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OF MEDICINE AND HEALTH SCIENCES

**EVALUATION OF THE MENTAL FORAMEN AND  
THE MANDIBULAR CANAL COURSE IN EMIRATI  
POPULATION: A CONE-BEAM COMPUTED  
TOMOGRAPHY STUDY**

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## ABSTRACT

### **Evaluation of the mental foramen and the mandibular canal course in emirati population: a cone-beam computed tomography study**

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**Principal supervisor: Mohamed Jamal – Assistant Professor – Endodontics**

**Background:** The mandibular canal (MC) is an important bony structure presents in the mandible that contains a bundle of nerves and vessels including the inferior alveolar nerve (IAN) and the mandibular division of the trigeminal nerve (V3). During surgical or non-surgical dental treatment physical damage can occur to the contents of the inferior alveolar canal. Therefore, a comprehensive knowledge of the anatomy of the MC, its variants and relation to other anatomical structures is essential in the prevention and management of any damages to the IAN during surgical and non-surgical endodontic therapies involving mandibular teeth. It has been recommended to use CBCT to locate the MC course and relation to mandibular teeth prior to endodontic surgical procedures. Furthermore, due to its availability and its conservative nature, CBCT have been used as a tool to study the morphological characteristics of the MC, its course and its intra-bony location of different ethnic groups.

**Aim:** The aim of this study was to Describe the morphological characteristics of the MC, its intra-bony location, and relation to the apices of mandibular posterior teeth in an Emirati subpopulation, using CBCT.

**Material and methods:** this was a retrospective study designed to analyze the cone-beam computed tomography scans of Emirati patients who were treated at Healthpoint Dental Center (Mubadala, Abu Dhabi), United Arab Emirates, between 2017- 2018. 3700 CBCT scans were taken during that period as part of a treatment plan and 154 scans were selected for this study according to inclusion/exclusion criteria. Every patient treated at HDC signs a consent form which allows for research use of available patient data. All CBCT scans were acquired using Orthophos SL (Dentsply Sirona, USA) using a standard imaging protocol (CBCT at HDC are taken by same technician, using same CBCT machine with same parameters; 85 Kv, 7 mAs, with exposure time of 5 seconds and voxel size of 0.15 mm). The data were extracted and anonymized to remove all patient identifiers. The principal investigator (author) evaluated all scans on diagnostic quality monitors.

**Results:** 154 CBCT scans were examined. Examining the selected patients' scans details showed that 72 patients (46.8%) were female, while 82 patients (53.2%) were male. Selected patients' age ranged from 16 to 71 years; more specifically, 26% were younger than or aged 30, 28.5% were between 31 and 40 years and 45.5% were older than 40 years. Overall, the mean distance of the mental foramen (MF) in relation to the line between the mandibular premolars was distal by  $0.83\text{mm} \pm 1.84$ . The mean distances of the root apices with the superior border of the MC in relation to the second premolar, mesial and distal roots of the first molar and mesial and distal roots of the second molar were  $4.02\text{mm} \pm 2.02$ ,  $4.54\text{mm} \pm 1.96$ ,  $4.07\text{mm} \pm 2.08$ ,  $2.58\text{mm} \pm 1.79$  and  $2.06\text{mm} \pm 1.83$  respectively. The mean distances between the buccal aspect of the mandible with the MC in relation to the second premolar, mesial and distal roots of the first molar and mesial and distal

roots of the second molar were  $3.59\text{mm} \pm 1.03$ ,  $4.52\text{mm} \pm 1.13$ ,  $5.05\text{mm} \pm 1.21$ ,  $5.11\text{mm} \pm 1.27$  and  $4.83\text{mm} \pm 1.36$  respectively. The mean distances between the lingual aspect of the mandible with the MC in relation to the second premolar, mesial and distal roots of the first molar and mesial and distal roots of the second molar were  $2.79\text{mm} \pm 1.03$ ,  $1.92\text{mm} \pm 0.8$ ,  $1.68\text{mm} \pm 0.68$ ,  $1.77\text{mm} \pm 0.69$  and  $1.73\text{mm} \pm 0.74$  respectively. The mean distances between the inferior border of the mandible with the MC in relation to the second premolar, mesial and distal roots of the first molar and mesial and distal roots of the second molar were  $6.6\text{mm} \pm 1.61$ ,  $5.52\text{mm} \pm 1.41$ ,  $5.16\text{mm} \pm 1.24$ ,  $5.11\text{mm} \pm 1.36$  and  $5.46\text{mm} \pm 1.51$  respectively. Statistical analysis showed that for the MF location there is no significant difference found between males and females (males  $-0.3\text{mm} \pm 2.2$  and females  $-0.5\text{mm} \pm 2.4$ ) ( $P=0.635$ ). However, the distances between root apices of mandibular teeth to the MC was significantly higher in males compared to females. Interestingly, all mean distances were higher in males compared to females except for the distance between the lingual aspect of the mandible and the IAC in relation to the mesial root of the second molar where females had greater distance compared to males (males  $1.4\text{mm} \pm 0.7$  females  $1.9\text{mm} \pm 0.7$ ) ( $P < 0.001$ ). The statistical analysis showed that there is a negative relationship between age and the location of the MF in relation with the premolars ( $P < 0.001$ ). On the other hand, distances between the root apices and the IAC have a significant positive relationship with age.

**Conclusion:** The most common location of the mental foramen is distal to the contact area between the mandibular first and second premolars ( $0.83\text{mm} \pm 1.84$ ), and this distance has a negative relationship with age. The distal root of the mandibular second molar is the closest root to the mandibular canal ( $2.06\text{mm} \pm$

1.83). The distance between the root apices of the mandibular teeth and the mandibular canal has a positive relationship with age and gender, as young female patients have smaller distance than older male patients. The common course of the canal being more lingual and inferior posteriorly and becoming more buccal and superior towards the mental foramen.

## DEDICATION

**This dissertation is dedicated:**

TO MY BELOVED FAMILY THAT HELPED ME THROUGHOUT THE YEARS OF MY  
STUDY AND SUPPORTED ME.

TO MY FRIENDS WHO ALWAYS BEEN ENCOURAGING.

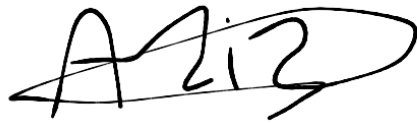
TO ALL MY MENTORS WHO GUIDED ME AND TEACHED ME TO BE A GREAT  
ENDODONTIST

## DECLARATION

I declare that all the content of the thesis is my own work. There is no conflict of interest with any other entity or organization.

Name: Abdulaziz Alazemi

Signature:

A handwritten signature in black ink, appearing to read 'A. Alazemi', enclosed within a large, loopy oval shape.

## **ACKNOWLEDGMENTS**

I wish to express my gratitude to the following individuals who assisted me in my work:

My supervisor, Dr Mohamed Jamal, Assistant Professor

Prof. Amar Omer

Dr. Nouf Al Harbi



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# **1. INTRODUCTION AND LITERATURE REVIEW**

The mandibular canal (MC) is an important bony structure presents in the mandible that contains a bundle of nerves and vessels including the inferior alveolar nerve (IAN) and the mandibular division of the trigeminal nerve (V3). During surgical or non-surgical endodontic treatment physical damage can occur to the contents of the MC. Therefore, a comprehensive knowledge of anatomy of the MC, its variants and relation to other anatomical structures is essential in the prevention and management of any damages to the IAN during surgical and non-surgical endodontic therapies involving mandibular teeth. It has been recommended to use CBCT to locate the MC course and relation to mandibular teeth prior to dental surgical procedures. Furthermore, due to its availability and its conservative nature, CBCT have been used as a tool to study the morphological characteristics of the MC, its course and its intra-bony location of different ethnic groups.

## **1.1 The relation between the mandibular canal anatomy and endodontic treatment**

The mandibular canal (MC) is an important bony structure in the mandible. It begins at the mandibular foramen in the middle third of the ascending ramus medially. Thereafter it runs obliquely downward and forward in the ramus, then horizontally forward in the body till it opens in the lateral surface as the mental foramen (MF) <sup>1</sup>. MF is located either at the apex of the mandibular second premolar or between the apices of premolars<sup>2</sup>. It contains the inferior alveolar nerve (IAN), vessels and lymph and together they are called the inferior alveolar neurovascular bundle<sup>3</sup>.

Despite several anatomical descriptions of the MC, there is no general agreement on its course and pattern of its distribution<sup>4</sup>. Juodzbalys et al.<sup>5</sup> in their review in 2010,

concluded that 70% of MC had an “S” shaped course within the body of the mandible. It is located more to the lingual surface of the mandible in the molars area, and, as it stretches forwards to the front part (mesial) of the mandible, it comes closer to the buccal surface. They also concluded that inferior alveolar neurovascular bundle exists in different locations and has many variations. It can also be influenced by different factors such as gender, race and degree of edentulous alveolar bone atrophy of the mandible.

The IAN innervates the mandibular molars, premolars and the proximal parts of the gingiva. It gives a branch known as the mental nerve, which is its largest branch, that exits the mandible through the MF. Three nerve branches emerge from the mental foramen. One innervates the skin of the mental area, and the other two proceed to the skin of the lower lip, mucous membranes, and the gingiva as far as the second premolar posteriorly. The incisive branch, a continuation of the IAN, supplies the canine and incisor teeth<sup>6</sup>.

In general, most endodontic procedures such as local anesthesia administration<sup>7</sup>, root canal preparation and irrigation<sup>8</sup>, root canal filling<sup>9</sup>, and surgical endodontic treatments<sup>10</sup>, that are performed in close proximity to the MC and its contents including IAN may cause a nerve injury<sup>9</sup>. Pogrel et al reported that impaired sensation due to a mental nerve injury is an infrequent but severe complication of endodontic treatment<sup>11</sup>. Injuries to the inferior alveolar and mental nerves have been reported several times in second mandibular molars and mandibular premolars<sup>12</sup>. Endodontic treatment-related nerve injuries can result from several reasons such as chemical, mechanical or thermal trauma to the neurovascular bundles. This can be either through direct trauma to the nerves during the treatment or indirect by a

secondary edema that develops after the treatment that results in an increased pressure inside the MC <sup>13</sup>. Nerve injuries were also often reported following local anesthesia administration (mostly mandibular nerve block). The exact reason is unknown, but it can be as a result of a direct contact with the needle, hemorrhage into the nerve, or neurotoxicity from the local anesthetic itself <sup>7,11</sup>.

Orstavik et al. <sup>14</sup> in a study they reviewed 24 cases with extruded endodontic filling materials beyond the apices of mandibular posterior teeth. They noticed that the overfilled second premolars and molars were more likely to be involved with paresthesia of the lip than other mandibular posterior teeth. Endodontic root canal filling materials can induce paresthesia via mechanical or chemical mechanisms. Their spread beyond the apical foramen can result in clinical manifestations related to the toxicity of the product or the mechanical force and pressure to the nerve <sup>15,16</sup>.

The risk of nerve injury during surgical and non-surgical endodontic therapies that involves mandibular teeth is a big concern to any dentist or endodontist. Therefore, several assessment and diagnostic tools have been proposed to avoid such injuries<sup>10</sup>. One of these tools is the comprehensive knowledge of the anatomy of the MC, its variations and relation to other anatomical structures and the effect of ethnicity/race on such variations. Such information is now available through several studies that have investigated the MC course, MF formation location in different populations. These studies were conducted using human cadavers as study model, or by analyzing images produced by different medical radiological methods. The section below describes these methods in detail.



## **1.2 Methods of inspecting mandibular canal**

The methods which are used for locating and studying the pattern of the MC would have a significant impact on our understanding and interpretation of the data. It is crucial to understand these different methods, including their advantages and drawbacks, in order to enhance our judgment and analysis of the data produced by these methods<sup>5</sup>.

### **1.2.1 Human cadaver's studies (dry mandibles)**

Dry mandibles or dissection method is an in vitro method involving obtaining dry mandibles from human cadavers. This method is a traditional method and used to describe the anatomy of human body. Dry mandibles have been used in deferent studiess to investigate the MC course, MF formation location<sup>17,18</sup>.

Littner et al. (1986).<sup>17</sup> used dry mandibles and the measurements was obtained by radiographs. The study was performed on forty-six randomly chosen dry mandibles. The molar areas of each mandible were radiographed by paralleling technique, and an additional radiograph at -20 ° angulation of the same area were taken. They found in most cases that the canal was buccal to the second molar and lingual to the first molar.

Whereas Denio et al. <sup>18</sup> in 1992 studied the spatial relationship of the mandibular canal to the posterior teeth in dried mandibles. Twenty-two mature dried mandibles were sectioned through the root apices of the first and second premolars and molars. Each section containing both the tooth and surrounding bone was photographed at an exact double-sized enlargement on a duplicator stand and measurements was obtained using a Boley gauge on each photograph.

## 1.2.2 Medical radiological methods

### 1.2.2.1 Panoramic radiography

Panoramic imaging is a technique for producing a single tomographic image of the facial structures that include both the maxillary and mandibular arch and their supporting structure. It is a curvilinear variant of conventional tomography and is based on the reciprocal movement of an x-ray source and an image receptor around a central point or plane called the image layer in which the object of interest is located.<sup>19</sup>

Its major disadvantage is that it is a 2-D image which will not provide an accurate and precise measurements especially for small details. Nevertheless, it has been widely used in the classification of the course of the MC.

In 1977, Nortje et al.<sup>20</sup> studied of a total of 3612 panoramic radiographs to locate and classify the MC. The main conclusion of this study was that MC are usually, but not invariably, have bilaterally symmetrical, and the majority of hemi-mandibles contain one major canal.

In other study, Sato et al.<sup>21</sup> in 2005 used panoramic radiograph on a total of 75 mandibles from adult Japanese cadavers. They made different measurements including the distance from the upper border of the mandibular canal to the apices of the mandibular teeth.

### 1.2.2.2 Computed tomography

Computed tomography (CT) is a 3-dimensional analysis that uses multiple exposures to a fan shaped X-ray beam to show the inner complex anatomy of an object. It was introduced into the endodontics field by Tachibana and Matsumoto in 1990. CT scans have the advantages of identifying the anatomical configuration of

teeth and their association with the periodontal tissues. Furthermore, CT makes it possible to determine buccolingual and mesiodistal diameters of teeth as well as the presence or absence of root canal filling materials and metal posts<sup>22</sup>.

In 2011, Forum et al.<sup>23</sup> used 41 CT scans and measured the distance between root apices and the MC. They concluded that pre-extraction CT scans may present a useful diagnostic aid to assess the risk of inferior alveolar nerve injury and lingual plate perforation.

The main disadvantages of CT are: 1) it requires a high radiation dose, 2) it is expensive, 3) it involves large equipment that requires a vast amount of space, 4) it involves a time-consuming scanning process, and 5) it has poor resolution for investigating small anatomical areas (such as root canal systems)<sup>22</sup>

#### 1.2.2.3 Micro-computed tomography

Micro-computed tomography (MCT) is a non-invasive 3-dimensional imaging tool used to produce magnified images of small object. A tremendous amount of data can be collected from MCT scans. Models can be assessed qualitatively and quantitatively by slices reconstruction in any plane. Data can be interpreted as 2-dimensional or 3-dimensional images. The disadvantage of this technique, as with all other in vitro experimental studies, is that teeth are typically collected from patients of unknown age, sex, and race<sup>24</sup>.

Massey et al.<sup>25</sup> in 2013 studied MCT images of 16 cadaveric hemimandibles. Each hemimandible was then sectioned at 6 predetermined locations between the ramus and the mental foramen, to yield 5 cortcocancellous bone specimens. The superior, inferior, buccal and lingual distances for bone surrounding the MC were measured by direct digital caliper. Their findings indicates that MCT is a reliable method to locate and describe the course of MC.

Hur et al. in 2011, also used MCT to locate the IAN within the MC in 30 hemifaces of embalmed Korean cadavers. They found that the incidence of bifid canals of MC was 23.3%.<sup>20,26</sup>

#### 1.2.2.4 Cone-beam computed tomography

Cone-beam computed tomography (CBCT) is a diagnostic imaging system introduced in the late 1990 particularly to generate three-dimensional images of the maxillofacial skeleton at a significantly lower radiation dose than CBCT<sup>27,28</sup>.

