±0.065	**0.0001*** **
	6 mm	1.272±0.156	1.441±0.074	**0.0001*** **
	8 mm	1.322±0.143	1.487±0.064	**0.0001*** **
Premolar-Canine	4 mm	1.169±0.177	1.371±0.067	**0.0001*** **
	6 mm	1.223±0.162	1.415±0.057	**0.0001*** **
	8 mm	1.281±0.149	1.458±0.069	**0.0001*** **

n=39 for cleft side for the 2nd Premolar-1st premolar measurements, *** $p<0.001$

4.5.2. Comparison of Buccal Cortical Bone Thicknesses between Non-Cleft Side of UCLP and Control Groups

In the maxillary buccal region, in all the posterior interradicular areas, the control group had significantly higher values compared with the non-cleft side of the UCLP group (p<0.001) (Table 4.4.2.1).

Table 4.5.2.1. Comparison of buccal cortical bone thicknesses between non-cleft side of unilateral cleft lip and palate group and control group with independent t test

Site		Buccal Cortical Bone Thickness (mm)		
		UCLP Group Non-Cleft Side (n=50)	Control Group (n=50)	p
		Mean±SD	Mean±SD	
1st Molar-Premolar	**4 mm**	1.26±0.15	1.40±0.08	**0.0001*****
	6 mm	1.33±0.16	1.45±0.07	**0.0001*****
	8 mm	1.40±0.14	1.50±0.07	**0.0001*****
2nd Premolar-1st Premolar	**4 mm**	1.21±0.17	1.40±0.06	**0.0001*****
	6 mm	1.27±0.16	1.44±0.07	**0.0001*****
	8 mm	1.33±0.16	1.49±0.06	**0.0001*****
Premolar-Canine	**4 mm**	1.18±0.18	1.37±0.07	**0.0001*****
	6 mm	1.25±0.17	1.41±0.06	**0.0001*****
	8 mm	1.31±0.16	1.46±0.07	**0.0001*****

n: 40 for cleft side for the 2nd Premolar-1st premolar measurements, *** p<0.001

4.5.3. Comparison of Buccal Cortical Bone Thicknesses between Cleft and Non-Cleft Side of UCLP Group

The mean value of buccal cortical bone thickness of cleft side between premolar and canine at 8 mm, was significantly lower than that of the non-cleft side (p<0.05). No statistically significant differences were found in the mean values of buccal cortical bone thickness between the cleft and non-cleft sides at other interradicular areas (p>0.05) (Table 4.5.3.1.).

Table 4.5.3.1. Comparison of buccal cortical bone thickness between cleft and non-cleft side of unilateral cleft lip and palate group with paired t-test

Site		Buccal Cortical Bone Thickness (mm)		
		Cleft Side (n=50)	Non-Cleft Side (n=50)	p
		Mean±SD	Mean± SD	
1st Molar-Premolar	4 mm	1.25±0.16	1.26±0.15	0.507
	6 mm	1.31±0.13	1.33±0.16	0.423
	8 mm	1.38±0.12	1.4±0.14	0.292
2nd Premolar-1st Premolar	4 mm	1.17±0.18	1.19±0.17	0.242
	6 mm	1.26±0.15	1.26±0.17	0.656
	8 mm	1.32±0.14	1.33±0.17	0.520
Premolar-Canine	4 mm	1.17±0.18	1.18±0.18	0.400
	6 mm	1.22±0.16	1.25±0.17	0.087
	8 mm	1.28±0.15	1.31±0.16	**0.037***

n=39 for cleft side and n=40 for non-cleft side for the 2nd Premolar-1st premolar measurements, *p<0.05

4.6. Comparison of Buccal Cortical Bone Thickness at Different Interradicular Areas in UCLP Group

Except at the level of 4 mm, the buccal cortical bone thickness of the canine and premolar interradicular area was found to be significantly thinner compared to the site between premolar and first molar (Tables 4.6.1.- 4.6.2.)

Table 4.6.1. Comparison of buccal cortical bone thickness at different interradicular areas with one way ANOVA test

UCLP Group	Distance from the alveolar crest	Site			p
		Canine-Premolar	1st Premolar-2nd Premolar	Premolar-1st Molar	
		Mean± SD	Mean± SD	Mean± SD	
Cleft Side	4 mm	1.17±0.18	1.18±0.18	1.25±0,16	0.067
	6 mm	1.22±0.16	1.27±0,16	1.31±0,13	**0.012***
	8 mm	1.28±0.15	1.32±0,14	1.38±0,12	**0.003****
Non-Cleft Side	4 mm	1.18±0.18	1.21±0,17	1.26±0,15	0.075
	6 mm	1.25±0.17	1.27±0,16	1.33±0,16	**0.043***
	8 mm	1.31±0.16	1.33±0.16	1.40±0.14	**0.017***

* p<0.05, ** p<0.001

Table 4.6.2. Tukey multi comparison test for buccal cortical bone thickness at different interradicular areas

Tukey Multi Comparison Test		6 mm	8 mm
Cleft Side	**3/4 - 4/5**	0.297	0.360
	3/4 - 5/6	**0.008****	**0.002****
	4/5 - 5/6	0.373	0.131
Non-Cleft Side	**3/4 - 4/5**	0.858	0.825
	3/4 -5/6	**0.042***	**0.017***
	4/5 -5/6	0.180	0.106

3/4 : Canine- Premolar, 4/5: 1^{st} Premolar- 2^{nd} Premolar, 5/6: 1^{st} Molar- Premolar

4.7. Comparison of Buccal Cortical Bone Thicknesses at Different Levels in UCLP Group

4.7.1. Comparison of Buccal Cortical Bone Thickness between First Molar and Premolar at Different Levels

At both sides of UCLP group, the measurements at 4 mm from the alveolar crest were significantly lower than the measurements at 6 mm and 8 mm ($p<0.001$) (Tables 4.7.1.1-4.7.1.2. and Figure 4.7.1.1.). Also, the buccal cortical bone thicknesses at 6 mm were significantly lower compared to the measurements at 8 mm ($p<0.001$). The buccal cortical bone thicknesses between 1^{st} molar and premolar showed a tendency to increase from the alveolar crest toward the apical region.

Table 4.7.1.1. Comparison of buccal cortical bone thicknesses at different levels between first molar and premolar with paired one way ANOVA

UCLP	Distance from the alveolar crest	BCBT Mean±SD	p
Cleft Side	**4 mm**	1.25±0.16	**0.0001*****
	6 mm	1.31±0.13	
	8 mm	1.38±0.12	
Non-Cleft Side	**4 mm**	1.26±0.15	**0.0001*****
	6 mm	1.33±0.16	
	8 mm	1.40±0.14	

*** p<0.001

Table 4.7.1.2. Results of Newman Keuls multiple comparison test for buccal cortical bone thickness between 1st molar and premolar

Newman Keuls Multiple Comparison Test	Cleft Side	Non-Cleft Side
4 mm / 6 mm	**0.0001*** **	**0.0001*** **
4 mm / 8 mm	**0.0001*** **	**0.0001*** **
6 mm / 8 mm	**0.0001*** **	**0.0001*** **

*** p<0.001

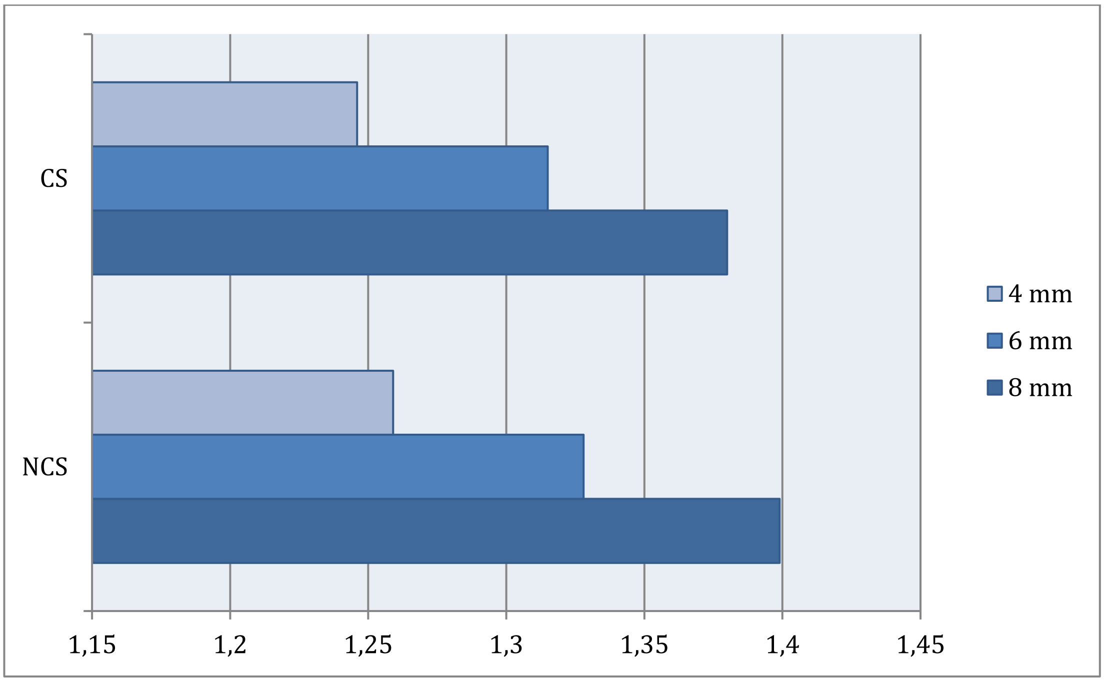

Fig. 4.7.1.1. The graphical illustration of comparison of buccal cortical bone thickness at different levels between 1st molar and premolar

4.7.2. Comparison of Buccal Cortical Bone Thickness between Second Premolar and First Premolar at Different Levels

For all groups, the measurements at 4 mm from the alveolar crest were significantly lower than the measurements at 6 mm and 8 mm (p<0.001) (Tables 4.7.2.1.- 4.7.2.2. and Figure 4.7.2.1.). In addition, the cortical bone thicknesses at 6 mm were significantly lower compared to the measurements at 8 mm (p<0.001). The buccal cortical bone thickness between 2nd premolar and 1st premolar increased from the alveolar crest to the apical region.

Table 4.7.2.1. Buccal cortical bone thicknesses at different levels between second premolar and first premolar with paired one way ANOVA

UCLP	Distance from the alveolar crest	Values	p
Cleft Side	4 mm	1.18±0.18	0.0001***
	6 mm	1.27±0.16	
	8 mm	1.32±0.14	
Non-Cleft Side	4 mm	1.21±0.17	0.0001***
	6 mm	1.27±0.16	
	8 mm	1.33±0.16	

*** $p<0.001$

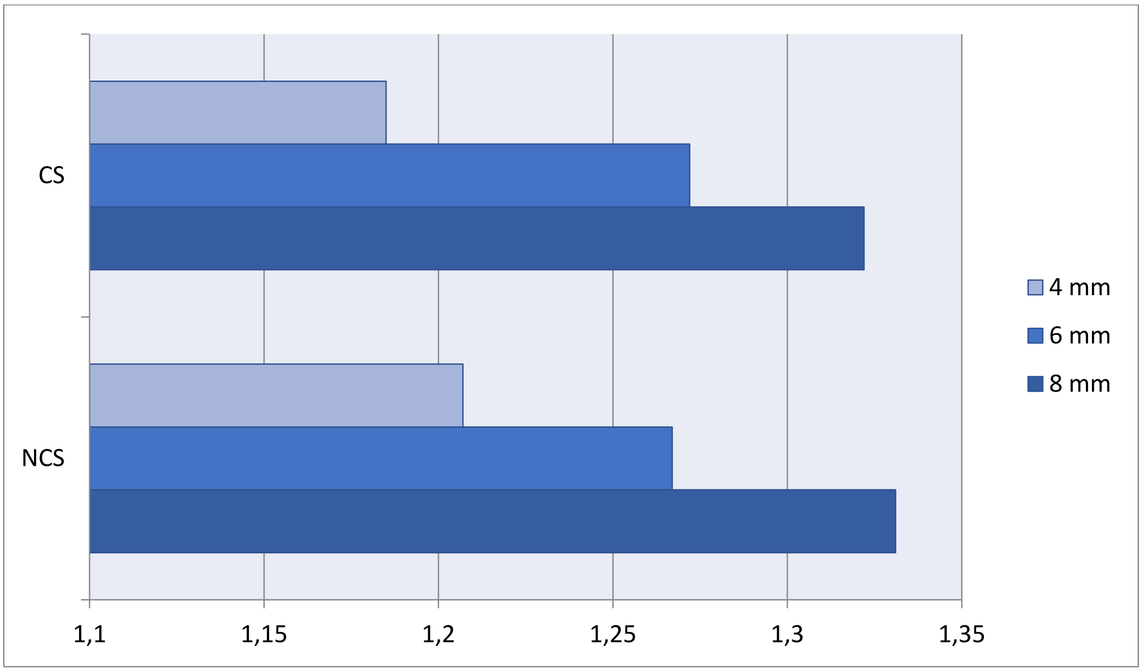

Fig. 4.7.2.1. The graphical illustration of comparison of buccal cortical bone thickness at different levels between 2nd premolar and 1st premolar

