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DOUBLE INFERIOR ALVEOLAR NERVE CANALS AND MENTAL FORAMINA IN THE MANDIBLE: A RETROSPECTIVE COMPUTED TOMOGRAPHYSTUDY AT A PRIVATE DENTAL CLINIC IN KENYA

By

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Submitted in fulfilment of the requirements for the degree
Master of Science in Dentistry

in the

Department of Periodontics and Oral Medicine

UNIVERSITY OF PRETORIA

13th September 2017

DECLARATION

I hereby confirm that this thesis is my own original work and has not been presented elsewhere for examination.

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ACKNOWLEDGEMENTS

I am grateful to God for His mercies in every step of this project. Sincere appreciation goes to my supervisors Prof. Andre van Zyl, Prof. Johan Marnewick and Dr. Tom Ochola for their guidance, criticism and encouragement. Special thanks go to Dr. Edwin Kagereki for his bio statistical assistance and taking his time to read the manuscript and offering useful suggestions. Dr. Sunil Vinayak, Smile Africa Dental Clinic, Nairobi, Kenya is also acknowledged for kindly permitting access to the CBCT scans. Lastly, I show gratitude to Ms. Mary Wanjiru Wainaina whose patient encouragement aided in the whole process of completing this thesis in an innumerable manner.

EXECUTIVESUMMARY

Aberrant inferior alveolar nerve canals (IANC) and mental foramina (MF) have been well documented and can have significant implications if injured during invasive procedures of the human mandible. Geographical and ethnic differences have been observed in the occurrence of these variations. The primary objective of this study was to determine the pattern of occurrence of double IANC and MF among a sample of patients attending a dental clinic in Kenya through cone beam computed tomography (CBCT) image analysis.

The occurrence, location, configuration and morphometric measurements of double inferior alveolar canals and mental foramina were recorded in a data extraction form (Appendix 1). Data was captured in a Microsoft Excel 2010 data sheet. With the use of Bayesian statistics, exploratory and inferential data analysis was done in R (R Development Core Team, Vienna, Austria) software version 3.1.2. The results were presented as posterior distributions of means and mean differences including standard deviations (SD), Credible Intervals (CrI) and effect sizes (ES). In all outputs, the 95% most credible values (CrI) were shown as a High-Density Interval (HDI) in the respective histograms. Gender and side differences were rated.

A total of 800 images were included in the present study of 347(43.38%) male and 453(56.62%) female patients. The mean age was 39.18 years$\pm$12 SD while median age was 39 years (range: 19 to 67 years). Double IANC were observed in 26 (3.25%) of the 800 images (29 of 1600 sides, 1.81%). The most frequently encountered type of double IANC was type 1 (23 / 29, 79.31%), followed by type 3 (4 /29, 13.79%) and then type 2 (2 / 29, 6.9%). The double IANC were more in the angle region than at the body area of the mandible. The mean diameter and length of the double IANC were 1.57$\pm$0.41mm (95% CrI: 1.40, 1.73) and 13.10 $\pm$3.45mm (95% CrI:11.60, 14.5) respectively. In total, 21 double MF were found in 19(2.4%) patients, with 11 being posterior, seven anterior and three superior to the main mental foramen (MF). The mean diameter of double MF was 1.27 [95% CrI: 1.05, 1.47] mm with a standard deviation of $\pm$0.41mm. The mean distance between double MF and the main MF was 4.69mm [95% CrI: 3.47, 5.59] with a standard deviation of 2.26mm.

Based on the findings reported in this study, the rate of occurrence of double IANC and double MF was typically low in the study population. The diameter of the main MF was always smaller than that of the side without the double MF. This was not the case with the IANC. There was also no gender predilection elicited in any of these occurrences. CBCT imaging is recommended as it has better resolution to enable detailed analysis of structures that are less than a millimeter in diameter. Ensuring a safe distance of 9 mm from the walls of the main MF would greatly reduce the risk of injury to the neurovascular contents of the double MF in case CBCT imaging is not available.