CBCT involves a significantly lower radiation dose, shorter exposure period (ranging from 2 to 5 seconds), is cheaper than conventional CT scanning, and can be very accurate<sup>29</sup>. Additionally, images produced by CBCT are geometrically precise because the CBCT voxels (3-dimensional pixels carrying data) are isotropic. On the other hand, CBCT has a disadvantage related to its large pixel size, which leads to low resolution and may produce errors in the identification of complex and very small features such as the root canal system.<sup>28</sup>

CBCT has the potential to overcome most of the limitations of conventional two-dimensional radiography by generating geometrically accurate, three-dimensional images of the area under investigation, making it more appropriate as an adjunct system in endodontics than other systems<sup>30</sup>. In addition, adjacent anatomical noise can be easily eliminated by the three orthogonal planes that can be created using slices<sup>28,31</sup>.

On the other hand, x-ray beam artefacts such as cupping artefacts (i.e. distortion of metallic structure), and the manifestation of streaks and dark bands between two dense structures<sup>31</sup>, arising when x-ray beam CBCT strikes a very high-density object, such as enamel or metallic posts and crowns, are major problems that

considerably downgrade image quality and diagnostic accuracy of CBCT<sup>32</sup>. This may lead to inappropriate CBCT-based decision-making and treatment planning<sup>28</sup>.

In 2014 Cantekin et al.<sup>33</sup>, compared CBCT and panoramic radiograph in detecting mandibular anatomical landmarks. Their study included one hundred panoramic and CBCT images from one hundred children and adolescent. In panoramic images, the MC could be observed in 92.5% of cases, with good visibility in 12%. While in CBCT images, the mandibular canal could be observed in 100% of the cases with good visibility in 51%. This shows the superiority of CBCT for visualization of the MC over panoramic radiographs.

CBCT have the advantage that it is a non-invasive tool that allows analysis to be done in vivo, which facilitates the correlation with race, gender, age, and specific clinical scenarios<sup>34</sup>. Nevertheless, clinicians must have appropriate training for the CBCT and must ensure that the radiation doses to patients are maintained as low as reasonably achievable (ALARA)<sup>35</sup>.

### **1.3 Classification of the course of the mandibular canal**

The MC usually courses from posterior to anterior and from lingual to buccal directions in the mandible. Often the path of the canal demonstrates a curve in all three anatomical planes. Many attempts have been done to classify the course of the mandibular canal. In this section the most widely used classifications will be discussed.

#### **1.3.1 Carter and Keen study (1971)**

In a study using gross and microscopic dissection of eight mandibles, Carter and Keen<sup>36</sup>, described three distinctive courses of the canal relative to the pattern of distribution of the inferior alveolar nerve and formulated morphological types.

Type I: The IAN was a single large structure lying in a bony canal. The branches supplying the molar were very short and direct (Figure 1).

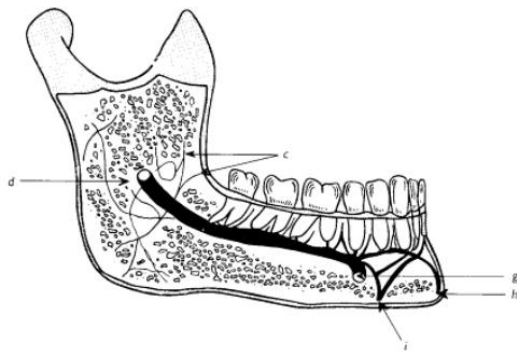


Figure 1. Type I

Type II: the IAN was situated substantially lower down in the mandible at some distance from the molar roots. The dental branches branched off more posteriorly and were consequently longer and more oblique than in type I (Figure 2).

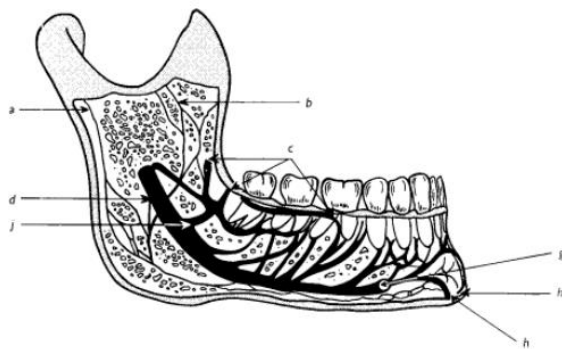
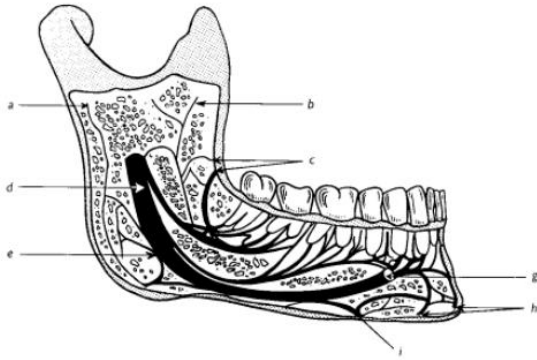


Figure 2. type II

Type III: The IAN gave off a separate molar branch shortly after entering the mandibular foramen, while the main trunk of the IAN occupied a more inferior position and continued toward the mental foramen (Figure 3).



**Figure 3.** Type III

### 1.3.2 Nortje et al. (1977)

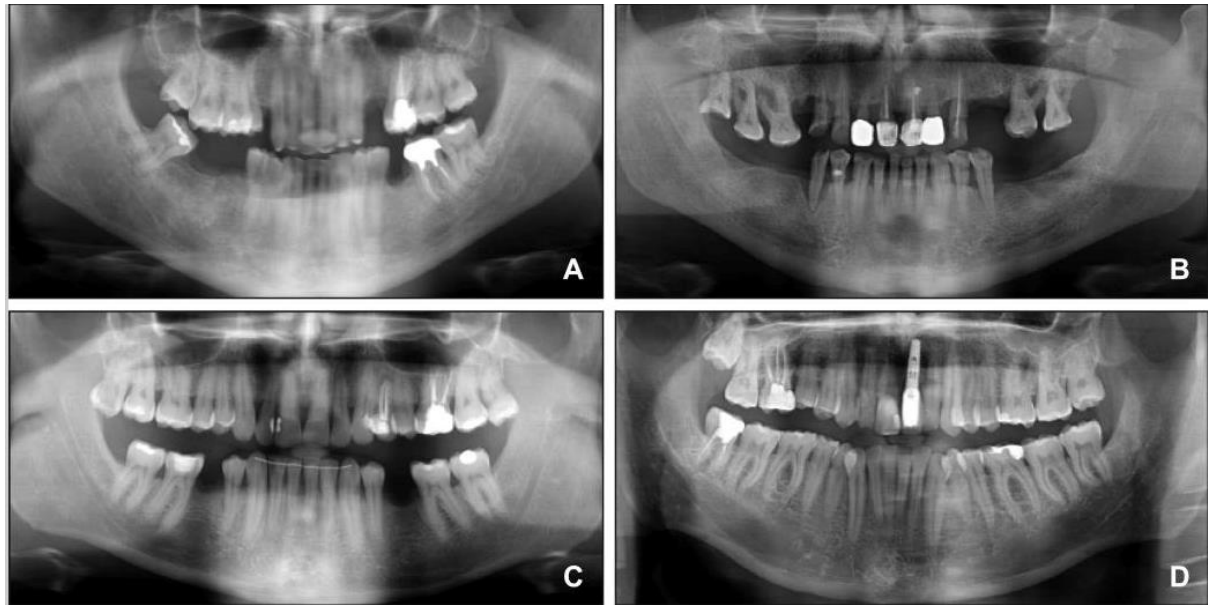
The position in the vertical plane of the MC was evaluated from 3612 panoramic radiographs<sup>20</sup>. The MC courses on panoramic radiographs were divided into four categories (Figure 4), namely:

Type I: Bilateral single high mandibular canals- either touching the apices or within 2 mm of the apices of the first and second permanent molar teeth (Fig. 4.A)

Type II: Bilateral single intermediate mandibular canals- not fulfilling the criteria for either high or low canals (Fig.4.B)

Type III: Bilateral single low mandibular canals- either touching or within 2 mm of the cortical plate of the lower border of the mandible (Fig.4.C)

Type IV: Other variations- includes duplication or division of the canal (Fig.4.D)



**Figure 4. Nortje classification** A= type I, B= type II, C= Type III, D= type IV

Of the 3612 radiographs, 48% of the canals were high, 49% were low, and only 3% could not be fitted into high or low canal categories. The main conclusion was the mandibular canals are usually, but not invariably, bilaterally symmetrical and contain single major canal.

### 1.3.3 Liu et al. (2009)

Liu and coworkers in 2009<sup>37</sup>, described four different courses of the mandibular canal (Figure 5) following the assessment of 386 panoramic radiographs:

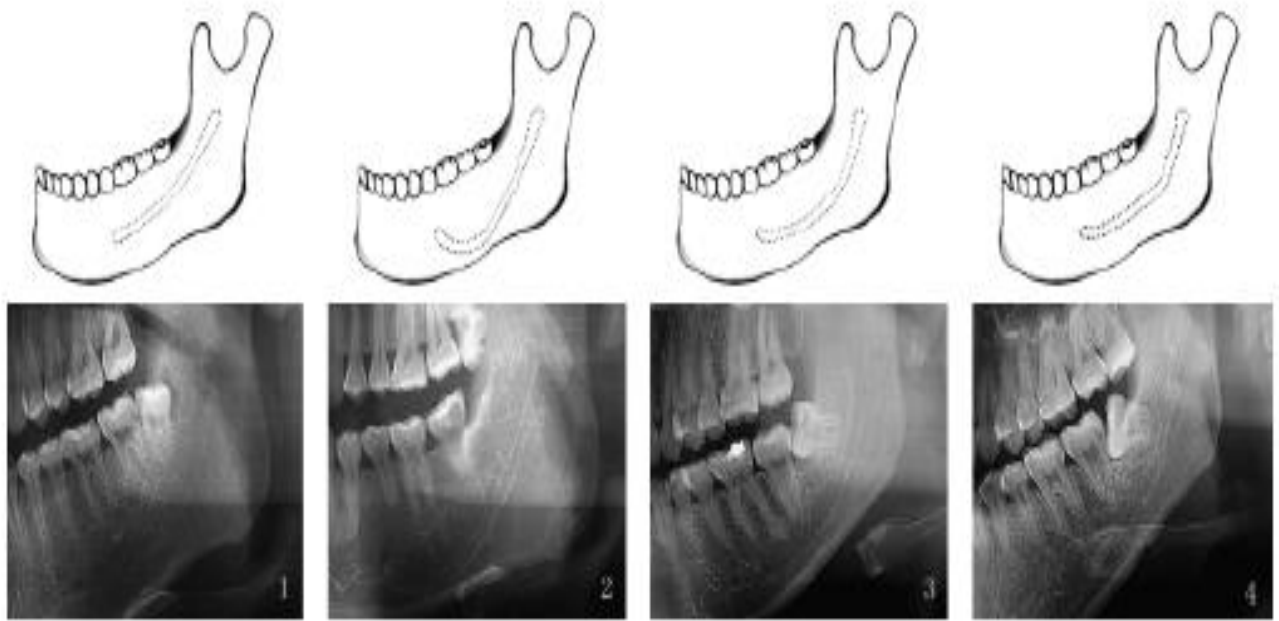
Type I: Linear curve, approximate to straight line (Figure 5, 1)

Type II: spoon-shape curve, approximate to a spoon shape which is similar to dissymmetry elliptic (Figure 5, 2)

Type III: elliptic curve, approximate symmetry (Figure 5, 3)

Type IV: turning curve, an unsmooth course which has a turning point (Figure 5, 4)





**Figure 5.** Liu et al. classification

Among the four types, Type I, a steep ascent, had the smallest curvature. Type III was the most common (48.5%). Type II had the largest curvature and the highest bone height above MC.

#### **1.4 The mental foramen location**

MF is an opening located on the anterolateral aspect of the mandible which represents the end of the mandibular canal. The MF contains nerves and vessels that provide sensory innervations and blood supply to important facial structures<sup>38</sup>. A detailed knowledge of MF morphometry is significant to preserve integrity of the mental nerve bundle in surgical interventions such as apicectomy, implant placement and anesthetic block.

Gershenson et. al. <sup>39</sup> in 1986 in their study they tried to find the common location of the MF using 525 dry mandibles. They found that the MF was located in front of

mandibular second premolar root's apex in 43.6% of the cases. In another study on human dry mandibles, Phillips et. al. in 1990 studied 75 adult human mandibles to determine the location of the MF. They found that the common location of the MF was inferior to the crown of the mandibular second premolar.

In a CBCT study of the MF location in Arabic population in 2017, 395 CBCT scans were analyzed, and they found that the most common location of mental foramen was in line with the long axis of the mandibular second premolar in 41.3%<sup>40</sup>.

### **1.5 Distance of the canal to the buccal, lingual and lower border of the mandible**

The course of the MC is important in dentistry especially in planning for surgeries such as implant placement, surgical endodontic procedures and surgical extractions. Unfortunately, studies of the course of the MC and the distances to the lingual, buccal and inferior borders are limited. The previous studies mainly illustrate the branching pattern of the IAN from the MC to the teeth.

Denio et. al. in their study on 22 mature dried mandibles, described the course of the MC as a typical S-shaped configuration and it was located buccal to the distal root of the second molar, crossed the lingual below the second molar mesial root, ran lingual to the first molar and crossed back to the buccal apical to the apex of the second premolar<sup>18</sup>.

Liu et al. in 2009 used 386 OPG to study the course of the canal, they found that the shortest distance between the inferior border of MC and the inferior border of the mandible was at the position of the first molar ( $7.56 \pm 1.62$  mm) and longest at the third molar ( $10.28 \pm 2.77$ mm)<sup>37</sup>.

In a CBCT study of the MC in 52 adult skulls, Ozturk et. al. in 2012 concluded that the MC was located either in contact with or close to the lingual border of the

mandible (< 2mm) in the molar region of the majority of the cases. As it proceeds anteriorly it moves toward the buccal border of the mandible, where it finally exits the mandible as the MF<sup>41</sup>.

### **1.6 The relation of mandibular canal and root apices**

The distance between the mandibular canal and the adjacent root apices is probably the most clinically relevant distance from the clinician perspective<sup>8,10,13</sup>. As a consequence, previous knowledge of the common distance separating the MC from the apices of mandibular posterior teeth is essential prior to any intervention in the area of the posterior mandible<sup>10</sup>.

Littner et al.<sup>17</sup>, studied the proximity of the MC and the apices of the mandibular teeth in 46 dried adult mandibles with the use of radiographs. They found that, most frequently, the upper border of the MC was located 3.5 to 5.4 mm below the root apices of the first and second molars.

In a similar study, Denio et al.<sup>18</sup>, twenty-two mature dried mandibles were sectioned through the root apices of the first and second premolars and molars. Second premolars and second molars had the closest distances to the canal with a mean of 4.7 mm and 3.7mm, respectively. With the mean of 6.9 mm, the apices of the mesial roots of the first molars were farthest from the canal.

Sato et al.<sup>21</sup> in 2005, examined 75 mandibles of Japanese cadavers with the use of panoramic and CBCT radiography. They found the distance from the upper border of the MC to the apex of the first molar was larger than that of the second molar however not exceeded 10 mm in the examined samples.

In 2011 Kovisto et al.<sup>42</sup> tried to relate the proximity of the root apices to the MC to age and gender. They analyzed CBCT scans of 139 patients by subgrouping them by

age and sex. In all groups, root apices of mandibular second molars were closer to the MC than other teeth. The mesial root of the second molar was closer to the nerve in female patients compared with male patients. Root apices in younger patients (< 18 years) were generally closer to the MC than in older patients.