Table 4.7.2.2. Newman Keuls multiple comparison test for buccal cortical bone thickness between 2nd premolar and 1st premolar

Newman Keuls Multiple Comparison Test	Cleft Side	Non-Cleft Side
4 mm / 6 mm	0.0001***	0.0001***
4 mm / 8 mm	0.0001***	0.0001***
6 mm / 8 mm	0.0001***	0.0001***

***$p< 0.001$

4.7.3. Comparison of Buccal Cortical Bone Thickness between Premolar and Canine at Different Levels

When the buccal cortical bone thicknesses between premolar and canine were evaluated at different levels, the measurements at 4 mm showed significantly lower values than the measurements at 6 mm and 8 mm ($p<0.001$) (Tables 4.7.3.1.- 4.7.3.2. and Figure 4.7.3.1.). The measurements at 6 mm were significantly lower than the measurements at 8 mm as well ($p<0.001$). The buccal cortical bone thickness between premolar and canine increased from the alveolar crest to the apical region.

Table 4.7.3.1. Buccal cortical bone thicknesses at different levels between premolar and canine with paired one way ANOVA

Groups	Distance from the alveolar crest	Values	p
Cleft Side	**4 mm**	1.17±0.18	**0.0001*** **
	6 mm	1.22±0.16	
	8 mm	1.28±0.15	
Non-Cleft Side	**4 mm**	1.18±0.18	**0.0001*** **
	6 mm	1.25±0.17	
	8 mm	1.31±0.16	

*** $p<0.001$

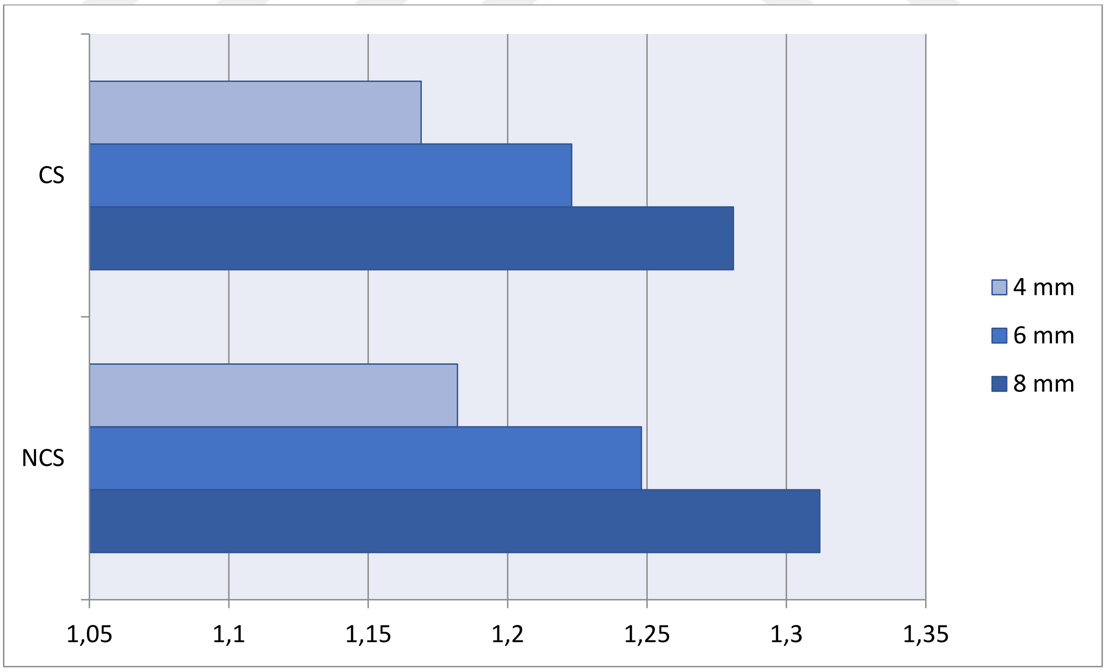

Fig. 4.7.3.1. The graphical illustration of comparison of buccal cortical bone thickness at different levels between premolar and canine

Table 4.7.3.2. Newman Keuls multiple comparison test for buccal cortical bone thickness between premolar and canine

Newman Keuls Multiple Comparison Test	Cleft Side	Non-Cleft Side
4 mm / 6 mm	**0.0001*** **	**0.0001*** **
4 mm / 8 mm	**0.0001*** **	**0.0001*** **
6 mm / 8 mm	**0.0001*** **	**0.0001*** **

***** p<0.001**

4.8. Palatal Cortical Bone Thickness of UCLP and Control Groups

The palatal cortical bone thicknesses of UCLP and control groups were measured at 4, 6, 8, 10 and 12 mm from the alveolar crest and the mean, minimum and maximum bone thickness values were obtained for the analysis (Table 4.8.1.- Table 4.8.2.) (Fig. 4.8.1.)

Table 4.8.1. The mean, minimum and maximum values of palatal cortical bone thickness of cleft side of unilateral cleft lip and palate group

Site		**Palatal Cortical Bone Thickness (mm)**		
		Mean±SD	**Minimum**	**Maximum**
1st Molar-Premolar	**4 mm**	1.29±0.14	0.94	1.54
	6 mm	1.34±0.13	1.06	1.59
	8 mm	1.38±0,13	1.08	1.61
	10 mm	1.42±0.12	1.13	1.61
	12 mm	1.46±0.13	1.01	1.63
2nd Premolar-1st Premolar	**4 mm**	1.27±0.16	0.95	1.52
	6 mm	1.31±0.15	0.95	1.54
	8 mm	1.34±0.14	1.12	1.59
	10 mm	1.38±0.13	1.14	1.61
	12 mm	1.37±0.26	1.02	1.65
Premolar-Canine	**4 mm**	1.22±0.18	0.88	1.50
	6 mm	1.26±0.15	0.99	1.51
	8 mm	1.30±0.15	1.07	1.55
	10 mm	1.33±0.15	1.06	1.59
	12 mm	1.37±0.13	1.08 mm	1.60 mm

Table 4.8.2. The mean, minimum and maximum values of palatal cortical bone thickness of non-cleft side of unilateral cleft lip and palate group

Site		**Palatal Cortical Bone Thickness (mm)**		
		Mean±SD	**Minimum**	**Maximum**
1st Molar-Premolar	**4 mm**	1.30±0.16	0.95	1.60
	6 mm	1.34±0.15	1.00	1.61
	8 mm	1.38±0.13	1.03	1.66
	10 mm	1.41±0.12	1.09	1.65
	12 mm	1.45±0.12	1.13	1.69
2nd Premolar-1st Premolar	**4 mm**	1.25±0.16	0.91	1.59
	6 mm	1.29±0.15	0.96	1.59
	8 mm	1.33±0.14	1.00	1.60
	10 mm	1.37±0.13	1.06	1.62
	12 mm	1.39±0.13	1.06	1.69
Premolar-Canine	**4 mm**	1.23±0.15	0.86	1.41
	6 mm	1.29±0.16	0.96	1.59
	8 mm	1.31±0.13	0.96	1.57
	10 mm	1.35±0.12	1.03	1.51
	12 mm	1.38±0.12	1.03	1.52

Table 4.8.3. The mean, minimum and maximum values of palatal cortical bone thickness of control group

Site		Palatal Cortical Bone Thickness (mm)		
		Mean±SD	**Minimum**	**Maximum**
1st Molar-Premolar	**4 mm**	1.44±0.05	1.30	1.57
	6 mm	1.48±0.05	1.33	1.59
	8 mm	1.51±0.04	1.38	1.60
	10 mm	1.53±0.05	1.40	1.63
	12 mm	1.57±0.04	1.42	1.66
2nd Premolar-1st Premolar	**4 mm**	1.42±0.05	1.26	1.52
	6 mm	1.45±0.05	1.31	1.59
	8 mm	1.49±0.04	1.32	1.59
	10 mm	1.51±0.05	1.32	1.64
	12 mm	1.54±0.05	1.48	1.66
Premolar-Canine	**4 mm**	1.41±0.05	1.24	1.49
	6 mm	1.44±0.05	1.29	1.53
	8 mm	1.46±0.05	1.32	1.60
	10 mm	1.49±0.05	1.33	1.59
	12 mm	1.51±0.04	1.34	1.59

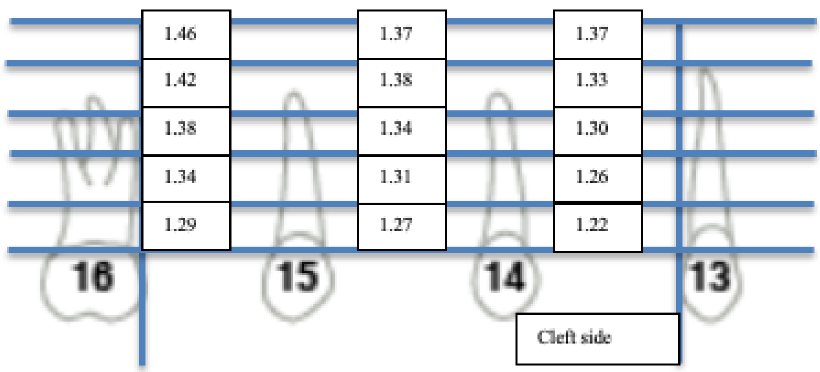

Fig. 4.8.1. The mapping of palatal cortical bone thickness of cleft side of unilateral cleft lip and palate group given as the mean value in mm

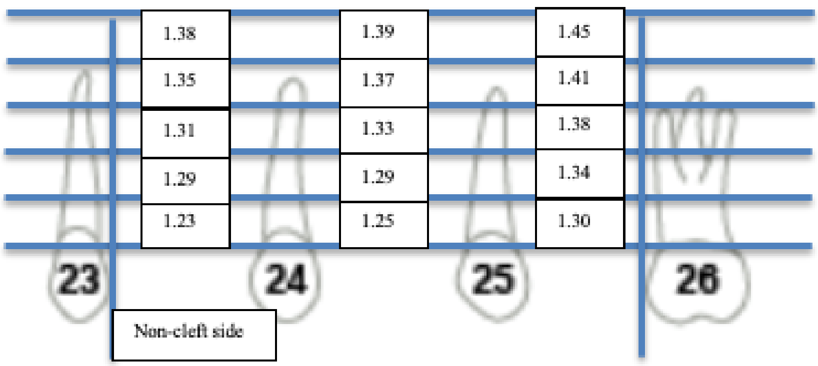

Fig. 4.8.2. The mapping of palatal cortical bone thickness of non- cleft side of unilateral cleft lip and palate group given as the mean value in mm

Fig. 4.8.3. The mapping of palatal cortical bone thickness of control group given as the mean value in mm

4.9. Comparison of Palatal Cortical Bone Thicknesses of UCLP and Control Groups

4.9.1. Comparison of Palatal Cortical Bone Thicknesses of Cleft Side of UCLP and Control Groups

The evaluation of palatal cortical bone thickness of the cleft side revealed significantly lower values of bone thickness than that of the control group in all measured areas ($p<0.001$) (Table 4.9.1.1.).