Keywords: Anatomic variation, dental implants, neurovascular injury, risk reduction, bayes theorem

LIST OF ABBREVIATIONS

IANC	Inferior alveolar nerve canal
MF	Mental foramen
CT	Computed tomography
CBCT	Cone beam computed tomography
UIN	Unique identification number
CrI	Credible interval
HDI	High density interval
mm	Millimetre
SD	Standard deviation
ES	Effect size
3D	Three dimensional

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CHAPTER 1: DEFINING THE RESEARCH PROBLEM

Placement of dental implants in the mandible involves surgical preparation of an osteotomy site and occasional autologous bone harvesting for guided bone regeneration. Like any other surgical procedure, this treatment is prone to complications such as nerve and vascular damage. Double inferior alveolar canals (IANC) and mental foramina (MF) are anatomical variations of neurovascular structures that have been documented in the literature and pose a risk of excessive bleeding and/or nerve damage when perforated or penetrated during surgery, if not identified pre-operatively.[1] In addition, the presence of double IANC in the retro-molar area have also been implicated with failure of achieving anesthesia in the posterior mandibular region.[2,3]

Geographical differences in the occurrence of mandibular neurovascular variations have been shown to exist.[4] In a 2-dimensional (panoramic) radiographic study, a prevalence of under one percent was reported.[5] Conversely, Cone Beam Computed Tomography (CBCT) is a more recent imaging modality which gives highly accurate 3-dimensional images with reported prevalence of up to 65% for the double IANC.[6]CBCT is therefore pivotal in documenting the pattern of occurrence of double IANC and MF in any patient population and thereby aiding in the formulation of guidelines on prevention of complications during implant surgery.

CHAPTER 2: LITERATURE OVERVIEW

2.1. Dental Implant Therapy

The surgical placement of dental implants has certain anatomical risks attached to it. One of the most important risks is permanent damage to the inferior alveolar nerve[7] which can have dire consequences for the patient.[8] The presence of double IANC may be missed by a dentist when preoperative investigations are not well done. Identifying these structures therefore becomes extremely important in implant planning and surgical placement in the mandible.

2.2. Inferior Alveolar Nerve Canal

The IANC is the bony channel through which the inferior alveolar neurovascular structures run within the mandible.The canal starts at the mandibular foramen and ending at the mental foramen.[9] This channel appears as a narrow radiolucent ribbon bordered by two radiopaque lines[10] although in 43.7% of the times,[11] the superior wall may be uncorticated in some areas leading to interruptions in its continuity when viewed radiographically. This phenomenon has been found to be more prevalent in women due to a lower bone density caused by osteoporotic conditions.[11]Decreased bone trabeculation in the region of the submandibular gland fossa also reduces the visibility of the IANC.[12]

This canal is formed during the seventh week of intrauterine development because of intramembranous ossification along the lateral border of Meckel's cartilage with formation of a gutter, later converted into a canal, around the inferior alveolar nerve.[13]Although commonly assumed to be a single canal,[2,6,9,12,14,15,16,17] bifid and trifid canal[3,18]variations of the IANC have been reported. Accessory mandibular foramina have also been documented superolateral to the main mandibular foramen.[3,17]

In an anthropological study of human prenatal mandibles, Chavez-Lomeli et al.[19] concluded that the mandibular canal existed as three separate nerves providing innervations to three groups of mandibular teeth (incisors, premolars and molars) which later fuse to form a single nerve. Incomplete fusion of these three separate nerves may account for the occurrence of multiple IANC.[20] The fact that these canals are formed during embryonic development implies that the occurrence of double IANC has no correlation with the age of a patient.[21]

Various imaging modalities have been used to investigate the existence of double IANC variations. In 1977, Nortje et al.[5] reported a prevalence of 0.91% after reviewing 3612 panoramic radiographs in a South African sample population. In a study based on 6000 radiographs in the United States of America, double IANC were observed in 0.95% cases,[22] while a review of 2012 panoramic radiographs of a Spanish population revealed aprevalence of 0.35%.[20]A recent study on an Iranian population based on 5000 digital panoramic radiographs revealed an incidence of 1.22 %.[21]

