



TURKISH REPUBLIC OF NORTHERNCYPRUS  
NEAR EAST UNIVERSITY  
INSTITUTE OF GRADUATE STUDIES

**THREE-DIMENSIONAL IMAGING COMPARISON FOR CLEFT  
PALATE INFANTS UP TO 6 MONTHS OF AGE**

MOHANNAD ZEIDAN

PhD Thesis

Department of Orthodontics

Assistant Professor Dr. Beste KAMILOĞLU

2021-NICOSIA



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**NEAR EAST UNIVERSITY**  
**THESIS APPROVAL**  
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NEAR EAST UNIVERSITY GRADUATE SCHOOL OF HEALTH SCIENCES  
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## **List of Abbreviations**

CP:	Cleft palate
CLP :	Cleft lip and palate
CAD/CAM:	Computer-aided design computer-aided manufacturing
NAM:	Nasoalveolar molding appliance
PSIO:	Presurgical infant orthopedics
IDS:	Intraoral digital scanner
CBCT:	Cone-beam computed tomography
3D:	Three-dimensional
2D:	Two-dimensional
RF:	Reverse face view
RA:	Retenoid acid
PRS :	Pierre Robin Sequence

TMJ :	Temporomandibular joint
PAR:	The peer assessment rating index
A-A':	Unilateral anterior cleft width
P-A:	Left anterior cleft width
P'-A':	Right anterior cleft width
C-C' :	Inter canine distance
T-T' :	Intertuberosity distance

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**Three-Dimensional Imaging Comparison Using A Digital Impression Cerec Omnicam Intraoral Camera (Cad) And Tri-Dimensional Cone-Beam Computed Tomography, To Measure Maxillary Casts: Unilateral And Bilateral Cleft Lip And Palate In Infants Up To 6 Months Of Age**

**Öğrencinin adı:** Mohannad Zeidan

**Danışman:** Assistant Professor Dr. BESTE KAMILO LU

**Bölüm:** Department of Orthodontics



## Özet

**Amaç:**Bu çalışma, 6 aya kadar dudak-damak yarığı (CLP) ile doğan bebeklerin alçıları üzerindeki belirli parametrelerin ölçümlerini kullanarak iki farklı dijital üç boyutlu tarama yöntemi arasındaki herhangi bir ilişkiyi değerlendirmeyi amaçlamaktadır.

**Ortam/Evren ve Örneklem:**Bu çalışmada kullanılan iki farklı yöntem arasındaki ilişkiyi araştırmak için çeşitli CLP türlerini içeren 44 yayınlık bir set kullanıldı, üç boyutlu (3D) konik ışınli bilgisayarlı tomografi ve dijital ölçü CEREC Omnicam intraoral kamera (CAD).

**Araçlar ve Yöntem:**İstatistiksel analizler, SPSS yazılım 25. versiyonu kullanılarak yapıldı. Tanımlayıcı analizler, ortalamalar, standart sapmalar, değişkenler, Kolmogorov-Smirnov testi kullanılarak incelenen değişkenler kullanılarak, normal dağılıp dağılmadıklarını belirlemek için sunuldu. Değişkenler normal olarak dağıtıldığı için ( $n > 40$ ), yöntemleri aynı ölçümlerle karşılaştırmak için eşleştirilmiş örneklem t-testi kullanıldı. Değişkenler normal dağılmadığından ( $n < 5$ ), aynı ölçümlerle yöntemleri karşılaştırmak için Wilcoxon'un işaret sıralama testi kullanıldı. Güvenilirlik ve doğruluk, sınıf içi korelasyon katsayısı (ICC'ler) kullanılarak değerlendirildi.

**Bulgular:**Elde edilen ölçümlerin birbirine yakın olduğu görüldü. Bununla birlikte, analiz edilen yalnızca 1 tip ölçümle ilgili istatistiksel olarak önemli farklılıklar ( $P < \% 5$ ) bulunmuştur, Tüm ölçümler istatistiksel olarak anlamlı-mükemmel güvenilirliği gösterir (Tüm ICC'ler  $> 0,9$ 'dur). Dijital ölçü CEREC Omnicam intraoral kamera (CAD) kullanılarak 3D görüntüler elde etme yeteneği daha kolay ve daha az karmaşık bulunurken, CBCT anatomik yapıları yansıtmada daha hassas ve taramada daha hızlı bulundu.

**Sonuç:** Ölçüm amaçlı iki yöntem her zaman daha geniş bir ölçekte kabul edilir, evrensel ve eşdeğer olarak kullanılabilir.

**Anahtar Kelimeler:**Yarık dudak – damak – sayısallaştırma - alçı alçıları - üç boyutlu koni - ışınli bilgisayarlı tomografi - CEREC Omnicam 3D intraoral tarayıcı - gözlemciler arası – doğruluk - güvenilirlik.

**Three-Dimensional Imaging Comparison Using A Digital Impression Cerec Omnicam Intraoral Camera (Cad) And Tri-Dimensional Cone-Beam Computed Tomography, To Measure Maxillary Casts: Unilateral And Bilateral Cleft Lip And Palate Infants Up To 6 Months Of Age**

**Örencinin adı:** Mohannad Zeidan

**Danışman:** Assistant Professor Dr. BESTE KAMILO LU

**Bölüm:** Department of Orthodontics

**Abstract**

**Objective:** This study aims to evaluate any relationship between two different methods of digital three-dimensional scanning using measurements of specific parameters on casts of infants born with cleft lip & palate (CLP) up to 6 months of age.

**Setting/Sample Population:** a set of 44 casts including various kinds of CLP were used to investigate the relationship among two different methods used in this study, including tridimensional (3D) cone-beam computed tomography & digital impression CEREC Omnicam intraoral camera (CAD).

**Materials and Methods:** Statistical analyses were performed using SPSS software version 25. Descriptive analyses were presented using means, standard deviations, the variables investigated using Kolmogorov-Smirnov test to determine whether or not they are normally distributed. Since the variables were normally distributed ( $n > 40$ ), paired sample t-test was used to compare the methods with same measurements. Since the variables are not normally distributed ( $n < 5$ ), Wilcoxon's sign rank test was used to compare the methods with same

measurements. Reliability & accuracy were assessed through using intraclass correlation coefficient (ICC's).

**Results:**Measurements obtained were found to be close to each other. However, statistically significant variations ( $P < 5\%$ ) has been found regarding only 1 type of measurements analyzed, All the measurements indicate statistically significant-excellent reliability (All ICC's are  $>0.9$ ).The ability to obtain 3D images was found easier & less complicated by using the digital impression CEREC Omnicam intraoral camera (CAD) whereas CBCT was found more precise in reflecting anatomical structures & faster in scanning.

**Conclusion:**The two methods for measurement purposes are always accepted on a wider scale & can be employed universally & equivalently.

**Keywords:**Cleft lip & palate, digitization, plaster casts, tri-dimensional cone-beam computed tomography, CEREC Omnicam 3D intraoral scanner, interobserver, accuracy, reliability.

## **Introduction**

The treatment of Cleft Lip and Palate (CLP) is a long, difficult, and detailed process, to which different departments of medicine and dentistry contribute in an integrating manner (Horch HH et al., 1998). A successful treatment for CLP infants demands accurate diagnostic methodology, a detailed treatment plan, and a multi-disciplinary approach. Although these craniofacial defects are common, the exact etiology remains still unclear. These defects have a multi-factorial background with an active interaction between genetic and environmental factors (Wong FK et al., 2004). Cleft lip and palate among the other types of orofacial clefts are the most complicated to be treated. The location, the width, and the severity of the cleft lip and palate have an impact on speech, facial appearance, dental relationships, and craniofacial growth, hearing, social and psychological problems. The most desirable improvements in appearance for the patients with CLP and their relatives are in the area of lip and nose. Especially, the uncorrected nasal deformity has been unacceptable and patients with this condition have been ridiculed, which has generated major psychosocial impact on the patients and the parents (Semb G et al., 2005).

The control and treatment protocols of neonates with clefts have developed significantly in the last decades. In children born with a CLP, presurgical infant orthopedics (PSIO) is performed during infancy mainly in order to facilitate feeding, to reduce the cleft width, to actively mold and reposition the deformed nasal cartilages and alveolar processes and to lengthen the deficient columella in the neonatal period, prior to the primary lip and nasal surgery. While the first weeks of birth the cartilage remains soft and flexible, apparently due to the hyaluronic acid. In 1993 Grayson and Cutting (Grayson BH et al., 1999) 4 introduced the most popularized system of

PSIO, the Nasoalveolar Molding (NAM). However, its effectiveness is still not well documented and is a controversial subject between proponents and opponents (Park BY et al., 1998). The presurgical nasoalveolar molding process takes advantage of the malleability of immature cartilage and its ability to maintain permanent correction of its form. A survey showed a wide diversity in models of care and national policies as well as clinical practices in Europe (Shaw WC et al., 2000). Of the 201 centers that registered, the survey showed 194 different protocols being followed for only unilateral clefts.

The principal objectives of treatment for individuals with clefts are to improve feeding, hearing, speech, facial appearance, and reducing the negative social and psychological impact on these individuals. The success of these goals is maximizing the chances of children with cleft growing up and developing normally to their social and physical environment. Often in the past, children born with CLP received inadequate care due to diagnostic errors, inadequate or ill-timed procedures as well as failure to identify the full spectrum of problems associated with it (Cameron AWR.2009).

For decades dental casts, X-rays, and photographs were used for analyzing and documenting CLP patients. The transfer and exchange of these documents for communication and information are very important between the physicians. The time spent during transfer, the low resilience to natural damage and the lack of space for storage are major disadvantages of plaster models. These disadvantages lead the scientific community to create digitized study and analysis models.

This study tends mostly to discover the correlation & make a detailed comparison among two methods of latest 3D scan technologies, the 3D cone-beam computed tomography (CBCT) & CEREC Omnicam 3D intraoral cam scanner determining their accuracy & usability especially for cleft palate patients as well as discussing their current applications & alterations on CLP treatment.

## **General Information**

### **2.1. Historical Perspective of the Cleft Lip and Palate:**

The most advanced ancient marks of cleft lip and palate expose fear and absolute disbelief. In ancient chronologies even in medieval ages, many congenital deformities, including the cleft lip and palate, were estimated to be a sign of the residence of an evil ghost in the injured child (Converse JM et al., 1930). Face deformations were most convicted and the infants were abandoned and left to die in the surrounding forests, a tradition that remains predominates now in certain African societies. In Sparta, the poor infected neonates were left dying on Mount Tagete in an area known as ‘Kaiadas‘, even in Rome they were killed in the Tiber River or dropped off the Tarpeian rock. The well-known philosopher Plato, cleared it in one of his discussions in the Republic, demonstrating that it was a method of removing evil omens and maintaining the soundness of the race.

George Dorrance reviewed a case of a mummy that had been published in 1929 by Smith and Dawson in their work Egyptian Mummies publications in London. Thus, Egyptians recognized this deformity. In the ancient Mediterranean cultures, those kids were said to own superhuman abilities (Ortiz-Monasterio F et al., 1971). In 1808 Meckel (Meckel JF. 1908) declared his theory of the formation of the lips. He stated that five divided processes that eventually fused, three for the upper lip and two for the lower lip. In Europe, the first accurate representation of a cleft lip surgery was given by Johan Yperman (1325-1351) (Fig 1.1). This surgeon was the first to do a two-layer surgery with waxed, twisted strings that were grasped by stitches implanted at a distance from the cleft. He suggested that oblique parallel incisions to reduce strain should not be done, as they would produce distortions of the lip later on. (Perko M.1986).



Fig. 1. Lip repair by Pancoast (1844) similar to the method used by Yperman (35)

<sup>1</sup> Children's University Hospital, Department of Surgery, Strickwiesstr. 25, CH-4052 Zurich, Switzerland

Figure 2.1 Lip repair by Pancoast (1844) similar to the method used by Yperman.

## 2.2. Cleft lip and palate embryological development:

The primary morphological developments of the face produced within the 4th and 10th weeks through developing and fusion of five prominences: an unpaired frontonasal process, two maxillary processes and two mandibular processes (Marazita and Mooney, 2004).

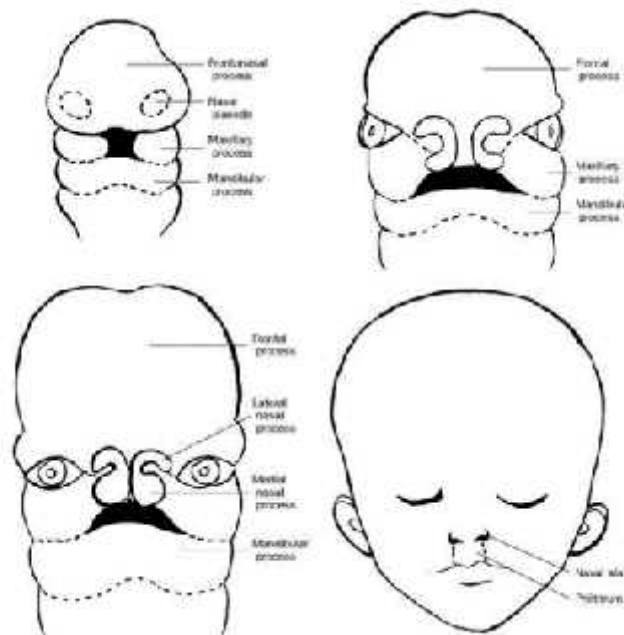


Figure 2.2.1. Development of the face

[http://www.med.umich.edu/lrc/coursepages/m1/embryology/embryo/images/development\\_of\\_face.gif](http://www.med.umich.edu/lrc/coursepages/m1/embryology/embryo/images/development_of_face.gif) (Accessed on: 1/6/2012)

Through the 5th week, a pair of departed clots of ectoderm, the nasal placodes, grow on the frontonasal process. In the 6th week, the ectoderm in the middle of the nasal placodes encloses to create the nasal pits and separates the elevated rim of the placodes into a lateral and medial nasal process. While, the paired maxillary processes grow and expand ventrally and medially. The medial nasal processes migrate and join to produce the intermaxillary process. Naturally, at the end of the 7th week, the tips of the maxillary processes reach the intermaxillary process and combine with it to create the upper lip and premaxilla. This happens during the mesodermal transition and merging. Any breakdown during this step may cause a cleft of the lip and palate that ranges in severity.

The nasal pits extend and join to make a single ectodermal nasal pouch superior and posterior to the process of the intermaxilla. The floor and posterior wall of the nasal sac then grow into a tiny membrane, the oronasal membrane, which divides the nasal sac from the oral cavity. This membrane tears through the 7th week and makes the primitive choana. Through the 8th and 9th weeks, the medial walls of the maxillary processes reproduce into a couple of tiny medial branches called the palatine shelves. These shelves develop downwards to the lateral surfaces of the tongue, however at the end of the 9th week, they twist upwards into a horizontal position and combine with each other and the primary palate to create the secondary palate. The formation of secondary palate clefts happens if shelves of the maxillary processes are not joined together. During the secondary palate formation, the ectoderm and mesoderm from the frontonasal- and intermaxillary process multiplies by proliferations to create the nasal septum. The nasal septum passes down from the roof of the nasal cavity and combines with the primary and secondary palates at the midline, thus, separating the nasal cavity into two nasal portions (Larsen, 1993; Wyszynski, 2002; Marazita and Mooney, 2004; Rice, 2005).

Cleft lip often happens at the intersection between the lateral maxillary process and the intermaxillary process. The cleft may involve only the lip, or it may continue more intensely into the alveolar process and primary palate. Clefts of the secondary palate can develop individually or it could be combined with clefts of the lip and primary palate. Different clefts arise and various combinations of clefts can appear depending on which stage of embryonic development happens. It could be clefts of the lip and/or palate, unilateral, bilateral, complete or incomplete. (Larsen, 1993; Wyszynski, 2002; Marazita and Mooney, 2004; Rice, 2005).



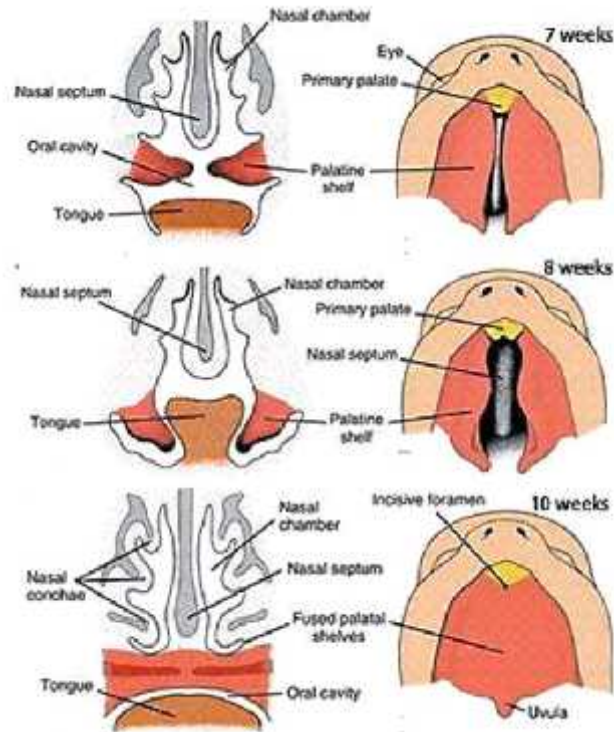


Fig. 2.2.2 Development of the Palate

<http://www.duke.edu/web/anatomy/embryology/craniofacial/headEmbryoImage15.jpg>

### 2.3. Prenatal Diagnosis

Fetal health diagnoses and examination can be performed through various techniques that investigate the health of an embryonic fetus. Without previous inspections for fetus health before giving birth there could be an unfortunate consequence for the fetus or the mother or both. Till today the only possible technology providing prenatal detection and evaluation of an orofacial cleft is the High-resolution ultrasound.

Even though the mid-face structures are joined within the 8th week of pregnancy, reliable ultrasound imaging cannot be performed till the 15th week because of the position of the head and the small size of the face in comparison with the transducer. The examination of the face should be performed in three-dimensional planes, coronal, sagittal, and transverse to ensure that the highest details to be collected. The best planes to view the lips, the fetal profile and the alveolar ridge were in coronal, sagittal, and transverse respectively. Multiple views in different sections should be performed to assess the important structures, the earliest diagnosis for

orofacial clefts, essential for the doctors to evaluate further options like fetal surgery or even termination of the fetus (Blumenfeld Z et al., 1999).

Isolated CP is more difficult to diagnose during pregnancy because of the phonic shadow from the facial bones (Johnson N et al., 2003). Lately, the 3D ultrasonography has been offered and is especially useful for analysis of the fetus facial structures in which it mainly demonstrates facial deformities with precision and accuracy (Michailidis GD et al., 2001). Until 2003 both the 2D & 3D ultrasound techniques cannot provide accurate information for the clefts of the secondary palate. Campbell et al, in 2003 introduced a modern technique, the "3D reverse face view". The 3D RF view can present diagnostic data about the integrity of the secondary palate(Campbell S et al., 2005).