Table 4.9.1.1. Comparison of palatal cortical bone thicknesses of cleft side of unilateral cleft lip and palate group and control group with independent t test

Site		Palatal Cortical Bone Thickness (mm)		
		UCLP Group Cleft Side (n=50)	Control Group (n=50)	p
		Mean±SD	Mean±SD	
1st Molar-Premolar	**4 mm**	1.29±0.14	1.44±0.05	**0.0001*** **
	6 mm	1.34±0.13	1.48±0.05	**0.0001*** **
	8 mm	1.38±0.13	1.51±0.04	**0.0001*** **
	10 mm	1.42±0.12	1.53±0.05	**0.0001*** **
	12 mm	1.46±0.13	1.57±0.04	**0.0001*** **
2nd Premolar-1st Premolar	**4 mm**	1.27±0.16	1.42±0.05	**0.0001*** **
	6 mm	1.31±0.15	1.45±0.05	**0.0001*** **
	8 mm	1.34±0.14	1.49±0.04	**0.0001*** **
	10 mm	1.38±0.13	1.51±0.05	**0.0001*** **
	12 mm	1.37±0.26	1.54±0.05	**0.0001*** **
Premolar-Canine	**4 mm**	1.22±0.18	1.41±0.05	**0.0001*** **
	6 mm	1.26±0.15	1.44±0.05	**0.0001*** **
	8 mm	1.30±0.15	1.46±0.05	**0.0001*** **
	10 mm	1.33±0.15	1.49±0.05	**0.0001*** **
	12 mm	1.37±0.13	1.51±0.04	**0.0001*** **

n:39 for cleft side for the 2nd Premolar-1st premolar measurements, ***p<0.001

4.9.2. Comparison of Palatal Cortical Bone Thicknesses of Non-Cleft Side of UCLP and Control Groups

In all interradicular areas and at all levels, the non-cleft side palatal cortical bone thicknesses had significantly lower values compared to the control group ($p< 0.001$) (Table 4.8.1.2.1.).

Table 4.9.2.1. Comparison of palatal cortical bone thicknesses of non-cleft side of unilateral cleft lip and palate group and control group with independent t test

Site		Palatal cortical bone thickness (mm)		
		UCLP Group Non-Cleft Side (n=50)	Control Group (n=50)	p
		Mean±SD	Mean±SD	
1st Molar-Premolar	4 mm	1.30±0.16	1.44±0.05	**0.0001*** **
	6 mm	1.34±0.15	1.48±0.05	**0.0001*** **
	8 mm	1.38±0.13	1.51±0.04	**0.0001*** **
	10 mm	1.41±0.12	1.53±0.05	**0.0001*** **
	12 mm	1.45±0.12	1.57±0.04	**0.0001*** **
2nd Premolar- 1st Premolar	4 mm	1.25±0.16	1.42±0.05	**0.0001*** **
	6 mm	1.29±0.15	1.45±0.05	**0.0001*** **
	8 mm	1.33±0.14	1.49±0.04	**0.0001*** **
	10 mm	1.37±0.13	1.51±0.05	**0.0001*** **
	12 mm	1.39±0.13	1.54±0.05	**0.0001*** **
Premolar-Canine	4 mm	1.23±0.15	1.41±0.05	**0.0001*** **
	6 mm	1.29±0.16	1.44±0.05	**0.0001*** **
	8 mm	1.31±0.13	1.46±0.05	**0.0001*** **
	10 mm	1.35±0.12	1.49±0.05	**0.0001*** **
	12 mm	1.38±0.12	1.51±0.04	**0.0001*** **

n:40 for non-cleft side for the 2nd Premolar-1st premolar measurements, ***$p<0.001$

4.9.3. Comparison of Palatal Cortical Bone Thicknesses of Cleft Side and Non-Cleft Side of UCLP Group

No statistically significant differences were found in the palatal cortical bone thicknesses between the cleft and non-cleft sides at any site measured (p>0.05) (Table 4.8.1.3.1.).

Table 4.9.3.1. Comparison of palatal cortical bone thicknesses between cleft and non-cleft sides of unilateral cleft lip and palate group with paired t-test

Site		Palatal Cortical Bone Thickness (mm)		
		Cleft Side (n=50)	Non-Cleft Side (n=50)	p
		Mean±SD	Mean±SD	
1st Molar-Premolar	4 mm	1.30±0.16	1.29±0.14	0.888
	6 mm	1.34±0.15	1.34±0.13	0.882
	8 mm	1.38±0.13	1.38±0.13	0.718
	10 mm	1.41±0.13	1.42±0.12	0.815
	12 mm	1.46±0.12	1.46±0.13	0.948
2nd Premolar-1st Premolar	4 mm	1.25±0.17	1.27±0.16	0.463
	6 mm	1.29±0.15	1.31±0.15	0.369
	8 mm	1.33±0.15	1.34±0.14	0.636
	10 mm	1.37±0.14	1.38±0.13	0.719
	12 mm	1.39±0.14	1.40±0.14	0.748
Premolar-Canine	4 mm	1.23±0.15	1.22±0.18	0.468
	6 mm	1.29±0.17	1.26±0.15	0.203
	8 mm	1.30±0.13	1.30±0.15	0.768
	10 mm	1.35±0.12	1.33±0.14	0.341
	12 mm	1.38±0.13	1.38±0.13	0.863

n=39 for cleft side and n=40 for non-cleft side for the 2nd Premolar-1st premolar measurements

4.10. Comparison of Palatal Cortical Bone Thickness at different interradicular areas in UCLP Group

Except the level of 4 mm, at 6, 8 and 10 mm, the palatal cortical bone thickness was found to be significantly thinner between canine and premolar compared to the area between premolar and first molar. At 12 mm, PCBT was significantly thicker at interradicular area between premolar and first molar than the area between first premolar and second premolar, and canine and premolar (Tables 4.10.1.- 4.10.2.).

Table 4.10.1. Comparison of palatal cortical bone thickness at different interradicular areas with one way ANOVA test

UCLP	Distance from the alveolar crest	Site			p
		Canine-Premolar	1st Premolar-2nd Premolar	Premolar-1st Molar	
		Mean± SD	Mean± SD	Mean± SD	
Cleft Side	4 mm	1.22±0.18	1.27±0.16	1.29±0.14	0.109
	6 mm	1.26±0.15	1,31±0.15	1.34±0.13	**0.014***
	8 mm	1.30±0.15	1.34±0.14	1.38±0.13	**0.011***
	10 mm	1.33±0.15	1.38±0.13	1.42±0.12	**0.006****
	12 mm	1.37±0.13	1.37±0.26	1.46±0.13	**0.039***
Non-Cleft Side	4 mm	1.23±0.15	1.25±0.16	1.30±0.16	0.145
	6 mm	1.29±0.16	1.29±0.15	1.34±0.15	0.212
	8 mm	1.31±0.13	1.33±0.14	1.38±0.13	**0.028***
	10 mm	1.35±0.12	1.37±0.13	1.41±0.12	**0.046***
	12 mm	1.38±0.12	1.39±0.13	1.45±0.12	**0.01***

*p<0.05, ** p<0.01

Table 4.10.2. Tukey multi comparison test for palatal cortical bone thickness

Tukey Multi Comparison Test		4 mm	6 mm	8 mm	10 mm	12 mm
Cleft Side	3/4 - 4/5		0.203	0.279	0.199	0.998
	3/4 / 5/6		**0.01***	**0.007****	**0.004****	**0.042***
	4/5 / 5/6		0.546	0.363	0.360	**0.043***
Non-Cleft Side	3/4 / 4/5			0.765	0.881	0.862
	3/4 / 5/6			**0.026***	**0.044***	**0.012***
	4/5 / 5/6			0.172	0.197	0.065

3/4 : Canine- Premolar, 4/5: 1st Premolar- 2nd Premolar, 5/6: 1st Molar- Premolar, *p<0.05, **p<0.01

4.11. Comparison of Palatal Cortical Bone Thicknesses at Different Levels

4.11.1. Comparison of Palatal Cortical Bone Thickness at Different Levels between First Molar and Premolar

The evaluation of palatal cortical bone thickness between first molar and second premolar showed significant differences between different levels (p<0.001). The thinnest palatal cortical bone was found at 4 mm whereas the thickest was found at 12 mm and the cortical bone thickness significantly increased when moving from the most closest level to the alveolar crest to the most apical level (Tables 4.11.1.1- 4.11.1.2. and Figure 4.11.1.1.).

Table 4.11.1.1. Palatal cortical bone thicknesses at different levels between first molar and premolar with paired one way ANOVA

Groups	Distance from the alveolar crest	Values	p
Cleft Side	**4 mm**	1.29±0.14	**0.0001*** **
	6 mm	1.34±0.13	
	8 mm	1.38±0.13	
	10 mm	1.42±0.12	
	12 mm	1.46±0.13	
Non-Cleft Side	**4 mm**	1.30±0.16	**0.0001*** **
	6 mm	1.34±0.15	
	8 mm	1.38±0.13	
	10 mm	1.41±0.12	
	12 mm	1.45±0.12	

*** p<0.001

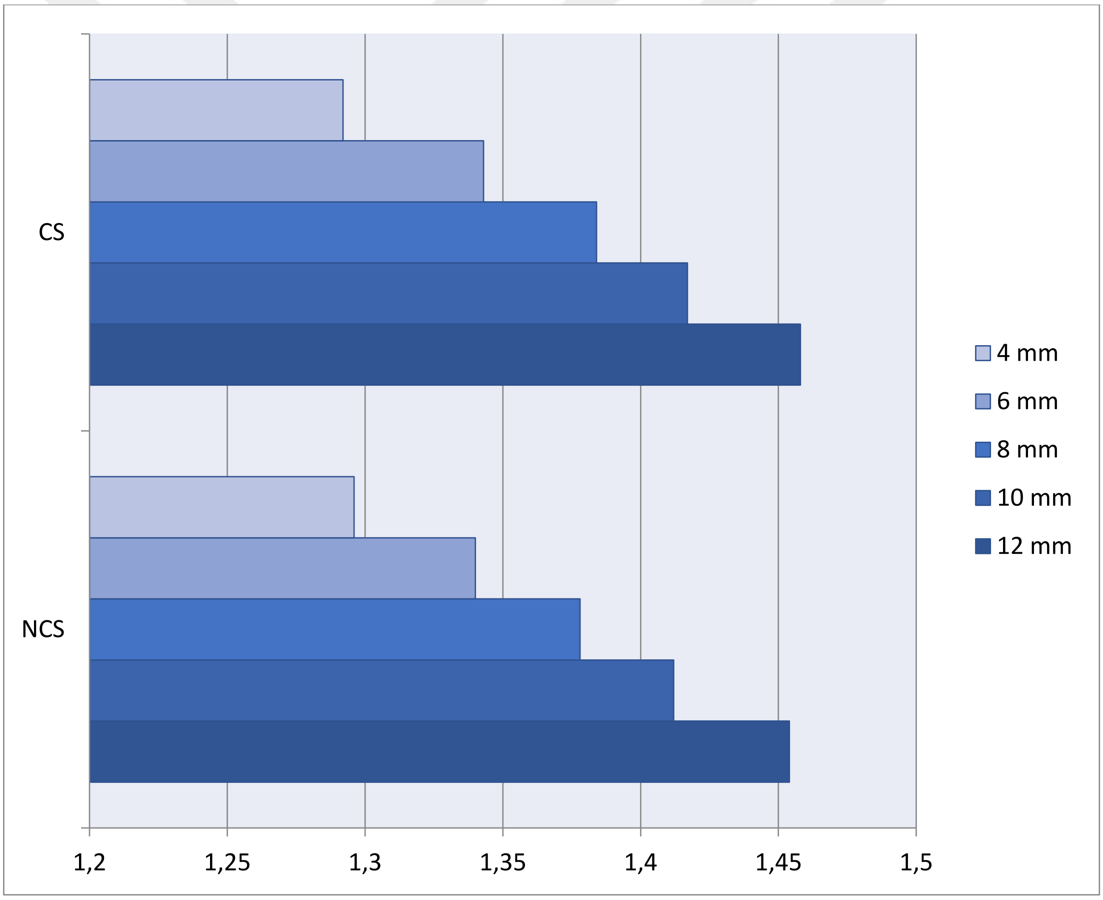

Fig. 4.11.1.1. The graphical illustration of comparison of palatal cortical bone thickness at different levels between 1st molar and premolar

Table 4.11.1.2. Newman Keuls multiple comparison test for palatal cortical bone thickness between 1st molar and premolar

Newman Keuls Multiple Comparison Test	Cleft Side	Non-Cleft Side
4 mm/ 6 mm	0.0001***	0.0001***
4 mm/ 8 mm	0.0001***	0.0001***
4 mm/ 10 mm	0.0001***	0.0001***
4 mm/ 12 mm	0.0001***	0.0001***
6 mm/ 8 mm	0.0001***	0.0001***
6 mm/ 10 mm	0.0001***	0.0001***
6 mm/ 12 mm	0.0001***	0.0001***
8 mm/ 10 mm	0.0001***	0.0001***
8 mm/ 12 mm	0.0001***	0.0001***
10 mm/ 12 mm	0.0001***	0.0001***

*** p<0.001

4.11.2. Comparison of Palatal Cortical Bone Thickness at Different Levels between Second Premolar and First Premolar

The evaluation between second and first premolar showed that the palatal cortical bone thickness significantly increased from 4 mm towards 12 mm at each level (p<0.001) with the exception that there were no differences in terms of thicknesses between 8 mm and 12 mm, also between 10 mm and 12 mm at the cleft side (p>0.05) (Tables 4.11.2.1.- 4.11.2.2. and Figure 4.11.2.1.)