Conversely, studies based on CBCT images have revealed a higher incidence of double IANC ranging from 10.2% to 66.5% with no age or gender predilection.[1,6,14,23,24] In a comparative study on 46 dry mandibles,[3]it was found that double IANC were visible in 19.6% of CBCT scanned cases and only in 0.2% of panoramic images of these mandibles. This huge discrepancy between the two modalities means that there is an underestimation of the incidence of double IANC when using panoramic radiography.[23,25] These findings werelikethose of another study that found rotational panoramic radiographs to only show 48.6% of mandibular bony canals observed on 365CBCT images.[26] Panoramic radiographs can therefore only suggest but not confirm the presence of double IANC.[15]

Ethnic variations and differences in the methodology used, could explain the differences in the reported prevalence in CBCT studies. For instance, Christiano et al.[12] included only bifid mandibular canals with a diameter greater than 1mm to minimize the chances of including false canals in their study of 100 CBCT scans on a Brazilian population. Naitoh et al.[27] in their study of 28 patients only considered bifid mandibular canals if they had a length greater than 5mm.

Naitoh et al.[6] classified double IANC as retro-molar canal (type 1) when the foramen of the double canal is observed on the bone surface of the retro-molar region. A double IANC is defined as a dental canal (type 2) when it terminates at the root apex of the second or third molars. When a double canal arises from the superior wall of the IANC, it is defined as a forward canal (type 3) and can either be with confluence (if it inserts back into the main canal) or without confluence (if it does not insert back into the main canal). A bucco-lingual canal (type 4) is when the double canal arises from the buccal or lingual wall of the mandibular canal. The bifurcations in this study were all observed in the mandibular ramus. Trifid IANC have also been reporteds.[18,24,28]

In a Japanese population study of 122 patients by Naitoh et al.[29]aforward canal was the commonest (44.3%) followed by the retro-molar canal (25.4%). In a study on 242 Turkish patient-CBCT images, Orhan et al.[1] found the forward canal to be the most frequent (29.8%), followed by the retro-molar (28.1%). However, Ju-Han et al.[14]studied 1933 CBCT images among Koreans and found that a retro-molar double IANC was more prevalent (52.5%) followed by the forward double IANC (40.9%), without any significant difference with regards to age or gender. In another Korean study (n=500), a retro-molar canal was the most common at 71.3% followed by a dental type canal at 18.8%, trifid type at 5.8% and the forward type at 4.1%.[24] Retro-molar canal was the commonest in a study done on a Brazilian population.[12] These variations show that bifurcations of the IANC are not uncommon and that there is no agreement on the most common variant of the double IANC.

Within the body of the mandible, the IANC is commonly positioned 10.20mm to 10.52mm above the inferior border of the mandible[30,31]being closer to the lingual surface posteriorly while lying close to the buccal surface anteriorly.[31] Its diameter ranges from 2mm to 4.3 mm, while that of the double IANC ranges from 1mm to 3mm.[12,24] Mean length of double IANC is reported to be 13.6- 16.9 mm without any statistically significant difference between the sides or gender.[1,24]When located within the body of the mandible, the bifurcated canal may sometimes end at a second mental foramen[15] The superior angle at which the double IANC bifurcates from the main mandibular canal has been reported to be 139 ^{o}-149.2^{o} while the inferior angle is documented as 32 ^{o} -38^{o}.[1,24]

False mandibular canals may be occasionally observed because of an imprint of the mylohyoid nerve or due to the radiologic osseocondensation image produced by the insertion of the mylohyoid muscle both of which are located on the medial aspect of the mandible.[18,20] A case of pseudo enlarged canal due to a deep mylohyoid groove on the medial surface of the mandible has also been reported previously.[32]