Parents reveal many emotional reactions, including confusion, hurt, weakness and frustration, when they informed with the information of a cleft bearing child. Stress because of the cleft deformation at the baby birth time may be overwhelming. By using prenatal diagnosis, a perspective neonatal care can be prepared for the baby immediately after birth which includes feeding plates and preparation for nasoalveolar moulding appliance.

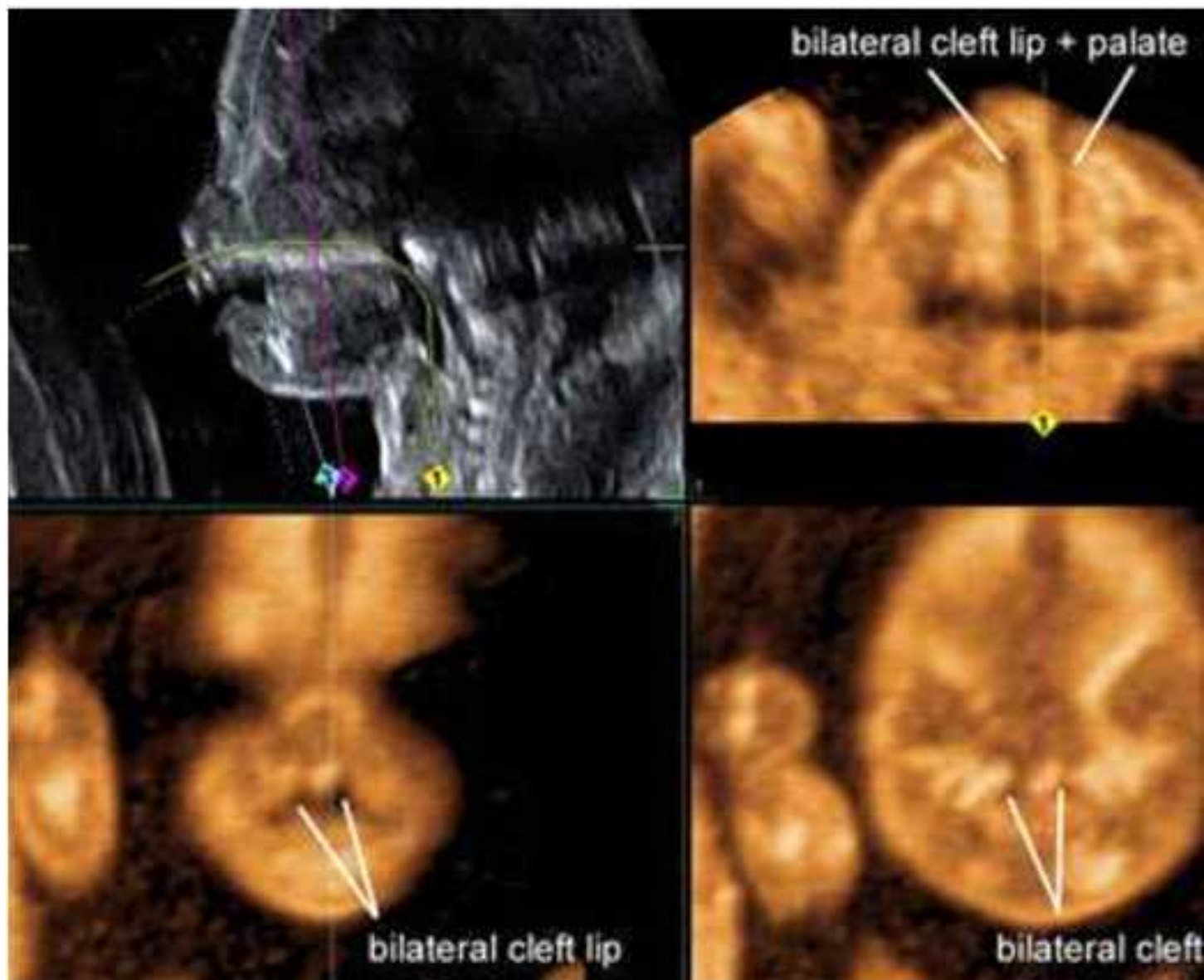


Figure.2.3. Bilateral cleft lip and palate with 3D RF

[http://www.glowm.com/resources/glowm/graphics/atlas/Atlas\\_of\\_ultrasound/thumbs/09\\_cleft-lip-and-palate-bilateral-copia.jpg](http://www.glowm.com/resources/glowm/graphics/atlas/Atlas_of_ultrasound/thumbs/09_cleft-lip-and-palate-bilateral-copia.jpg) (Accessed 5/6/2012)

## 2.4 Etiology

The etiology of both cleft lip and palate (CLP) and isolated cleft palate (CP) is still unknown and controversial. It is recognized as **multifactorial**, with both hereditary and environmental factors associating with each other (Cobourne, 2004; Rice, 2005; Mossey et al., 2009).

The genetic factors that have a positive association in non-syndromic CLP, CP, or both have identified as candidate loci or regions on seven chromosomes that are responsible as the main genetic cause. (Marazita and Mooney, 2004). Environmental factors that have an association with cleft lip and palate include maternal alcoholism (Romitti et al., 1999), smoking during pregnancy (Little et al., 2004; Zeiger et al., 2005), drugs consumption like anti-epileptics and corticoids (Abrishamchian et al., 1994; Kallen, 2003), and depressed rates of folic acid (Bienengraber et al., 2001; Malek et al., 2004; Johnson and Little, 2008).

#### **2.4.1 Genetic Factors**

Diversity of genes are involved in the etiology of lip and palate. These genes regulate some important signaling molecules (growth and transcription factors) that are capable of the development of specific proteins which in turn switch initiation and differentiation of the tissue of lip and palate. Studies and scientific reports for Clefts confirm that hereditary factors for causing nonsyndromic clefts are about 76% (Kulesa PM et al., 2007).

The incidence of cleft palate for a child whose both parents have a cleft palate is around 15% whereas if one of the parents is infected then the incidence decreases to 2%-5% (Curtis EJ et al., 1961).

It has been assessed that certain genes are involved and represent the main etiologic factor which is responsible for causing cleft lip and palate. among the discovered genes:

- 1) Msh homeobox (MASX1)
- 2) Paired box (Pax) genes (PAX2).
- 3) Transforming growth factor-alpha (TGF )
- 4) Transforming growth factor-beta (TGF $\beta$ ).
- 5) RARA, and p63.

Although, the 100% genetic correlation of these genes were confirmed the searches are not sufficient due to small numbers of families that are participating in the studies (Lidral AC et al., 2005; Murray JC et al, 1999; Susan HB et al., 2010).

#### **2.5 Environmental Factors**

Several environmental causes were confirmed as risk factors for oral clefts. The main of these factors are:

## **2.6 Maternal Smoking**

Smoking creates a specific mutation in TGF $\alpha$ , Poliovirus receptor-related 1 known as (PVRL1) or Interferon regulatory factor 6 (IRF6) causing CLP (Kouskoura T et al., 2011). Moreover, smoking the gestation period is linked with various outcomes such as low birth weight, premature baby weight (Lumeley J et al., 2000).

### **2.6.1 Alcohol Consumption**

It has been estimated that alcohol creates modification of the MSX1 and Transforming growth factor-beta 3 genes (TGF $\beta$ 3) which can cause specific congenital malformations including cleft lip and palate as well as other orofacial clefts (Mossey PA et al., 2009).

Women who drink five or more alcoholic shots per drinking moment have a high risk of having a neonate with orofacial clefts including malformations of the ear, face, anterior neck, and upper heart (Rommiti PA et al., 2007).

### **2.6.2 Nutritional Factors**

Various nourishment factors are associated with the CLP including folic acid, zinc, vitamin B12, cholesterol, folate, and vitamin B6 (Jeffrey C. et al., 2010; Murray JC et al., 1999). Women taking vitamins including folic acid at the time of pregnancy were proved to have a lower risk of having children with orofacial clefts. It is confirmed that consuming folic acid supplements through the first 4 months of gestation offers vital protection against cardiovascular deficits and neural tube defects (CShaw GM et al., 1995; Czeizel A. et al., 1996; Wilcox AJ. et al., 2007). Vitamins like B complex involving folic acid supplementation during pregnancy demonstrated effective care against cleft lip and palate in humans (Schubert J. et al., 2002).

### **2.6.3 Medications**

Steroid medications consuming through the first three months of gestation has been correlated with clefts, raising the risk between three to five times more than normal (Carmichael SL et al., 2007; carmichael SL et al., 1999; Park-Wyllie L. et al., 2000). Anticonvulsants like phenytoin,

oxazolinediones, and valproic acid are linked with a high risk of congenital defects. (Czeizel A. 1988 ; Gorlin RJ et al., 2001 ; Safra MJ et al., 1975).

Retinoid Acid (RA) is necessary for several biological processes and natural fetal development but is teratogenic at high concentration levels and can cause clefts (Park-Wyllie L. et al., 2000).

#### **2.6.4 Epidemiology**

The entire prevalence of CLP is estimated to be about 1.5 to 2.0 per 1000 births and is more distinguished between males than females (Henriksson, 1971; Jensen et al., 1988; Hagberg et al., 1997). The frequency varies with cleft type, gender, and ethnic origin. The highest prevalence is between American Indians and Japanese, with the lowest among Africans (Vanderas, 1987).

A considerable number of syndromes are associated with oral clefts, especially in patients with CP (Stoll et al., 2000), and estimated malformations are described in 20 to 35.8 percent of children with clefts (Hagberg et al., 1997; Milerad et al., 1997; Stoll et al., 2000; Andersson et al., 2010; Chetpakdechit et al., 2010). A usual syndrome associated with isolated CP is the Pierre Robin sequence (PRS). PRS is characterized by micrognathia in the mandible, cleft palate, and various respiratory problems during the natal period (Laitinen, 1998). The prevalence of PRS is undetermined, but is estimated to occur in 1 in 9000 to 1 in 21,000 births (Bush and Williams, 1983; Tolarova and Cervenka, 1998). Pierre Robin sequence in children can be classified into isolated PRS and PRS as part of a syndrome. PRS, as involved in a more complicated syndrome, is reported in about 40 percent of PRS children (Marques et al., 2001). Cleft Lip and Palate (CLP) is estimated in 65% of all head and neck anomalies (van den Elzen et al., 2001).

According to the World Health Organization in every 700 newborn neonates, there is one born with a cleft lip and/or palate globally. In the U.S there are 25 infants born every day with an orofacial cleft or nearly 7500 every year. The non syndromic CLP has a prevalence of 65 to 75% of the entire cleft population. The cleft to birth incidence ranges geographically from 2.7:1000 in Native Americans to 0.65-4.25:1000 in Asians to 0.21-1.70:1000 in Africans, to 0.6:1000 in African Americans, and finally, to 0.73-2.49:1000 in Caucasians (Marques et al., 2001).

#### **2.6.5 Classification**

Orofacial clefts are often classified by anatomical and embryological features. Fogh Andersen (1942) identified the oral clefts in three main groups: clefts of the lip and the alveolus; cleft of the lip and palate including unilateral and bilateral clefts and, isolated cleft palate being median and not reaching past the incisive foramen. To describe the diversity of the cleft in cleft palate cases more accurately, Jensen et al. (1988) separated the cleft palate into four categories: (1) clefts of the soft palate; (2) cleft in one-third of the hard palate; (3) cleft in more than one-third of the hard palate; and, (4) cleft of the entire palate. The Kernahan and Stark classification, the “striped Y” Kernahan and Stark classification was invented in 1958 and until today it is one of the most commonly used among cleft palate classifications. Recently modern classifications have been introduced that are also based on the level of severity of the cleft (Friedman et al., 1991; Ortiz-Posadas et al., 2001; Rossell-Perry, 2009)

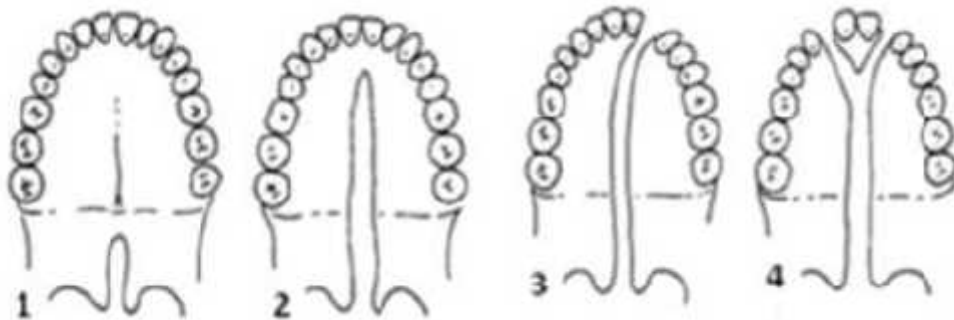


Figure 2.6.2. Veau's classification of cleft lip and palate

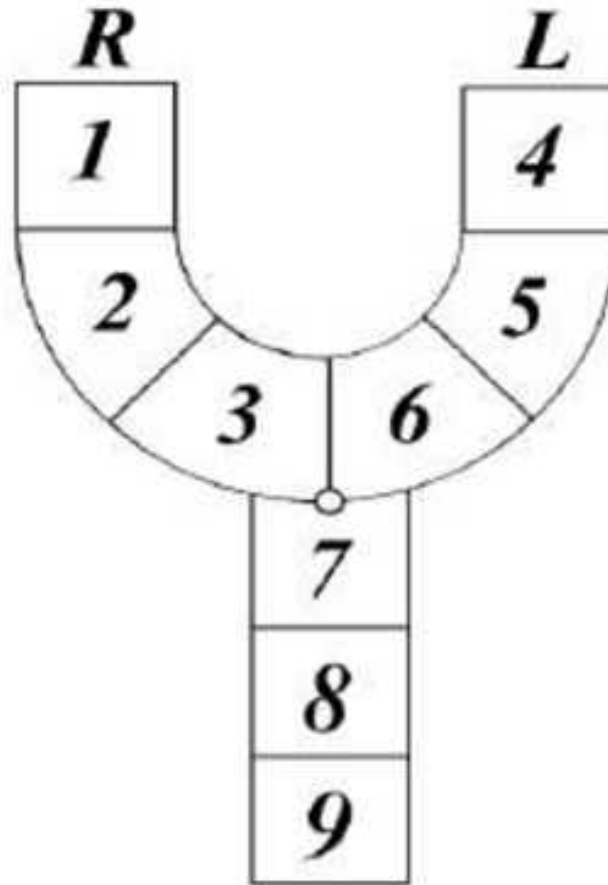


Figure 2.6.1 The Kernahan striped Y classification of cleft lip and palate (91).

- 1 - Right lip, 2 - right alveolus, 3 - right premaxilla, 4- left lip,  
 5 -left alveolous, 6 left premaxillae, 7, 8, 9 –hard/soft palate

## 2.7. Anatomy of UCLP and CP

(A) Complete unilateral cleft lip and palate (UCLP) is correlated with several anatomical defects. A cleft on the left or right side of the lip, alveolus, and nose. The cleft then extends into the palatal segment of the maxilla and divides the palatal bone at the surface of the nasal septum. The alveolar arch and palate are divided into a large and a small segment. The segments are usually laterally replaced and the anterior end of the larger segment protrudes, and there is a midline shift to the non-cleft side. The smaller segment is usually located dorsally and the anterior part is insignificantly curved upwards, in comparison to the larger segment (Prahl, 2008).



UCLP is moreover linked with a specific deformity of the nose. Spina nasalis anteriorly and the nasal septum follow the larger palatal segment and usually deviate to the non-cleft side. oppositely, the bony nasal septum often deviates to the cleft side (Verwoerd et al., 1995). The columella is shortened and the alar cartilage on the cleft side is dislodged from its normal position. The medial crus is depressed into the columella, isolated from the opposite alar cartilage, and the lateral crus is depressed and expanded across the cleft at an obtuse angle. The alar base is twisted outwards in a flare and the alar rim often has a network, which moreover decreases the visible length of the columella on the cleft side. The resulting nostril aperture on the cleft side is located on a horizontal axis rather than in a vertical axis as in the natural nostril aperture (Millard, 1976).

(B) The main contrast among unilateral and bilateral cleft lip and palate is the consequence of the foremost displacement of the intermediate part of the premaxilla. The intermediate part of the lip and gums are partly or entirely separated from the nearby lip and gums. The front displacement of the central lip and gums also creates a critical shortening of the columella which significantly alters the nasal shape.

(C) Isolated CP the area of the cleft varies. The cleft can be submucous characterized by a bifid uvula, a notch in the posterior hard palate, and a muscular cast that is not fused. The cleft can continue only into the soft palate or spread among ranging degrees toward the hard palate. In complete cases, the cleft reaches forward to the incisive foramen. The palatal muscle fibers attachments and orientations in the soft palate are affected and the muscles regularly connecting at the midline are instead inserted along the posterior side of the hard palate. Consequently, the velopharyngeal muscle sphincter function is affected as well, leading to velopharyngeal problems with speech development. Furthermore, the muscle control of the Eustachian tube is suffered, often causing chronic otitis media and the risk of permanent hearing loss. (van Aalst et al., 2008).