Table 4.11.2.1. Palatal cortical bone thicknesses between second premolar and first premolar with paired one way ANOVA

Groups	Distance from the alveolar crest	Values	p
Cleft Side	4 mm	1.27±0,16	0.0001***
	6 mm	1.31±0.15	
	8 mm	1.34±0.14	
	10 mm	1.38±0.13	
	12 mm	1.37±0.26	
Non-Cleft Side	4 mm	1.25±0.16	0.0001***
	6 mm	1.29±0.15	
	8 mm	1.33±0.14	
	10 mm	1.37±0.13	
	12 mm	1.39±0.13	

*** p<0.001

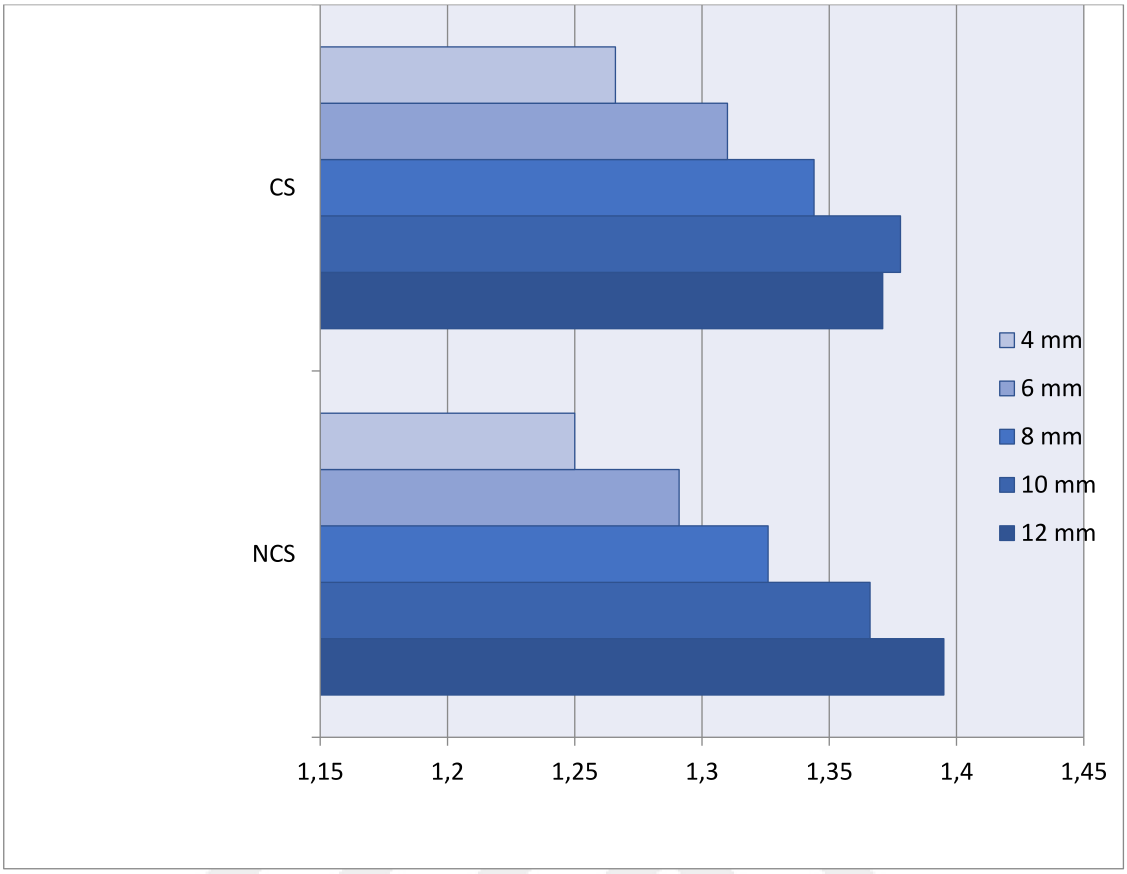

Fig. 4.11.2.1. The graphical illustration of comparison of palatal cortical bone thickness at different levels between 2nd premolar and 1st premolar

Table 4.11.2.2. Newman Keuls multiple comparison test for palatal cortical bone thickness between 2nd premolar and 1st premolar

Newman Keuls Multiple Comparison Test	Cleft Side	Non-Cleft Side
4 mm/ 6 mm	**0.0001*** **	**0.0001*** **
4 mm/ 8 mm	**0.0001*** **	**0.0001*** **
4 mm/ 10 mm	**0.0001*** **	**0.0001*** **
4 mm/ 12 mm	**0.002** **	**0.0001*** **
6 mm/ 8 mm	**0.0001*** **	**0.0001*** **
6 mm/ 10 mm	**0.0001*** **	**0.0001*** **
6 mm/ 12 mm	**0.01* **	**0.0001*** **
8 mm/ 10 mm	**0.0001*** **	**0.0001*** **
8 mm/ 12 mm	0.453	**0.0001*** **
10 mm/ 12 mm	0.832	**0.0001*** **

*p<0.01, **p<0.002, ***p<0.0001

4.11.3. Comparison of Palatal Cortical Bone Thickness at Different Levels between Premolar and Canine

In all areas of the cleft and non-cleft side, it was found that palatal cortical bone thickness significantly increased from 4 mm to 12 mm away from the alveolar crest ($p<0.001$) (Tables 4.11.3.1.- 4.11.3.2. and Figure 4.11.3.1.). Every higher level showed significantly higher values compared to the lower levels.

Table 4.11.3.1. Palatal cortical bone thicknesses at different levels between premolar and canine

Groups	Distance from the alveolar crest	Values	p
Cleft Side	**4 mm**	1.22±0.18	**0.0001*** **
	6 mm	1.26±0.15	
	8 mm	1.30±0.15	
	10 mm	1.33±0.15	
	12 mm	1.37±0.13	
Non-Cleft Side	**4 mm**	1.23±0.15	**0.0001*** **
	6 mm	1.29±0.16	
	8 mm	1.31±0.13	
	10 mm	1.35±0.12	
	12 mm	1.38±0.12	

*** $p<0.001$

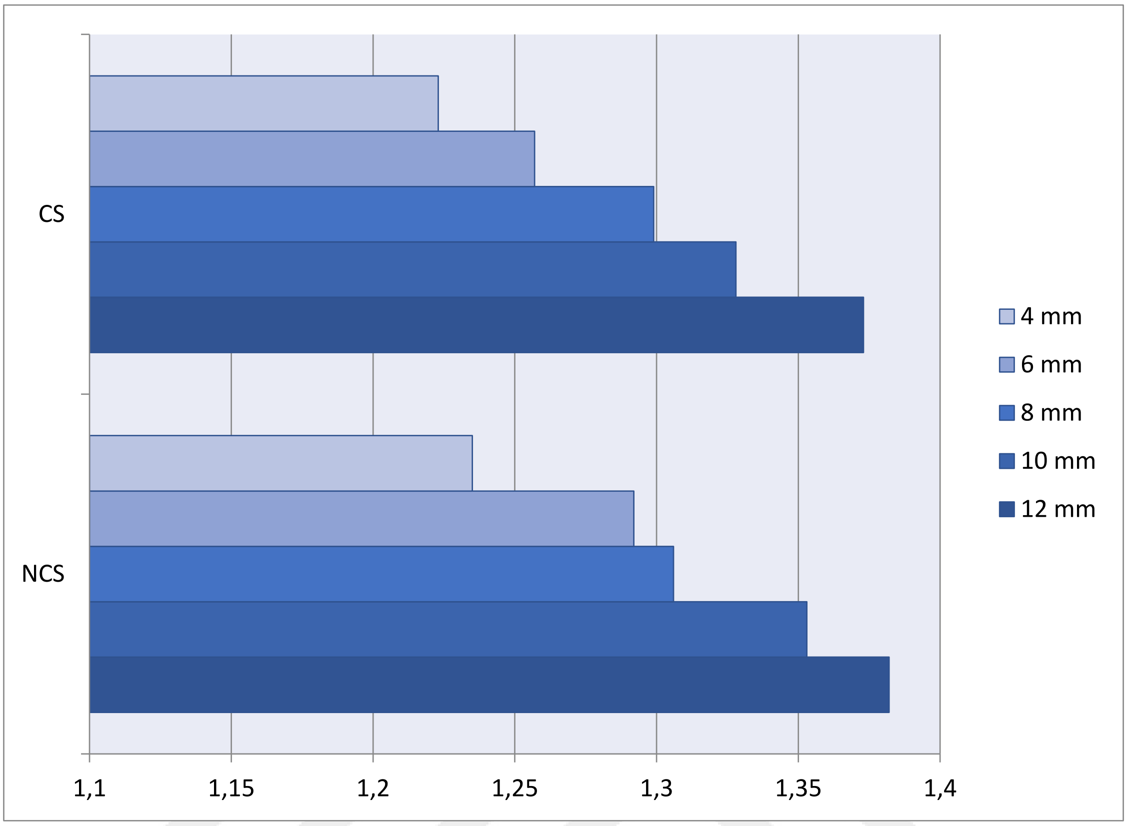

Fig. 4.11.3.1. The graphical illustration of comparison of palatal cortical bone thickness at different levels between premolar and canine

Table 4.11.3.2. Newman Keuls multiple comparison test for palatal cortical bone thickness between premolar and canine

Newman Keuls Multiple Comparison Test	Cleft Side	Non-Cleft Side
4 mm/ 6 mm	0.0001***	0.0001***
4 mm/ 8 mm	0.0001***	0.0001***
4 mm/ 10 mm	0.0001***	0.0001***
4 mm/ 12 mm	0.0001***	0.0001***
6 mm/ 8 mm	0.0001***	0.0001***
6 mm/ 10 mm	0.0001***	0.0001***
6 mm/ 12 mm	0.0001***	0.0001***
8 mm/ 10 mm	0.0001***	0.0001***
8 mm/ 12 mm	0.0001***	0.0001***
10 mm/ 12 mm	0.0001***	0.004**

** $p<0.01$, *** $p<0.001$

4.12. Comparison of Buccal and Palatal Cortical Bone Thickness of UCLP and Control Groups for the Same Level

At 4 mm, the palatal cortical bone was significantly thicker than buccal cortical bone for cleft side. At other levels there were no statistically significant differences between buccal and palatal cortical bone.

For non-cleft side, there were no significant differences between buccal and palatal cortical bone at any level.