In a study of a German population in 2015, 627 full size CBCT scans were analyzed. A total of 821 second mandibular premolars and 597 first, 508 second, and 48 third mandibular molars were included, and the mean distances were 4.2, 4.9, 3.1, and 2.6 mm, respectively. They observed that patients that are younger than 35 years had significantly shorter distances from the MC to the root apices compared with older patients. The authors concluded that a direct communication between root apices and MC is not rare and must be taken into consideration when performing surgical or endodontic procedures<sup>43</sup>.

An attempt was done to compare 3 different populations in term of the relation between the root apices and the MC in 2018<sup>44</sup>. Random 1224 CBCT scans from Isreal (408 scans), South Korea (416 scans), and India (400 scans) were selected and examined. The mean distance for all measurements between the MC and root apices was 4.81mm. They found that the average distance from the MC and the first molar was 6.18 mm for the mesial root and 5.54mm for the distal root, and for the second molar 4.09 mm for the mesial root and 3.42 mm for the distal root. The distance in samples obtained from South Korea was significantly larger than the distance in samples obtained from the other 2 populations. They concluded in their study that a difference in the distance of the apices to the IAN exists between populations.

Aljarbou et al.<sup>45</sup> in 2019, evaluated the relationship of the first and second mandibular molar roots to the MC using 60 CBCT scans in Saudi population. They

found that the mean distance between the root apices of the mandibular molars and the MC ranged from 1.68-4.79 mm.

**Table 1.** List of studies that investigated the relation of MC with the root apices.

<b>Study/year</b>	<b>Population</b>	<b>Methods</b>	<b>Sample size</b>	<b>2<sup>nd</sup> premolar</b>	<b>1<sup>st</sup> molar</b>	<b>2<sup>nd</sup> molar</b>
<b>Littner et al. (1986)<sup>17</sup></b>	<b>Unknown</b>	<b>Dry mandibles (radiographs)</b>	<b>42 right</b>	-----	<b>M root:</b> <b>5.5+/-</b> <b>2.48</b> <b>D root:</b> <b>5.4 +/-</b> <b>2.31</b>	<b>M root:</b> <b>3.9+/- 2.13</b> <b>D root:</b> <b>3.5+/- 2.06</b>
			<b>42 left</b>		<b>M root:</b> <b>5.3+/-</b> <b>2.11</b> <b>D root:</b> <b>5.4+/-</b> <b>1.91</b>	<b>M root:</b> <b>4.1+/- 2.16</b> <b>D root:</b> <b>3.7+/- 1.94</b>
<b>Denio et al. (1992)<sup>18</sup></b>	<b>Unknown</b>	<b>Dry mandibles</b>	<b>22 mandibles (264 sections)</b>	<b>4.8+/- 3.1</b>	<b>M root:</b> <b>7.3+/- 3.4</b> <b>D root:</b> <b>7.2+/- 4.3</b>	<b>M root:</b> <b>5.3+/- 2</b> <b>D root:</b> <b>5.2+/-2.3</b>
<b>Sato et al (2005)<sup>21</sup></b>	<b>Japanese</b>	<b>Panoramic on cadaveric mandibles</b>	<b>75 mandibles (135 teeth)</b>	-----	<b>M root:</b> <b>10.6+/-</b> <b>4.9</b> <b>D root:</b>	<b>M root:</b> <b>7.9+/- 4.4</b> <b>D root:</b> <b>7.0+/- 4.5</b>

					<b>9.9+/-4.7</b>	
<b>Kovisto et al. (2011)<sup>42</sup></b>	<b>Not mentioned</b>	<b>CBCT</b>	<b>139 patients</b>	<b>&lt;18 years</b>	<b>&lt;18 years</b>	<b>&lt;18 years</b>
				<b>Males: 1.8</b>	<b>Males: M:1.5 D:1.4</b>	<b>Males: M:1.3 D:1.2</b>
				<b>Females: 1.7</b>	<b>Females M:1.4 D:1.2</b>	<b>Females M:1.0 D:0.6</b>
				<b>18-49 years</b>	<b>18-49 years</b>	<b>18-49 years</b>
				<b>Males: 4.2</b>	<b>Males: M:4.3 D:3.8</b>	<b>Males: M:2.6 D:2.0</b>
				<b>Females: 2.9</b>	<b>Females M:3.0 D:3.0</b>	<b>Females M:1.6 D:1.4</b>
				<b>&gt;49 years</b>	<b>&gt;49 years</b>	<b>&gt;49 years</b>
				<b>Males: 3.8</b>	<b>Males: M:4.8 D:4.7</b>	<b>Males: M:4.3 D:3.8</b>
				<b>Females: 2.6</b>	<b>Females M:2.8 D:2.9</b>	<b>Females M:2.0 D:1.6</b>

<b>Burklein et al. (2015)<sup>43</sup></b>	<b>German population</b>	<b>CBCT</b>	<b>627 patients</b>	<b>All: 4.9+/-2.5 Males: 4.6+/-2.4 Females: 4.0+/-2.3</b>	<b>All: 4.9+/-2.5 Males: 5.6+/-2.4 Females: 4.0+/-2.3</b>	<b>All: 3.1+/-2.3 Males: 3.8+/- 2.3 Females: 2.8+/-2.1</b>
<b>Aljarbou et al. (2019)<sup>45</sup></b>	<b>Saudi population</b>	<b>CBCT</b>	<b>60 patients</b>	<b>----</b>	<b>M root 4.79+/- 2.29 D root: 4.28+/- 2.12</b>	<b>M root: 2.33+/-2.16 D root: 1.68+/-1.98</b>

## **2. AIM OF THE STUDY:**

To identify the relative position of the MF and describe the morphological characteristics of the MC, its intra-bony location, and relation to the apices of mandibular posterior teeth in a sub-group of Emirati population.

### **2.1 Specific objectives**

In order to achieve the aim of the study, the following objectives were formulated:

- Identify the bilateral location of MF and its relation to the mandibular teeth
- Measure the bilateral distance between the MC and the root apices of mandibular posterior teeth (1<sup>st</sup>, 2<sup>nd</sup> molars and 2<sup>nd</sup> premolars)
- Measure the bilateral distance between MC and buccal, lingual and inferior mandibular outer cortex.
- Describe the bilateral intra-bony course and configuration of the MC.
- Investigate the possibility of correlation between age and gender with the MF and with the course and location of the MC



### 3. MATERIAL AND METHODS:

#### 3.1 Samples:

This is a retrospective study, and the CBCT scans have already been obtained as part of an approved and completed master thesis project at HBMCDM. These scans were obtained from patients who have been treated at HealthPoint dental center (HDC), HealthPoint, Mubaddala, Abu Dhabi, United Arab Emirates, between 2017-2018. The CBCT scans were taken as part of treatment plans. Every patient treated at HDC signs a consent form which allows for research use of available patient data. All CBCT scans were acquired using Orthophos SL (Dentsply Sirona, USA) using a standard imaging protocol (CBCT at HDC are taken by same technician, using same CBCT machine with same parameters; 85 Kv, 7 mAs, with exposure time of 5 seconds, voxel size of 0.15 mm and field of view 8 cm x 8 cm). Institutional review board approvals for collecting the CBCT scans were already obtained from HBMCDM and HDC (HDC IRB: REC009), and new IRB approval from HDC and MBRU have been obtained to use the same CBCT scans for the purpose of this study (HDC IRB: MF2467-2020-11) and attached in appendix 1-3.

The following formula was used for sample size calculation:

$$n = \left(\frac{Z \delta}{E}\right)^2 \dots\dots\dots (I)$$

And E given by

$$E = Z \frac{\delta}{\sqrt{n}} \dots\dots\dots (II)$$

Where  $Z$  is the quartile of 95% which is equal to 1.96 and  $\delta$  is the standard deviation of the difference between the two samples and  $E$  the width of 95% CI of the difference.

Owing to the data from study by Shokry et al 2019 <sup>46</sup>

For female (68) average is 9.2 (SD= 1.03)

For male (56) average is 10.9 (SD= 1.5)

Using the equation of pooled variance estimate

$$S^2 = \frac{n_1*s_1^2+n_2*s_2^2}{n_1+n_2} \dots\dots\dots (III)$$

Then the common variance is 1.597913 and standard deviation is 1.264086 and

$$E = 1.96 * (1.264086/\text{SQRT}(124)) = 0.2$$

Using the common deviation above and the total number of 124 the sample size is given by

$$N = \frac{(1.96*1.264086)^2}{(0.02)^2} = 153$$

The sample size is 153 subjects. <sup>46 47</sup>

### **3.2 Selection criteria:**

CBCT scans of patients who meet the following criteria were included in the study:

- Inclusion criteria
  - Emirati population
  - Fully matured and erupted mandibular teeth
  - Age from 16-75 years old.
  
- Exclusion criteria
  - One or more missing mandibular premolars or molars bilaterally
  - Supernumerary or impacted teeth affecting the measurements
  - Large pathological lesion
  - Mandibular fracture or a history of mandibular fracture treated with surgical plates

### **3.3 Radiographic evaluation and data collection**

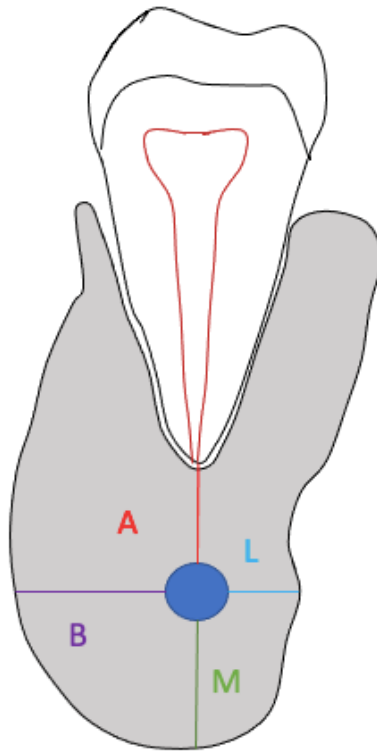
The available CBCT scans from HDC have already been anonymized using Horos imaging software, ensuring all patient identifiers were removed except age and gender. Furthermore, HDC serves only Emirati nationals for dental treatment, satisfying the first inclusion criteria of involving only Emirati nationals for the study. The principle investigator (Dr.Abdulaziz Alazemi) reviewed all available CBCT scans. Based on the selection criteria, 77 CBCT scans from the year 2017 and 77 CBCT scans from the year 2018 have been randomly selected to reach 154 CBCT scans. The randomization for the scans for each of the years was done using Microsoft Excel. CBCT scans taken in year 2017 were assigned random numbers. These scans were then reordered based on the assigned numbers and the first 77 scans satisfying the inclusion criteria were chosen for the study. The same exercise was repeated to randomly choose 77 CBCTs for the year 2018 as well.

The principle investigator evaluated all scans on an iMAC computer (27-inch screen size with Retina 5K display, 5120 × 2880 resolution with support for 1 billion colors, 500 units brightness) in a room with controlled lighting using Horos DICOM viewer. The intra-bony MC location has been assessed using a 3-dimensional multiplanar reconstruction (3D MPR) tool which examination in the axial, coronal, and sagittal plans. The PI trained before the evaluation process by evaluating a sample of CBCT scans and under the supervision of the study supervisor. Moreover, the PI have read 25% of the scans twice with 3 months interval for intra-rater reliability and data validation.

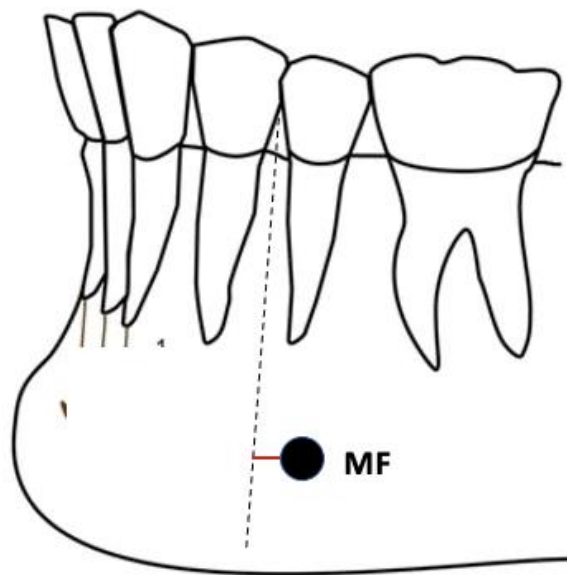
The evaluator recorded the following measurements:

- The distance between the MC and the root apices, linear line has been drawn from superior outer surface of the MC to the root apex on the coronal plan of the CBCT scans (Figure 6, red line)
- The distance between MC and buccal, lingual and inferior mandibular outer cortex, 3 linear lines have been drawn on the coronal plan. First line will be from the outer cortex of the buccal side to outer buccal surface of MC (Figure 6, purple line). Second line from the outer cortex of the lingual side to outer lingual surface of MC (Figure 6, blue line). The third line from the outer cortex of the inferior side to outer inferior surface of MC(Figure 6, green line).
- The location of the MF, a vertical line has been dropped apically from the contact point between the mandibular premolars. Then, another perpendicular line has been drawn from this line to the mesial border of MF. When the center of the mental foramen is distal to this line, a negative value will be assigned to this measurement and when it is mesial to it will have a positive value (Figure 7).<sup>48</sup>

Finally, the findings were tabulated, analyzed and correlated with age and gender.



**Figure 6.** Illustration of the coronal view. A= apical, B= buccal, L= lingual and M= inferior border of the mandible



**Figure 7.** Illustration of the sagittal view, MF= mental foramen

### **3.4 Statistical analysis**

Data was entered in computer using SPSS for windows version 25.0 (SPSS Inc., Chicago, IL). The Measurements were tested for normality by using Shapiro-Wilk / Kolmogorov-Smirnov test as appropriate. The measurement was described by means and standard deviation and with 95%CI, bars and Error bars were used to describe graphically the MF location measurements. Where two continuous independent variables (MF locations) were examined, independent t-test if the measurement are normally distributed. In case of non-normality of measurement Mann-Whitney test for continuous related data. Correlation coefficient was used to test the association between Age and location of MF in relation with the premolars. The intra-rater reliability was examined using paired t-test.

### **3.5 Ethical considerations**

This study was conducted in full conformance with principles of the “Declaration of Helsinki”, Good Clinical Practice (GCP), and within the laws and regulations of the UAE/DHCC/HAAD. Institutional review board approvals for collecting the CBCT scans were already obtained from HBMCDM and HDC (HDC IRB: REC009), and new IRB approval from HDC and MBRU have been obtained to use the same CBCT scans for the purpose of this study (HDC IRB: MF2467-2020-11) and attached in appendix 1-3.

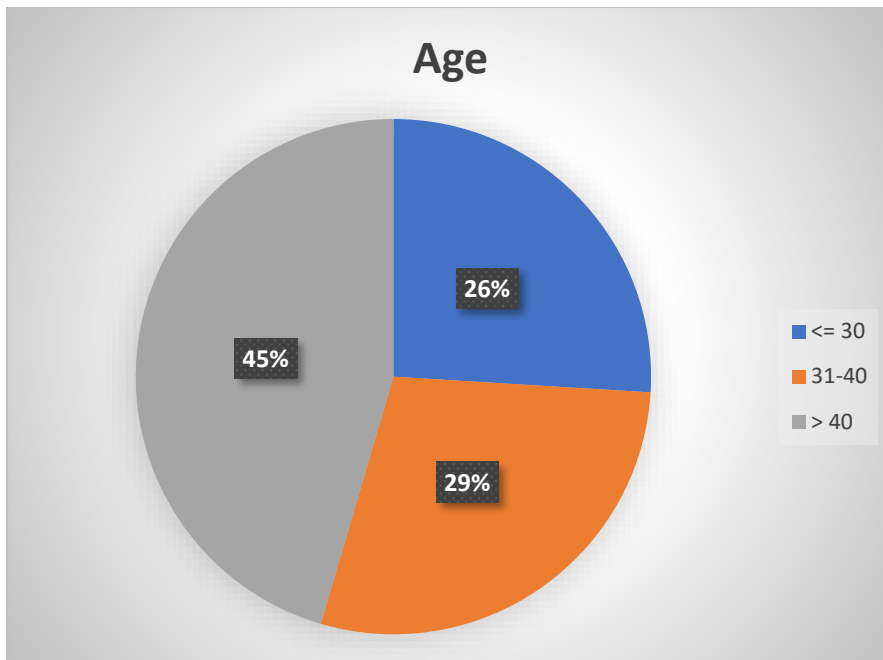
## 4. RESULTS

Overall, 3700 CBCT scans were taken from January 2017 to December 2018; these were reviewed, and 154 scans were selected based on inclusion and exclusion criteria. Examining the selected patients' scans details showed that 72 patients (46.8%) were female, while 82 patients (53.2%) were male (Table 2). Selected patients' age ranged from 16 to 71 years; more specifically, 26% were younger than or aged 30, 28.5% were between 31 and 40 years and 45.5% were older than 40 years (Figures 8-10).