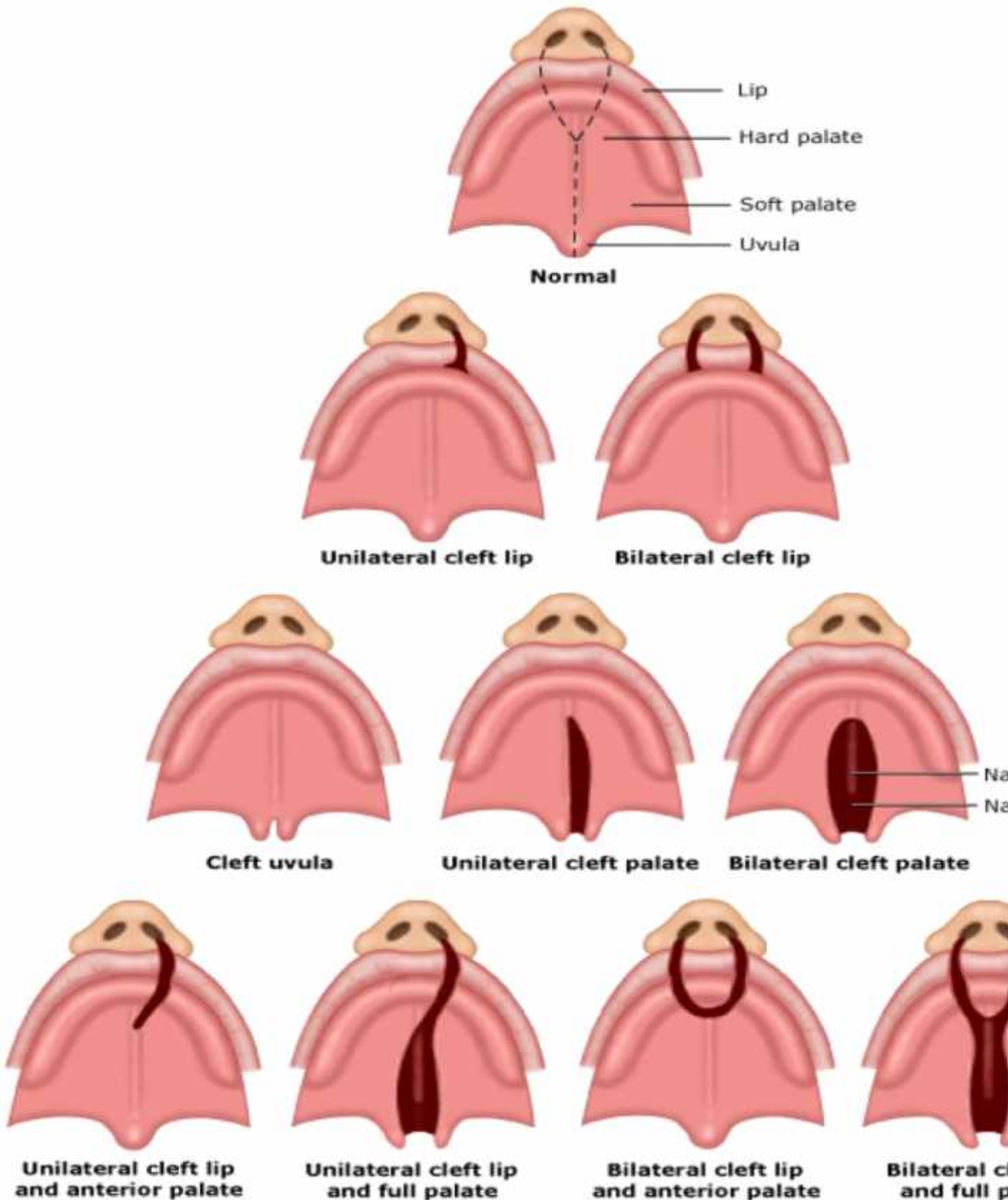


Figure 3: Classification of cleft lip and palate  
(Source: Haug et al., 2012 [www.uptodate.com](http://www.uptodate.com) )

Figure 2.7. Different types of CLP

## **2.8. Presurgical Orthopedics in CLP treatment**

The orthodontic treatment for cleft lip and/or palate patients proposes to form an aesthetically attractive occlusion with a satisfactory function. To achieve these goals collaboration among professionals in varied sections of medicine and dentistry such as pediatric dentists, orthodontists, and maxillofacial surgeons is necessary (Burstone WR.1965, Subtelny J. D. 1990).

The impact of infant orthopedics on maxillary arch dimensions in CLP has been investigated for years. Infant orthopedics proposes to promote feeding, decrease the cleft width, and to maintain the normal shape of the upper dental arch, before and after surgical intervention. Antagonists of infant orthopedics treatment declared that lip surgery alone has the exact outcome and that the presurgical orthopedic plate is only an expensive appliance applied to support the parents by starting treatment at the earliest moment possible that makes them feel comfort (Catharina AM et al., 2006). Infant orthopedics tries to mold the alveolar segments either passively or actively and to promote feeding.

During 1950s Mc Neil, a pediatric dentist, announced a novel treatment method for decreasing the cleft palate width to speed up the surgery. This technique depends on the stimulation of bone growth exerting gentle pressure across a wide area of the hard palate. McNeil's appliance was formed by manual handcrafting and sectioning the maxillary segments on the dental cast. A plate was then made on the plaster cast, which pushed the palatal segments in the favored position. He believed that by this way he could prevent undesirable effects of lip closure on the dentition and the subsequent development of cross bites, and favor speech development (McNeil CK.1954,McNeil CK. 1950).

Robertson in 1971 found considerable variation in the differences created by presurgical orthopedics regarding the growth. Also, he noticed that there was the chance to decrease of the palatal cleft width without collapsing or decreasing the arch width. (Robertson NRE et al., 1971)

Hotz et al (Hotz MM et al., 1979, Hotz M 1976) supported the use of these devices to produce and preserve good palatal width and occlusion. Hotz declined that combination of orthopedic device followed by well-timed primary surgery has a useful effect on maxillary development and therefore, facial profile.



Figure 2.8.1. Hotz Appliance

Hellquist (Hellquist R. 1971) in 1971 utilized presurgical orthopedics in combination with a periosteoplasty to perform expansion of the markedly collapsed maxillary segments.

In 1980 Latham (Latham RA. 1980) announced a screw aided intraoral appliance used before surgical intervention. This intra-oral appliance appeared to utilize the maxillary sutures in order to maintain the collapsed palate in the unilateral cleft lip and palate infant.



Figure 2.8.2 Latham Appliance

## 2.9. Nasoalveolar Molding (NAM) in CLP treatment

In 1993 Grayson et al introduced the Nasoalveolar Molding appliance (NAM)( Grayson BH et al., 1999). In the first months of birth, the flexibility of cartilage and mouldability of the alveolar bone segments is increased because of the raised levels of hyaluronic acid and maternal estrogen circulation in the baby (Grayson BH et al., 2001). Utilizing this manner, NAM appliance affects the premaxilla by retracting; rotating and approximating the alveolar segments can be achieved before surgery (Ijaz A et al., 2010). NAM devices generally consist of palatal base plates formed of clear acrylic resin that fill the oronasal deficit and external attachments consist of, adhesive tapes connect the device to the cheeks and a nasal stent applied to the nose.

The principal objective of the NAM appliance is to obtain alignment of the premaxillary segments, to improve the alveolar ridges and the lip segments and to extend the columella promoting the neonate's condition to receive cheiloplasty and nasoplasty operations. (Santiago Pe et al., 1998).

The orthodontist should modify the acrylic palate every week by selective removing the hard acrylic and mixing the soft acrylic to the molding plate. In each visit, no more than 1 mm of adjustment should be done. The alveolar segments must be delivered to their correct position as well as the cleft's gab must be reduced. Meanwhile, the alveolar cleft width is reducing till 6mm, then the nasal stent can be attached to the appliance and the nasal cartilage molding process begins. Nasal stents are manufactured utilizing 0,036 inch round stainless-steel wire. They are coated at the ends by resin heads which are embedded into the nostrils. The molding plate is examined for sharp edges and rough surfaces particularly in the area of the vestibular folds and among the posterior margin to check to prevent any irritation to the soft tissue. The device is fastened bilaterally to the cheeks using surgical tapes with orthodontic elastic bands at one end.

The applied orthodontics elastics have an inner diameter of 0.25 inch, and the activation force about 100 grams depends on clinical objective and the mucosal toleration to ulcers and irritation. Parents were given instructions to held the plate in the mouth all time and to remove it only for cleaning. The infant may require time to adjust to feeding with the NAM appliance even from the first day (Grayson BH et al., 2009)



Figure 2.8.3. Nasoalveolar moulding appliance

## 2.9. Cleft palate maxillary arch dimensions and occlusion

In cleft lip and palate investigation, a general approach for analyzing the consequences of different treatment managements is by evaluating the measurements of maxillary archdimensions on dental casts. Various surgical treatment approaches are constantly compared through the result of maxillary arch dimensions and occlusion (Dahl et al., 1981; Friede et al., 1991; Berkowitz et al., 2004; Kitagawa et al., 2004; Stein et al., 2007; Fudalej et al., 2011a).

Maxillary arch dimensions are often decreased in cases with clefts (Nystrom and Ranta, 1989; da Silva Filho et al., 1992; McCance et al., 1993; Garrahy et al., 2005; Lewis et al., 2008), and are further diminished with complete clefts than with incomplete clefts (Derijcke et al., 1994). In cases with clefts, maxillary measurements, like arch widths and arch depths, are frequently grater at birth, but lesser in the primary dentition than in normal children. As a consequence of the diminished transverse arch widths, crossbite is an initial and general malocclusion in infants with clefts(Kramer et al., 1996; Heidbuchel et al., 1998).

For UCLP, the published incidence of anterior crossbite varies between 8% to 75% and for posterior crossbite ranges from 33% to 98 % (Hellquist and Ponten, 1979; Molsted et al., 1987; McCance et al., 1990; Turner et al., 1998).

In CP, the reported frequencies are lower, ranging from 14 to 27 percent for anterior crossbite and 22 to 37 percent for posterior crossbite (Hellquist et al., 1978). Crossbite in cases with clefts can be accompanied by speech difficulties such as defective articulation and deflecting masticatory muscle function (Li et al., 1998).

The most popular techniques to determine maxillary arch constriction for cleft palate dental casts are the Golson Yardstick (Mars et al., 1987) and the 5-Year-Old Index (Atack et al., 1997a; Atack et al., 1997b).



Figure 2.9. cleft palate with maxillary arch constriction

### **2.11. The use of digitized models as a replacement of plaster and gypsum models in orthodontics:**

Unique revolutionary innovation of digital techniques that have occurred in the last years has also affected orthodontics considerably. Nowadays orthodontists have a great opportunity to organize and document patients' data to facilitate orthodontic treatment, case diagnosis, as well as patient follow-up. Conventional ways of physical imaging have been displaced by Digital radiographs and digital photographs moreover accompanying it with cone-beam computed tomography (CBCT) is being more helpful. As a consequence of this development, digital models are now gradually replacing plaster models. Digital models have various benefits like precision and urgency in collecting data for diagnosis; less area required for storing; the opportunity to convey information within a modern digitized system; more convenient orthodontic analysis, as well as the ability to simulate several treatment modalities using the same digital model. (Mullen SR et al., 2007, Sousa MV et al., 2012, Stevens DR et al., 2006, Wiranto MG et al., 2013, Camardella LT et al., 2016)

Orthodontists always employ modern technologies to resolve past communication difficulties, maximize patient control, and as a result increase productivity. Using digital models as an alternative of plaster models will create a full digitized workflow for the patient, considering additional elements of for saving orthodontics data digitally, such as taking camera images, x-rays, and CBCT scans, which are now normally utilized in a digital pattern. Orthodontists can use various orthodontic computer application programs; in addition to using a digital printer to print the digitized cast models as well as orthodontics appliances.

Several limitations for usage of digitized casts in orthodontics would be the expenses of the machine, loss of comfort and experience while utilizing digital planning applications also the loss of physical tactile sensation. Besides, the electronic files and scans can be unexpectedly erased or harmed by malware or spam files, so that the files must be securely saved in an external hard drive or the internet cloud to prevent losing them forever. Digitized casts can be estimated as the current gold standard in orthodontic routine treatment plannings. Several studies compared the accuracy of measurements done

using standard digital calipers on gypsum casts and digital measurements using computer application programs on digitized casts. they concluded that the reliability is comparable (Rossini G et al 2016).

In 2014, 35% of the orthodontists in America started to apply digitized casts for analysis and planning in the majority of cases treated and they are gradually increasing in numbers (Shastry S et al., 2014).

To safely utilize digital casts in the clinic, the orthodontist should be guaranteed the accuracy of the devices and software that he uses. This study tends mostly to discover the correlation & make a detailed comparison among the values of the latest technologies to obtain 3d digital models using cone-beam computed tomography (CBCT) & CEREC Omnicam 3D intraoral cam scanner determining their accuracy & reliability especially for cleft palate patients as well as discussing current applications & alterations on CLP treatment.

## **2.12. Techniques for generating DIGITAL MODELS:**

### **2.12.1. INDIRECT techniques:**



The digital model can be obtained directly and indirectly (Cuperus AM et al., 2012). Under the indirect technique, the dentist takes an impression regards the child's dentition, & then the impression is scanned to get the digital model. In the direct technique, the digital model can be produced instantly through intraoral scanners or the CBCT. Considering the use of a plaster or gypsum cast as a part of every orthodontic treatment planning procedure, the scanning of them is still the most generally applied method. Plaster or gypsum casts may not represent the precise correct measurement of the teeth, as a consequence of the possible dimensional differences of the material throughout the impression taking as well as transferring time to the laboratory; nevertheless, it is still identified as the gold standard of any orthodontics treatment planning. While scanning the plaster casts, it should demonstrate a real image and present an accurate occlusal relation to the patient's teeth.

Modern software applications offer options that can fix undesirable bubbles furthermore inter-arch disproportions. Various technologies were available for the scanning process of the plaster model, with the most common being computed tomography (CT), structured light scanning, and laser surface scanning. (Mullen SR et al., 2007, Stevens DR et al., 2006, Asquith J et al., 2007)



Figure 2.12.1.1. The CBCT device & the intraoral camscanner

Basically, the intraoral scanner is composed of a light reservoir with single or multiple cameras to promote specific acquisition of the model while scanning. The reservoir of the light designs precisely well-defined points the model while the camera captures images (Hollenbeck K et al., 2012). For analyzing the distances as well as the angles between the light reservoir and the cameras, a mesh is established throughout all the points as mentioned in the figure (2.12.1.2).

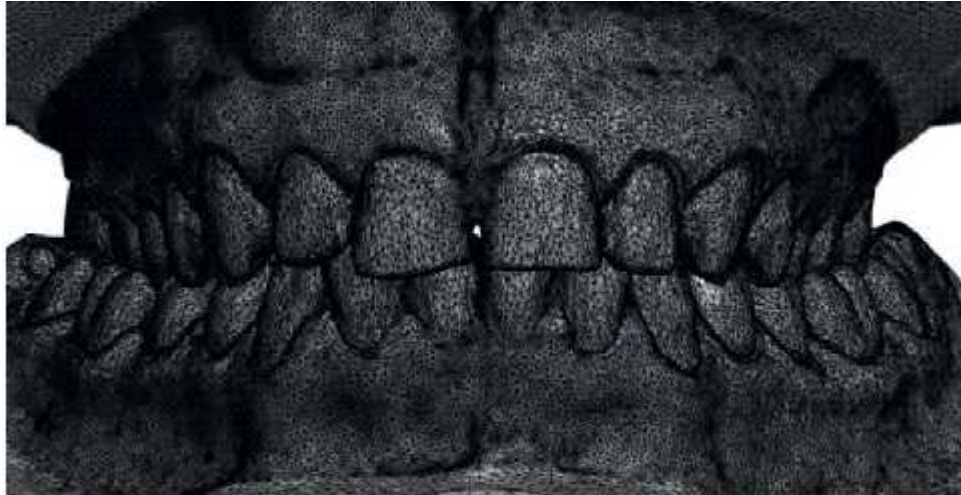


Figure 2.12.1.2. A mesh of points created by intraoral cam scanners

### **2.12.2. Direct Scanning Methods**

Digital models can be obtained directly through intraoral scanners or the CBCT film of the patient.

The cone-beam computed tomography affords information that is not available by using cam scanners like the exact position of impacted teeth, the length and anatomy of the root, the quality of bone as resorption and thickness, and assessment of the TMJ state. Nevertheless, there are some drawbacks like exhibit a high radiation dose. Also, because of the appearance of artifacts, such as metal restorations or braces the morphology of the teeth is not so well-defined (De Waard O et., 2014).

On the other hand, the use of intraoral scanners offers an exceptional option to obtain the digitalized casts in the direct technique, including high-quality details of the teeth morphology, especially regarding the occlusal surfaces. Utilizing intraoral scanners orthodontists can eliminate the traditional impressions disadvantages like gag reflexes, patient's anxiety and nervousness as well as no need for an extra space for storing trays and impression powders and materials. It's not required to take a bite registration with this method, this can decrease the chance of a wrong occlusal relation (Akyalcin S et al., 2013).

Patients always will favor these latest technologies of digitized impression procedures over alginate or other traditional impression materials due to higher satisfaction, nevertheless, the intraoral scanning process commands added chair side time than the impression taken using

alginate (Burzynski JA et al., 2018). Intraoral scanners are available also in colors, which improves the information for the orthodontist. Intraoral scanners digitize the dentition instantly and transmit the images to the system, consequently there is no requirement for the physical store for the impressions as well as there is no need to send the impression to the laboratory. Instead, the digital impression will be sent electronically by the internet or using external hard drives.

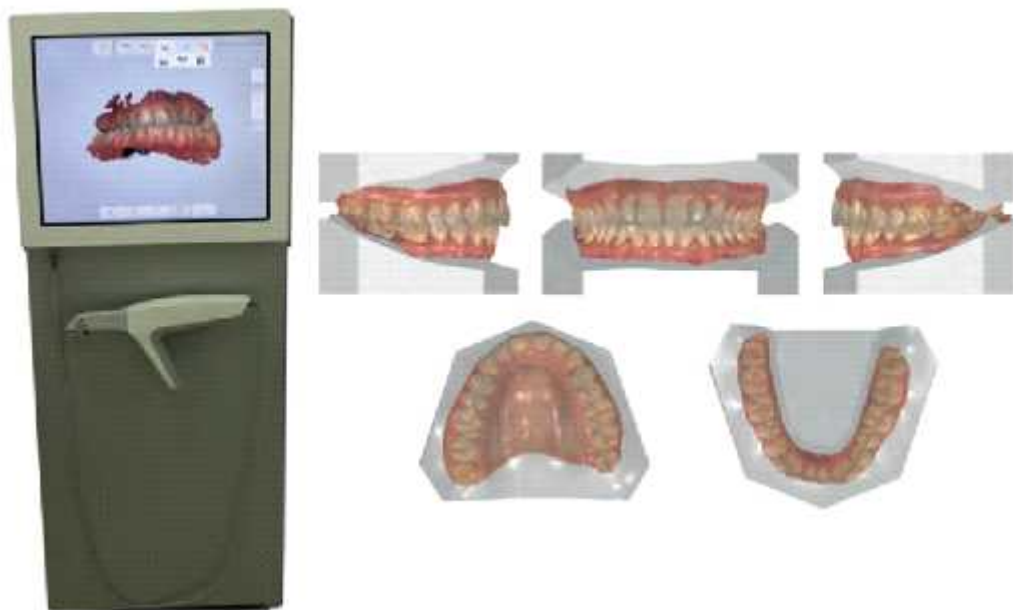


Figure 2.12.2 colorful digitized casts generated using cam scanners

Various systems for intraoral scanning were introduced recently, but the protocol of scanning is similar among most systems. the practitioner scans the upper arch setting the scanner device on the occlusal surfaces of the teeth, surfaces on the buccal side, and lastly, the lingual surfaces, starting from the posterior toward anterior t next scans will be for the mandibular arch in an identical manner. The scanning program arranges the occlusion between teeth in an automated manner (Camardella LT et al., 2017).

Even with whole the advantages, intraoral scanners still have some obstacles especially for cleft palate patients like the dimensions of the scanning tip, cleft patients complex oral anatomy, the opposition of patient's coronoid process, and improper control of saliva and moisture. The preservation of a dry area through scanning is essential during scanning especially in the posterior region of the mouth regarding patients with small mouth opening. Nevertheless, while

scanning technologies proceed to improve, the practice of scanning will be quicker as well as easier and the design of the whole scanner going to be smaller to increase patient satisfaction and enhance patient approval for the scanning process (Camardella LT et al., 2017).