However, in control group, cortical bone thickness was statistically increased from buccal to palatal site at 4 mm in all interradicular areas. At 6 mm, between canine and premolar, and premolar and first molar, palatal cortical bone was significantly thicker compared to buccal cortical bone. There were no significant differences between palatal and buccal cortical bone at 8 mm (Table 4.12.1.)

Table 4.12.1. Comparison of buccal and palatal cortical bone thickness with independent t test

Groups	Levels	Interradicular Area	BCBT	PCBT	p
Cleft Side of UCLP Group	4 mm	3/4	1.17±0,18	1.22±0,18	0.144
		4/5	1.18±0,18	1.27±0,16	**0.044***
		5/6	1.25±0,16	1.29±0,14	0.128
	6 mm	3/4	1.22±0,16	1.26±0,15	0.300
		4/5	1.27±0,16	1.31±0,15	0.266
		5/6	1.31±0,13	1.34±0,13	0.303
	8 mm	3/4	1.28±0,15	1.30±0,15	0.567
		4/5	1.32±0,14	1.34±0,14	0.492
		5/6	1.38±0,12	1.38±0,13	0.862
Non-Cleft Side of UCLP Group	4 mm	3/4	1.18±0,18	1.23±0,15	0.122
		4/5	1.21±0,17	1.25±0,16	0.245
		5/6	1.26±0,15	1.30±0,16	0.248
	6 mm	3/4	1.25±0,17	1.29±0,16	0.188
		4/5	1.27±0,16	1.29±0,15	0.484
		5/6	1.33±0,16	1.34±0,14	0.704
	8 mm	3/4	1.31±0,16	1.31±0.13	0.843
		4/5	1.33±0,16	1.33±0.14	0.874
		5/6	1.40±0,14	1.38±0.13	0.450
Control Group	4 mm	3/4	1.37±0,07	1.41±0,05	**0.002***
		4/5	1.40±0,06	1.42±0,05	**0.027***
		5/6	1.40±0,08	1.44±0,05	**0.012***
	6 mm	3/4	1.41±0,06	1.44±0,05	**0.026***
		4/5	1.44±0,07	1.45±0,05	0.347
		5/6	1.45±0,07	1.48±0,05	**0.048***
	8 mm	3/4	1.46±0,07	1.46±0,05	0.643
		4/5	1.49±0,06	1.49±0,04	0.927
		5/6	1.50±0,07	1.51±0,04	0.710

3/4 : Canine- Premolar, 4/5: 1st Premolar- 2nd Premolar, 5/6: 1st Molar- Premolar

* p<0.05

5. DISCUSSION

5.1. Discussion of Aim and Method

The use of mini-implants has become a preferred choice for providing orthodontic anchorage without unwanted tooth movement. The determining factors for mini-implant success are listed as sex and age (15, 63), root proximity (59), length and diameter of the implant (10, 11), soft tissue character (4), anatomic location (16, 169), insertion angle and placement torque (6, 7), predrilling and the use of pilot holes (8, 70), orthodontic load (12), and cortical bone thickness (3, 18, 20, 23, 42, 48, 50, 59, 66, 78, 80, 169, 174). Among them, cortical bone thickness plays a critical role on mini-implant stability. Marquezan *et al*. (175) did a meta-analysis investigating a relationship between the success of OMIs and cortical bone thickness. They found a significant positive relationship between the cortical bone thickness and OMI stability. In addition, Motoyoshi *et al.* (66) claimed that the sites with more than 1 mm of cortical bone thickness allowed higher success ratio regarding mini-implant stability. However, there is not any knowledge about quantitative and qualitative bone characteristics, particularly cortical bone thicknesses of cleft lip and palate patients at posterior mini-implant insertion areas. The treatment options for CLP are more simpler and diverse when the mini-implants are used. To date, TADs are mostly used for expansion, internal or external distraction, or post-orthognatic surgery fixation in CLP treatment. Furthermore, it would be beneficial to use mini-implants in cleft patients for tooth movement by inserting them to the interradicular areas since the treatment usually requires complex orthodontic tooth movements without anchorage loss. Regarding these information, we designed this study to assess one of the main patient-related variable, cortical bone thickness, in a UCLP group and to create a schematic outline showing the appropriate anatomical areas for OMI insertion in terms of cortical bone thicknesses. Thus, the main objective of this study was to quantitatively evaluate the cortical bone bone thickness at interradicular areas for mini-implant insertion in the posterior maxilla of the patients with UCLP and design a map for the clinicians. The secondary aims were to compare the cortical bone thicknesses at these specific locations between the cleft and non-cleft sides and between the subjects with and without UCLP.

Our study consisted of two groups; study group with cleft lip and palate patients and control group with non-cleft patients. The study group included 31 female and 19 male patients with a mean age of 14.76±5.06 years while the control group consisted of 25 female and 25 male patients with a mean age of 16.54±4.55 years. Although the mean age of the control subjects was slightly greater than that of the subjects with UCLP, there was no statistically significant difference between groups. On the other hand, the age interval of both groups was wide. In our retrospective study, first the UCLP group was composed from the archive, then a matching control group was composed in terms of age and sex. Because we included both growing and non-growing subjects in UCLP group to reach a considerable sample size, the age interval varied between 8 to 27 years in the study group, while in the control group it was between 8 and 28 years. Because of this large variation of age and the possible but not definitely proven association between age and cortical bone thickness, we further tried to explain the relation between age and cortical bone thickness using a correlation analysis in our study. No statistically significant relationship was reported between age and maxillary interradicular cortical bone thicknesses of the subjects. Therefore, we did not compose subgroups according to the age.

In the literature, the relation between age and cortical bone thickness is still controversial. Similar to our findings, Ono *et al.* (49) who studied patients in two groups with different age intervals (13-19 years, n=14, and 20-48 years, n=29) measuring the maxillary mesio-buccal and disto-buccal side of the first molars, showed no significant change according to age. Similarly, Deguchi *et al.* (45), who conducted a CT study, did not find any significant correlation between age and cortical bone thickness. In a recent study by Schneider *et al.* (53), it was stated that cortical bone did not differ between growing (n=141, mean age: 14.7 ± 1.6 years) and non-growing patients (n=149, mean age: 29.0 ± 9.1 years) and this result was statistically significant. Sathapana *et al.* (56) also claimed that age had relatively small impact on cortical bone thickness. On the other hand, some authors reported age-related differences in maxillary cortical bone thickness (42, 48). Taking a step further, as cortical bone thickness is considered a major factor contributing to the primary stability of the mini-implants, some clinical studies have been conducted and shown conflicting results in terms of the relationship between age and primary stability. Motoyoshi *et al.* (15) reported that the success ratio of mini-implants was significantly higher in adults (age range: 20.4-36.1 years) compared to the adolescents (age range: 11.7- 18.9 years). On the other hand, Miyawaki *et al.* (55) conducted a similar clinical study and found that the success rates in patients younger than 20 years (80%) were slightly lower than those older than 20 years (85-88%) but this difference was not significant. Similarly, Kuroda *et al.* (79) evaluating 75 patients with a mean age of 21.8±8.2 and Cheng *et al.* (46) assessing 44 individuals between 13 to 55 years old (29±8.9 years) concluded that there was no correlation between age and mini-implant success. The conflicting results of above-mentioned studies may arise from the greater variability of age range of the compared groups, indicating the necessity of further studies to clarify the influence of the age on cortical bone thickness and primary stability.

According to statistical analysis, the groups were compatible regarding sex distribution. In our study, the gender distribution of the groups was similar. The effect of gender on cortical bone thickness has been comprehensively analyzed in the literature. There are studies (3, 45, 46, 48, 53, 66, 79) showing no association between gender and cortical bone thickness whereas Ono *et al.* (49), Fayed *et al.* (42) and Cassetta *et al*. (176) found that the cortical bone was significantly thicker in males than in females. Ohiomoba *et al.* (52) concluded that there were no significant differences in male and female cortical bone in terms of thickness but cortical bone density was more in females than in males. On the other hand, Chun and Lim (54) reported no significant difference in cortical bone density between male and female subjects. Sathapana *et al.* (56) found a difference between genders at maxillary molar region with females having 0.26 mm more cortical bone thickness compared to males. They have not found any differences at other regions. In our study, we can assume that if there was any effect of the gender on the cortical bone thickness, this was eliminated by similar gender distribution in both groups.

As mentioned previously, the study and control groups of our retrospective study were composed by screening the archives of Yeditepe University, Dental Faculty. When composing the control group, age interval and sex distribution of the study group were taken into consideration to be able to create a comparable group. When both groups were compared regarding vertical facial pattern, the majority of the study subjects were found to be hyperdivergent (68%), whereas control subjects were mostly hypodivergent (52%). The distribution of vertical facial pattern of the groups (hyperdivergent 68% vs. 20%, hypodivergent 8% vs. 52%, normodivergent 24% vs. 28% for UCLP and control group, respectively) showed statistically significant difference. Since no attempt was made to compose similar groups regarding vertical growth pattern of the subjects, this distribution is partly coincidental but also explicable. Similar to our study group, it has been reported that patients with CLP usually display a high angle facial pattern (177-181). According to Lin *et al.* (181), a high angle growth pattern and an increased clockwise rotation of mandible in the UCLP patients might be the camouflage for the maxillary growth deficiency, maintaining the anteroposterior position of the maxilla and mandible.

In our study, both sides of the UCLP group were evaluated as the cleft and the non-cleft side. Since the cortical bone thickness in cleft patients has not been investigated yet, the possibility of different bone thicknesses between cleft and non-cleft side, cleft side and control group, and non-cleft side and control group were studied. Whereas in the control group, since previous studies found no difference in cortical bone thickness between right and left sides, only one side of the jaws was assessed (27, 45, 182).

In our study, we used CBCT technology which enabled us to evaluate interradicular buccal and palatal cortical bone thicknesses. CBCT has become very popular in many dental field because of reduced radiation exposure, increasing accessibility, and favorable cost-benefit analysis (152). The 2D and 3D images obtained from the CBCT are informative and have been used to quantitatively and qualitatively analyze the dental implant or orthodontic mini-implant insertion sites as well as determining the cortical bone thickness at the interradicular areas (17, 21, 29, 42, 53, 90, 148, 153, 169, 183, 184). Also, in CLP patients, CBCT was used by many researchers and found to be more accurate for the assessment of the alveolar defect (112, 185, 186), secondary alveolar bone grafting (117, 186-196), alveolar bone thickness of the teeth adjacent to the cleft, facial asymmetry (158, 197, 198), maxillary morphology (199), maxillary expansion (134, 200-202), maxillary sinus (203-205), nasal morphology (206-209), pharyngeal airway (200, 210-215), facial soft tissue thickness (216, 217), mandibular morphology (218-221), tooth morphology (156, 157, 222, 223), the morphometric analysis of sella turcica (224, 225), orthognatic surgery planning (226), and finally the incidental findings (227).

As in other studies (215, 228), to obtain a standardized orientation of the head and standardization of the measurements, a midline was constructed passing through crista galli on coronal slice, and nasion and sella points on axial slice. The midsagittal plane that included these points with being perpendicular to the computer screen was considered to be the midline of the face. The head orientation was finalized using the horizontal plane passing through both orbitale points, perpendicular to the midsagittal plane.

On the buccal side, the measurements were made at 4 mm, 6 mm and 8 mm apical to the alveolar crest while the measurement levels at palate were 4 mm, 6 mm, 8 mm, 10 mm and 12 mm. In the literature, it has been shown that the most appropriate level for mini-implant stability and maximum anchorage is at the level or above mucogingival junction (11, 25, 30, 35, 140). In order to assess cortical bone thickness for mini-implant insertion, measurements should be made from the clinically most convenient area which is the keratinized tissue assuring the lower possibility of infection, and is approximately 4 to 6 mm from the alveolar crest (4, 20, 42, 58). Ono *et al.* (49) concluded that the distance from the alveolar crest to the MGJ could be 2 to 4 mm in maxilla, and this should be the limit for preventing the irritation of the non-keratinized tissue and the peri-implant infection. Therefore, in our study, the starting point was chosen as 4 mm from the alveolar crest. In addition to 4 mm level from the alveolar crest, to fulfill the cortical bone thickness mapping purpose of our study, we also evaluated other levels of the bone in UCLP patients in accordance with previous studies conducted on subjects without cleft (4, 80, 81, 229). Measurements were stopped at 8 mm at the buccal side because of the clinical limitation of inserting mini-implants in the kretinized tissue for the stability and the success (79, 230). On the other hand, at the palatal site, there is a clinical possibility of more apical mini-implant insertion compared to the buccal site. Also, due to the cleft, a remarkable difference in palatal anatomy between the groups was considered. Therefore, the measurements were made more apically at the palatal area. Furthermore, at the palatal side, although the midpalatal area was shown to be the thickest and the most appropriate bone in the maxilla for mini-implant placement (80), because of the presence of the cleft we did not measure that area.