Gross anatomical and histological studies have confirmed that the bifid canals contain a nerve bundle accompanied by an artery.[9,17]The neurovascular contents of a retromolar double IANC that ends in a retromolar foramen may be at risk of damage during bone harvesting in the retromolar region[1] or may be traumatized by a denture that extends to this area.[21,22] It may also be at risk of damage during the alignment of bones during fracture reduction.[22] Presence of double IANC has also been suggested as the cause of

paresthesia, bleeding during surgery, traumatic neuroma, failure to achieve anesthesia or even formation of fibrous tissue around an implant placed within a double IANC.[1,2,3,15,22]

2.3. Mental Foramen

At the mental foramen (MF), the inferior alveolar nerve terminates by dividing into the incisive and mental branches, of which the latter supplies the skin of the chin, mucous membrane of the lower lip and the gingiva of that side. [33] The MF is found either inferior and in line with the 2nd premolar, between 2nd premolar and 1st molar, or between the two premolars (57.8%, 25%, and 9.4%, respectively) according to a Kenyan dry mandible study.[34] This position is however not fixed in all stages of life as a backward migration of the MF from prenatal stage through to adult age has been observed.[35] Previous studies showed that there has been an anterior migration of the MF from the region of the first molar to its current position when human mandibles from different chronological periods were compared.[36,37]

Double MF is an anatomical variation where two mental foramina exist. Its prevalence, based on CBCT and medical CT studies is 4% to 10.7% and have been found both unilateral[26,29,33,38,39], bilateral.[39] In a study on different ethnic populations, Sawyer et al.[4]found a lower incidence of double mental foramina in White Americans and Asian Indians compared to African Americans and Nazca Indians. Previous studies reported no statistically significant difference in the occurrence of double MF with respect to gender or side of the jaw.[29] Cases of absence of MF has also been reported in literature.[4,38,40]

Naitoh et al.[29] defined an accessory mental foramen as one which has continuity with the mandibular canal or a nutrient foramen as one without continuity with the mandibular canal. In a study by Christiano et al.[38]on a Brazilian population**,** additional mental foramina were considered as ‘double mental foramen’ when their size was at least half of their corresponding ipsilateral MF or ‘accessory mental foramen’ when they were smaller than half the size of the ipsilateral MF. Failure of complete formation of the mental foramen by the 12th week of intra-uterine, the time during which the mental nerve separates into numerous fasciculi at that site, could account for the formation of accessory mental foramina.[29,35]

Accessory MF are mainly located posterior and either superior or inferior to the main foramen, and is of an average diameter of 1.95mm while the main mental foramen is

4.2mm.[29,38,39] The presence of accessory MF does not seem to influence the size of the MF on the ipsilateral or contralateral sides.[38] In 37% of cases, the accessory mental foramina were found to be virtually the same diameter as the main MF in a previous study.[38] The horizontal position of double MF from the main MF ranges from 4.5mm to 9.6mm.[29] The accessory canal connecting a double MF to the IANC is about 6.4 mm in length,[26] and has been described as having a posterior-superior direction towards the mandibular canal.[39]

2.4. Cone Beam Computed Tomography

CBCT radiography is an excellent diagnostic method that gives a better insight of the diameter and precise direction of double IANC especially in the bucco-lingual position.[18,24,25] This is because it provides high-resolution three-dimensional images and do not suffer from deformations and superimposition experienced with 2-dimensional radiographs.[15]CBCT however exposes patients to higher radiation doses (5 to 74 times) than a single panoramic radiograph.[41] Conventional radiography is therefore recommended for initial screening followed by additional CBCT scanning to give further details if an anatomical variation is observed.[18]

CHAPTER 3: RELEVANCE AND MOTIVATION FOR THE STUDY

As more dental implants are being placed in Kenya by an ever-increasing number of practitioners with different levels of skill and experience, it is likely that the cumulative number of patients with neurovascular injury may also increase. The location and configuration of the IANC and MF are important factors to consider before performing invasive surgical procedures. Findings from a population based survey on anatomic variations of these structures, is a reasonable justification for the use of CBCT as a complimentary radiographic investigation. So far, no CBCT studies have been published on the pattern of occurrence of double IANC and MF in this patient population. Accordingly, this study sought to fill that knowledge gap and as such provide useful information to dental surgeons involved in placement of implants in the lower jaw.