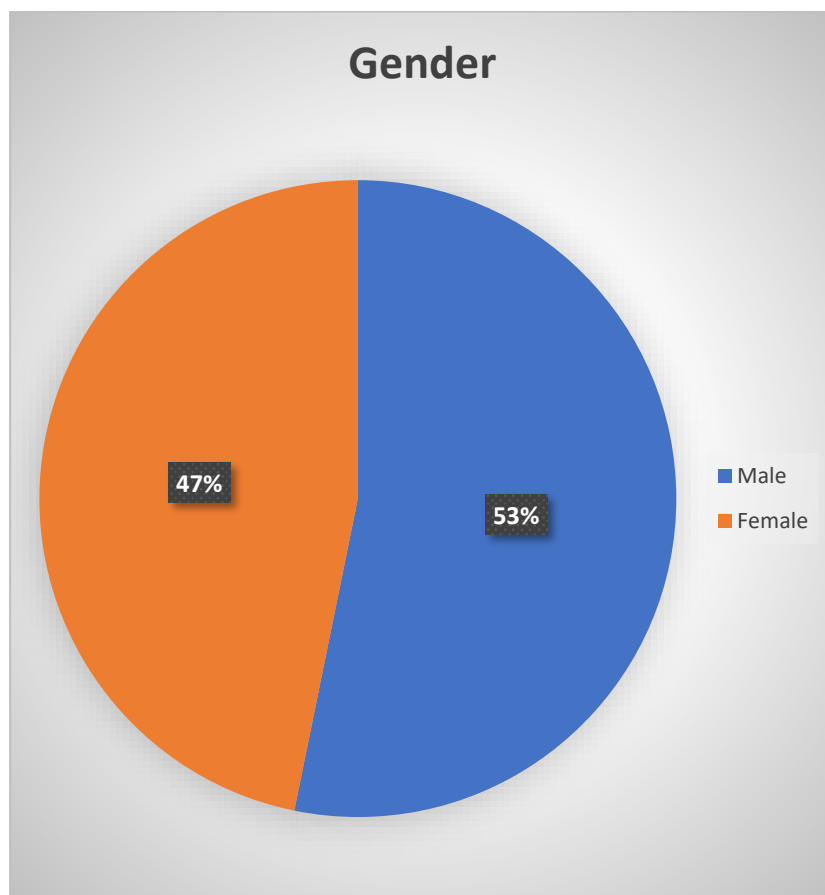
**Table 2.** Demographical data of patients

	Age			Gender	
	<= 30	31-40	> 40	Male	Female
Frequency	40	44	70	82	72
Percentage	26%	28.6%	45.5%	53.2%	46.8%

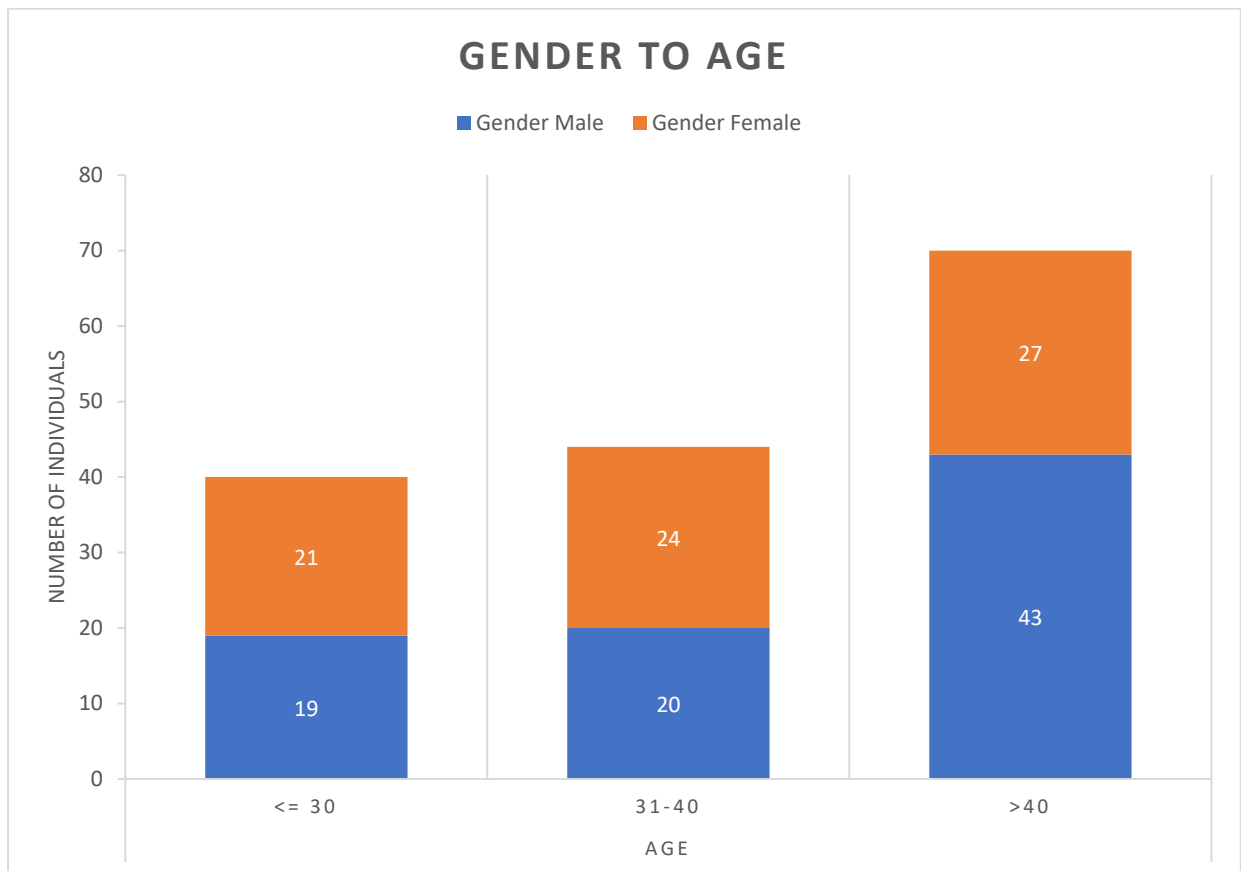




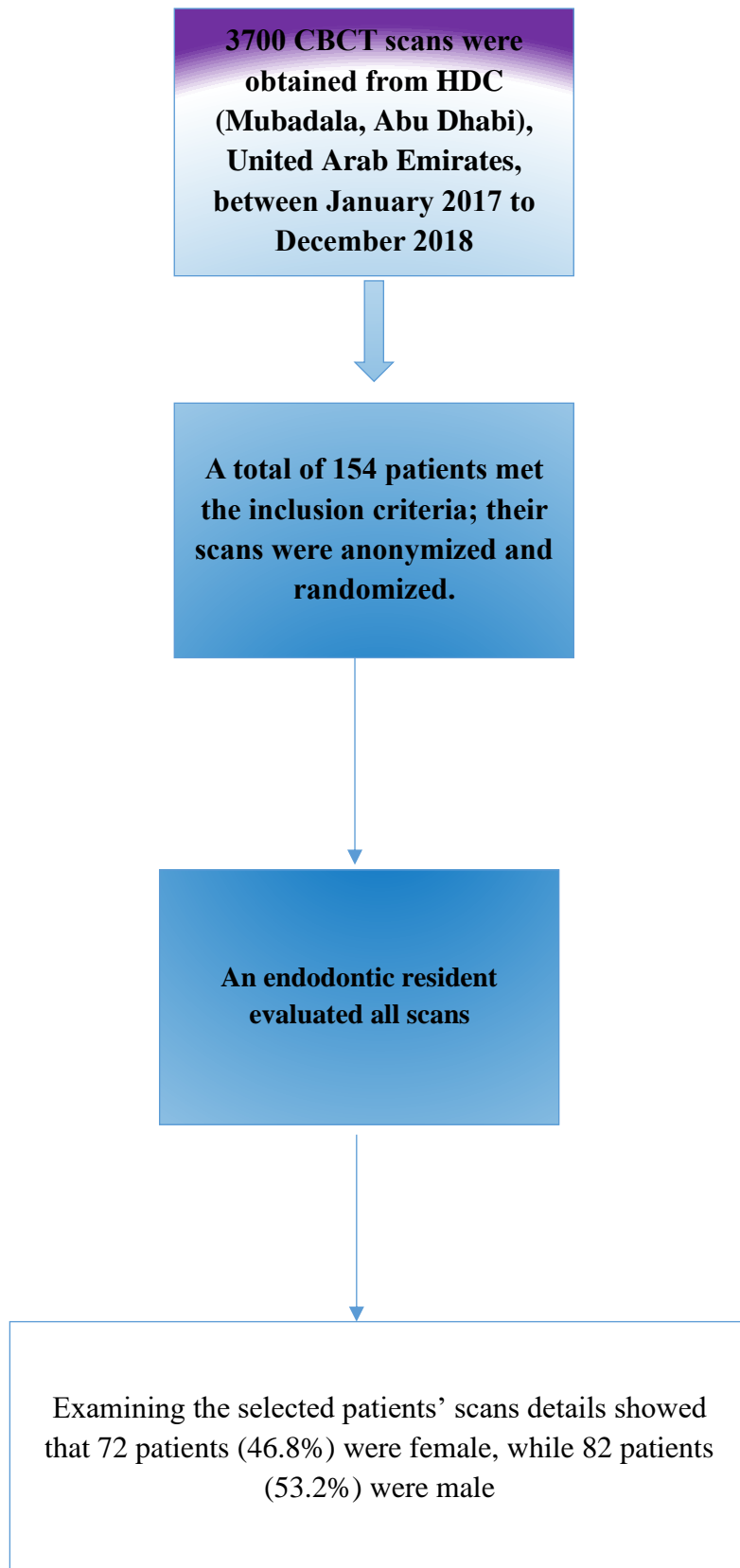
**Figure 8.** Pie chart represent age distribution



**Figure 9.** Pie chart represent Gender distribution



**Figure 10.** Bar chart showing distribution of gender according to age



**Figure 11.** Research outline

As planned, the principal investigator evaluated the 154 CBCT scans for the right and left side of the mandible starting from the first premolar to the distal root of the second molar. Moreover, the location of the mental foramen was measured in relation to the premolars for the left and right sides for all the scans (Figure 11). The results of the intra-rater reliability tests showed nearly perfect intra-rater agreement ( $r= 0.99$  and  $P <0.001$ ).