In accordance with previous studies (42, 45, 48, 52), the measurement sites in our study were determined as interradicular spaces between canine and first premolar, first premolar and second premolar, and second premolar and first molar. We did not include the anterior maxilla to the measurements because in our study group, there were patients with (n=43) or without alveolar bone graft (n=7). Alveolar bone graft affects the quality and quantity of the bone at the cleft area (93, 111, 231). Because of this heterogeneity of UCLP group, we excluded the anterior maxilla. Another reason was the high number of cleft patients (n=35) who had one or two missing laterals, which would compromise the direct comparison. Lastly, there are reports that suggest avoiding insertion of mini-implants in the anterior part of both jaws because that area provides less cortical bone for anchorage with less attached gingiva and insufficient interradicular distances (232, 233).

When there was one (n=9) or two missing premolar (n=6), their data at premolar area was excluded from the statistical analysis instead of including them as zero values because it would have affected the mean values unrealistically and have lowered the reliability of the comparisons. Since the study design is observational and retrospective, we have formed two groups from our archive. Although our groups were compatible within each other, there were patients in mixed dentition stage in both groups. There were 96 areas with primary teeth out of 285 areas in the study group, while in the control group, there were 18 areas with primary teeth out of 150 areas. In patients with primary teeth, we have used second primary molar as second premolar, first primary molar as first premolar, and primary canine as permanent canine. We choose this method since there was no other way to measure cortical bone thickness in adolescent patients.

5.2 Discussion of the Results

Scientific literature lacks studies for cortical bone thickness mapping in patients with UCLP, therefore we think that this study will be a very remarkable guideline for future researchers to broaden their knowledge and for orthodontists to acquire a presumable success ratio with OMIs in their practice.

At buccal side, according to our findings, the maximum buccal cortical bone thickness for the cleft side of UCLP group was 1.61 mm while for the non-cleft side of UCLP group it was 1.62 mm at 8 mm between 1st molar and premolar. The minimum buccal cortical bone thickness for the cleft side of UCLP group was 0.86 mm, whereas for the non-cleft side it was 0.79 mm at 4 mm between premolar and canine.

When the cleft and non-cleft side were compared, there were no significant differences in buccal cortical bone thickness except at 8 mm between premolar and canine. This difference might be due to the proximity of the interradicular area between canine and premolar to the cleft region. The comparison between the cleft side and the control group showed that in all interradicular areas and at every level, the control group had significantly greater cortical bone thickness than the cleft side of UCLP group. Similarly, the non-cleft side of the UCLP group had thinner cortical bone compared to the control group in all areas. The difference between the UCLP group and control group might be partly explained by the vertical growth pattern of the groups. While the majority of the UCLP group (68%) had high angle growth pattern, the majority of the control group (52%) had low angle growth pattern. Occlusal forces, that are greater in hypodivergent subjects, must be assisted by a solid and resistant buccal cortical bone. Thus, the thickness and density of buccal cortical bone in hypodivergent subjects are greater than hyperdivergent subjects (18). There are many reports that claim a correlation between vertical growth pattern and cortical bone thickness. Gaffuri *et al.* (21) stated that hyperdivergent individuals had thinner maxillary buccal and palatal cortical bone compared to hypodivergent individuals. Their results are in accordance with the study of Sadek *et al.* (22) who showed that while hypodivergent group had the thickest measurement values, hyperdivergent group had the thinnest measurements. The difference was more dominant at posterior maxilla and ranged between 0.16 to 0.62 mm. Miyawaki *et al.* (55) also suggested that a high mandibular plane angle, that is often in relation with thin cortical bone, was associated with mini-implant failures. It means that these differences in CBT in different facial types might have a clinical impact on mini-implant success. Klinge *et al.* (234) and Horner *et al.* (23) conducted a study on adolescents to assess interradicular cortical bone and alveolar ridge thicknesses to investigate mini-implant placement sites and reported that cortical bone was prone to be thicker in low angle patients compared to high angle patients. Horner *et al.* (23) concluded that this difference in cortical bone thickness was 0.08 to 0.64 mm. Ozdemir *et al.* (18) measured cortical bone thickness at 4 mm from the alveolar crest and investigated a correlation between growth pattern and cortical bone thickness. At the interradicular areas between canine and second molar, they found that low angle patients had thicker cortical bone in all measured areas. Swasty *et al.* (235) evaluated the mandibular cortical bone thickness in patients with different facial growth on CBCT images. They reported that high angle group had thinner cortical bone in almost all the measurement sites. Masumoto *et al.* (236) also claimed that hypodivergent patients had thicker cortical bone compared to hyperdivergent and normal patients. Overall, considering the findings of above-mentioned studies, the difference between cleft side and non-cleft side of UCLP group, and control group could be explained by the different facial types of the groups to some extent.

Another possible explanation of the thinner buccal cortical bone in UCLP group may be the anatomical and bone quality differences. When our findings were compared with the findings of other studies, we can argue that the BCBT of maxillary posterior interradicular areas in UCLP patients is thinner than subjects without cleft. In Özdemir *et al.*'s study (18), the buccal cortical bone thickness values of the high angle adults at 4 mm above alveolar crest were higher than that of our study group. In Schneider *et al*.'s study (53) where BCBT in hyperdivergent group composed of both growing and non-growing subjects were evaluated, the authors found that the intermediate BCBT at 6 mm between maxillary canine and first premolar, first premolar and second premolar, and second premolar and first molar were 1.56 mm, 1.40 mm, and 1.38 mm respectively. It appears that BCBT in our UCLP group between canine and first premolar and first and second premolars (approximately 1.22 mm and 1.27 mm, respectively) were lower compared to their findings. This may indicate a tendency toward a thinner maxillary cortical bone in cleft patients. However, we think that this interpretation should be justified with further studies.

At the palatal side, the maximum PCBT value of cleft side of UCLP was 1.65 mm between 2nd premolar and 1st premolar at 12 mm while the minimum value was 0.88 mm between premolar and canine. Looking into non-cleft side of UCLP group, the maximum bone thickness value was 1.69 mm at 12 mm between 1st molar and premolar, and 1st premolar and 2nd premolar. Both the cleft side and non-cleft side of UCLP group showed significantly lower PCBT values compared to control group. As explained for the buccal cortical bone thickness, this may be partly due to dominant vertical growth pattern of the UCLP patients. On the other hand, there is no doubt that the palatal bone morphology of the cleft patients differs from that of the healthy individuals and reduced bone thickness may be expected. Although there is no other study evaluating the palatal cortical bone thickness at the mini-implant placement sites, our results are in line with the only study investigating palatal bone and soft tissue thickness and looking for possible anchorage sites in cleft palate patients (237). In their study, Moscarino *et al.* (237) found that the palatal bone of the cleft patients was thinner compared to the healthy controls and they associated cleft palate deformity with the reduced bone thickness. Interestingly, they found that patients with the right/left cleft showed the highest bone thickness at the anterior palatal region of the non-cleft side. They reported that at the cleft side, the bone was partially missing and the soft tissue was significantly thicker. On the non-cleft side, their results showed lower bone support and an average greater soft tissue thickness than in the control group. Overall, the soft tissue thickness was significantly greater at cleft regions compared to non-cleft and control groups and non-cleft side also had a thicker soft tissue than control group. On the other, in our study, although the palatal cortical bone thickness of both cleft and non-cleft side was lower than the control group, we did not find any statistically significant differences in PCBT between cleft and non-cleft side whereas Moscarino *et al.* (237) showed that the patients with right or left side cleft showed the highest vertical bone volume on the contralateral side. In unilateral cleft lip and palate, although the palatal bone morphology and volume may be affected, it seems that the palatal cortical bone thickness is similar on the cleft and the contralateral side.

At the buccal side, our results indicate that the BCBT increased moving from alveolar crest towards apex both in cleft and non-cleft side of UCLP group. Our results were compatible with the knowledge that cortical bone plates are prone to be thicker towards apex from the alveolar crest (42, 49, 52, 53, 81). This finding is confirmed by Ono *et al.* (49) who measured mesial and distal side of the molars at 1-15 mm from the alveolar crest. Even if our measurement areas are not fully compatible, their well-designed method and homogeneous study group make their results valuable. Fayed *et al.* (42) measured 2, 4, and 6 mm from CEJ from right second molar to left second molar. They showed that the BCBT increased when moving apically. As in previous studies, Ohiomoba *et al.* (52) reported that BCBT and PCBT increased from the coronal to the apical in their study for which they measured 2, 4, 6, and 8 mm from the alveolar crest at the anterior (1-3), middle (3-6) and posterior (6-8) maxilla. On the other hand, Kim *et al.* (4) reported that the buccal cortical bone thickness was greatest at the points closest to and farthest from the CEJ between 1st molar- 2nd premolar and 2nd premolar- 1st premolar. Their measurement levels were 2, 4, 6, 8, and 10 mm from CEJ both in buccal and palatal sides. They concluded that the BCBT was thinnest at the middle. Our thinnest measurement site (4 mm) was close to their thinnest middle point (4-6 mm) since we have not measured 2 mm from the the alveolar crest. At the palatal side, however, the PCBT increased from 2 mm to 6 mm, and then decreased from 6 mm towards 10 mm between 2nd premolar- 1st premolar. Between 1st molar- 2nd premolar, the PCBT has been decreased from 2 mm towards 10 mm. The difference might be caused by different patient sample and age range. Baumgaertel and Hans[20] also showed similar results claiming that the buccal cortical bone thickness has been decreased from 2 mm towards 4 mm before it has been increased at 6 mm. These results indicate that mini-implants should be inserted at least more than 4 mm apical to the alveolar crest, close to the muco-gingival junction.

Another finding that is worth mentioning is that the buccal cortical bone between premolar and canine was significantly thinner than the bone between 1st molar and premolar at 6 and 8 mm from alveolar crest in both groups. At the palatal side, cleft side of UCLP group showed statistically thinner bone between premolar and canine at 6, 8, 10, and 12 mm compared to the area between 1st molar and premolar. Also, at 10 mm from the the alveolar crest, PCBT was significantly thinner between 1st molar and premolar in comparison with the area between 2nd premolar and 1st premolar at the cleft side of UCLP group. However, in non-cleft side of UCLP group, the only significant difference was seen at 8, 10, and 12 mm with the palatal cortical bone between premolar and canine being thinner than the palatal cortical bone between 1st molar and premolar. In control group, the palatal cortical bone between premolar and canine was thinner at all levels compared to the cortical bone between 1st molar and premolar. It was also thinner at 12 mm compared to the cortical bone between 2nd premolar and 1st premolar. Also, the palatal cortical bone between 1st premolar and 2nd premolar was thinner compared to the cortical bone between 1st molar and premolar at 6, 8, and 12 mm. It is noticeable that in the majority of the measurement areas, the buccal and palatal cortical bones are prone to get thicker from anterior to posterior. Our results are supported by Fayed *et al.* (42) who reported a consistent increase in cortical bone thickness at the interradicular areas between 2nd molar and central incisor when moving posteriorly. Baumgaertel and Hans (20) reported that buccal cortical bone increased progressively towards posterior. Vakil and Sable (50) concluded in their study for which they measured the CBT at the interradicular areas between 2nd molar and central incisor, the total cortical bone thickness was greater in the posterior region as compared to the anterior region. Hu *et al.* (238) showed a similar result with the posterior region having 0.2 mm more buccal cortical bone thickness than the anterior region in the maxilla. In contrast with these findings, Holmes *et al.* (169) reported that the buccal cortical bone remained constant from canine to 1st molar. The reason of this contradiction might be the different measurement areas. They included the most mesial and distal points and the midpoints to their cortical bone thickness measurements in all interradicular areas. Also, in our results, any difference did not occur at 4 mm at the buccal region but the difference was present at 6 and 8 mm. In their study, they only measured 4 mm and 6 mm from the alveolar crest. This might be another reason to have different results.