CHAPTER 4: AIM AND OBJECTIVES

4.1. Aim

- Describe the patterns of occurrence and factors associated with the bifurcations of the IANC and MF.

4.2. Objectives

- To determine the number of double IANC and MF.
- To describe the location, pattern of double IANC and MF.
- To estimate the diameters of the double IANC and MF.
- To estimate the length of the double IANC.
- To estimate the distance between the main MF and the double MF.
- To determine gender and side of the jaw differences in the occurrence of double IANC and MF.

CHAPTER 5: METHODS

5.1. Study Design

This study was an observational retrospective record-basedstudy.

5.2. Setting

5.2.1. Location

This study was conducted at a private dental clinic (Smile Africa Dental Clinic, School Lane, Westlands, Nairobi, Kenya) where pre-operative CBCT imaging is performed for third molar extractions, dental implant placement and orthodontic treatment. CBCT is a relatively new mode of radiographic investigation in Kenya and is only available at three privately owned facilities all located within the capital city, Nairobi. This dental clinic was chosen because of availability of completed patient records. More importantly, the personnel who take the scans at this facility are well trained by Sirona Dental Company and many dentists refer patients to this clinic for CBCT scans.

5.2.2 Image acquisition process

A Galileos Comfort Plus® CBCT unit(Sirona Dental Systems Inc., Bensheim, Germany) with an image intensifier (II) detector and a charge-couple device camera was used to take all the radiographs. The exposure volume was to display a spherical field of view of 15cm (resulting in a scan volume of 15 x 15 x 15 cm) and voxel size (slice thickness = 0.3mm) at 0.3 x 0.3 x 0.3mm. The tube voltage and current were fixed at 85kV and 7mA, as recommended by the manufacturer. A bite block was utilized while scanning in addition to the x-ray unit height being adjusted to ensure that the occlusal plane was perfectly horizontal. The detector unit completes a 200^0 rotation around the patient's head in 14 seconds.

Sidexis XG software (Sirona Dental Systems Inc., Bensheim, Germany) is used to capture, process and store reconstructed 3-dimensional data together with the original 2-dimensional projection views. A sagittal view for each tooth was reconstructed and analyzed by a computer using Galaxis/Galileos (Sirona Dental Systems Inc., Bensheim, Germany) 3-D visualization and measurement software.

5.3. Patient/Research Object Selection

5.3.1. Theoretical Population

Patients requiring dental treatment in Kenya.

5.3.2. Study population

Patients (approximately 2340) who have had mandibular CBCT scans taken at Smile Africa Dental Clinic between January 2013 and December 2015.

5.3.3. Sampling

CBCT images electronic database was the sampling frame. Consecutive sampling method was used to select the study CBCT images. When a sampled image did not meet the inclusion criteria, the next image in the sampling frame was selected.

5.3.4. Sample

5.3.4.1 Inclusion Criteria

- Mandibular images of adult dentate patients since the classification of IANC was partly based on the proximity to the roots of the molars.

5.3.4.2 Exclusion criteria

- Incomplete medical record- If gender and age were not indicated.
- Edentulous mandibles and mixed dentitions- The presence of developing permanent teeth may obscure the visibility of IANC and MF.
- Poor quality CBCT scans with scatter or insufficient accuracy of bony borders.
- Notable facial bony malformations/surgical procedures in the body/ramus of the mandible.
- Cysts or tumors of significant size.
- CBCT images that failed to show any part of the mandible.

5.4. Measurements

5.4.1. Variables

Independent Variables

- Gender
- Side of the Jaw

Dependent Variables

- Presence of double IAN canal
- Presence of double MF
- Location of IANC bifurcation within the mandible
- Orientation of bifurcated canals
- Diameter of double IANC and main IANC
- Diameter of double MF and main MF
- Distance between double MF and main MF
- Position of double MF in relation to the main MF

5.4.2. Viewing of the CBCT images

2-Dimensional images of various orthogonal planes of the mandible were reconstructed on a 27-inch (diagonal) iMac® (Apple Inc, CA, USA) computer (LED-backlit display with IPS technology; 2560-by-1440 resolution) using Galaxis/Galileos (Sirona Dental Systems Inc., Bensheim, Germany) 3D visualization and measurement software. Viewing was done in a dark room to improve the visibility.