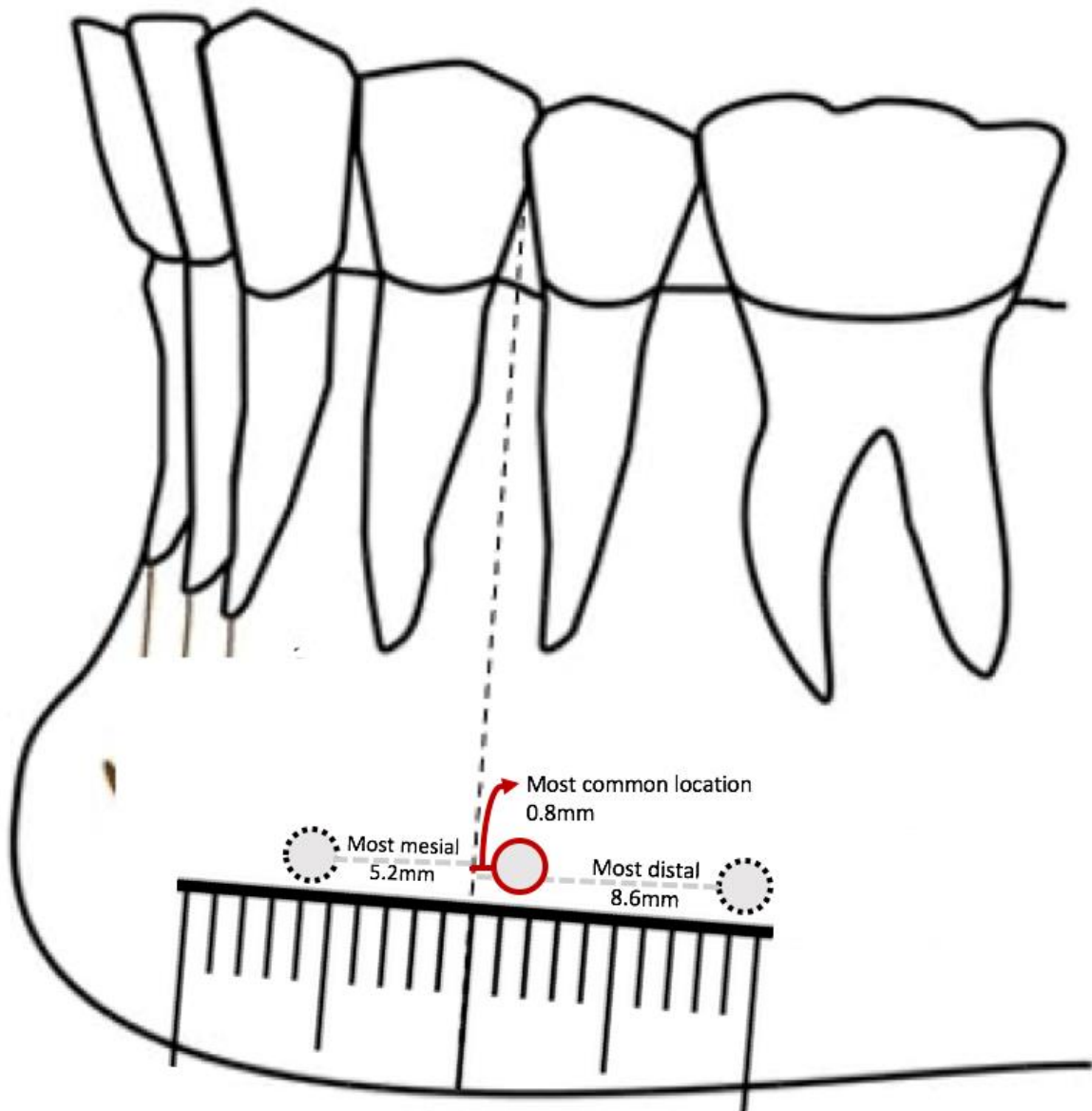
#### 4.1 The anatomical relations

##### 4.1.1 Mental foramen relation with the first and second premolars

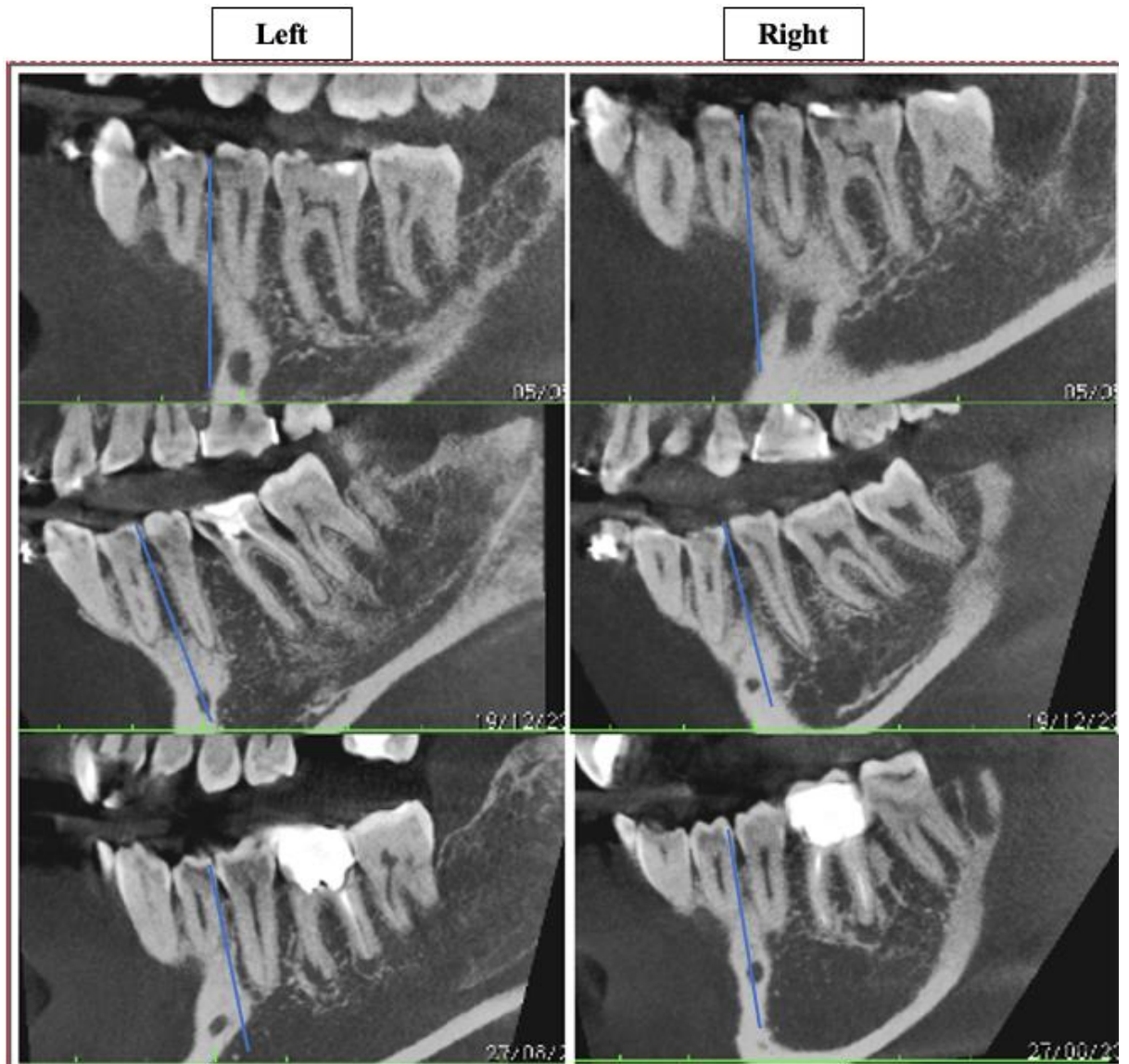
Overall, the reading of the distance from the mesial border of the mental foramen with the line drawn from the contact point of the premolars showed that the mean distance for the left side of the mandible was distal to the line by  $0.63\text{mm} \pm 2.54$ , and for the right side distal to the line by  $0.2\text{mm} \pm 2.42$ . Whereas the cumulated overall mean distance of the location of the mental foramen in relation with the premolars was distal by  $0.83\text{mm} \pm 1.84$  as shown in Table 3 (Figures 12,13). The most distal location was 8.6mm, while the most mesial location was 5.2mm.

**Table 3.** Distance from MF to the line between 1<sup>st</sup> and 2<sup>nd</sup> premolars

<b>Foramen</b>	<b>Mean (SD)</b>	<b>95% CI</b>
Left side	-0.63 (2.54)	[ 0.81, 1.98]
Right side	-0.2 (2.42)	[ 0.65, 2.12]
Total	-0.83 (1.84)	[0.4,1.27]



**Figure 12.** Illustration showing the mean distance between the line and the mental foramen

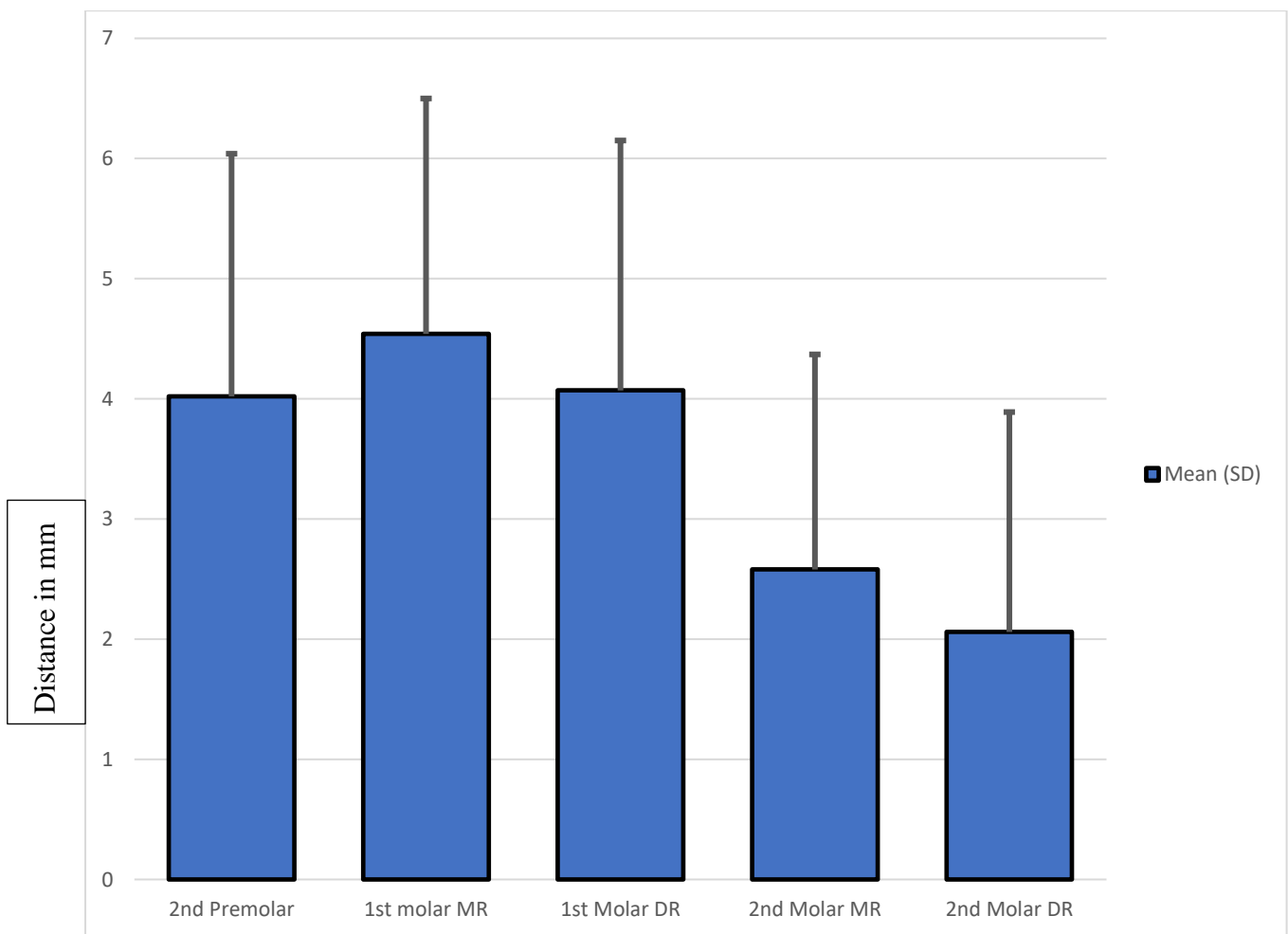


**Figure 13.** Deferent locations of MF

#### 4.1.2 The distances between the root apices and the inferior alveolar canal

The distances of the root apices with the superior border of the MC were measured for the left and right sides of the mandible in the coronal view for all 154 scans. The mean distances in relation to the second premolar, mesial and distal roots of the first molar and mesial and distal roots of the second molar were  $4.02\text{mm} \pm 2.02$ ,  $4.54\text{mm} \pm 1.96$ ,  $4.07\text{mm} \pm 2.08$ ,  $2.58\text{mm} \pm 1.79$  and  $2.06\text{mm} \pm 1.83$  respectively. All

measurements are listed in Table 4 (Figure 14). Comparing the different distances, shows that both the mesial and distal roots of the mandibular second molar were significantly closer to the MC when compared to their respective roots of the mandibular first molar ( $P<.001$ ). Moreover, the distal root of the mandibular second molar was significantly closer to the MC than the mesial root ( $P<.05$ ). Comparisons are illustrated in Figure 15.

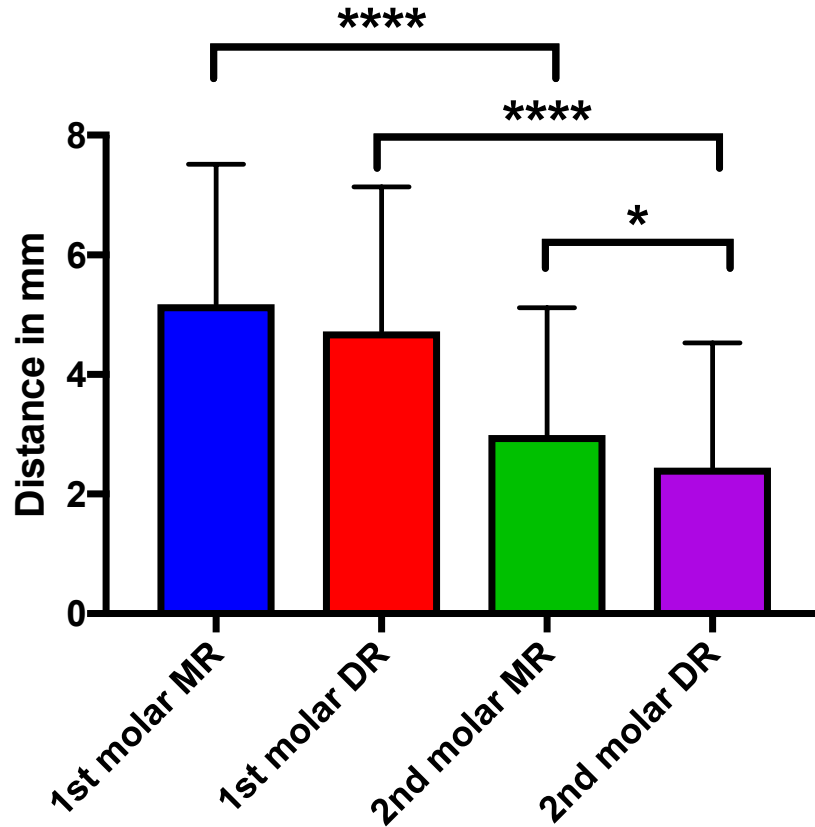


**Figure 14.** Bar chart showing the distances between the root apices and the MC. Error bar equals the SD

**Table 4.** Distances between the root apices and the MC (A), MR= mesial root, DR= distal root

Tooth	Left side		Right side		Total	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
2 <sup>nd</sup> premolar	4.01 (2.27)	[3.26, 4.77]	3.84 (2.3)	[3.05, 4.62]	4.02 (2.02)	[3.55, 4.5]
1 <sup>st</sup> molar MR	4.36 (2.29)	[3.56, 5.16]	4.37 (2.4)	[3.57, 5.17]	4.54 (1.96)	[4.08, 5]
1 <sup>st</sup> Molar DR	4 (2.37)	[3.18, 4.82]	3.5 (2.46)	[2.63, 4.38]	4.07 (2.08)	[3.58, 4.56]
2 <sup>nd</sup> Molar MR	2.64 (2.14)	[2.13, 3.16]	2.28 (0.97)	[1.65, 2.91]	2.58 (1.79)	[2.16, 3]
2 <sup>nd</sup> Molar DR	1.95 (2.06)	[1.39, 2.51]	1.65 (2.12)	[1.09, 2.21]	2.06 (1.83)	[1.63, 2.5]





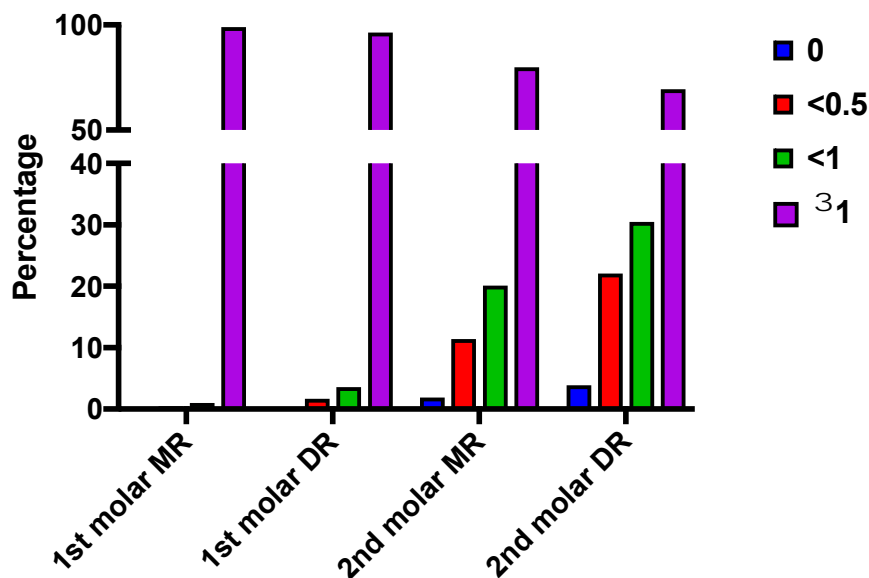
**Figure 15.** Distances between root apices of 1<sup>st</sup> and 2<sup>nd</sup> molars and MC

Furthermore, the different distances of the root apices to the MC have been categorized in to 4 categories: (A) at the MC (distance = 0mm), (B) within 0.5 mm, (C) within 1mm and (D) more than 1mm, from the MC. None of the apices of the mesial and distal root of the mandibular first molars were at the MC. While the apices of the mesial and distal roots of the mandibular second molars were at the MC in 1.9% and 3.9% of the studied samples. The distal root's apex of the mandibular second molars was within 0.5mm of the MC in 22.1% of the cases when compared to the mesial root's apex which was 9.4%. Almost 30.5% of the studied distal root apices of the mandibular second molars were within 1mm of the MC, while 69.5% were more than 1mm from the MC. Most of the studied samples, had

their mesial and distal root apices of the mandibular first molars to be more than 1mm from the MC (99% and 96.4% respectively). (Table 5, Figure 16).