### **2.13. The accuracy and reliability of digitized casts**

Numerous researches and investigations have confirmed the reliability of utilizing various methods for obtaining digital casts including the laser scanning for plaster and gypsum casts, the scan for impressions (Mullen SR et al., 2007, Stevens DR et al., 2006, Bootvong K et al., 2010, Abizadeh N et al., 2012), intra-oral scanning (Mullen SR et al., 2007, Kau CH et al., 2010, Zilberman O et al., 2003) and lastly obtaining the digital cast from the CBCT of the patient (Grunheid T et al., 2014, de Waard O et al., 2014, Kim J et al., 2014, Creed B et al., 2011). Most researchers estimate that there is no clinically significant difference in the measurements concerning digitized casts in comparison to plaster casts. On the other hand, few investigations detected statistically notable differences for the measurements done on plaster and digital casts, authors assumed that the dimensions measured on the plaster casts were smaller (Mullen SR et al., 2007, Abizadeh N et al., 2012) while some studies detect larger values for measurements on the digitized casts (Sousa MV et al., 2012, Stevens DR et al., 2006, Asquith J et al., 2007, Naidu D et al., 2013). Some articles found reliable values regarding to intermolar and intercanine distance (Asquith J et al., 2007, Bootvong K et al., 2010, Abizadeh N et al., 2012), mesiodistal diameter (Grunheid T et al., 2014, Naidu D et al., 2013), crown height (Camardella LT et al., 2017), overjet and overbite (Bootvong K et al., 2010, Abizadeh N et al., 2012). These variations between outcomes of each research can be caused because of the differences between devices used or due to researcher technique errors, properties of the impression materials, and the discrepancies among the computer applications used (Fleming PS et al., 2011).

However, studies regarding acquisition of digital models for cleft palate patients are still few especially studies that uses most recent developing technologies. The orthodontist should be confident to use the digital models in the clinic. Both the digital model acquisition methods, as well as the available measurement computer applications for orthodontics, must additionally be precise and accurate.

### **2.14. Digital planning in orthodontics**

Recently lots of orthodontics digital planning software were available. Generally, these software programs allow the orthodontist to view the model in three-dimensional views. An arsenal of options serves the practitioner like zooming in and out, evaluating the models using cross-section functions, measuring linear and angular distances, measuring volumetric spaces, customizing of digital appliances, and lots of other beneficial options. Most electronic programs used for investigating digital models can show occlusal contacts as well as able to do measurements between different points or planes. Utilizing digital casts in the clinic will allow the orthodontist to perform various essential routine model analyses like Moyers and Bolton analysis as well as the peer assessment rating index (PAR index) automatically using specific software programs. These software programs can also simulate orthodontic treatment through a virtual setup as well as providing setups for both diagnosis and therapeutic objectives. The diagnostic setup options produce simulations to show the treatment outcomes before starting the treatment. Tooth extractions or interproximal stripping treatment planning options can be simulated to enhance the discussion and understanding of the treatment outlines between the patient and the orthodontist. (Grauer D ET AL., 2011) (Kuo E ET al., 2003) (Camardella LT et al., 2016).

Consequently, the orthodontist now has the choice to approve, change or discard a recommended treatment modality, which can be helpful particularly in complicated cases.

## **Materials and Methods**

### **3.1. Materials**

The material of the current research contains digital models that were obtained from gypsum models located in the archive of Cleft Lip and Palate patients treated in the Orthodontic Department of Near East University, Northern Cyprus, Turkey.

A set of 44 casts of various types of cleft palate for both sexes have been selected according to specified criteria.

#### 3.1.1. Inclusion criteria

- Age ranges from six weeks to six months.
- No previous surgical or nonsurgical cleft treatment.
- All cases were only treated through the nasoalveolar molding (NAM) approach.

- All cases were treated through the same orthodontist & the same clinical setup.

### 3.1.2. Exclusion criteria

- Poor quality study models.
- Malnourished infants.
- Inadequate cooperation using NAM therapy by patient.

Our sample consisted of digital models of 16 boys and 11 girls with various types of cleft lip and palate. All cases were newborn Caucasians reported in Northern Cyprus and all of them were treated using the same protocol and the same clinical setup performed by Assist.Prof.Dr. Beste Kamiloğlu at the orthodontics department at Near East University.

A palatal impression had been taken from all patients at two stages of treatment before NAM and before the lip repair and nasal correction surgery. All infants were treated with NAM within one month of age.

### **3.2. Data collection:**

All casts were digitized through scanning using two different methods, which were CBCT (Sirona 3D) & intraoral digital scanner (IDS) (CEREC Omnicam 3D intraoral scanner, Dentsply, Sirona, Pennsylvania, US). All plaster models were arranged systematically & based on the same trays. For the CBCT each plaster model was placed in the CBCT device along identical direction & angulation to secure the homogenous shape of the study models.

For an intraoral digital scanner, similar plaster casts have been scanned using a hand-controlled scanner. To achieve homogeneity each plaster model was scanned along in the same conditions. The practitioner was also capable to check the three-dimensional analog cast on a screen.

CBCT scans were exported as Dicom files into Anatomage Invivo (Anatomage Invivo 5, San Jose, CA, The USA) & the intraoral cam scanner files were exported as Stl files into 3D Tool program (version 13.30 GmbH & CO.KG 2019) as well. For observing error included along



Accuracy & reproducibility regards digital models through scanning, the calculation of the whole sample was measured again after 14 days through the same examiner.

### **3.3. Measurements on the Digital Models:**

The measurements included in five categories:

- Unilateral anterior cleft width: linear distance measured around alveolar ridges when anterior area regards cleft, regards unilateral cases (points A & A').
- Left & right anterior cleft width: linear distance measured among alveolar ridges anteriorly regards bilateral cases (points P-A & P'-A').
- Posterior cleft width: linear space around points at edges regards cleft posteriorly at the intertuberosity area (U & U').
- Intercanine distance: the linear distance between the canine eminences located in the alveolar ridges (C & C').
- Intertuberosity distance: the linear distance between points T & T', at the ridges of tuberosity bone.

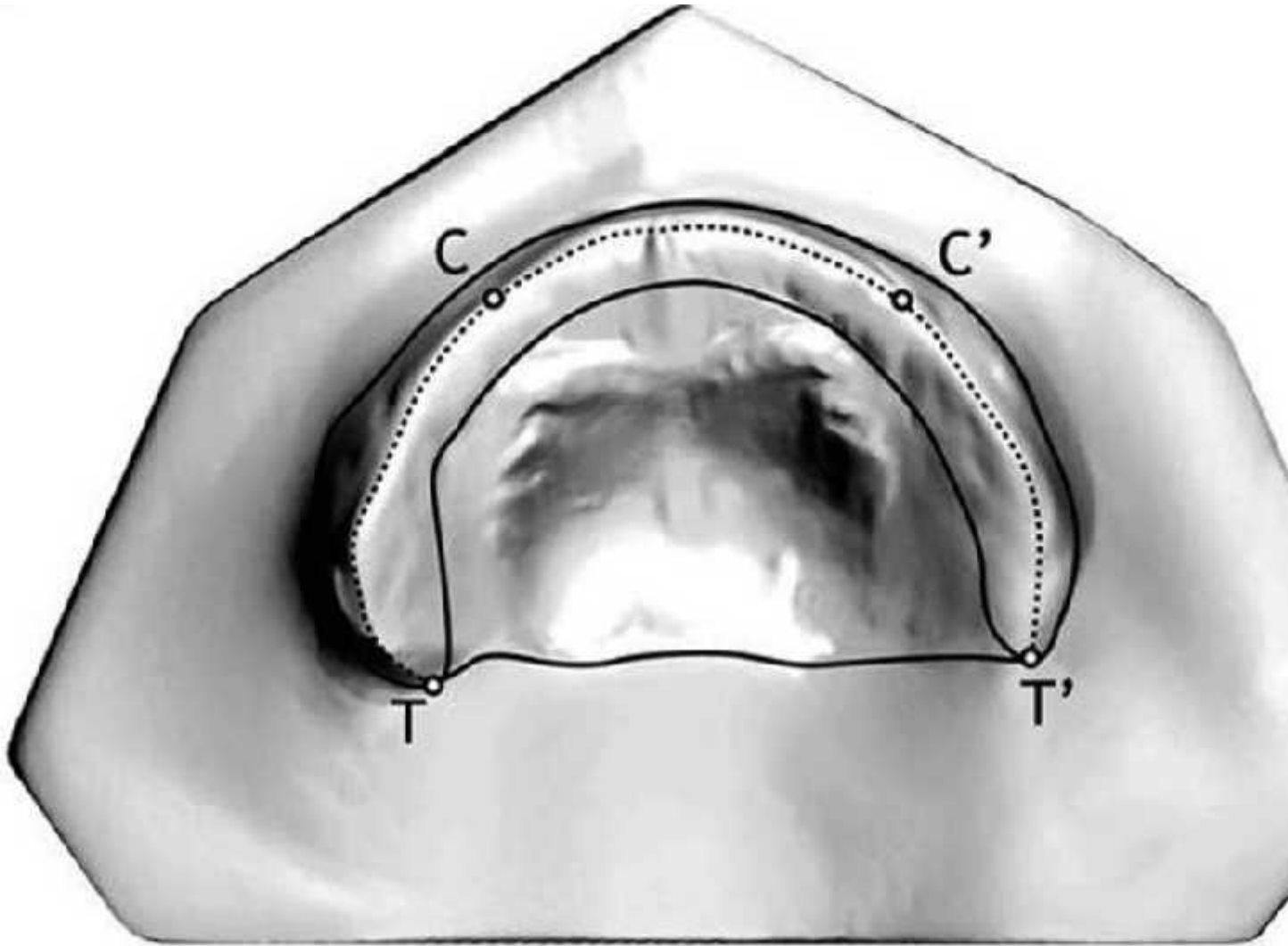


Figure 3.1. Digital mold of the maxillary arch of a child without cleft

(C & C') Intercanine distance: the linear distance between the canine eminences located in the alveolar ridges.

(T & T') Intertuberosity distance: the linear distance between points T & T', at the ridges of tuberosity bone.

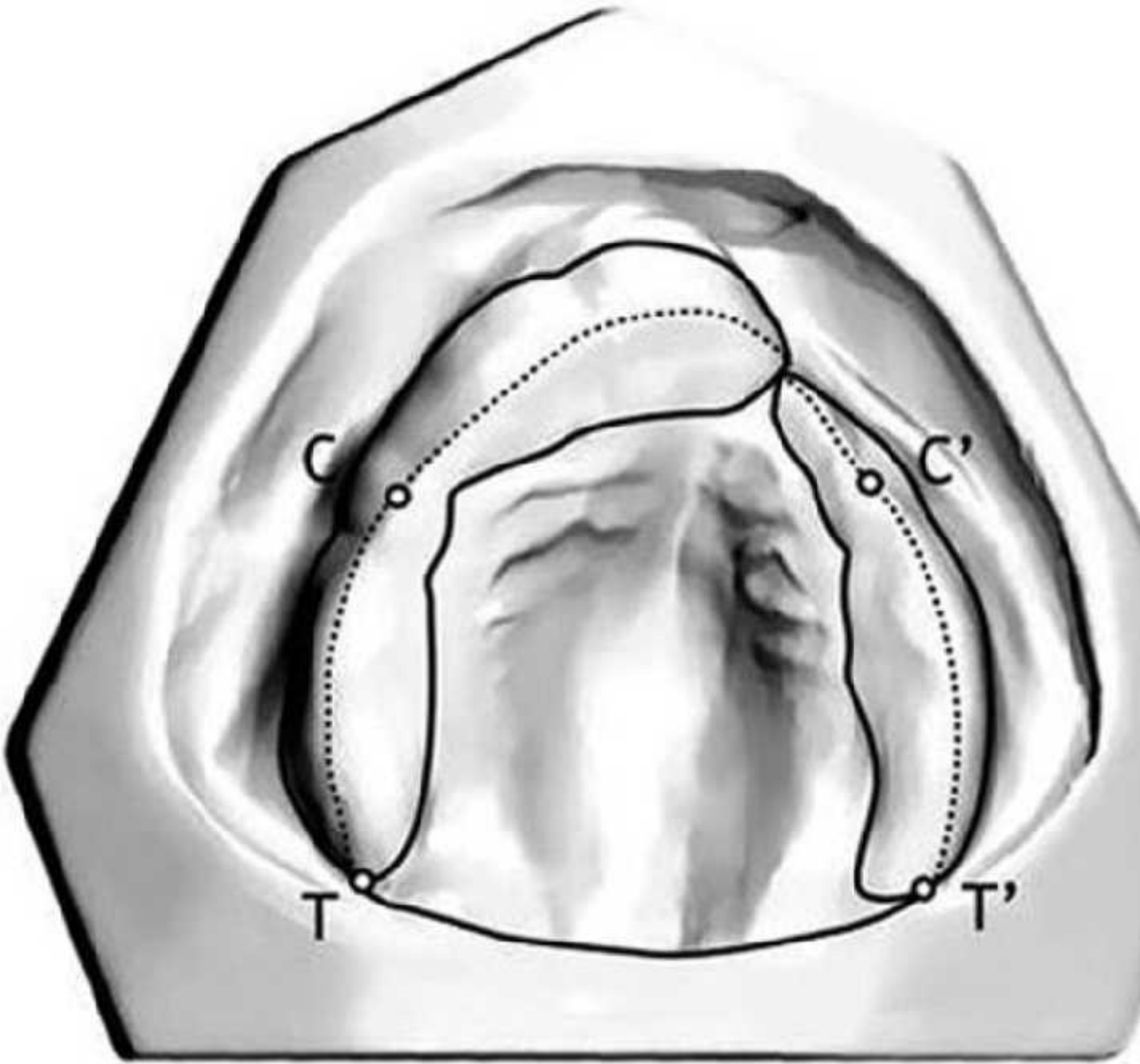


Figure 3.2. Digital mold of a unilateral and bilateral incomplete cleft lip and alveolus

(C & C') Intercanine distance: the linear distance between the canine eminences located in the alveolar ridges.

(T & T') Intertuberosity distance: the linear distance between points T & T', at the ridges of tuberosity bone.

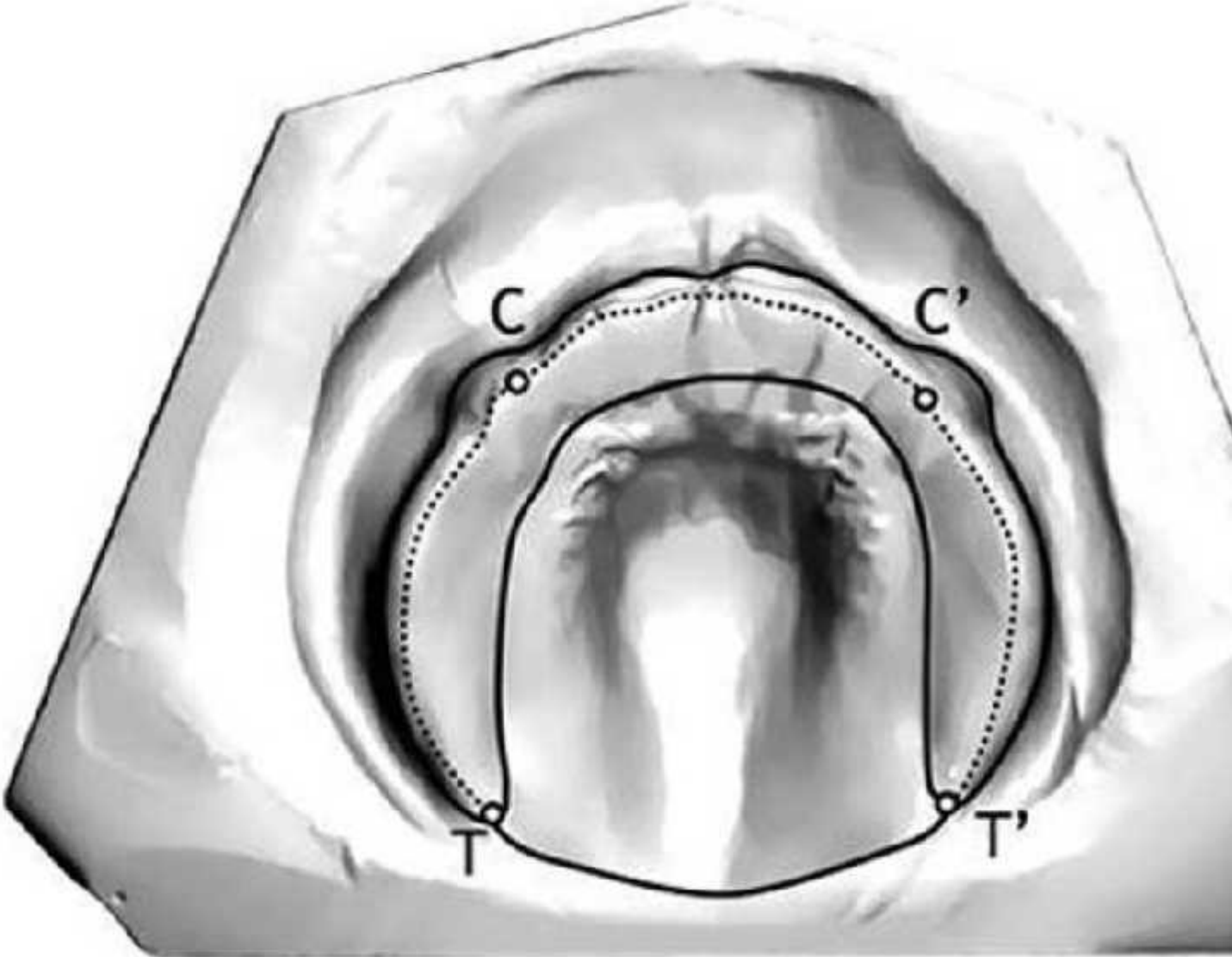


Figure 3.3. Digital mold of a bilateral incomplete cleft lip and alveolus

(C & C') Intercanine distance: the linear distance between the canine eminences located in the alveolar ridges.

(T & T') Intertuberosity distance: the linear distance between points T & T', at the ridges of tuberosity bone.