The presence of a double mandibular canal was recorded when the length was at least 5mm as earlier described.[27] A double mental foramen was only recorded when there was continuity with the main IANC.[29] The classification by Naitoh et al.[6] was followed for classification of the double IANC variations.

5.4.3. Image analysis for the double IANC and MF

Both the left and the right side of the mandible were studied. Axial, sagittal, coronal and panoramic views were evaluated and three-dimensional reconstructions evaluated accordingly to improve the accuracy of identification. The density and contrast of images were adjusted to improve the clarity of the IANC, MF and their double occurrences.

The course and length of the double IANC canals were measured in either the sagittal or para-panoramic reconstruction views starting from the point of separationthe main canal to the point where its clarity diminished (Figure 2a). These views enabled measurements of straight and curved canals. The diameters of the main IANC and the double IANC were measured at the point of bifurcation. A mental foramen that was smaller in diameter was considered a double MF (Figure 8). However, any MF without continuity with the IANC was regarded as a nutrient canal and therefore no morphometric measurements were done.

The distance between the main and double MF was measured from the margins of the foramina, while the diameters were measured as the widest dimensions between the walls of the foramina.

5.4.4 Precision and validity

For standardization, a bite block was utilized in all cases while scanning in addition to the x-ray unit height being adjusted to ensure that the occlusal plane was perfectly horizontal. The inferior border of the mandible was used as a reference for measurements on panoramic reconstructions, while the occlusal plane was used as a reference for measurements on cross-sectional image. For clear visualization of the mandibular canal, the center of rotation of the reference line for multi-planar reconstructions was initially set at the mandibular foramen. Then the reference lines for the sectional image was rotated horizontally per the course of the mandibular canal. Bucco-lingual and posterior-anterior movements of the reference lines was made to depict the clearest image of the IANC in oblique and sagittal views.

All measurements were done by one investigator (JG) who had earlier obtained training and was comfortable with manipulating the software and performing morphometric measurements. Accuracy was limited to the inherent voxel size (0.3mm) of the CBCT machine used in acquiring the scans. There was however no attempt to calibrate the examiner due to a lack of a suitably trained personnel on CBCT radiology.

5.4.5 Intraobserver reliability

To check whether there was reproducibility of measurements, the investigator repeated the morphometric measurements of all the cases with double IANC and MF after one month to prevent recall bias. Where the second measurement differed from the earlier one, an average of the two measurements was calculated.

5.5. Data Management

Microsoft Access 2016 data base was designed for data entry. This was then exported into Microsoft Excel data sheets for further management. The two datasets were checked for data completeness and data integrity. A data dictionary was generated for the final dataset. A copy of the final dataset was archived in a compact disk. Subsequently the data was used for the final analysis.

5.5.1 Statistical analysis

Bayesian estimation of posterior probabilities based on binomial probability distribution was done using non-informative priors (0.5,0.5). Data were analyzed under the following guidelines:

a) Exploratory data analysis

- Categorical variables were summarized by using the frequencies and percentages. The data was presented in form of tables and charts.
- The continuous variables were summarized as follows:
  - Central tendency –mean
  - Variation - range and standard deviation
  - Distribution - skewness and kurtosis.

b) Inferential statistics

All the statistical analysis was done using R package version 3.1.2 (R Development Core Team, Vienna, Austria)[42] and a combination of Markov chain Monte Carlo (MCMC)[43], and the relevant packages. For inferential analysis of the various variables on the double IANC and double MF, the following were the aims:

I. Describe the patterns and factors associated with the bifurcations of the double IANC.

- Since it has been established that there are four types of double IANC (retro-molar canal, dental canal, forward canal, bucco-lingual canal), here theaim was to estimate the proportions of these types in the study population.
- Describe the location of double IANC (body or ramus).
- Association between the gender and the presence of double IANC (Proportion difference and CI).
- Association between the type of double IANC and the gender. (CI of difference in proportions).
- Association between type of double IANC and the side of the jaw. (CI of difference in proportions).
- Assess the association between the side of the jaw (right or left) and the prevalence of the double IANC (Proportion difference and the CI).