**Table 5.** The four categories of distances between the 1<sup>st</sup> and 2<sup>nd</sup> molar and MC

	0	<0.5	<1	>1
1st molar MR	0%	0.3%	1.0%	99.0%
1st molar DR	0%	1.7%	3.6%	96.4%
2nd Molar MR	1.9%	11.4%	20.1%	79.9%
2nd molar DR	3.9%	22.1%	30.5%	69.5%



**Figure 16.** Percentage of the distances between the root apices and the MC

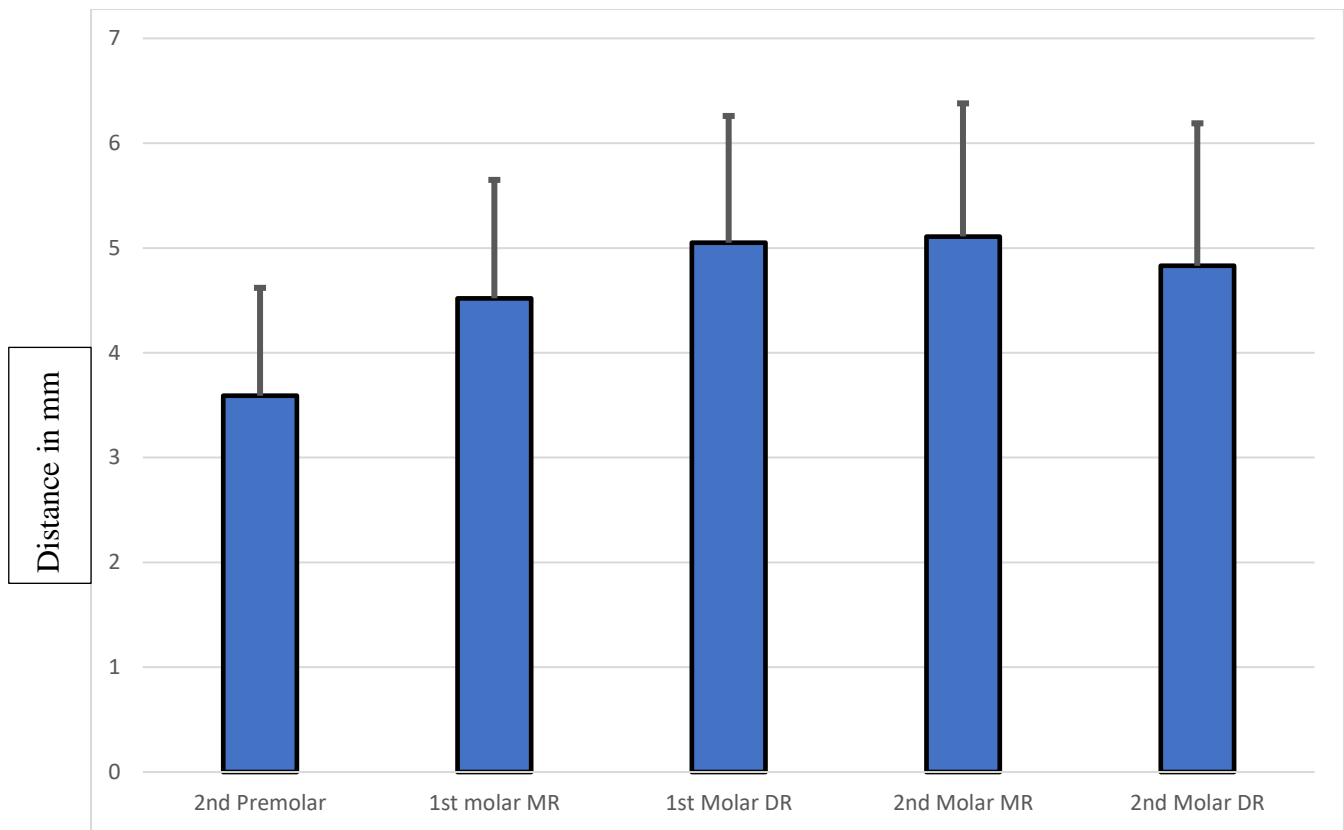
Moreover, it was noticed that the mesial and distal roots' apices of the mandibular first molar were within 2mm, 3mm and 4mm from MC in 8-13%, 19-26% and 35-43% of all studied samples. While the mesial and distal roots' apices of the mandibular second molar were within 2mm, 3mm and 4mm from MC in 38-51%, 55-66% and 71-80% of all studied samples.

**Table 6.** Percentage of the distances between the root apices of the 1<sup>st</sup> and 2<sup>nd</sup> molars and the MC

Percentage				
	1st molar MR	1st molar DR	2nd Molar MR	2nd molar DR
<2mm	8%	13%	38%	51%
<3mm	19%	26%	55%	66%
<4mm	35%	43%	71%	80%

#### 4.1.3 The distances between the buccal aspect of the mandible and the MC

The distances between the buccal aspect of the mandible with the MC in relation to the mandibular teeth were measured for the left and right sides of the mandible in the coronal view for all 154 scans. The mean distances in relation to the second premolar, mesial and distal roots of the first molar and mesial and distal roots of the second molar were 3.59mm ± 1.03, 4.52mm ± 1.13, 5.05mm ± 1.21, 5.11mm ± 1.27 and 4.83mm ± 1.36 respectively. All measurements are listed in Table 7 (Figure 17).



**Figure 17.** Bar chart showing the distances between the buccal aspect of the mandible and the MC. Error bar equals the SD

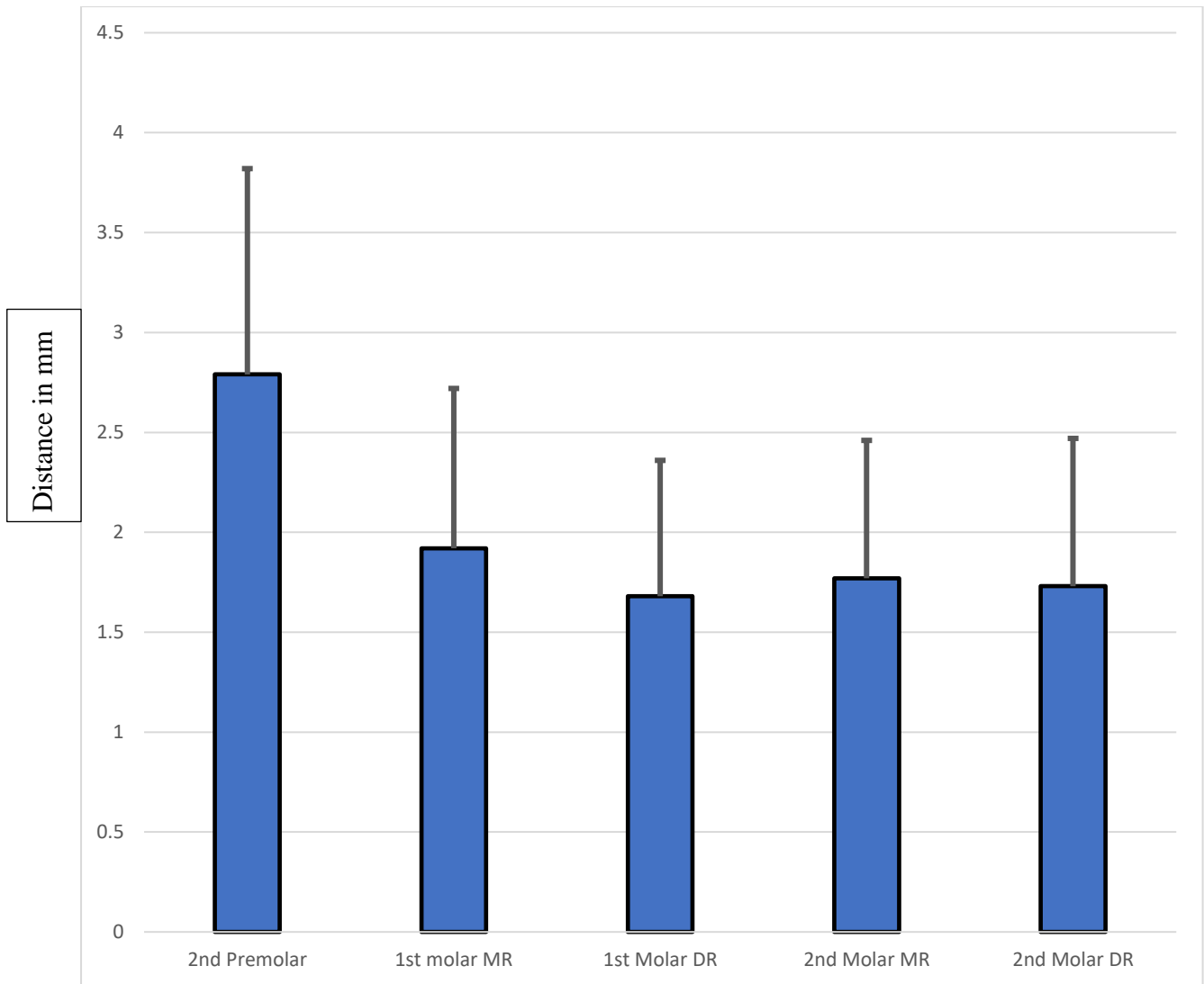
**Table 7.** Distance between the MC and buccal surface of the mandible (B)

Tooth	Left side		Right side		Total	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
2 <sup>nd</sup> premolar	3.77 (1.21)	[3.34, 4.2]	3.78 (1.05)	[3.41, 4.15]	3.59 (1.03)	[3.35, 3.84]
1 <sup>st</sup> molar MR	4.51 (1.4)	[4.07, 4.94]	4.72 (1.27)	[4.3, 5.13]	4.52 (1.13)	[4.25, 4.78]
1 <sup>st</sup> Molar DR	5.15 (1.33)	[4.76, 5.54]	5.32 (1.32)	[4.9, 5.73]	5.05 (1.21)	[4.77, 5.34]

2 <sup>nd</sup> Molar MR	4.87 (1.35)	[4.42, 5.31]	5.51 (1.57)	[4.98, 6.05]	5.11 (1.27)	[4.82, 5.41]
2 <sup>nd</sup> Molar DR	4.71 (1.47)	[4.25, 5.17]	5.35 (1.72)	[4.68, 6.03]	4.83 (1.36)	[4.51, 5.15}

#### 4.1.4 The distances between the lingual aspect of the mandible and the MC

The distances between the lingual aspect of the mandible with the MC in relation to the mandibular teeth were measured for the left and right sides of the mandible in the coronal view for all 154 scans. The mean distances in relation to the second premolar, mesial and distal roots of the first molar and mesial and distal roots of the second molar were  $2.79\text{mm} \pm 1.03$ ,  $1.92\text{mm} \pm 0.8$ ,  $1.68\text{mm} \pm 0.68$ ,  $1.77\text{mm} \pm 0.69$  and  $1.73\text{mm} \pm 0.74$  respectively. All measurements are listed in Table 8 (Figure 18).



**Figure 18.** Bar chart showing the distances between the lingual aspect of the mandible with the MC. Error bar equals the SD

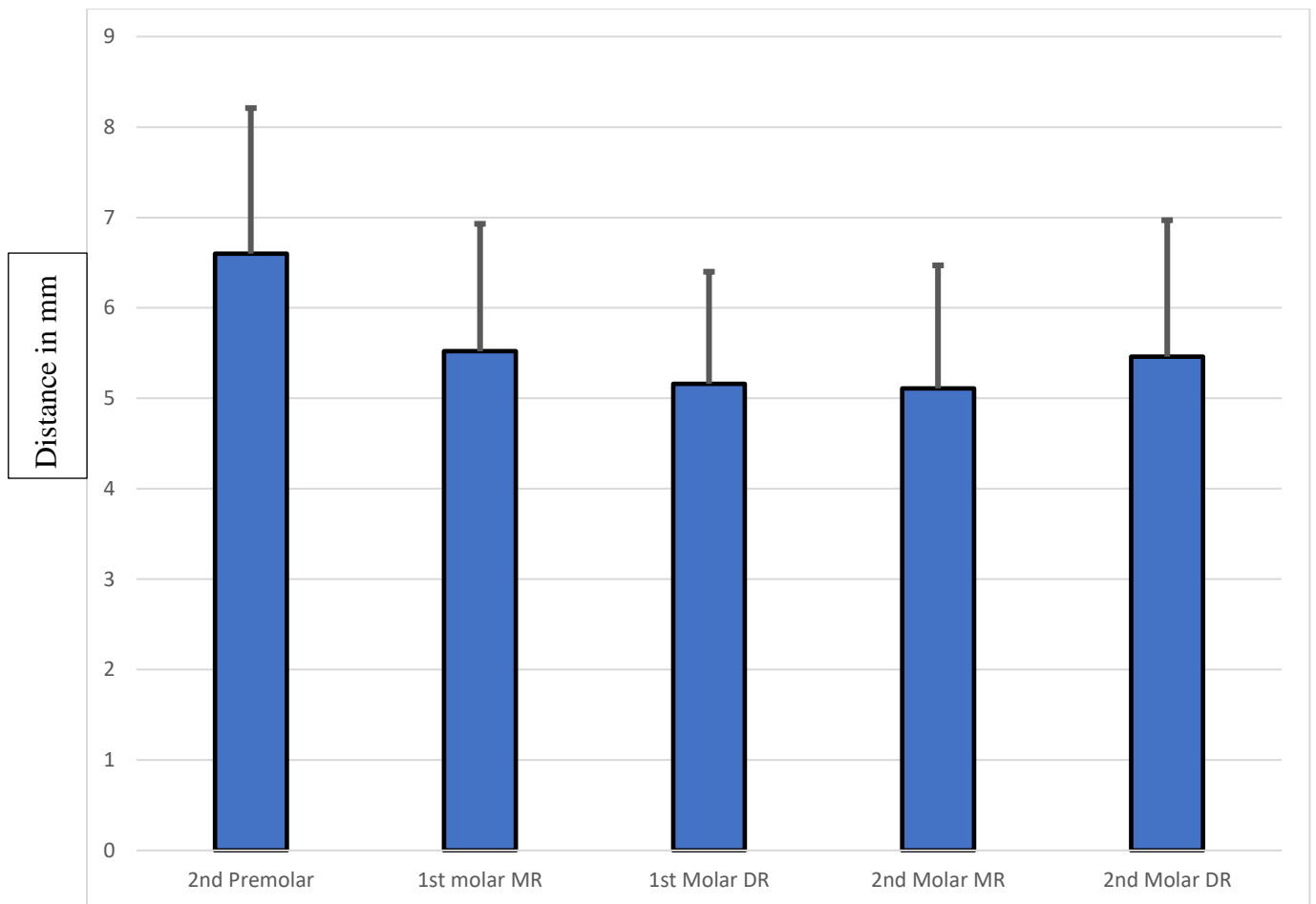
**Table 8.** Distance between the MC and Lingual surface of the mandible (L)

Tooth	Left side		Right side		Total	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
2 <sup>nd</sup> premolar	2.68 (1.59)	[2.29, 3.07]	2.75 (1.03)	[2.37, 3.12]	2.79 (1.03)	[2.55, 3.03]
1 <sup>st</sup> molar MR	1.84 (1.11)	[1.48, 2.19]	1.87(0.74)	[1.6, 2.14]	1.92 (0.8)	[1.73, 2.11]
1 <sup>st</sup> Molar DR	1.69 (0.9)	[1.42, 1.96]	1.64 (0.73)	[1.37, 1.9]	1.68 (0.68)	[1.52, 1.84]

2 <sup>nd</sup> Molar MR	1.89 (0.88)	[1.57, 2.21]	1.69 (0.83)	[1.39, 1.99]	1.77 (0.69)	[1.61, 1.94]
2 <sup>nd</sup> Molar DR	1.67 (0.68)	[1.42, 1.92]	1.82 (1.02)	[1.44, 2.19]	1.73 (0.74)	[1.56, 1.9]

#### 4.1.5 The distances between the inferior border of the mandible and the MC

The distances between the inferior border of the mandible with the MC in relation to the mandibular teeth were measured for the left and right sides of the mandible in the coronal view for all 154 scans. The mean distances in relation to the second premolar, mesial and distal roots of the first molar and mesial and distal roots of the second molar were  $6.6\text{mm} \pm 1.61$ ,  $5.52\text{mm} \pm 1.41$ ,  $5.16\text{mm} \pm 1.24$ ,  $5.11\text{mm} \pm 1.36$  and  $5.46\text{mm} \pm 1.51$  respectively. All measurements are listed in Table 9 (Figure 19).