Cleft side of the UCLP group showed significantly thicker bone at the palatal side compared to buccal side at 4 mm from alveolar crest in all interradicular areas. There were no significant differences in other measurement areas between BCBT and PCBT. For non-cleft side of the UCLP group, there were no significant differences between BCBT and PCBT at any area and at any level. In control group, however, CBT was significantly greater in palatal side compared to buccal side at 4 mm in all interradicular areas. At 6 mm, between premolar and canine, and between 1st molar and premolar, palatal cortical bone was significantly thicker compared to buccal cortical bone. There were no significant differences in BCBT and PCBT at 8 mm. The pattern might be different between the study and the control groups because of the presence of the cleft. As previously mentioned, the palatal bone of the cleft patients exhibits a reduced thickness with a lower bone support both in cleft and in non-cleft side (237). The results of the control group are compatible with the results of Kim *et al.* (4) who reported that the PCBT was significantly greater than BCBT. Farnsworth *et al.* (48) also showed in their CBCT study that the palatal cortical bone was thicker than buccal cortical bone at the interradicular areas between the 2nd molar and lateral incisor at 4 mm. In addition, at the middle maxilla (3-6), Ohiomoba *et al.* (52) showed that the PCBT was greater than BCBT. Vakil and Sable (50) found 0.2 mm of difference in favor of PCBT compared with BCBT. In contrary, Deguchi *et al.* (45) showed significantly thicker cortical bone on the palatal side compared to the buccal side at the distal part of the 2nd molar but found no significant difference at the mesial part. Their sample size was small (n=10) and they only measured at two different levels (3-4 mm and 6-7 mm). These might be the reasons of their contradictory results.

At the cleft side, the thickest buccal cortical bone between the 1st molar and premolar was found at 8 mm from the alveolar crest (max. value: 1.61 mm, mean thickness: 1.38 ± 0.13 mm) whereas the thinnest cortical bone was found at the 4 mm apical from the alveolar crest (min. value: 0.90 mm, mean thickness: 1.25 ± 0.16 mm). At the non-cleft side, the buccal cortical bone was thickest at 8 mm from the alveolar crest (max. value: 1.62 mm, mean thickness: 1.4 ± 0.15 mm), and was thinnest at 4 mm from the the alveolar crest (min. value: 0.91 mm, mean thickness: 1.26 ± 0.15 mm). The control group had the same pattern with the thickest buccal cortical bone being at the 8 mm (mean thickness: 1.5 ± 0.08 mm) and the thinnest cortical bone being at the 4 mm (mean thickness: 1.4 ± 0.08 mm). According to our measurements, the thickest buccal cortical bone was found between 1st molar and premolar in all groups. Our deduction was compatible with the results of Kumar *et al.* (81) (mean thickness at 4 mm: 1.54075 ± 0.504831 mm, mean thickness at 8 mm: 1.58342 ± 0.498982 mm), Fayed *et al.* (42) (mean thickness at the right side: 1.18 ± 0.30 mm, mean thickness at the left side: 1.27 ± 0.27 mm mentioning no significant difference between the sides), Baumgaertel and Hans (20) (mean thickness at the right side: 1.09 ± 0.24 mm, mean thickness at the left side: 1.04 ± 0.21 mm at the left side, mentioning no significant difference between the sides), Farnsworth *et al.* (48) (mean thickness in adolescents: 1.01 ± 0.19 mm, mean thickness in adults: 1.45 ± 0.28 mm), Sadek *et al.* (184) (mean thickness in high angle group: 0.900 ± 0.3162 mm, mean thickness in low angle group: 1.0883 ± 0.02440 mm, Holmes *et al.* (169) (mean thickness: 1.29 ± 0.21 mm) and Deguchi *et al.* (45) (mean thickness: 1.8 ± 0.6 mm). The results of Kim *et al.* (4) are not compatible with these results. They reported that the thinnest cortical bone between 6-5 was found at 8 mm (mean thickness: 1.13 ± 0.41 mm). The mean thickness at 4 mm was 1.18 ± 0.39 mm.

Our results showed that, at the buccal side, the interradicular area between the 2nd premolar and 1st premolar was the second thickest area at all levels in both groups. At the cleft side the thickest measurement at this area was found at 8 mm (max. value: 1.60 mm, mean thickness: 1.32 ± 0.14 mm) while the thinnest measurement was found at 4 mm (min. value: 0.91 mm, mean thickness: 1.19 ± 0.18 mm). At the non-cleft side, the thickest measurement was 1.63 mm (mean thickness: 1.33 ± 0.16 mm) and the thinnest measurement was 0.88 mm (mean thickness: 1.21 ± 0.17 mm). As for control group the highest values were seen at 8 mm (mean thickness: 1.49 ± 0.06 mm) while the lowest values were seen at 4 mm (1.21 ± 0.17 mm). Our results were in accordance with the studies of Farnsworth *et al.* (48) (mean thickness in adolescents at 4 mm:1.06 ± 0.21 mm, mean thickness in adults at 4 mm: 1.33 ± 0.24 mm), Holmes *et al.* (169) (mean thickness: 1.33 ± 0.23 mm), Sadek *et al.* (184) (mean thickness in high angle group: 0.9383 ± 0.07223 mm, mean thickness in low angle group: 0.9757 ± 0.12232 mm), Kumar *et al.* (81) (mean thickness at 4 mm: 1.282233 ± 0.405191, mean thickness at 8 mm: 1.43642 ± 0.348272 mm), Fayed *et al.* (42) (mean thickness at the right side: 1.18 ± 0.33 mm, mean thickness at the left side: 1.28 ± 0.34 mm), and Baumgaertel and Hans (20) (mean thickness at the right side: 1.01 ± 0.24 mm, mean thickness at the left side: 1.03 ± 0.20 mm). Kim *et al.* (4) found a mean thickness of 1.18 ± 0.40 mm at 4 mm and 1.07 ± 0.38 mm at 8 mm. Their results are not compatible with ours since they found higher values at 4 mm.

According to our results, the area between premolar and canine had thinner buccal cortical bone at all levels in both groups. At the cleft side, the thickest buccal cortical bone was found at 8 mm (max. value: 1.52 mm, mean thickness: 1.28 ± 0.15 mm) while the thinnest buccal cortical bone was measured at 4 mm (min. value: 0.86 mm, mean thickness: 1.17 ± 0.18 mm). At the non-cleft side, the thickest measurement was again at 8 mm (max. value: 1.58 mm, mean thickness: 1.31 ± 0.16 mm) and the thinnest measurement was at 4 mm (min. value: 0.79 mm, mean thickness: 1.18 ± 0.18 mm). The control group also had the highest values at 8 mm (mean thickness: 1.46 ± 0.07 mm) and lowest values at 4 mm (mean thickness: 1.18 ± 0.18 mm). Our results were in accordance with Fayed *et al.* (42) (mean thickness at the right side: 1.15 ± 0.37 mm, mean thickness at the left side: 1.19 ± 0.31 mm), Baumgaertel and Hans (20) (mean thickness at the right side: 0.98 ± 0.23 mm, mean thickness at the left side: 1.03 ± 0.17 mm) and Sadek *et al.* (184) (mean thickness in high group: 0.8950 ± 0.17479 mm, mean thickness in low angle group: 0.9886 ± 0.13108). Vakil and Sable (50) investigated the cortical bone thicknesses of the Indian population and found that at 4 mm, the mean maxillary BCBT was 1.38 ± 0.27 mm and at 8 mm the mean maxillary BCBT was 1.70 ± 0.26 mm. Miyamoto *et al.* (78) found that the mean maxillary buccal cortical bone thickness was 1.49 ± 0.34 mm. According to Ohiomoba *et al.* (52) the mean maxillary buccal cortical bone thickness was 0.78 ± 0.16 mm. They also reported that the thickest buccal cortical bone (1 mm) was found between 2nd premolar and 1st premolar at 8 mm from the alveolar crest. Park and Cho (80) found the mean cortical bone thickness as 1.17 to 1.31 mm in maxilla.

Overall, there are various values of buccal cortical bone thickness that were reported in the scientific literature. The comparison of our results was made with the studies that used same measurement levels and method. Since all the studies above-mentioned included non-cleft patients in their analysis, a true comparison with our study group could not have been made. When comparing the measurements of our control group with other studies, it has been noticed that the mean cortical bone thicknesses were in range with the literature. There were lower and higher values of cortical bone thicknesses compared to our results. The reason our results showed higher values compared to some studies might be the high percentage of low angle patients in our control group while the reason of lower values might be due to the individual factors such as different age range and racial background. However in our study group, the standard deviation was more than the control group. Therefore, we think that, in our study, a considerable individual variation was present in cortical bone thicknesses.

We should note that in both groups, the mean buccal cortical bone thicknesses were more than 1 mm in all areas and at all levels. This is important since Motoyoshi *et al.* (15, 66) reported that cortical bone thickness should be greater than 1 mm for the stability and success. They claimed that the odds of failure were 6.9 times greater when cortical bone was less than 1 mm thick than when it was thicker than 1 mm. In our study, the minimum values were mostly seen between canine and premolar. Therefore, the clinicians should be careful about these risky areas for mini-implant placement and they may prefer more suitable sites which are between 1st molar and premolar and between 2nd and 1st premolars, at the posterior maxilla.

At the palatal side, the overall thickest region was the interradicular area between 1st molar and premolar. At the cleft side, the maximum bone thickness value was 1.63 mm at 12 mm, with a mean thickness of 1.42 ± 0.12 mm. The minimal bone thickness value was 0.94 mm at 4 mm with a mean thickness of 1.29 ± 0.15 mm. Similarly, at the non-cleft side the highest value was 1.69 mm found at 12 mm with a mean thickness of 1.45 ± 0.13 mm. The lowest value, on the other hand, was 0.95 mm found at the 4 mm with a mean thickness of 1.3 ± 0.16 mm. The control group showed the same results. At 12 mm, the mean cortical bone thickness was 1.57 ± 0.04 mm while at 4 mm, it was 1.44 ± 0.05 mm. Kumar *et al.* (81) measured 4, 6, 8, and 10 mm in compatible with our measurement areas (1.70542 ± 0.448176 mm, 1.67742 ± 0.264545 mm, 1.68458 ± 0.184871 mm, 1.65067 ± 0.157011 mm, respectively). According to their results, the mean cortical thickness was decreased from 4 mm towards 10 mm. Kim *et al.* (4) measured the PCBT at 4, 6, 8, and 10 mm (1.72 ± 0.31 mm, 1.73 ± 0.23 mm, 1.70 ± 0.36 mm, 1.54 ± 0.31 mm, respectively). A dramatic decrease at 10 mm was noticeable in their results. Sadek *et al.* (184) found that the mean PCBT at 4 mm was 0.9683 ± 0.21470 in high angle group and 0.9800 ± 0.07071 mm in the low angle group. Deguchi *et al.* (45) found that the mean PCBT was 1.7 ± 0.9 mm at 4 mm. Farnsworth *et al.* (48) recorded 0.98 ± 0.25 mm of mean PCBT in adolescent group and and 1.53 ± 0.34 mm in adult group.