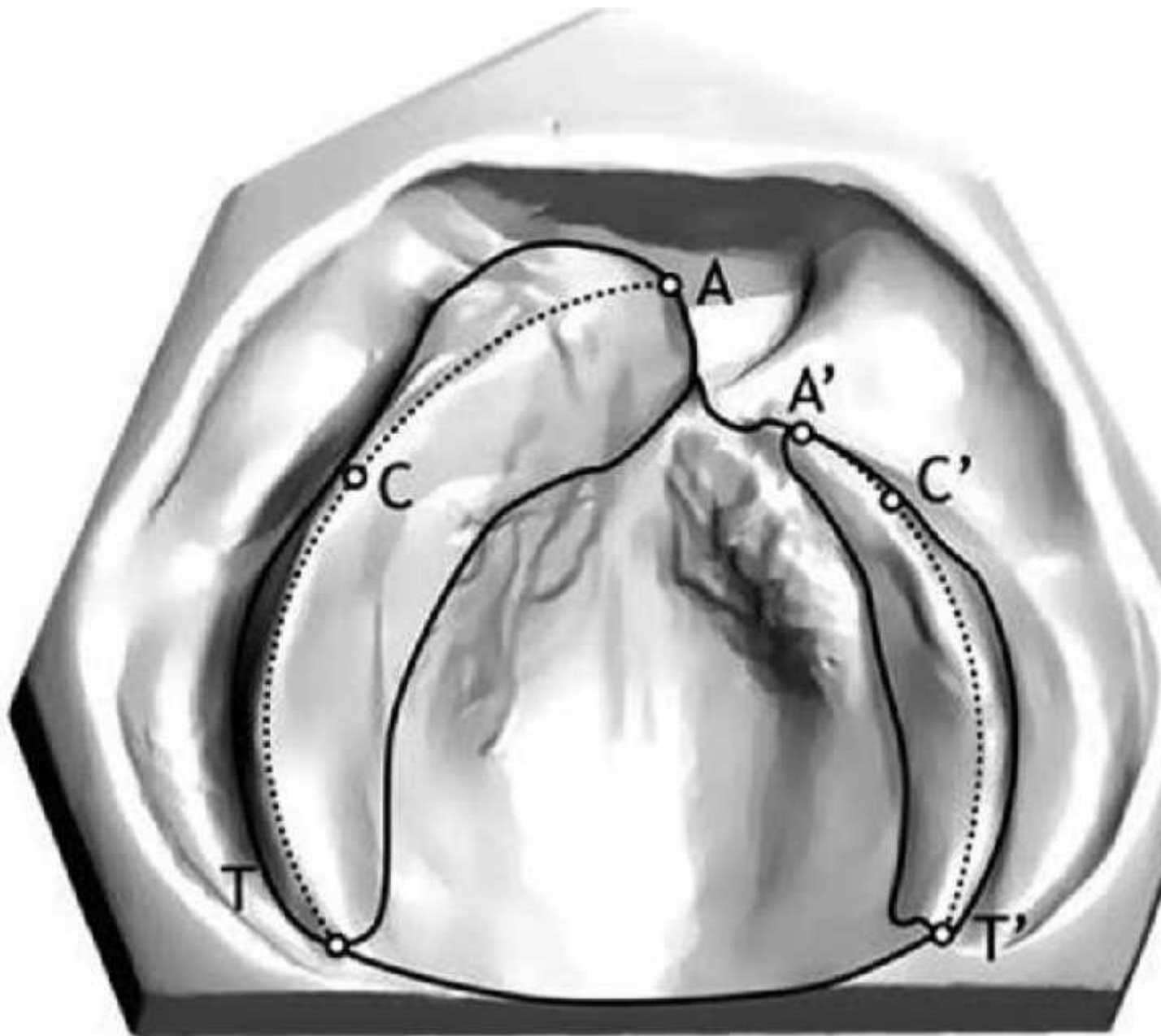


Figure3.4. Digital mold of a unilateral complete cleft lip and alveolus

(A & A') Unilateral anterior cleft width: linear distance measured among alveolar ridges at cleft area anteriorly.

(C & C') Intercanine distance: the linear distance between the canine eminences located in the alveolar ridges.

(T & T') Intertuberosity distance: the linear distance between points, at the ridges of tuberosity bone.

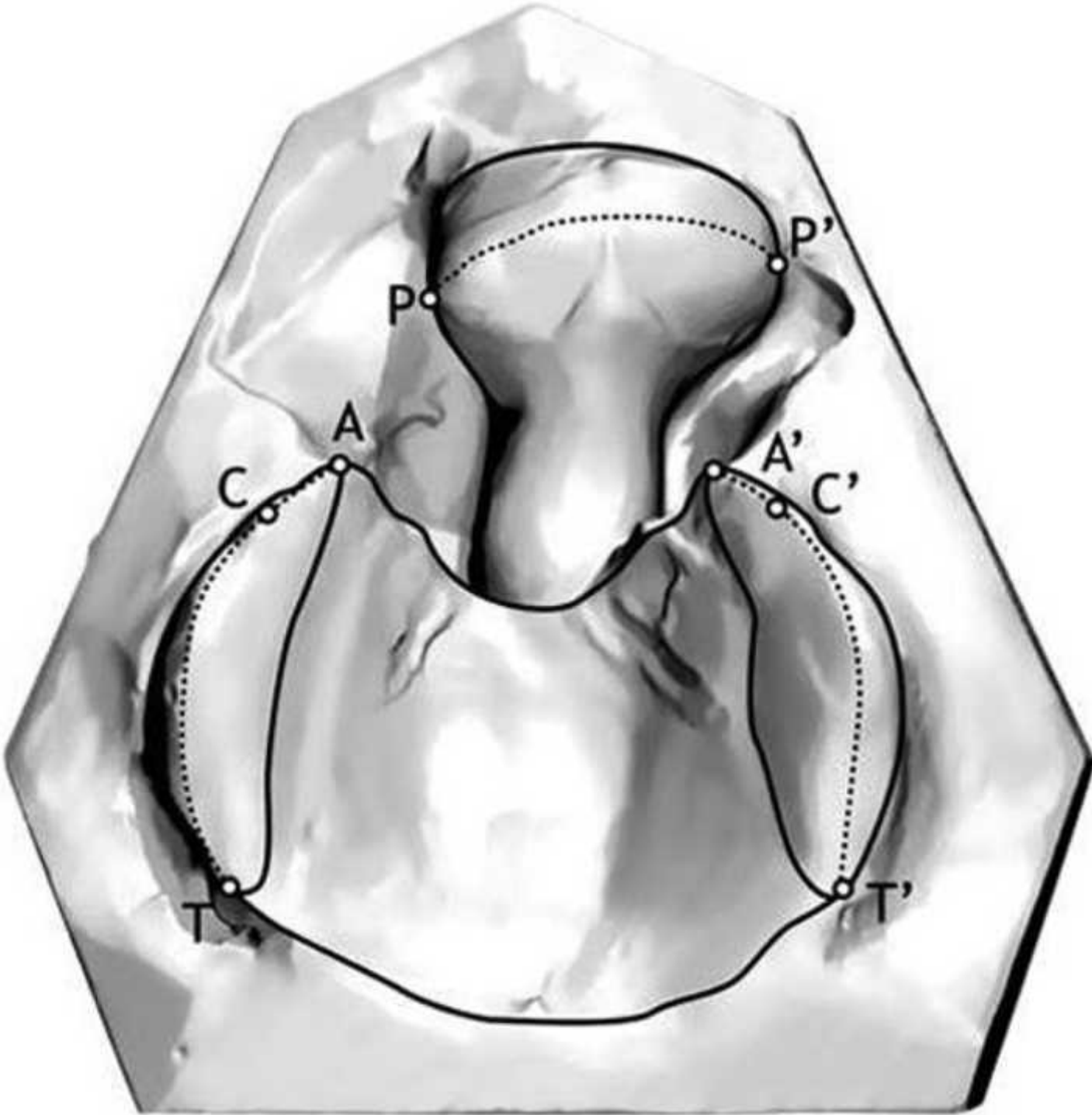


Figure 3.5. Digital mold of a bilateral complete cleft lip and alveolus

(A & A') Unilateral anterior cleft width: linear distance measured among alveolar ridges at cleft area anteriorly.

(U & U') Posterior cleft width: linear distance among points at cleft edges posteriorly at the intertuberosity area.

(C & C') Inter canine distance: the linear distance between the canine eminences located in the alveolar ridges.

(T & T') Intertuberosity distance: the linear distance between points, at the ridges of tuberosity bone.

(P-A & P'-A') Left & right anterior cleft width: linear distance measured among alveolar ridges anteriorly.



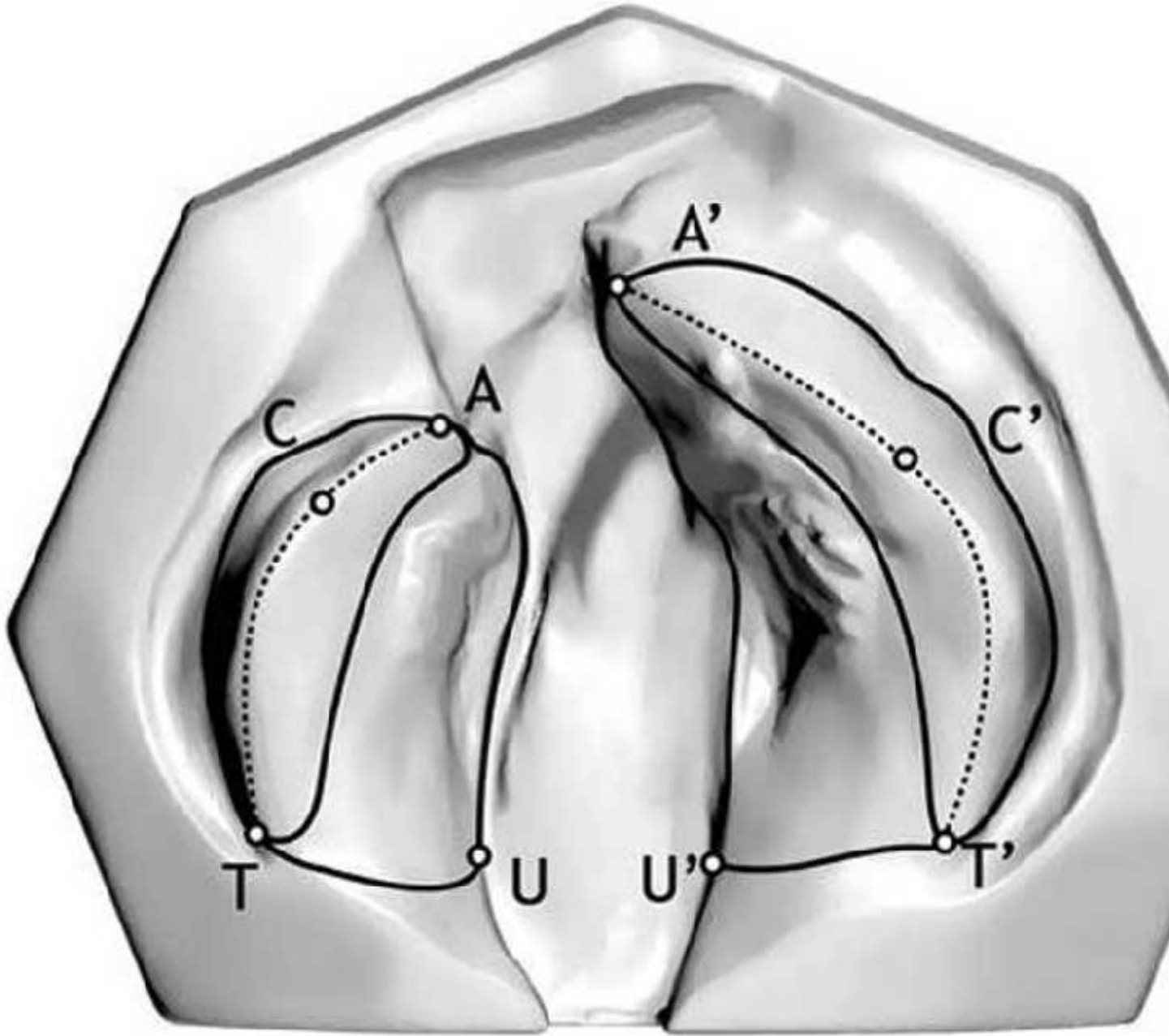


Figure 3.6. Digital mold of a unilateral complete cleft lip and palate

(A & A') Unilateral anterior cleft width: linear distance measured among alveolar ridges at cleft area anteriorly.

(U & U') Posterior cleft width: linear distance among points at cleft edges posteriorly at the intertuberosity area.

(C & C') Inter canine distance: the linear distance between the canine eminences located in the alveolar ridges.

(T & T') Intertuberosity distance: the linear distance between points, at the ridges of tuberosity bone.

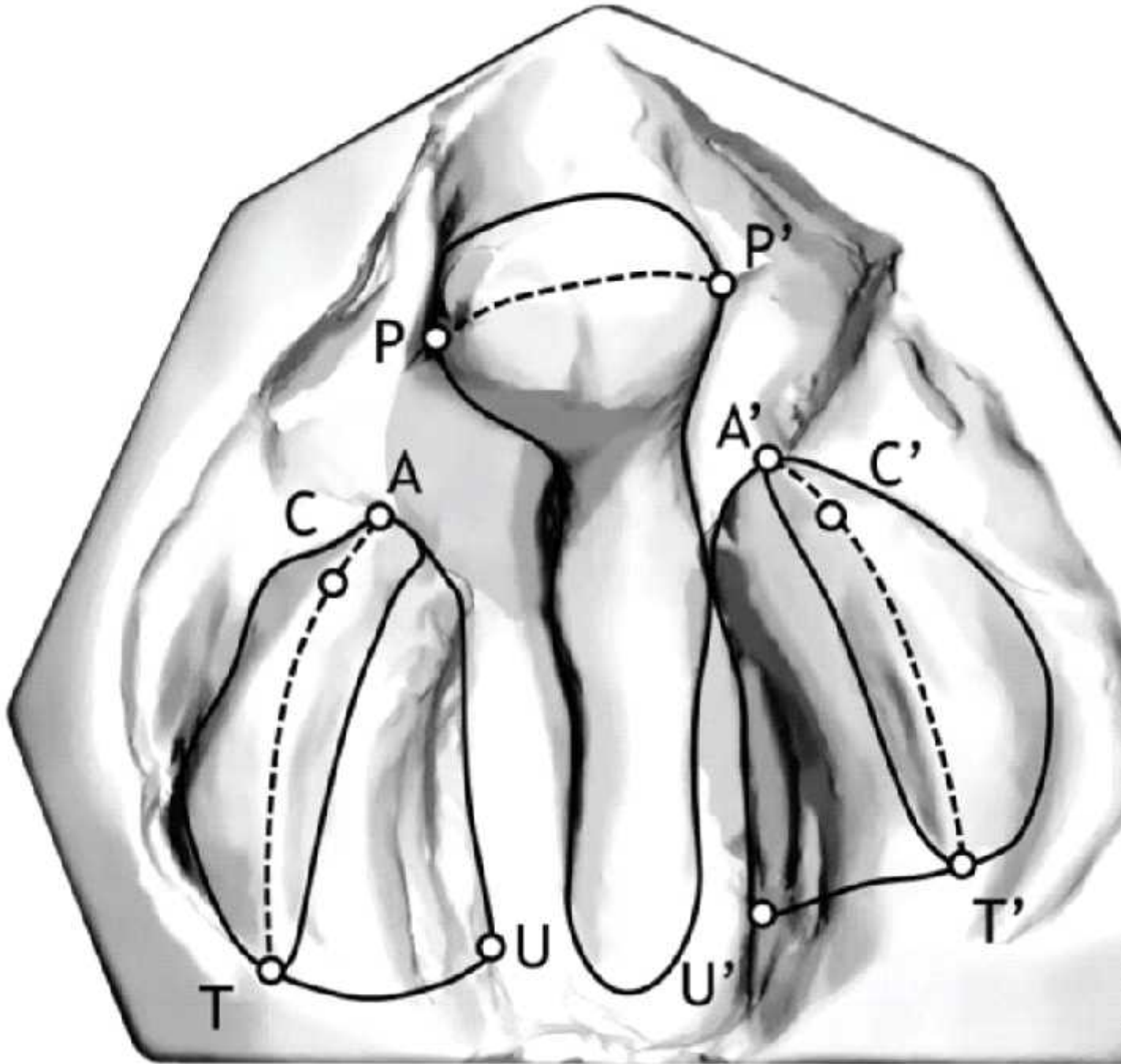


Figure 3.7. Digital mold of a bilateral complete cleft lip and palate

(A & A') Unilateral anterior cleft width: linear distance measured among alveolar ridges at cleft area anteriorly.

(U & U') Posterior cleft width: linear distance among points at cleft edges posteriorly at the intertuberosity area.

(C & C') Inter canine distance: the linear distance between the canine eminences located in the alveolar ridges.

(T & T') Intertuberosity distance: the linear distance between points, at the ridges of tuberosity bone.

(P-A & P'-A') Left & right anterior cleft width: linear distance measured among alveolar ridges anteriorly.

### **3.4. Statistical analysis**

- **Kolmogorov-Smirnov test**

The measurements were analyzed utilizing the Kolmogorov-Smirnov test to decide if they are normally distributed. The Kolmogorov-Smirnov test is a nonparametric statistical test for the equivalence of sequenced or non-sequenced one-dimensional probability distributions that can be used to compare a sample with a reference probability distribution (one-sample K-S test), or for comparison of two samples. It takes its name from its inventors Andrey Kolmogorov and Nikolai Smirnov (Kolmogorov A 1933).

It is one of the most useful and general nonparametric tests for comparing two samples, as it is susceptible to discrepancies in both position and form of the empirical cumulative distribution functions of the two samples. Kolmogorov-Smirnov test belongs to a collection of tests called goodness of fit tests. It indicates whether there is a significant difference between an observed frequency distribution and a given theoretically proposed frequency distribution (Stephens, M. A. 1974).

- **Paired T-Test**

The paired t-test provides a theoretical analysis of the discrepancy between means for a set of random samples that have varieties with almost normal distribution (Paired t-test, 2019).

- **Paired T-Test Formula**

Paired T-test is an analysis that depends on the contrasts between the values of a single pair, that is one diminished from the other. In the formula for a paired t-test, this difference is stated as d.

Since the measurements have regular distribution, matched free examples t-test was utilized to contrast the techniques with the same estimations. Investigations were introduced utilizing means & standard deviations.

$$t = \frac{\sum d}{\sqrt{\frac{n(\sum d^2) - (\sum d)^2}{n-1}}}$$

- **Wilcoxon's sign position test**

To explore the errors related with the accuracy & reproducibility of the scanned computerized models, the measurements were reviewed utilizing Wilcoxon's sign position test. To investigate the errors related with the accuracy & reproducibility of the scanned computerized models, the measurements were reviewed utilizing Wilcoxon's sign position test. The Wilcoxon signed-rank test is a non-parametric analog to the pair-wise (repeated measures) (Wilcoxon, F. 1992).

The Wilcoxon test is proper to apply when the used measurement is on a cardinal scale or the distribution of a second variable is highly altered. It can be accepted as another option to the paired Student's t-test when the distribution of the discrepancy within the pair samples can't be considered to be regularly distributed (Wilcoxon, F. 1992).

- **The intraclass correlation coefficient (ICC)**

the intraclass correlation coefficient (ICC), is a representative statistic analysis that can be applied when quantitative measurements are performed on means that are arranged into samples. It explains how actively units in the same group match each other. It works on information stated as groups, rather than data stated as matched observations. Intraclass correlation coefficients were employed to decide how well the two methods were coordinated with each other. Factual examinations were applied utilizing SPSS programming (Pallant J. 2007).

Intraclass correlation coefficients were utilized to decide how well the two methods were correlated to each other. Factual examinations were performed utilizing SPSS programming (V.25).