**Figure 19.** Bar chart showing the distances between the inferior border of the mandible with the MC. Error bar equals the SD

**Table 9.** Distance between the MC and inferior border of the mandible (M)

Tooth	Left side		Right side		Total	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
2 <sup>nd</sup> premolar	6.17 (1.44)	[5.64, 6.7]	6.02 (1.42)	[5.5, 6.54]	6.6 (1.61)	[6.22, 6.98]
1 <sup>st</sup> molar MR	5.21 (1.55)	[4.64, 5.78]	5.02 (1.25)	[4.56, 5.48]	5.52 (1.41)	[5.19, 5.85]
1 <sup>st</sup> Molar DR	4.67 (1.36)	[4.17, 5.16]	4.97 (1.47)	[4.43, 5.51]	5.16 (1.24)	[4.85, 5.48]



2 <sup>nd</sup> Molar MR	5 (1.5)	[4.45, 5.55]	5.02 (1.67)	[4.41, 5.63]	5.11 (1.36)	[4.79, 5.43]
2 <sup>nd</sup> Molar DR	5.25 (1.69)	[4.63, 5.87]	5.71 (1.89)	[5.01, 6.4]	5.46 (1.51)	[5.12, 5.83]

#### 4.2 the relationship with gender

Statistical analysis showed that for the MF location there is no significant difference found between males and females (males  $-0.3\text{mm} \pm 2.2$  and females  $-0.5\text{mm} \pm 2.4$ ) ( $P=0.635$ ). However, the distances between root apices of mandibular teeth to the MC was significantly higher in males compared to females. Most mean distances of the MC and different border of the mandible were higher in males compared to females (with some being statistically significant, as seen in table 10). Interestingly, the distance between the lingual aspect of the mandible and the MC in relation to the mesial root of the second molar was greater in female compared to males, with statistical difference (males  $1.4\text{mm} \pm 0.7$  females  $1.9\text{mm} \pm 0.7$ ) ( $P < 0.001$ ) (Table 10).

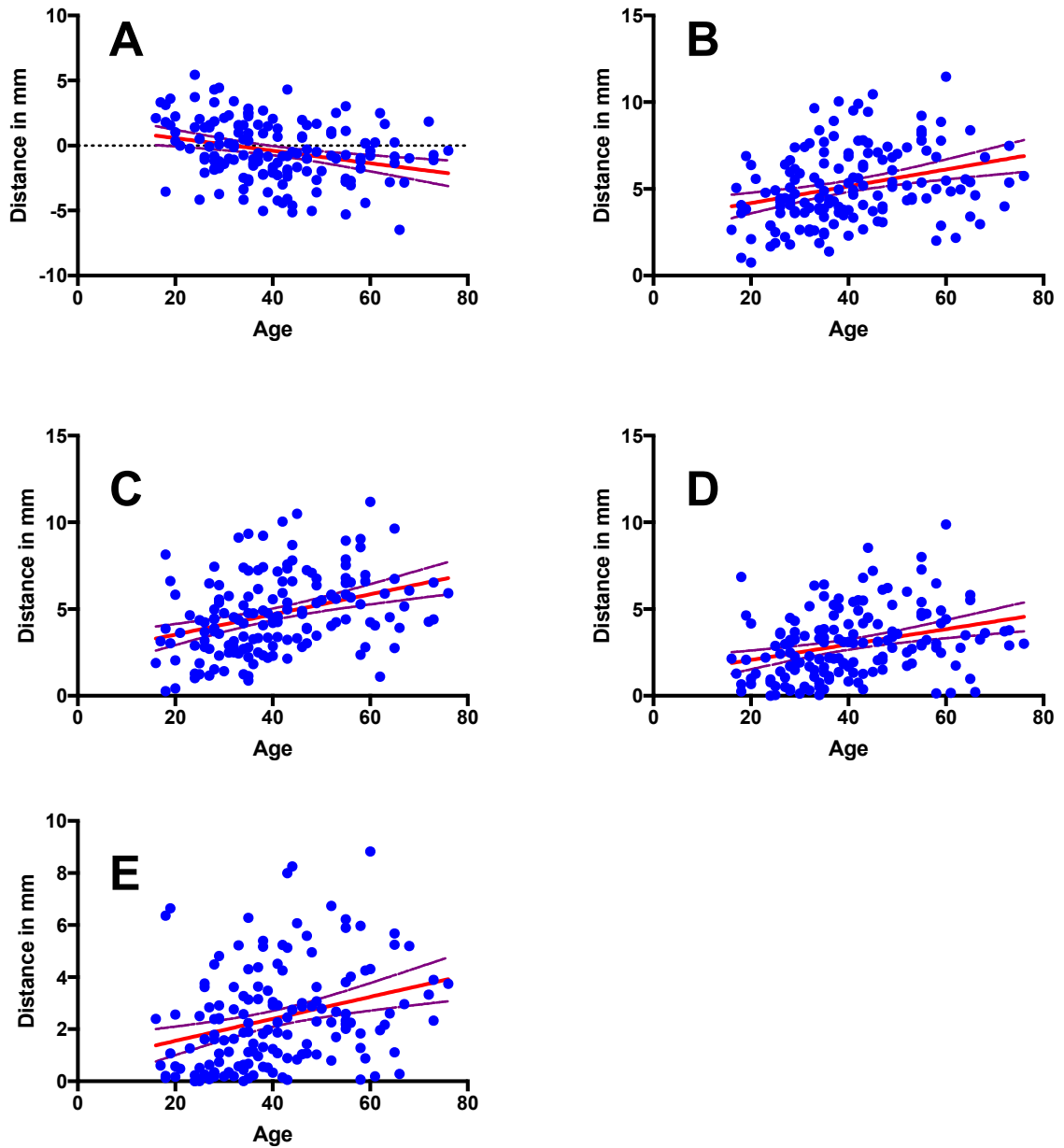
Table 10. Gender comparisons, \* statistically significant

Distance between MF and interproximal line between premolars	Gender	Mean	SD	P- value
Foramen	Male	-0.3331	2.19763	0.635
	Female	-0.5120	2.43639	
Apical distance with IAC	Gender	Mean	SD	P- value
Second premolar	Male	4.6516	2.39856	0.092
	Female	3.9167	1.93301	
Mesial root of the first molar	Male	5.7071	2.20011	0.001*
	Female	4.5900	1.97301	
Distal root of the first molar	Male	5.2999	2.28291	0.001*
	Female	4.0900	2.04641	

Mesial root of the second molar	Male	3.4710	2.09689	0.001*
	Female	2.4372	1.67752	
Distal root of the second molar	Male	2.8722	2.11662	0.002*
	Female	1.8939	1.64609	
<b>Distance between the buccal wall of the mandible and the IAC</b>	<b>Gender</b>	<b>Mean</b>	<b>SD</b>	<b>P- value</b>
Second premolar	Male	3.6329	1.05180	0.246
	Female	3.4041	.92575	
Mesial root of the first molar	Male	4.4835	1.26555	0.178
	Female	4.2265	1.05336	
Distal root of the first molar	Male	5.3271	1.23576	0.003*
	Female	4.7389	1.14163	
Mesial root of the second molar	Male	5.6797	1.37317	0.009*
	Female	5.1161	1.25300	
Distal root of the second molar	Male	5.4801	1.40120	0.005*
	Female	4.8360	1.33550	
<b>Distance between the lingual wall of the mandible and the IAC</b>	<b>Gender</b>	<b>Mean</b>	<b>SD</b>	<b>P- value</b>
Second premolar	Male	2.8546	1.27768	0.853
	Female	2.8944	.87565	
Mesial root of the first molar	Male	2.0217	.91446	0.162
	Female	2.2238	.85067	
Distal root of the first molar	Male	5.4473	36.27034	0.397
	Female	1.8130	.68478	
Mesial root of the second molar	Male	1.4685	.71308	<0.001*
	Female	1.9283	.78534	
Distal root of the second molar	Male	5.6033	36.62280	0.388
	Female	1.7838	.71739	
<b>Distance between the inferior border of the mandible and the IAC</b>	<b>Gender</b>	<b>Mean</b>	<b>SD</b>	<b>P- value</b>
Second premolar	Male	7.1527	1.67423	0.001*
	Female	5.9367	1.43578	
Mesial root of the first molar	Male	6.2200	1.65185	0.012
	Female	5.5632	1.32414	
Distal root of the first molar	Male	5.8498	1.71254	0.021
	Female	5.2554	1.37687	
Mesial root of the second molar	Male	5.7850	1.63660	0.006*
	Female	5.1182	1.28021	
Distal root of the second molar	Male	6.0171	1.76539	0.024
	Female	5.4086	1.42195	

### **4.3 the relationship with age**

Pearson correlation test was done to detect any relation between age and the measurements. The statistical analysis showed that there is a negative relationship between age and the location of the MF in relation with the premolars ( $P < 0.001$ ). As age increases the MF tends to be more distal to the line drawn between the premolars. In regard to the distance of the MC to the different borders of the mandible, the only significant relationship was noticed with the distances between the root apices and the MC. Here, there was significant positive relationship ( $P < 0.001$ ), in which as age increases, the distance of the root apices and MC increases. (Table 11 and Figure 20).



**Figure 20.** Scatter plot showing a linear relationship between age and distances of MC and A) MF, B) 1<sup>st</sup> molar mesial root, C) 1<sup>st</sup> molar distal root, D) 2<sup>nd</sup> molar mesial root and E) 2<sup>nd</sup> molar distal root

**Table 11.** Age comparisons, \* statistically significant

<b>Anatomic structure</b>	<b>Pearson correlation</b>	<b>P-value</b>
<b>Foramen</b>	-0.286	<0.001*
<b>Second premolar</b>	A= 0.171	0.084
	B= -0.036	0.717
	L= 0.042	0.674
	M= .307	0.007*
<b>First molar MR</b>	A= .307	<0.001*
	B= -0.091	0.267
	L= 0.109	0.181
	M= .244	0.004*
<b>First molar DR</b>	A= .354	<0.001*
	B= -0.057	0.484
	L= .189	0.019
	M= .184	0.024
<b>Second molar MR</b>	A= .307	<0.001*
	B= 0.096	0.238
	L= -0.142	0.078
	M= .222	0.006*
<b>Second molar DR</b>	A= .297	<0.001*
	B= 0.008	0.922
	L= .190	0.02
	M= .245	0.003*

## 5. DISCUSSION

MC is considered as an essential structure that is located in the mandible with its relationship with the mandibular teeth<sup>1,4,6</sup>. Determining the exact location of the MC and its proximity to the roots of mandibular teeth can represent a challenge. Failure to locate the MC and its proximity to the mandibular teeth can result in a damage to the MC and its contents during surgical and non-surgical dental procedures<sup>7-10</sup>. Therefore, identifying the common course and location of the canal can enhance diagnosing and treatment planning for different case types. Recently, a peri-radicular surgery guidelines has been published that recommends the use of CBCT scans in treatment planning and diagnosis prior to the surgery to avoid iatrogenic damage to important structures such as the MC<sup>49</sup>. The aim of this present study was to identify the relative position of the MF and to provide a comprehensive anatomical description of the MC and its relationship to mandibular posterior teeth among Emarati subpopulation based on a retrospective investigation of CBCT scans.

CBCT is used as a research tool to study the morphology of the mandible and its structures, such as the MC, for several reasons. CBCT allows a 3-dimensional assessment of teeth and their relationship to the surrounding structures. It has been successfully used to locate the MC in the mandible. Moreover, CBCT imaging technique have proven to be superior to other radiographic modalities in locating the MC<sup>33</sup>. Furthermore, CBCT is a non-invasive tool that allows analysis to be done in vivo, which facilitates the correlation with race, gender, age, and specific clinical scenarios. Finally, CBCT is widely available in many major clinical centers in the UAE, therefore, scans are readily available.

To analyze the CBCT scans and to study the MF location and MC course, we used the 3D MPR tool of the Horos software. The MC was observed, and the distance was measured to its surrounding structures (apex of the roots, lingual, buccal and inferior borders of the mandible) for each root of posterior mandibular teeth starting from the second mandibular molar to the second mandibular premolar bilaterally. Moreover, the horizontal location of the MF was identified in relation to the interproximal contact of the first and second mandibular premolars.

The 154 CBCT scans that were selected for this study covered a wide range of age (16-71 years) and were almost equally distributed between male and female patients (53.2% and 46.8% were males and females respectively). Therefore, selected sample was statistically appropriate to study the MC anatomy and to perform a correlation analysis.

### **5.1 Mental foramen**

MF is an opening located on the anterolateral aspect of the mandible which represents the end of the mandibular canal. The MF contains nerves and vessels that provide sensory innervations and blood supply to important facial structures<sup>38</sup>. The identification of the actual location of the MF aid in diagnostic, surgical, operative, prosthetic as well as in endodontic procedures.

Our analysis showed that the overall mean distance between the mesial border of the MF to the line drawn between at the interproximal contact area of the mandibular first and second premolar was distal to the line by  $0.83\text{mm} \pm 1.84$ . That means the mental foramen was commonly located between the premolars and towards the mandibular second premolar. This finding is consistent with previous

radiographic studies regarding the location of MF and distances between MF and adjacent anatomic structures<sup>40,50-56</sup>.

Gershenson et. al. <sup>39</sup> in 1986 tried to find the common location of the MF using 525 dry mandibles. They found that the MF was located in front of the apex of the root of the second premolar in 43.6% of the cases. In another study on human dry mandibles, Phillips et. al. in 1990 studied 75 adult human mandibles to determine the location of the MF. They found that the common location of the MF was inferior to the crown of the second premolar.

Moiseiwitsch et al. in 1998 studied the position of the MF in a north American, white population by regional dissection of 105 human cadavers. They found that the MF was, on average, between the mandibular premolars area<sup>57</sup>.

In a study of the position of the MF in Jordanian population, 860 panoramic radiographs were used. They concluded that the most frequent anterior-posterior position of the MF was in the area between the long axes of first and second mandibular premolars<sup>58</sup>.

In a CBCT study of the MF location in Arabic population in 2017, 395 CBCT scans were analyzed, and they found that the most common location of mental foramen was in line with the long axis of the second premolar in 41.3%<sup>40</sup>.



Our results show no significant association between the location of the MF and gender (males  $-0.3\text{mm} \pm 2.2$  and females  $-0.5\text{mm} \pm 2.4$  with  $P=0.635$ ). Therefore, the horizontal location of the MF according to our study cannot be taken as a landmark to determine gender. However, several studies found that the size and the vertical location of the MF could be an indicator in identifying gender. Pele et al. in 2021 in their systematic review they found that there is a significant difference in terms of the mean diameter of the mental foramen between males and females where it was bigger in males compared to females with a difference of up to  $0.62\text{mm}$  between them <sup>54</sup>. In another study conducted by Ghouse et al. with a sample of 60 patients from both genders (30 males and 30 females) four linear vertical measurements (D1-4) were performed on all radiographic images. The following measurements were taken, D1: vertical distance from the most inferior point on the mental foramen to the most inferior point on the base of the mandible. D2: vertical distance from the most superior point on the mental foramen to the most superior point of the alveolar crest. D3: vertical distance from the lowest point of the mandibular notch to the most superior point on the MF. D4: vertical distance from the lower point of the mandibular notch to the inferior edge of the mandibular ramus. Results showed that the mean readings between the two genders for D1-D4 values were significantly higher in males compared to females. This finding was coinciding with several studies indicating that the vertical measurements from lower mandibular border and the MF are a valid indicator for gender determination and useful in differentiating males from females<sup>59</sup>. Therefore, future studies are required in Emirati population to confirm the association of the vertical distance of MF with gender.

Another finding from our study, showed that there is a negative relationship between age and the horizontal location of the MF in relation to the premolars ( $P < 0.001$ ). That means as age increases the MF tends to be more horizontally distal to the line drawn between the premolars. In other words, the MF tends to be towards the apex of the second premolar in older individuals. A study that comes in agreement with our finding done by Al-Khateeb et al. in 2007 where they found that with advancing age, there is tendency of the MF to be in a more posterior position among Jordanians population<sup>58</sup>. On the other hand, A contradicting finding was found among Polish population, in which a study that was conducted in 2019, noticed that individuals above 45 years old, the MF was detected most frequently between the first and second premolars. Whereas, in those individuals who are below 45 years old the MF was found mostly in line with the second premolar, but the differences were not statistically significant<sup>60</sup>. This deference in findings could be attributed to the difference in ethnicity.

Many studies concentrated on the vertical position of the MF when compared to deferent age groups. In a study conducted on 525 dry mandibles, they found that in children before tooth eruption the MF is somewhat closer to the alveolar margin; during the eruption period the MF descends to halfway between the margins and in adults with the teeth preserved the MF is somewhat closer to the inferior border. With loss of teeth and bone resorption the MF moves upwards closer to the alveolar border<sup>39</sup>.