In our study, the palatal interradicular area between 2nd premolar and 1st premolar was found to be a suitable area for mini-implant placement. At the cleft side, the highest value was seen at 12 mm (1.65 mm) with a mean thickness of 1.37 ± 0.26 mm but the mean values were higher at 10 mm (1.38 ± 0.13 mm). The lowest value was measured at 4 mm (0.91 mm) with a mean thickness of 1.27 ± 0.17 mm. Similarly, at the non-cleft side, the highest value was measured at 12 mm (1.69 mm) with a mean thickness of 1.4 ± 0.14 mm. The lowest value was measured at 4 mm (0.91 mm) with a mean thickness of 1.25 ± 0.16 mm. Looking into control group, while the highest mean cortical bone thickness was seen at 12 mm (1.54 ± 0.05 mm), the lowest mean cortical bone thickness was seen at 4 mm (1.42 ± 0.05 mm). Kumar *et al.* (81) assessed the PCBT at 4, 6, 8, and 10 mm and the mean values were 1.54783 ± 0.381648 mm, 1.47767 ± 0.464692 mm, 1.37708 ± 0.420351 mm, and 1.36567 ± 0.400337, respectively. A decreasing pattern from the alveolar crest towards apex was seen in their study unlike our results. Kim *et al.* (4) measured the PCBT at 4, 6, 8, and 10 mm (1.76 ± 0.46 mm, 1.85 ± 0.63 mm, 1.73 ± 0.56 mm, 1.68 ± 0.61 mm, respectively). The thickness increased until 6 mm and then decreased towards 10 mm. Sadek *et al.* (184) reported 0.8083 ± 0.41282 mm of mean thickness in high angle group and 1.0171 ± 0.15185 mm in low angle group at 4 mm. Farnsworth *et al.* (48) recorded 0.97 ± 0.26 mm of mean thickness in adolescent group and 1.38 ± 0.30 mm in adult group at 4 mm.

Being the thinnest palatal cortical bone, the area between premolar and canine was mostly favorable for mini-implant usage according to our results. However, closer to the alveolar crest, palatal cortical bone thickness lower than 1 mm was present. At the cleft side, the thickest palatal cortical bone was measured 1.60 mm at 12 mm with a mean thickness of 1.37 ± 0.14 mm. The thinnest palatal cortical bone was measured as 0.88 mm at 4 mm with a mean thickness of 1.22 ± 0.18 mm. At the non-cleft side, however, the highest value was 1.59 mm at 6 mm, followed by 1.57 mm at 8 mm, 1.52 mm at 12 mm, 1.51 mm at 10 mm, and 1.41 mm at 4 mm. The lowest value was 0.86 mm at 4 mm. The mean PCBT of 4, 6, 8, 10, and 12 mm were 1.24 ± 0.15 mm, 1.29 ± 0.16 mm, 1.31 ± 0.13 mm, 1.35 ± 0.12 mm, and 1.38 ± 0.12 mm, respectively. In control group, the highest mean palatal cortical bone thickness was 1.51 ± 0.04 mm and the lowest mean value was 1.41 ± 0.05 mm. Fayed *et al.* (42) reported 1.78 ± 0.54 mm and 1.75 ± 0.50 mm of mean cortical bone thickness at 4 mm at the right and left side of the subjects, respectively. Vakil and Sable (50) reported the mean palatal cortical bone thickness for 4, 6, 8, and 10 mm: 1.65 ± 0.25 mm, 1.82 ± 0.27 mm, 1.92 ± 0.30 mm, and 1.75 ± 0.35 mm, respectively. According to their results, the thickness tended to increase until 8 mm before it decreases at 10 mm. They did not measured 12 mm, so we are not able to truly compare our results but we see the increasing pattern towards basal bone in our results as well. Ohiomoba *et al.* (52) reported 0.96 ± 0.18 mm of mean PCBT for the middle maxilla (1^{st} molar- canine) but they concluded that the maximum thickness was found between 2^{nd} and 1^{st} premolars and between 1^{st} premolar and canine.

In the literature, there are many reports investigating the palatal cortical bone thickness at the mini-implant placement sites. Thus, there are several different results from many studies. The contradictory results might be caused by the differences in sample size, ethnicity, age, method, study design, etc. The main objective of all studies is to give an insight about the alveolar bone morphology at the mini-implant insertion areas. However, particularly in the palatal area, the soft tissue thickness is also very important as well as the cortical bone thickness. Thinner soft tissue is preferred due to the lowered risk of inflammation. Kim *et al.* (4) suggested to place mini-implants near the CEJ on palatal side where they found that the soft tissue was thinnest. When it comes to the cleft patients, Moscarino *et al.* (237) showed that cleft patients had significantly thicker soft tissue thickness compared to non-cleft patients. Furthermore, the variations in soft tissue thickness in palate has been shown to be greater than in cortical bone thickness (237). They suggested the consideration of using longer mini-implants in cleft patients. Looking at our mapping results, although most of the palatal interradicular areas exhibited safe cortical bone thicknesses for mini-implant placement, clinicians should consider the likelihood of thicker palatal mucosa with compromised quality due to scar tissue from previous palatal surgeries. Furthermore, buccal and tongue flaps commonly used for repair of the large oronasal fistulas may complicate the placement and stability of palatal mini-implants in cleft cases.

There were some limitations of the present study. First, the facial types of the study and the control groups were not compatible with each other. Therefore, we had to compare UCLP group that was mostly composed of high angle patients with the control group that mostly consisted of low angle patients. Although the relationship between growth pattern and cortical bone thickness is controversial, there are above-mentioned reports that suggest a correlation between these two variants. Second, the study and control group were not divided according to growth status. The relation between age and cortical bone thickness remains controversial but there are reports showing a correlation between them. Also, the groups were not divided according to primary and permanent dentition phases. In cleft patients, because of the frequently seen congenital tooth agenesis, the adult patients might have persistent primary teeth at the place of permanent tooth. Because of the limited number of subjects, subgrouping according to dentition phase, age or vertical growth pattern was not possible in our study. Lastly, the soft tissue thickness has not been measured in this study. Soft tissue thickness is one of the determinants of mini-implant success. Due to the scar tissue at cleft region, the morphology of the soft tissue in cleft patients might be different than that of the non-cleft patients. Furthermore, the soft tissue flaps that are used in cleft patients to close the fistula might change the soft tissue characteristics at palatal region. Since our study is observational and retrospective, we tried to create patient groups as homogeneous as possible. In further studies, the study and the control groups could have a limited age range with similar vertical facial types, and dentition phases and the soft tissue thickness measurements could have been included to the study.

Several clinical implications can be drawn from our study. First, higher levels and more posterior interradicular areas may be more suitable for mini-implant insertion in patients with UCLP. Secondly, on the cleft side, less than 1 mm of buccal cortical bone thicknesses may be seen particularly between canine and premolar and at levels closer to the alveolar crest in posterior interradicular spaces, and less than 1 mm of palatal cortical bone thicknesses may be present particularly at levels closer to the alveolar crest in posterior interradicular spaces. The clinicians must be aware of the possibility of thin cortical bone plates and risk of mini-implant failures at these sites in patients with UCLP. Lastly, due to great individual variety of the cortical bone thickness of the patients with UCLP, prior to mini-implant placement, clinicians may consider evaluating CBCT of the patients when available.

6. CONCLUSION

The results of our study evaluating maxillary buccal and palatal cortical bone thicknesses at mini-implant insertion sites in UCLP patients revealed that;

- In patients with UCLP, the mean buccal and palatal cortical bone thicknesses at posterior maxilla ranged between 1.2 and 1.5 mm.
- Less than 1 mm buccal cortical bone thicknesses were particularly found between canine and premolar and at levels closer to the alveolar crest in posterior interradicular areas on the cleft side.
- The thickest maxillary buccal and palatal cortical bone was found between first molar and premolar.
- Considerable individual variation was seen in cortical bone thickness.
- Buccal and palatal cortical bone thicknesses did not differ between cleft and non-cleft sides.
- At buccal and palatal site, the cortical bone generally tended to increase from anterior to posterior and from the alveolar crest to apex.
- No difference was seen between buccal and palatal cortical bone thicknesses.
- Buccal and palatal cortical bone thicknesses of patients with UCLP were lower than that of the healthy individuals due to the differences in vertical facial pattern of both groups.

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8. APENDICEA

8.1. Ethics Committee Approval

T.C. YEDİTEPE ÜNİVERSİTESİ

Sayı : 37068608-6100-15- 1844

Konu: Klinik Araştırmalar
Etik kurul Başvurusu hk.

09/04/2020

İlgili Makama (Feyza Nur Bulut)

Yeditepe Üniversitesi Diş Hekimliği Fakültesi Ortodonti ABD Prof. Dr. Derya Çakan'ın sorumlu araştırmacı olduğu **"Tek Taraflı Dudak Damak Yarıklı Hastaların Maksiller Kortikal Kemik Kalınlıklarının Retrospektif Olarak Değerlendirilmesi"** isimli araştırma projesine ait Klinik Araştırmalar Etik Kurulu (KAEK) Başvuru Dosyası **(1827)** kayıt Numaralı KAEK Başvuru Dosyası, Yeditepe Üniversitesi Klinik Araştırmalar Etik Kurulu tarafından **08.04.2020** tarihli toplantıda incelenmiştir.

Sağlık Bakanlığı'nın Covid-19 pandemisi nedeniyle uygulamakta olduğu "toplumsal izolasyon veya karantina" uygulamalarının bitiminde başlanması şartıyla;

Kurul tarafından yapılan inceleme sonucu, yukarıdaki isimi belirtilen çalışmanın yapılmasının etik ve bilimsel açıdan uygun olduğuna karar verilmiştir (**KAEK Karar No: 1185**).

Prof. Dr. Turgay ÇELİK
Yeditepe Üniversitesi
Klinik Araştırmalar Etik Kurulu Başkanı

Yeditepe Üniversitesi 26 Ağustos Yerleşimi, İnönü Mahallesi Kayışdağı Caddesi 34755 Ataşehir / İstanbul
T. 0216 578 00 00   www.yeditepe.edu.tr   F. 0216 578 02 99

8.2. Curriculum Vitae

Kişisel Bilgiler

Adı	Feyza Nur	**Soyadı**	Bulut
Doğum Yeri		**Doğum Tarihi**	
Uyruğu	Türkiye Cumhuriyeti	**TC Kimlik**	
E-Mail			

Öğrenim Durumu

Derece	**Alan**	**Kurum Adı**	**Mezuniyet Yılı**
Doktora	Ortodonti	Yeditepe Üniversitesi	2021
Yüksek Lisans			
Lisans	Diş Hekimliği Fakültesi	Yeditepe Üniversitesi	2015
Lise		Galatasaray Lisesi	2009

Yabancı Diller

Yabancı Dil	**Yabancı Dil Sınav Notu**
İngilizce	87.5
Fransızca	

İş Deneyimi

Görevi	**Kurum**	**Süre (Yıl- Yıl)**
Diş Hekimi	Küçükyalı Diş Klinikleri	2020-
Diş Hekimi	DentGroup Diş Klinikleri	2020-

Bilgisayar Bilgisi

Program	**Kullanma Becerisi**
Microsoft Office	İyi

*Çok iyi, iyi, orta, zayıf olarak değerlendirin

Bilimsel Çalışmaları

SCI, SSCI, AHCI indekslerine giren dergilerde yayınlanan makaleler

Germec Cakan D, Nur Yilmaz RB, Bulut FN, Aksoy A. Dental Anomalies in Different Types of Cleft Lip and Palate: Is There Any Relation? *J Craniofac Surg.* 2018;29(5):1316-25.

Diğer Dergilerde Yayınlanan Makaleler

Uluslararası bilimsel toplantılarda sunulan ve bildiri kitabında (Proceedings) basılan bildiriler

Bulut, FN. Cakan, D. Interdisciplinary approach to frontonasal dysplasia. Poster presented at: 6th International Cleft Lip and Palate Congress; November 2019; Antalya, Turkey.
Bulut FN. Cakan D. Nur B. Aksoy A. Prevalence of Dental Anomalies in Different Types of Cleft Lip and Palate. Oral Presentation at 16th Annual Conference of Indian Society of Cleft Lip, Palate, and Craniofacial Anomalies; Chennai, India.

Hakemli konferans/sempozyumların bildiri kitaplarında yer alan yayınlar

Diğer (Görev Aldığı Projeler/Sertifikaları/Ödülleri)

Bulut FN. Cakan D. Nur B. Aksoy A. Prevalence of Dental Anomalies in Different Types of Cleft Lip and Palate. Scholarship Award at 16th Annual Conference of Indian Society of Cleft Lip, Palate, and Craniofacial Anomalies; Chennai, India.