- **Bland–Altman plot (difference plot):**

The Bland-Altman plot (Bland & Altman, 1986 & 1999) was utilized to assess the harmony among the two scanning procedures. In this graphical strategy, the proportions between the two methods were plotted against the average values as well as to investigate any possible relationship of the discrepancies between the measurements and the true value (Altman et al., 1985).

This method used in analytic chemistry or biomedicine for data plotting performed to analyze the agreement between two different techniques. One basic purpose of the Bland–Altman plot is to match two clinical measurements each of which provided little bias in their measures. Bland–Altman plots are greatly used to evaluate the balance among two different machines or two measurement devices. Bland–Altman plots provide recognition of any systematic difference between the measurements (Altman DG et al., 1995).

## Results

### 4.1. Evaluation of the statistical analysis:

Statistical analyses were performed using SPSS software version 25. Descriptive analyses were presented using means, standard deviations, the variables investigated using Kolmogorov-Smirnov test to determine whether or not they are normally distributed. Since the variables were normally distributed ( $n > 40$ ), paired sample t-test was used to compare the methods with same measurements. Since the variables are not normally distributed ( $n < 5$ ), Wilcoxon's sign rank test was used to compare the methods with same measurements.

Since, with large enough sample sizes ( $> 30$  or  $40$ ), the violation of the normality assumption should not cause major problems (Pallant J et al., 2007), this implies that we can use parametric procedures even when the data are not normally distributed (Elliott AC et al., 2007). If we have samples consisting of hundreds of observations, we can ignore the distribution of the data (Altman DG et al., 1995). According to the central limit theorem.

Results regarding the two independent samples t-test Wilcoxon signs test for each parameter are shown in Table 1. Results shows that there is only statistically significant difference ( $p < 0.01$ ) between the CEREC cam scan u-u' and CBCT u-u' measurements in favor

of CBCT u-u' which had higher mean (9,9477) than cam scan u-u' (9,7678). Otherwise, there is no statistically significant difference ( $p > 0.05$ ) between other paired measurements.

#### 4.2. Evaluation of the accuracy and Reliability:

Results regarding the reliability of the method calculated individually for each parameter are shown in Table 2. The intraclass correlation coefficient (ICC) and the lower and upper limits of 95% confidence interval determined for each measurement are given in Table 2

the correlation coefficients acquired for both techniques were high. All the estimations show excellent reliability (All ICC's are  $> 0.9$ . P-A and P'-A' cannot be computed because there are very few measurements.

Paired Samples Statistics						
	group	N	Mean	Std. Deviation	Std. Error Mean	P value
Pair 1	A-A' C.S	13	3,0877	3,07741	,85352	0,234a
	A-A' CBCT	13	3,4231	3,30812	,91751	
Pair 2	P-A C.S	3	5,4700	1,88963	1,09098	n.c.
	P-A CBCT	3	5,6567	1,82812	1,05547	
Pair 3	P'-A' C.S	2	4,8200	2,26274	1,60000	n.c.
	P-A' CBCT	2	5,1250	2,29810	1,62500	
Pair 4	U-U' C.S	40	9,7678	3,43882	,54373	0,007b
	U-U' CBCT	40	9,9477	3,47101	,54881	
Pair 5	C-C' C.S	43	23,9335	2,63442	,40175	0,259b
	C-C' CBCT	43	23,8000	2,72473	,41552	
Pair 6	T-T' C.S	44	29,3486	3,05230	,46015	0,443b
	T-T' CBCT	44	29,2709	2,93024	,44175	

Table 1:



*Paired Samples Statistics*

Table 2:  
*interclass correlation coefficients (\*p<0,001 statistically significant, n.c. not computed)*

<b>INTRACLASS CORRELATION COEFFICIENTS FOR BOTH TECHNIQUES</b>					
<b>TECHNIQUE</b>	<b>Measurements</b>	<b>ICC</b>	<b>95%CI for ICC Lower Limit</b>	<b>95%CI for ICC Upper Limit</b>	<b>P value</b>
<b>CAM SCANNER</b>	A-A'	0,994	0,981	0,998	0,000*
	P-A	-	-	-	n.c
	P'-A'	-	-	-	n.c.

	U-U'	0,976	0,954	0,987	0,000*
	C-C'	0,916	0,851	0,954	0,000*
	T-T'	0,953	0,916	0,974	0,000*
<b>CBCT</b>	A-A'	0,997	0,991	0,999	0,000*
	P-A	-	-	-	n.c.
	P'-A'	-	-	-	n.c.
	U-U'	0,996	0,992	0,998	0,000*
	C-C'	0,946	0,903	0,970	0,000*
	T-T'	0,985	0,973	0,992	0,000*

Bland and Altman founded the Bland-Altman (B&A) plot to represent the balance among two quantitative measures by creating boundaries of agreement in between. These statistical results are determined by utilizing the mean and the standard deviation ( $s$ ) of the differences between the two methods of measurements. To check the hypotheses of the normality of variations and other components, they applied a graphical approach. The resulting graphical chart is a distribute plot XY, in which the Y-axis presents the discrepancy between the two paired measurements (A-B) and the X-axis describes the rate of these measures  $((A+B)/2)$  (Altman DG et al., 1995).

In brief, the contrast between the two paired measurements is traced facing the mean of the two measurements. B&A confirmed that ninety-five percent of the measurement points should be within  $\pm 2s$  of the mean difference.

The bias is calculated as the rate defined by one method minus the rate defined by the opposite method. If one technique is seldom having a high rate, and seldom the other technique is higher, the mean of the differences will be adjacent to zero. If it is not near to zero, this means that the two methods are systematically providing inconsistent results (Altman DG et al., 1995).

### **Interpreting the Bland-Altman results**

Bland-Altman plots are usually described without additional analyses. To interpret these plots, we should ask several questions:

- (1) How large is the mean difference among the two methods (the bias)? We need to estimate this clinically. Is the discrepancy high enough to be mattering?
- (2) How separated are the boundaries of agreement? If it is wide (as determined clinically), the results are enigmatic. If the limits are modest and the bias is limited, then the two methods are actually equivalent.