In the present study a vertical line at interproximal contact point between mandibular premolars to estimate the location of the MF as it represents an easy and clinically relevant landmark, especially during dental procedures. As discussed previously, our findings showed that the most common location of the MF in

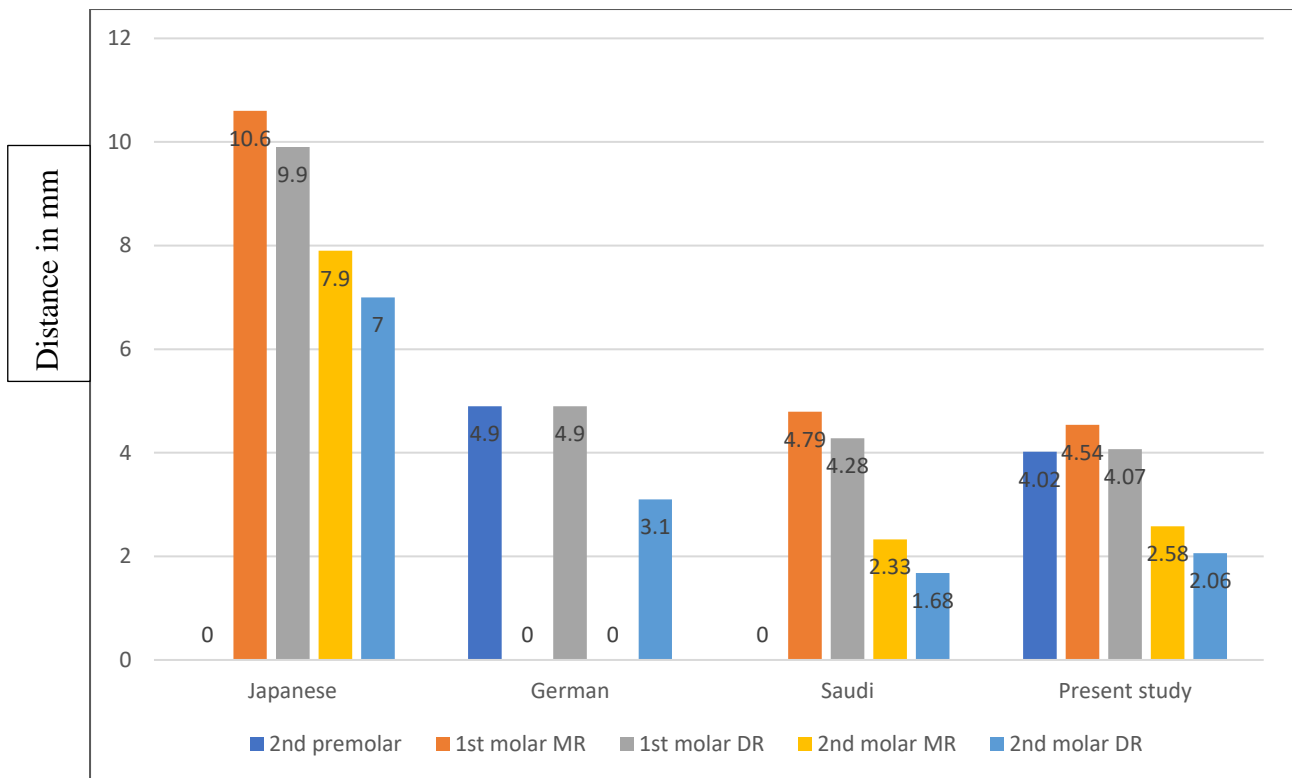
Emirati population was distal to the interproximal contact area of the mandibular premolars. This information is extremely important for clinicians treating this population, to supplement their other diagnostic tools (such as CBCT) in planning surgical and non-surgical dental procedures. For example, to ensure a successful mental nerve block, clinicians might consider the interproximal area between the premolars to be the ideal location to administer a suitable local anesthetic agent. Furthermore, in surgical procedures, that will involve a vertical incision, it will be highly recommended to avoid the interproximal area between mandibular premolars. It will be safer to have the vertical incision mesial to the mandibular first premolar or distal to the mandibular second premolar. This will aid in preventing possible iatrogenic damages to the MF and its contents. Similar recommendations were proposed by the royal college of surgeons periradicular guidelines<sup>49</sup>. Same applies to incision and drainage, surgical extraction or implant placement procedures at the mandibular posterior areas.

## **5.2 Mandibular canal**

### **5.2.1 The distance between the mandibular canal and root apices**

In our study the analysis of the mean distance between the MC and the root apices of mandibular teeth showed that the closest root to the MC was the distal root of the second molar  $2.06\text{mm} \pm 1.83$ . This comes in agreement with most previous studies where they found that the closest tooth to the MC was the mandibular second molar<sup>21,43,45</sup>. Aljarbou et al.<sup>45</sup> in 2019, evaluated the relationship of the first and second mandibular molar roots to the MC in Saudi population. After analyzing 60 CBCT scans, they found that the mean distance between the root apices of the mandibular molars and the MC ranged from 1.68-4.79 mm, with the distal root of mandibular second molar being the closest to the MC (1.68mm). In Japanese

population, Sato et al.<sup>21</sup>, examined mandibles of 75 cadavers with the use of panoramic and CBCT radiography. They found that the distance from the upper border of the MC to the apex of the first molar tooth was larger than that of the second molar. With the distal root of the second molar being the closest to the MC 7mm. Another study in German population, 627 full size CBCT scans were analyzed. A total of 821 second mandibular premolars and 597 first, 508 second, and 48 third mandibular molars were included. They found that second molar was the closest to the MC (3.1mm)<sup>43</sup>. In general, we can conclude that despite the deference in ethnicity and population, it is a consistent finding that the roots of the second molar are the closest tooth to the MC. However, Japanese population had a greater distance between the roots and the MC compared to our study and above the mentioned studies (Figure 19). Such difference in distances among different population was confirmed by another study that compared the distance of MC and root apices in 3 different populations<sup>44</sup>. Random CBCT scans from Isreal (408 scans), South Korea (416 scans), and India (400 scans) were examined. The mean distance for all measurements between the MC and root apices was 4.81mm. They found that the average distance from the MC and the first molar was 6.18 mm for the mesial root and 5.54mm for the distal root, and for the second molar 4.09 mm for the mesial root and 3.42 mm for the distal root. The distance in samples obtained from South Korea was significantly larger than the distance in samples obtained from the other 2 populations. They concluded that a difference in the distance of the apices to the MC exists between different populations.



**Figure 21.** Bar chart presenting the distances between the root apices and the MC among deferent populations

When comparing the proximity of the root apices with the MC in terms of age and gender, we found that males have a greater distance than females for all roots of mandibular teeth, except for the second premolar ( $P < 0.001$ ). Moreover, there was a significant positive relationship between the distance of the MC to root apices and age. With older individuals having a greater distance compared to young ones ( $P < 0.001$ ). These findings are consistent with studies conducted by Kovisto et al. and Burklein et al<sup>42,43</sup>. Kovisto et al. found that the mesial root of the second molar was closer to the nerve in female patients compared with male patients. In addition, they noticed that the root apices in younger patients (<18 years) were generally closer to the MC than in older patients. Whereas Burklein et al. observed that individuals that are younger than 35 years had significantly shorter distances from the MC to the root apices compared with older individuals.

The MC represents a special importance for clinicians, as it contains nerves and blood vessels which supplies the mandibular teeth and soft tissues<sup>5</sup>. Knowledge about the topography and the morphology of the MC and its distance to the root apices of mandibular teeth can prevent possible procedural errors and damage to its contents. Data from our study, shows that the distance between the mandibular second molar's distal root apex to the MC is within 0.5mm or 1mm in 22.1% and 30.5% respectively of all studied individuals. Furthermore, almost 4% of all studied samples had the distal root of the mandibular second molar at the MC. Consequently, extrusion of endodontic materials such as Sodium Hypochlorite, Calcium Hydroxide, root canal filling materials (such as Gutta Percha) or separated files, through mandibular second molar might cause transient or permanent damage to IAN. This was reported by several other studies<sup>9,11,12</sup>. Therefore, special care should be taken by clinicians when performing endodontic procedures involving mandibular second molars. Moreover, due to the reported thickness of the buccal bone over the mandibular second molars, and the close proximity of their roots' apices to the MC, apicoectomy is usual contraindicated. However, Bender et al. recommended intentional replantation procedure as an alternative option to surgical apicoectomy to avoid potential extensive damage to the buccal bone and violation of the MC<sup>61</sup>.

Our results showed that roots' apices of the mandibular first molar is within 2mm and 3 mm of the MC in 8-13% and 19-26% respectively of all studied samples. This information is extremely important for clinician performing apicoectomy procedure. As special should be taken during osteotomy, with to avoid potential violation of the MC that might results in direct damage of the neurovascular bundle housed

within MC. Therefore, pre-operative planning using CBCT is essential before performing any surgical endodontic procedure involving mandibular teeth. Furthermore, applying the latest technologies in endodontics and adopting the concept of microsurgical endodontics, will ensure a conservative bony crept preparation, therefore, avoid potential damage to the MC.

### 5.2.2 The mandibular canal course and relation to the buccal, lingual and inferior borders of the mandible

The mandible is a symmetrical bone which construct the lower third of the face. The MC starts at the mandibular foramen and runs through the body of the mandible anteriorly as it terminates as the MF<sup>5</sup>. We decided in our study to describe the course of the canal by measuring the distance between the MC and the buccal, lingual and inferior borders of the mandible in relation to each root starting posteriorly from the distal root of the second molar moving anteriorly to the second premolar. Our data suggest that the MC is located in the posterior part of the mandible close to the lingual and inferior borders of the mandible. As it extends anteriorly it moves more towards the buccal wall of the mandible and away from the inferior border of the mandible as it opens as the mental foramen. This finding of the course of the canal does not come in agreement with Denio et al. study where they found that the MC is buccal to the roots of the mandibular second molar<sup>18</sup>.

Our results showed that the shortest distance between the MC and the buccal border of the mandible is at the area of the root of the second premolar ( $3.59\text{mm} \pm 1.03$ ), and the farthest in the area at the mesial root of the second molar ( $5.11\text{mm} \pm 1.27$ ). As for the distance between the MC and the lingual border of the mandible the shortest was at the area of the distal root of the first molar ( $1.68\text{mm} \pm 0.68$ ) and

farthest at the area of the root of the second premolar ( $2.79\text{mm} \pm 1.03$ ). In a similar CBCT study of the mandibular canal in 52 adult skulls, Ozturk et. al. in 2012 found that the shortest distance between the MC and the buccal border of the mandible is at the area of the root of the second premolar (4.47mm), and the farthest in the area at the mesial root of the second molar (6.05mm). As for the distance between the MC and the lingual border of the mandible they found the shortest was at the area of the mesial root of the second molar (0.7mm) and farthest at the area of the root of the second premolar (1.81mm)<sup>41</sup>.

On the other hand, our results show that the MC is closest to the inferior border of the mandible at the area of the mesial root of the second molar ( $5.11\text{mm} \pm 1.36$ ) and farthest in the area of the second premolar ( $6.6\text{mm} \pm 1.61$ ). Liu et al. in 2009 used 386 OPG to study the course of the canal, they found that the shortest distance between the inferior border of MC and the inferior border of the mandible was at the position of the first molar ( $7.56 \pm 1.62$  mm) and longest at the third molar ( $10.28 \pm 2.77\text{mm}$ )<sup>37</sup>.

### **5.3 Limitations**

Several factors affect the image quality of CBCT scan and hence the ability of the evaluator to evaluate and detect certain characteristics in a CBCT scan is impacted by the quality of the image. These factors include type of the CBCT unit, field of view (FOV), voxel size, tube voltage and current and other technical factors. To overcome issues related to these factors on the CBCT image quality, in the present study all CBCT scans were acquired from HDC where standard imaging protocol was used for CBCT scans. CBCT scans at HDC are taken by the same technician, using the same CBCT machine (Orthophos SL Dentsply Sirona, USA) with the same parameters; 85 Kv, 7 mAs, with exposure time of 5 seconds and voxel size of



0.15 mm. The best CBCT scan image quality is achieved with a small FOV and small voxel size. On our study, the CBCT scans used had a voxel size of 0.15. however overall image resolution and quality was influenced due to the medium size FOV (8 cm x 8 cm) CBCT scans. To reduce the potential effects of this limitation, we used an ultra-high resolution display monitor (Retina 5K with 5120 by 2880 resolution), in comparison to similar studies. Another limitation of our study is that it's a retrospective study, therefore the inability to control certain factors like FOV, voxel size and the quality of CBCT scan image.

## 6. CONCLUSIONS

Based on the results of this study, the following conclusions can be drawn:

- The most common location of the MF is distal to the contact area between the mandibular first and second premolars (the distance from the mesial border of the mental foramen with the line drawn from the contact point of the premolars =  $0.83\text{mm} \pm 1.84$ ), and this distance have a negative relationship with age.
- The distal root of the mandibular second molar is the closest root to the mandibular canal ( $2.06\text{mm} \pm 1.83$ ).
- The distance between the root apices of the mandibular teeth and the mandibular canal has a positive relationship with age and affected by gender as male patients have a greater distance.
- The common course of the canal being more lingual and inferior posteriorly and becoming more buccal and superior towards the MF.
- Based on our findings it is extremely important for clinicians treating Emirati population, to supplement their other diagnostic tools (such as CBCT) in planning surgical and non-surgical dental procedures to prevent any injuries to the MF or the MC contents.

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## 8. APPENDICES

### Appendix 1



Date: 17/05/2018

Dear Dr Summayah

Re: Your research protocol

Titled: Use of cone-beam computed tomography .....

Thank you for submitting your research protocol to the Research and Ethics committee of the Hamdan Bin Mohammed College of Dental Medicine, MBRU.

It was considered at the meeting held on: 06/05/2018 and subsequently revised and re-submitted to the Chair.

The protocol is now approved.

With best wishes

Yours sincerely,

Prof A Milosevic

Chair, Research and Ethics Committee, HBMCDM

## Appendix 2



Date: 08/07/2018

Healthpoint Research Ethics Committee

Principal Investigator: Dr. Nouf Al Harbi

Telephone: 050 887 7242

Email: [N.alharbi@healthpoint.ae](mailto:N.alharbi@healthpoint.ae)

REC Reference: REC009

Title of Project: Use of cone-beam computed tomography to evaluate root canal morphology and C-shaped root canal morphology in mandibular second molars in Emirati population: a retrospective study

Dear Dr. Mai,

The Research Ethics Committee has reviewed the above application at its meeting held on Thursday 08 July 2018 at 16:00 p.m.

The Committee has given a favorable ethical opinion for the above project based on the application, protocol and supporting documentation that comply with the conditions and principles established by the International Conference on Harmonization – Good Clinical Practice (ICH GCP).

Yours sincerely,

Dr. Mai Ahmed Sultan Issa Al Jaber, MBBS, MPH  
Deputy Medical Director  
Medical Management  
Health Point Hospital LLC

Dr. Mai Al Jaber

Chair, Healthpoint Research Ethics Committee





Date: 11/10/2020

Healthpoint Research Ethics Committee

Principal Investigator: Dr. Nouf Al Harbi

Telephone: 050 887 7242

Email: [N.alharbi@healthpoint.ae](mailto:N.alharbi@healthpoint.ae)

REC Reference: MF2467-2020-11

Title of Project: Evaluation of the Inferior Alveolar Nerve Canal Course in a sub-group of Emirati population: a cone-beam computed tomography study.

Dear Dr. Nouf,

The Research Ethics Committee has expedited the above application. As there is no intervention and involves data collection. Therefore, a full IRB review is not required.

The Committee has given a favorable ethical opinion for the above project based on the application, protocol and supporting documentation that comply with the conditions and principles established by the International Conference on Harmonization – Good Clinical Practice (ICH GCP).

Yours sincerely,



Dr. Mai Al Jaber

Chair, Healthpoint Research Ethics Committee