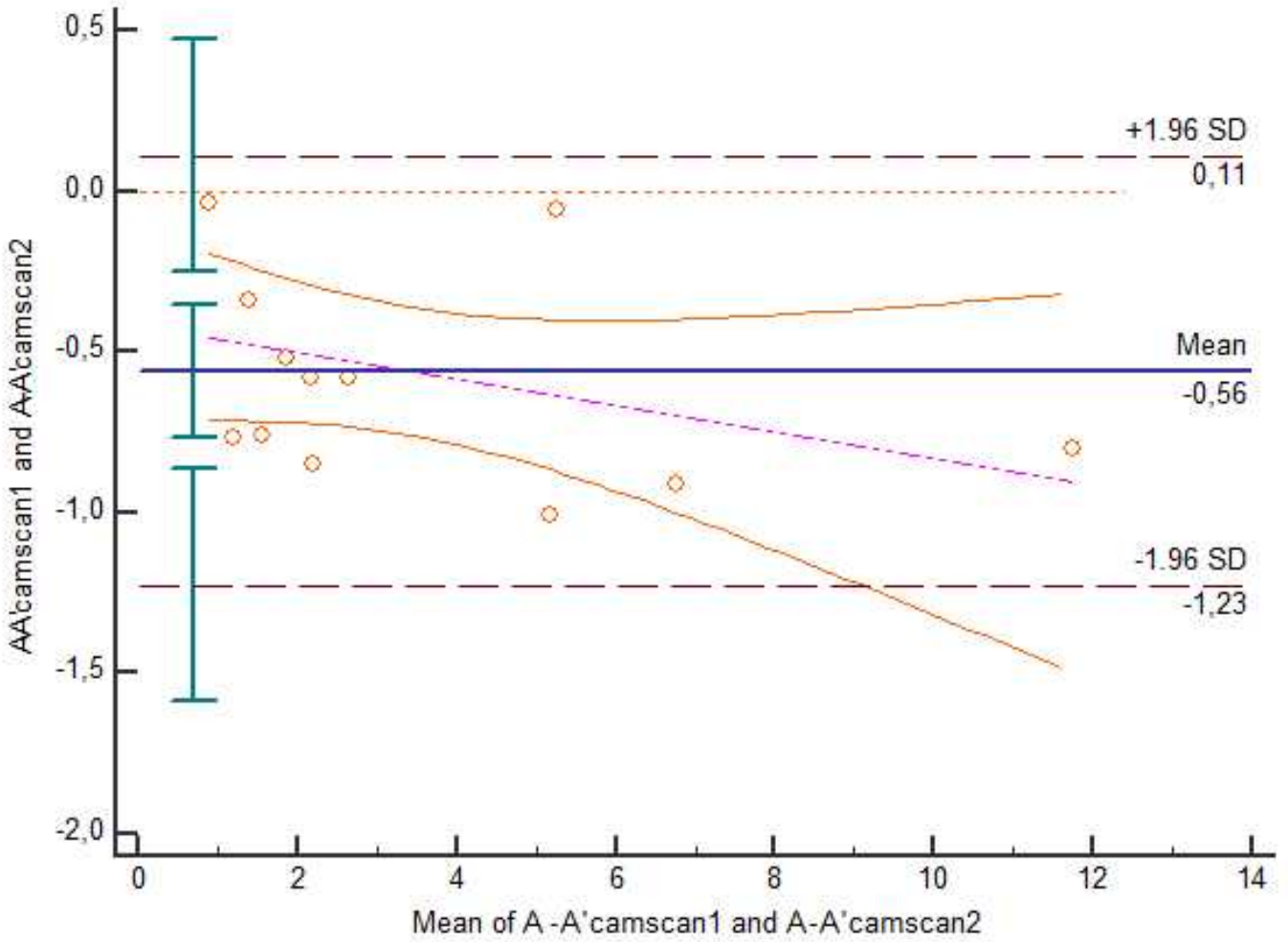


Figure 4.1. Means of A-A' camscanner means

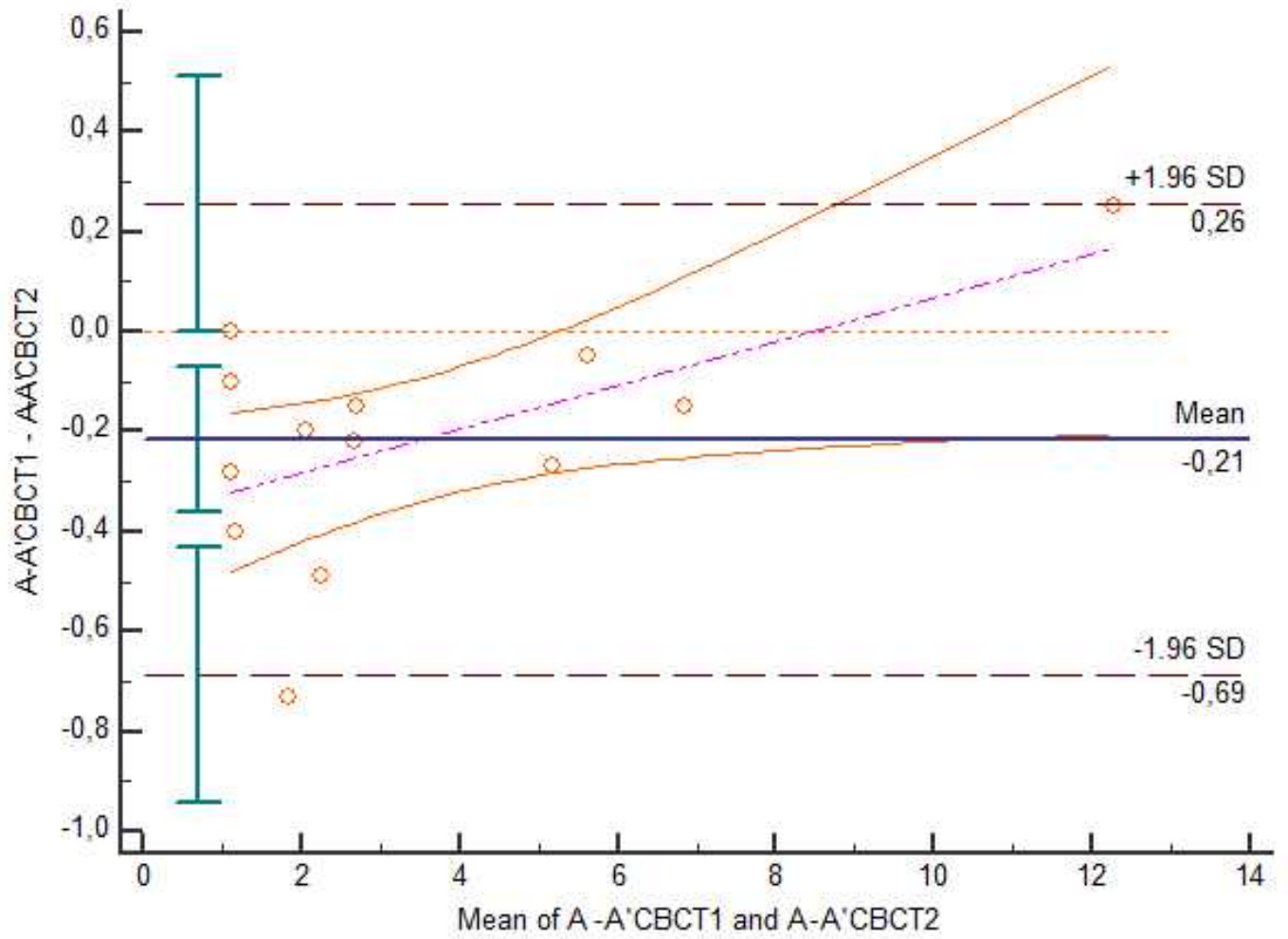


Figure 4.2. Means of A-A' CBCT means

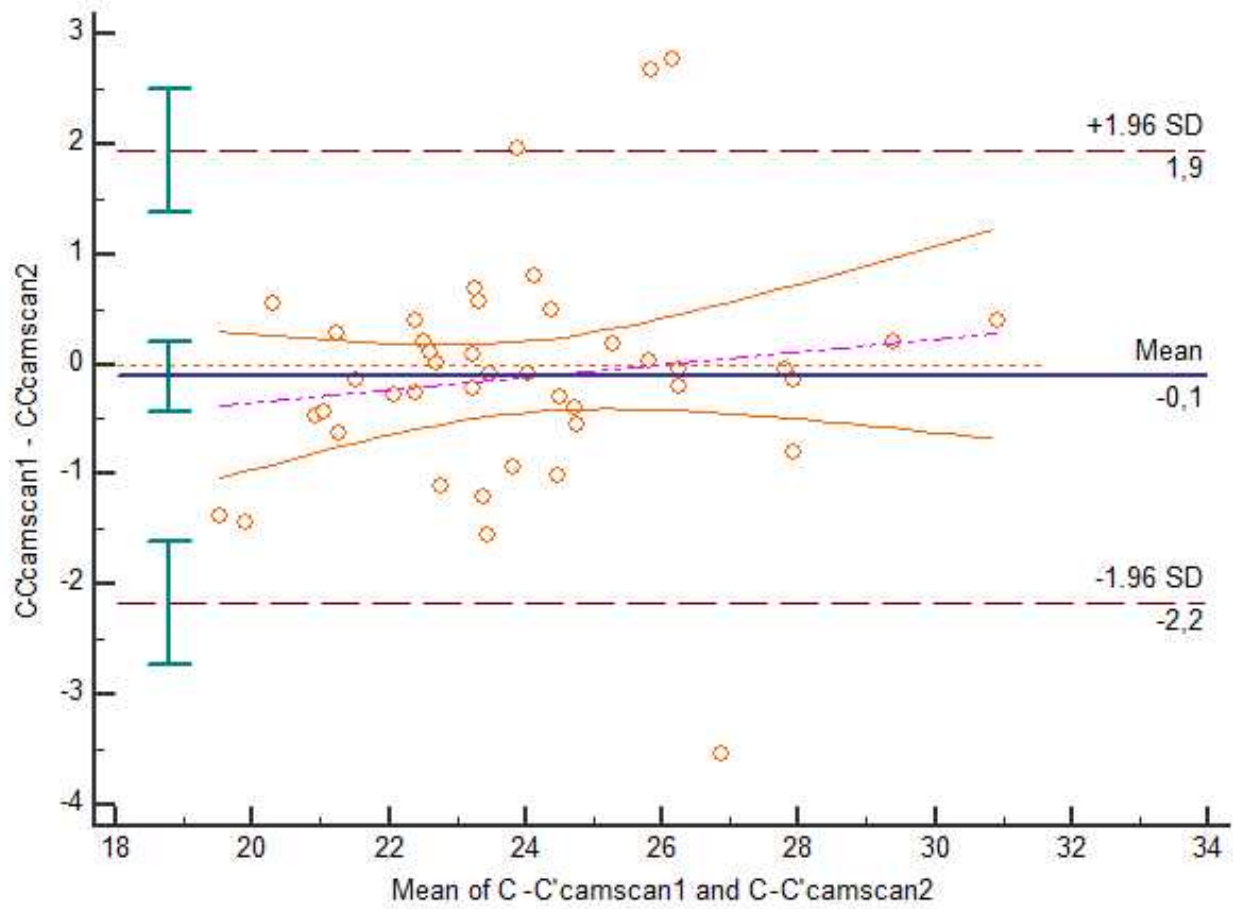


Figure 4.3. Means of C-C' camscanner means

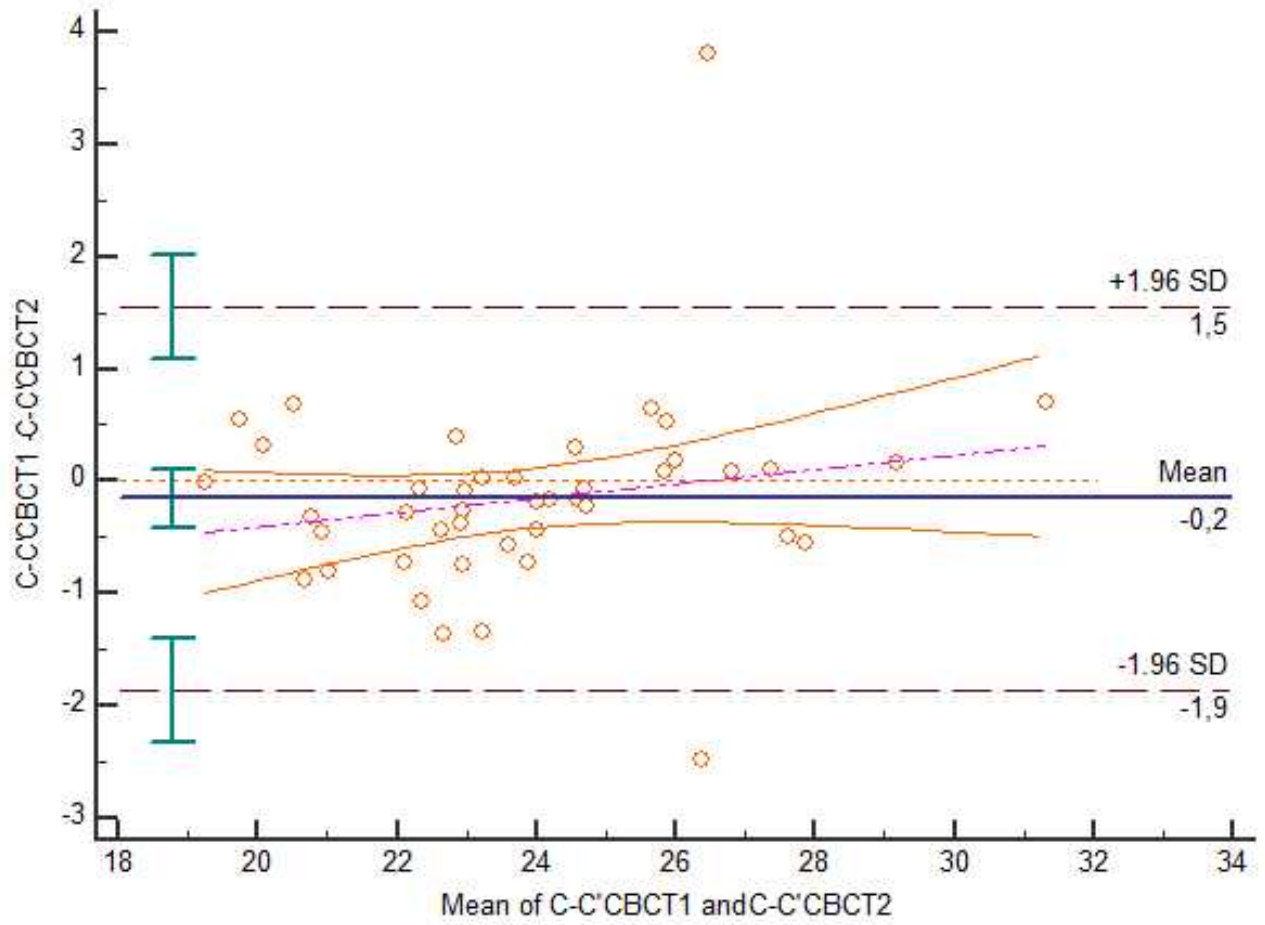


Figure 4.4. Means of C-C' CBCT means

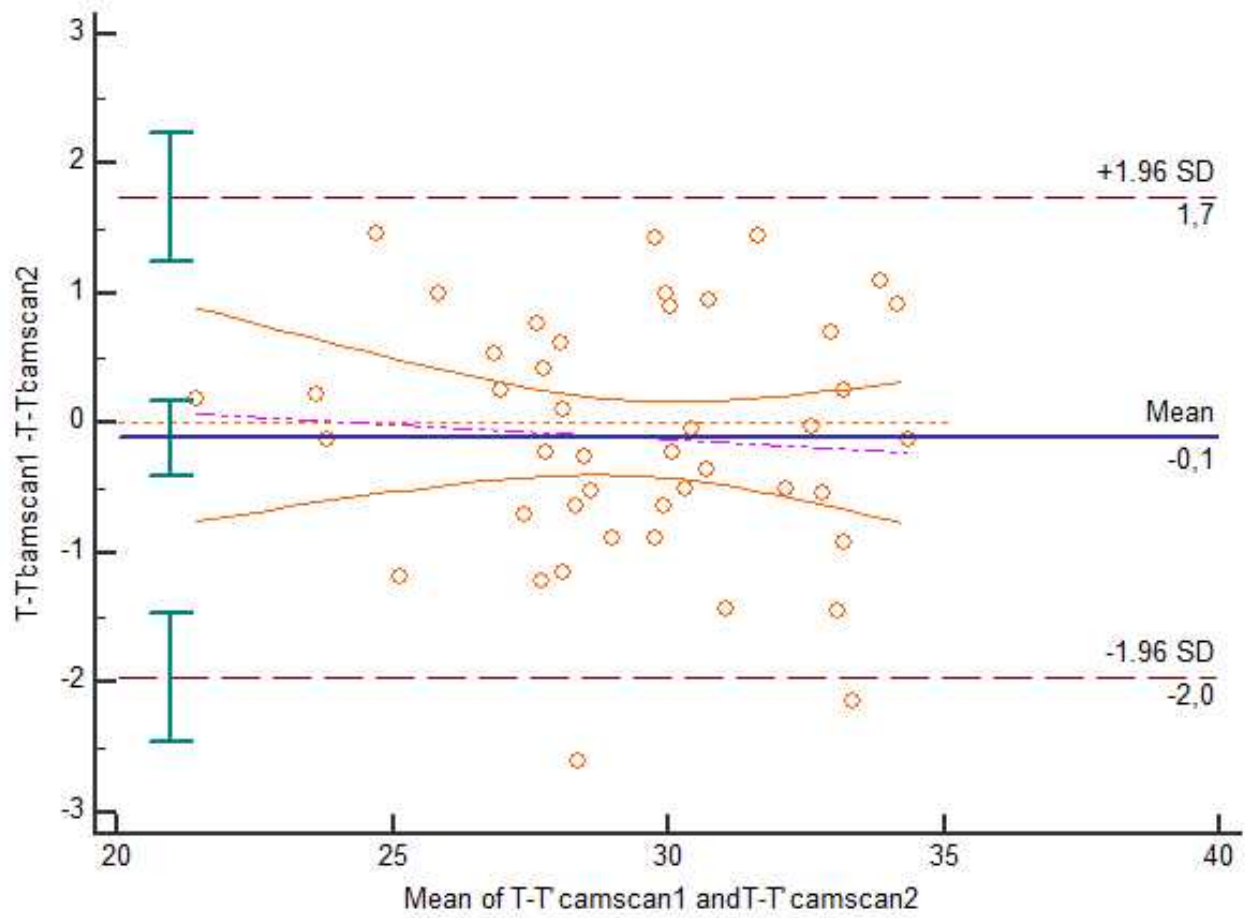


Figure 4.5. Means of T-T' camscanner means



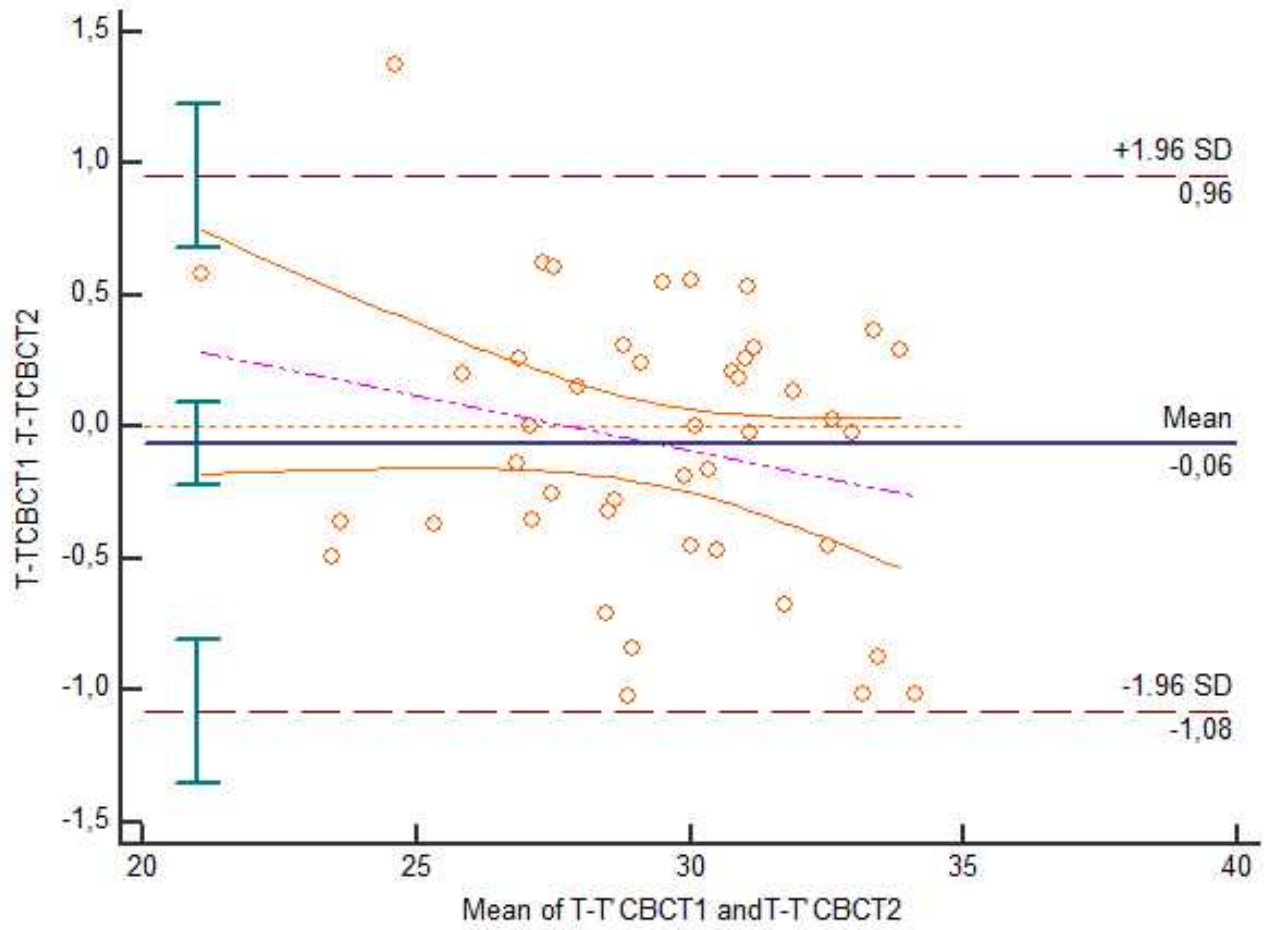


Figure 4.6. Means of T-T' CBCT means

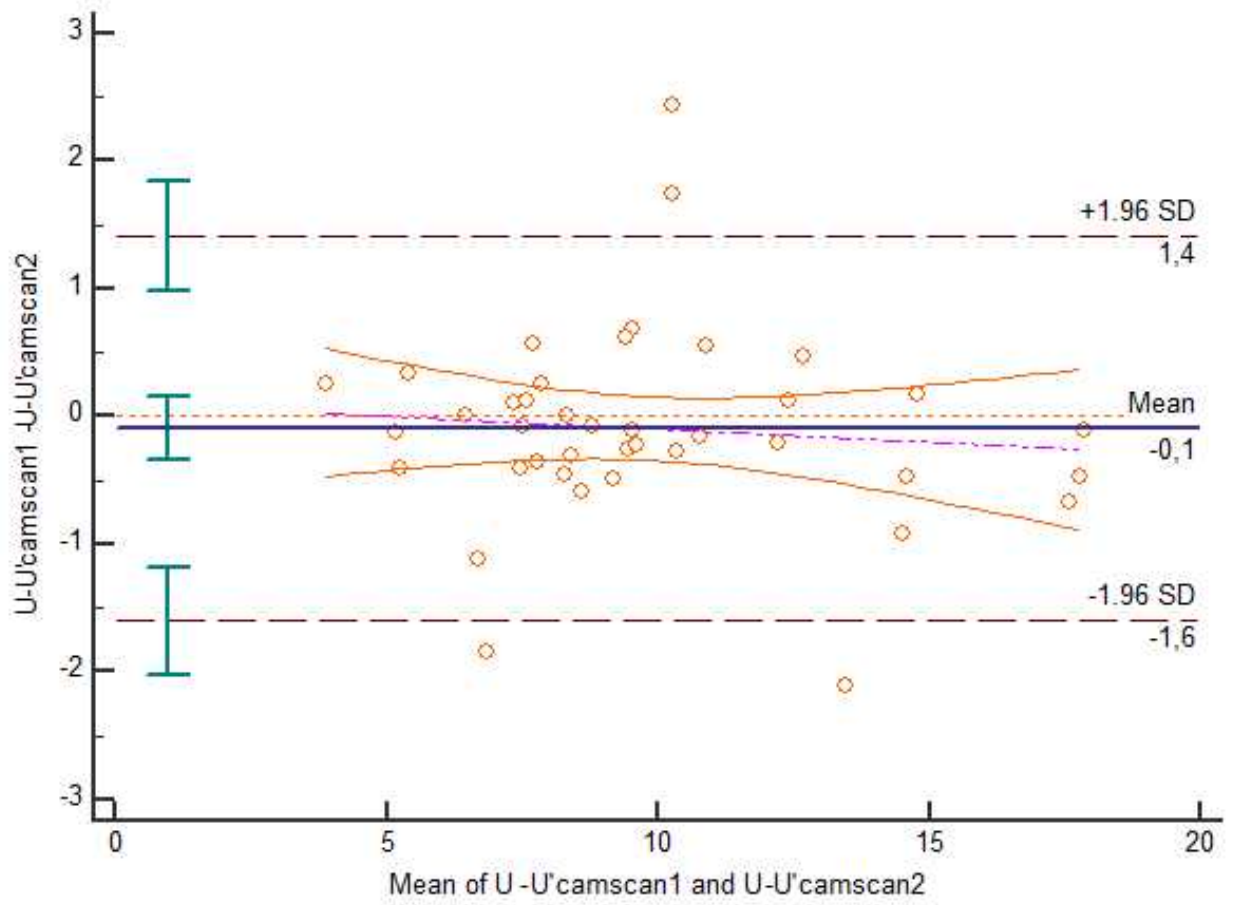


Figure 4.7. Means of U-U' camscanner means

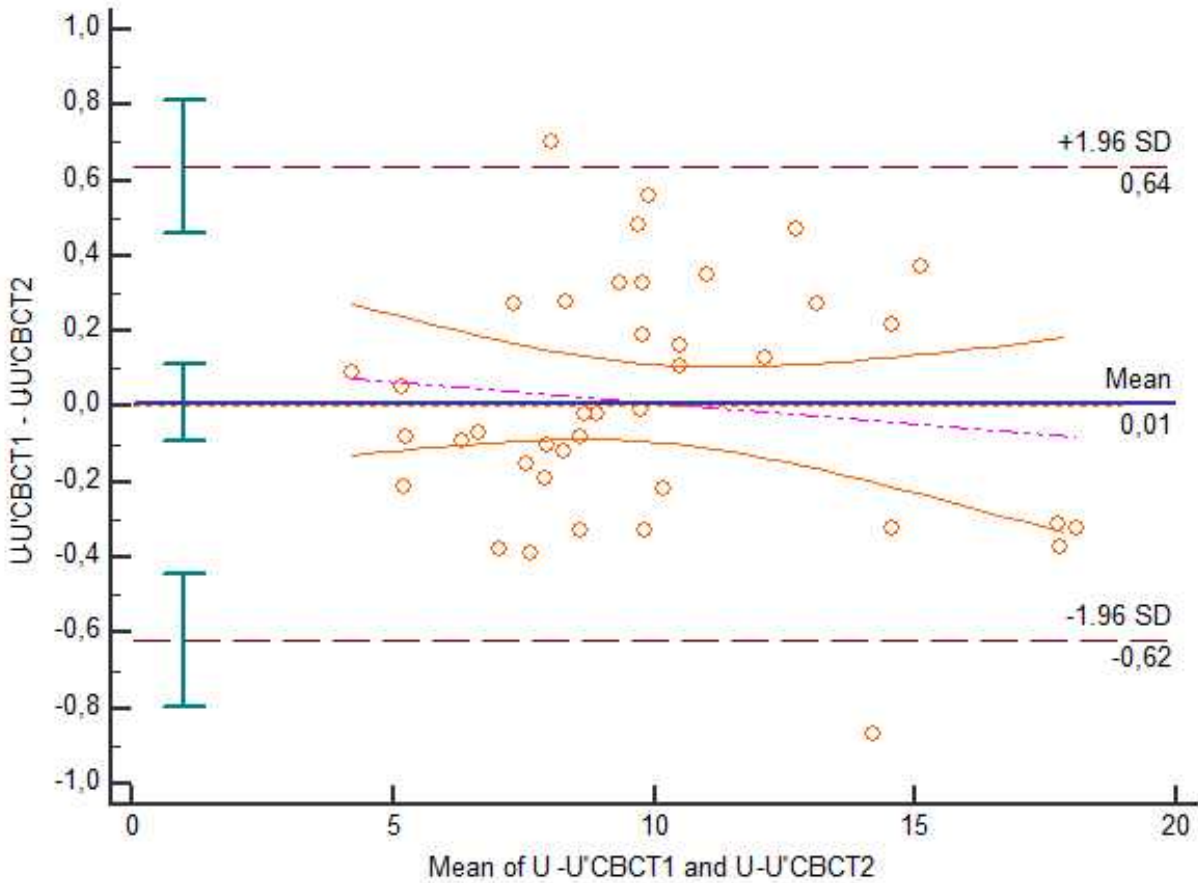


Figure 4.8. Means of U-U' CBCT means

From what described above for the Bland-Altman plots, Horizontal lines have been created mean variation & at limits regard agreement (LoA), which has been known as mean variation plus & minus 1.96 times standard deviation regards variations. All variations were under mean  $\pm$  1.96 SD and that's considered accepted clinically. Consequently, the two techniques can be utilized interchangeably & equivalently.

### Discussion

Digital technology has been employed remarkably in orthodontics because of the increasing developments, digitalized orthodontics continued to spread recently and its principal goal is the acquisition of digitized casts. Laser scanners started to be used for scanning of plaster and gypsum casts to be applied in the routine orthodontic treatment in the mid of 90s (Kuroda T et al.,1996). Nevertheless, digitized casts were offered to the commercial orthodontics field in 1997 with Ortho-Cad (USA) and 2000 with the Emodels (USA) (Fleming PS et al., 2011). Digital

technology is transforming the experience of clinical orthodontics. Nevertheless, digital planning can be available if the orthodontist uses photographs, radiographs and digital models and radiographs. And according to our study digital models acquisition using either cone beam computed tomography or intraoral cam scanners is accurate to be used for orthodontics digital planning.

Recently developers started to produce intra-oral scanners for orthodontics use and consequently, it becomes more practical and will apparently displace desktop scanners. After this development of scanner machines various software applications were introduced to enable orthodontists to do treatment plans for clinical cases with more precise data or even to produce computerized simulations for treatment results before the start of the orthodontic correction. Following computerized settings production, digital casts scans can also be printed by three-dimensional printers to manufacturer orthodontics appliances. The orthodontist who plans to attend this advancement of modern technology wants to understand the advantages as well as weaknesses of the currently used digital devices. Both plaster and digital study models were used for creating orthodontics treatment plans and always been a controversial subject for discussion between orthodontists for long time.

Lots of studies were assessed the accuracy and reliability for measurements done using manual and digital measurement instruments, lots of studies were comparing accuracy of two dimensional versus three-dimensional software for measuring orthodontics casts and less studies for comparing the accuracy of the latest three-dimensional technologies. This study is aiming to estimate reliability, accuracy, and reproducibility on measurements done over cleft palate casts using cone beam computed tomography (CBCT) and to compare them with the same measurements obtained using a three-dimensional cerec omnicaam scanner.

The objective of this thesis is to evaluate any relationship between two different methods of digital three-dimensional scanning using measurements of specific parameters on digital models created by scanning of casts regards infants born with cleft lip & palate (CLP) up to 6 months of age.

This is the first study that evaluates three-dimensional measurements on digital models of cleft palate patients treated using the NAM appliance. Most of the studies in this field, evaluate

only the conventional manual methods of measuring. Even fewer studies investigate measurements using two-dimensional software programs.

A total number of 27 newborns with various types of cleft palate patients who underwent treatment using presurgical NAM were assessed in the present research.

A total number of 44 casts were included after excluding poor quality casts and all the casts were digitized using both cone-beam computed tomography and intraoral cerec cam scanner.

In the current study, we can't have a control group because it is not moral and decent not to treat infants with CLP and to neglect them as controls. We only evaluate the accuracy and reproducibility of the two digital methods for scanning and digitizing the plaster casts to improve the practice of treatment of cleft palate and make it less sophisticated and less complex and to encourage orthodontists to start using three-dimensional scanning devices in the treatment of CLP patients.

The sample consisted of digital models of 16 boys and 11 girls with various types of cleft lip and palate. All cases were newborn Caucasians reported in Northern Cyprus and treated using the same clinical set up. Usually, the analyses for certain measurements are conducted on stone or plaster models with the aid of a digital caliper on images or photographs of the plaster models. Various researchers did measurements on CLP models using only conventional methods (Abida Ijaz. (2009), (Chien-Jung Pai et al., 2005), (Ezzat C. et al., 2007), (Shetty V., et al., 2012), (Williams E et al., 2012).

Nowadays the most common methods used for plaster model scanning were laser surface scanning and computed tomography (CT) scanning. The outcomes of this research estimating the accuracy of laser and CT scanners, revealed that both techniques can be utilized equivalently. Digitized casts produced by laser scanning of plaster or gypsum casts offered a clearer anatomical structure and appearance with better defined and clear outlines, while digitized casts were created by CT scanning of plaster or gypsum casts had a further blur image limited anatomical details according to anatomical contours and outlines. However, the precision of measures using digital models was comparable, which was confirmed in previous studies that done on casts other than CLP patients (Grunheid T et al., 2014), (Wan Hassan WN et al, 2016).Using the computed tomography scanning the whole cast will be scanned and exposed

without projections in a steady way. According to the literature, scanning using laser scanner devices can deliver higher image resolution in comparison to computed tomography scanners. Nevertheless, the laser scanning devices have a disadvantage in that their laser emission don't reach or enter completely through each sector of the dental cast. Some distortion between the laser transmitter and the target region causes a blind area, described by spaced, round deep creases and undercuts (Wan Hassan et al., 2017). In our study some trouble was found among laser scanning of the narrow undercuts regions like the area of (UU').

The voxel volume applied can influence the digitized cast accuracy in the case of using the CBCT. A voxel in radiology equals pixel in digital radiography, the fundamental structure segments of an image will be shown on a display like a monitor screen. A single voxel determines the amount of the linear attenuation coefficient of a particular XYZ coordinate in the radiograph information set (Steinhauser-Andresen S. et al., 2011). Accordingly, decreasing the voxel resolution or raising its capacity could produce a lesser radiograph quality, more blur, artifacts, and poor dental anatomy details for the produced cast. The most recent articles revealed that measures performed on mandibles using a CBCT voxel volume between 0.25 and 0.40 mm, were precise compares with traditional electronic caliper measurements on the same mandibles (Damstra J et al., 2010).

The CBCT utilized in our research has the latest technologies and we had the choice to decide the voxel resolution of 0.05 millimeters, so that the potential for decreasing the precision affected by the voxel size is pointless.

To assess the accuracy and precision of our linear measurements on the digitized models, Identical linear measurements were made on the scans of both the CBCT and the intraoral cam scanner.

Recently several studies attempted to document the reliability & accuracy of the measurements done on the casts of the CLP individuals. In 1995 Seckel et al. Declared that the reproducibility of placing landmarks can be accurate only if the used dental casts have a perfect quality and the practitioner who examines them has a good experience (Seckel NG et al., 1995).

Foong et al. in 1999 analyzed & characterized digitizing errors of a high-speed 3D laser scanning system. They evaluate the reliability of interactive 3D landmark localization & they assumed that

marks well represented through visible optical signs on the three-dimensional image had better reliability (Foong KW et al., 1999).

Prahl et al. in 2001 declared that the quantitative analysis of the palatal morphology throughout the treatment of cleft palate patients reported a better realization of the actual effect of the various rehabilitation protocols employed for their treatment including surgical interventions (Prahl C et al, 2001).

Oostercamp et al. in 2006 & Wutzl et al. in 2009 indicated that the studies beginning at birth are essential to determine the treatment protocol & that dental casts were an important tool for documenting the original maxilla tooth state.

Numerous studies utilized maxillary arch dimensions & landmarks for evaluating the development & growth of CLP patients (Oostercamp et al., 2006) (Wutzl et al., 2009).

Asquith et al in 2012 stated that the 3D digital models can be used to evaluate dental arch relationships in UCLP patients at 5 years of age through explaining if the 3D study models could replace the plaster casts, thus supporting the use of digitized casts, especially in CLP newborns (Asquith JA et al., 2012).

In 2013 Mello et al. utilized 3d imaging technology to measure 3–9-month-old untreated babies along with various kinds of the cleft. Their study concluded that BCLP & UCLP had considerably larger intercanine distance than the control group (Mello BZ et al., 2013).

In 2016 Falzoni et al. performed measurements through 3D images of CLP children at two treatment periods: previous to cheiloplasty & 1 year after palatoplasty. They stated that the lip surgery had a restrictive shaping effect on the anterior portion of the dental arch of unilateral cleft palate children, thus supporting the importance of the measurements done using three-dimensional cast images in this field of research (Falzoni MM et al., 2016).

Similarly, Lambert et al. in 2016 found out those differences in the CW between the groups along isolated cleft palate & along cleft of the lip & palate, thus supporting the work where the measurement accuracy could be attempted so that the best & innovative yet simple technique can be utilized for a larger population range (Lambert A et al., 2016).

- According to impression materials used for CLP patients, Traditional techniques apply elastomeric materials such as alginate or silicone to make a physical impression of the cleft, and the utility of the corresponding model depends upon the quality of the impression (Bauer FX et al., 2017). Indeed, artifacts associated with poor-quality impressions can detrimentally affect the identification of landmarks on digital cleft models manually by doctors and automatically by software (Bauer FX et al., 2016). Silicone-based materials are recommended to improve the quality of digital models in virtual treatment planning for NAM therapy (Loeffelbein DJ, et al 2013). However, in our research we have used alginate impression material for all of our cleft palate patients. The application of alginate is recommended because of the cheap cost, the comfort of use, hydrophilic characteristics, also it can be used in all types of trays including plastic and stainless-steel ones (White AJ et al., 2010), (Lee SM et al., 2016) However, some distortions happen after taking the impression due to the dimensional changes that occur after some time which estimates that the durability of alginate material is weak (Todd JA et al., 2013). As mentioned in most research, the durability of standard alginate such as Jeltrate Plus (Dentsply Sirona, USA) must be maintained within half an hour to 2 days of storing. However, alginate materials with elongated storing capacity like Kromopan (Kromopan USA) are demanded to be durable following storing within 2 days up to 4 days (Walker MP et al., 2010). Dimensional changes also can be happened by temperature changes while transporting into the laboratory, especially if the warmth temperature of the storing room is beneath zero (Todd JA et al., 2013).

A continuous reduction of measuring rates of digitized scans created by alginate impressions, after an extension of the alginate storage period causes that alginate impressions experienced dimensional changes reduction after time, because of a phenomenon described as syneresis. A study done by Lee et al showed that alginate impression material scans using CBCT can be applied appropriately to obtain digital casts by scanning during one day following taking the impressions (Lee SM et al., 2016). Although scanning alginate casts can be adequately used to obtain digitized casts for diagnosing orthodontic cases with clinical accepted accuracy (White AJ et al., 2010), (Wiranto MG et al., 2013). According to the minutes passed following getting the impression and the warmth of storing room while transporting, errors of measurement due to the dimensional changes can occur up to 2mm. This indicates that alginate impressions can produce notable deformities that could cause potential diagnosis faults. Polyvinyl siloxane is an outstanding substance for taking impressions because of its durability and stability for



maintaining dimensions and producing a detailed duplicate for the patient's mouth (White AJ et al., 2010), (Todd JA et al., 2013). Also, polyvinyl siloxane would not be affected by excessively warm or low temperatures while transporting like for alginate. Some companies suggest that the boundary of time for polyvinyl siloxane material is around two weeks. Nevertheless, a major drawback of using polyvinyl siloxane is that it's more expensive in comparison to alginate (Bootvong K et al., 2010).

Due to the increasing improvements of digital technology of intraoral scanning devices will advance become cheaper and more practical so that these scanners will logically be the prime alternative for taking impressions and scan casts directly and indirectly especially for orthodontics and other departments of dentistry. Even though the basic principles of the diagnostic process in orthodontics still identical, the establishment of modern technologies converts the practice of the orthodontic office from conventional old systems into fully digitized systems. The opportunity to affect orthodontic treatment plans utilizing applications provides numerous services for the orthodontist in comparison to the conventional setup with plaster and gypsum casts (Camardella LT et al., 2016). Digital technologies have several advantages over conventional methods that could effectively affect orthodontics planning especially in the way it can simulate treatment results even before starting the treatment. It can be a helpful assistant in evaluating the influence of complicated treatments, such as asymmetric extraction cases, space reassignment, and cases treated with orthognathic surgery. For orthodontists to guarantee perfect treatment planning for clinical cases utilizing modern planning technologies, the efficiency and prediction of the setups must be assessed (Gracco A et al., 2011), (Pauls A et al., 2017)

Just a couple of published studies analyzed and evaluate the accuracy of conventional and virtual setups, they only used measurements for linear distances (Barreto MS et al., 2016), or used indexes of occlusion for this evaluation (Im J et al., 2014).

Till this date, there is no study to compare conventionally versus virtualize setups using cast superimpositions. Concerning the predictability of virtualizing setups, some investigations assessed the reliability of therapeutic setups using cast superimposition with the best fit method and using the dentition's plans for reference. Studies that analyze the efficiency of conventional and virtualize setups by cast superimpositions are still lacking.

This research represents perspectives of the utilization of digital technology in orthodontics and concentrates on the basic essential step of creating a fully digitized workflow for treatment of cleft palate by application of digital model acquisition through scanning to improve digital treatment planning and promote the usability of other techniques to manufacture orthodontics various appliances like 3D printing and CAD/CAM technologies (Hernandez-Alfaro F et al., 2013). (3D orthognathic surgical splint protocol).

The understanding of the accuracy and sources of digital technology is essential for regular use during orthodontics treatment. Nowadays, the orthodontist must be able to learn how to efficiently utilize new techniques prior choosing to include these technologies in his clinical practice. Even though customized systems that use digital technologies should be recognized as a mechanism for controlling the orthodontic treatment planning and to enhance its period efficiency and treatment outcomes, this data is still questionable because it is still not verified yet, so that more research and investigation is still required in this field.

An extra benefit of digital planning is the opportunity to set digital models within three-dimensional extraoral images applying a digital smile design system to guide orthodontic movements from a facial aspect (Stanley M et al., 2016).

Three-dimensional photos can also be applied to control soft tissue differences in three dimensions by superimposition (Plooij JM et al., 2011). The combination of CBCT scans and digitized casts also supports the construction of surgical models digitally for mini-screws and implant positioning, as well as for orthognathic surgery.

In a future perspective, the combination of digital models with virtualizing setups in a simulation, CBCT scans, and three-dimensional images can be expected so particular algorithms will be generated to prognosticate the alveolar bone and soft tissues differences according to the dental movements applied, confirming the possible three-dimensional reconstruction of the craniofacial complex of the patient during orthodontic diagnosis, treatment planning, and progress evaluation.

Furthermore, most recent studies were investigating the impact of digital three-dimensional technologies on the cleft palate treatment how it can make it less sophisticated, more user

friendly & less time consuming for the patient as well as for the orthodontist utilizing cad-cam & digital printing technologies.

According to the measuring mechanisms utilized in CAD-CAM workflows, they are somehow identical. However, their efficiency must be tested to do accurate measurements. In our study we used two different software applications for doing measurements. The first program is the 3D tool program (version 13.30 GmbH & CO.KG 2019). This CAD viewer provides the automatic validation of 3D models in all sectors without CAD knowledge. 3D-Tool presents effective mechanisms for the evaluation of three-dimensional designs, including extended measuring capacities and analyses for researching. The second program is Anatomage Invivo (Anatomage Invivo 5, San Jose, CA, The USA). It is a 3D imaging software that is open to all CBCT DICOM data enabling a variety of measuring and treatment planning features for both dental and medical practitioners. Currently, there are various software programs provided by different companies to plan orthodontics treatment digitally. We recommend that all options and tools that were provided by these software applications be tested by experienced practitioners as the orthodontists will use these applications to treat complex clinical cases.

Numerous studies made comparisons for measurements done on gypsum or plaster and digital models estimate that measurements done on digitized casts with applications and programs are more accurate as well as more precise than measurements done on gypsum and plaster casts with digital calipers. Using these applications, practitioners have the choice to fixate any picked point location with a click on the mouse. Also, can do zooming in as well as zooming out functions, create cross-sections with rotating the casts to promote marking selections, whereas, on plaster or gypsum physical models, mistakes while measuring with the digital calipers can happen, because there is no fixation for pointing of the points and landmarks. (Kuo E et al., 2003). Concerning all measurements between the two techniques, all measurements present accurate reliability, as an exception for the intertuberosity distance, which showed a relevant difference that could have happened by chance as well as the difficulty of scanning that area. The outcomes of our research confirm that it is possible to use both the CBCT and the intraoral scanner equivalently to scan plaster models as the measurements were done show no clinically significant differences in the measurement.

Considering cleft lip and palate treatments computerized digital workflows producing digital models, virtually created treatment plans and three-dimensional printing have developed over the past decade to enhance the effectiveness of NAM therapy with a series of appliances that are manufactured digitally. Digital workflows to facilitate NAM therapy treatment usually start with scanning the plaster or stone model of the patient palatal cleft anatomy to establish virtual treatment planning and appliance manufacturing. Till today most digital workflows for fabricating nasoalveolar molding appliance utilize optical surface scan technology to produce a digital model either from a plaster cast or from a conventional impression. Regarding the weaknesses of the conventional impression technique, some articles support the application of intraoral scanners to provide digital models of the cleft palate anatomical details directly (Bauer FX et al., 2017), (Krey KF et al., 2018), (Grill FD et al., 2018). Obstacles to increase utilization of intraoral scanners in babies with clefts involve the size of the scanner monitor relative to the size of the infant oral cavity, the time required for scanning, and risks associated with anesthesia (Bauer FX et al., 2017), Loeffelbein DJ et al., 2013), (Grill FD et al., 2018). Precise digital model scans of the cleft palate present a basic framework for the virtual treatment plan and manufacturing of appliances for the NAM therapy, and few customized workflows have developed in the research articles to date. They include the management of software tools to plan digitally the areas of the alveolar segments within a series of subsequent steps and to create a series of models, and it is named as the 'CAD-NAM' (Yu Q et al., 2011), (Gong X et al., 2012), (Gong X et al., 2012), (Shen C et al., 2015), (Yu Q et al., 2013). The digitally scanned models were printed using a three-dimensional printer and then a series of NAM appliances were manipulated by hand, using conventional techniques. This method has been employed clinically in the treatment of patients with unilateral (Yu Q et al 2011), (Shen C et al., 2015), (Yu Q et al., 2013) and bilateral CL/P (Gong X, et al., 2016), (Gong X et al., 2017). Nevertheless, the outcomes seemed to be qualitative slightly than quantitative, and the digital methods of how the desired movements of the alveolar segments were performed were not cleared in detail.

Till today, the benefits of the CAD-NAM digital therapy combine enhanced efficiency, increased precision, and accuracy of appliance customization related to the traditional approach that depends considerably on the expertise and knowledge of the orthodontist for the manner of adding and removing the soft and hard acrylic to decrease the cleft area (Yu Q, et al., 2011). The digital virtualized treatment plan for creating the CADNAM gave consistency as well as speed

over conventional NAM appliance fabrication (Gong X et al., 2017), (Yu Q, et al., 2013). For the bilateral cleft palate cases virtualized digital planning for CADNAM provide better control for the low accepted biological forces required to relocation and reshaping of the alveolar bony segments in order to retract the premaxilla. (Gong X, et al., 2012), (Gong X et al., 2017). In addition, the construction of a comprehensive entire set of appliances manufactured at the start of treatment appeared to save time for the parents because of the fewer visits required to the clinic and considerably lesser time for the orthodontist in order to modify the NAM appliance each visit (Yu Q, et al., 2011), (Gong X et al., 2012). The application of scanning using intraoral cam scanners, CAD/CAM software, and precise three-dimensional printers can be counted as an essential step leading to increasing the effectiveness and quality standards of the appliances because of the nonexistence of impression powders, which have a possibility for malformation and errors leading to imprecision in the fabrication of the appliances.

A fully digital workflow can let the orthodontist to: 1) make original digital documentation, including images, radiographs as well as models; 2) create a virtual reality set up to evaluate the planned outcomes concerning the diagnosis as well as treatment planning; 3) determine digitally the bracket position applying indirect bonding trays; 4) perform the orthodontic practice practicing the most desirable mechanics suitable for every case according to the simulations and virtual setups; 5) store the case through digital documentation; 6) assess the results of treatment through computer superimpositions 7) assess the retention phase of the treatment through follow-ups to evaluate potential relapse of dental positions.

## 6. Conclusion:

Although the use of presurgical infant orthopedic devices remains controversial, a growing number of studies has shown that presurgical NAM provides safe, effective, and lasting improvements in the esthetics of the nasolabial complex in infants with unilateral cleft deformities.

By employing modern technologies, the orthodontist can enhance communication as well as promote a trusting connection with patients. It is challenging to predict when modern technologies will take place, on a wide range, the traditional methods of orthodontic treatment currently used. If an orthodontist takes the choice to utilize these digital technologies, he will face some challenges during practice and instant expertise cannot be expected.

The digital revolution of orthodontics has been utilized increasingly by professionals every year and with no doubt will be the major choice in the future of the specialty.

Nevertheless, currently, the logical scientific proof from randomized controlled trials to affirm the pros of using digital technology in orthodontics over conventional orthodontics, for instance, higher treatment impacts and consistency, shorter treatment interval, and greater patient fulfillment is still missing.

In this study, certain measurements were made on digital model files obtained from different sources including CBCT & a cerec cam scanner compared for their accuracy & reliability. No significant differences were found & both methods can be used equivalently. However, the ability to obtain 3D images was found easier & less complicated by using the digital impression CEREC Omnicam intraoral camera (CAD) whereas CBCT were found more precise in reflecting anatomical structures & faster in scanning.

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