- Estimate the diameter of the double IANC (CI of the mean, Effect size).
- Estimate the length of the double IANC (CI of the mean, effect size).

II. Describe the pattern and factors associated with the double MF.

- Assess the association between the prevalence of the double MF and the gender (Proportion difference – with CI).
- Assess the association between the side of the jaw (right or left) and the prevalence of the double MF (Proportion difference and the CI).
- Describe the position of the double MF in relation to the main mental foramen.
- Estimate the diameter of the double MF (Mean and CI, effect size).
- Estimate the distance between the double mental foramen and the main MF (Mean and CI, effect size).

5.6 Sample size statement

Since the study was intended to address multiple objectives, it was proposed to find a sample that could be a good compromise in achieving these contrasting goals. The overarching goal was to have optimal sample that maximized precision across these objectives:

a) Describe the pattern and factors associated with the bifurcation of the double alveolar nerve.

b) Describe the pattern and factors associated with the double mental foramen.

To study these aspects, sample size estimates were simulated through the spectrum of the prevalence's in the literature.[1,6,14,23,24,26,29,33,38,39]

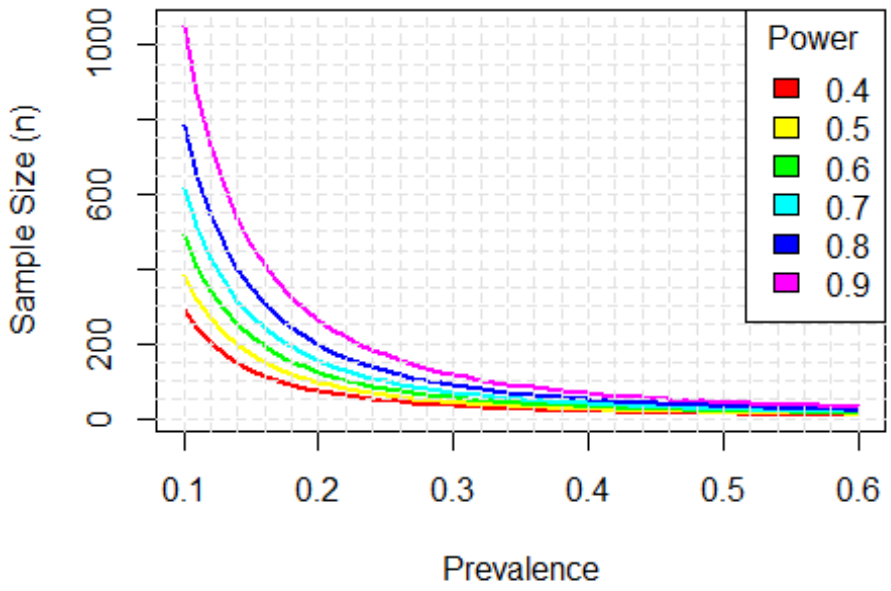


Figure1: Sample size estimation based on the prevalence of double IANC and double MF from the published studies reviewed. σ=0.5 (two tailed).

Thus, the sample size estimated to achieve all the objectives in the population was estimated at about 800 CBCT scans (Figure 1).

5.7 Ethical Considerations

Only patient records were assessed in this study for purposes of demographic data and past medical history. Utmost confidentiality was observed regarding patient records with no form of identification of the patients being captured in the data extraction form. Permission to carry out the study was sought from Smile Africa Dental Clinic. Ethical approval for this study was sought from Kenyatta National Hospital/University of Nairobi Ethics, Research and Standards committee (P685/09/2016) and the University of Pretoria, Faculty of Health Sciences Research Ethics Committee (6/2016).All data collected were captured in an extraction form with each record being allocated a unique identification number (UIN).

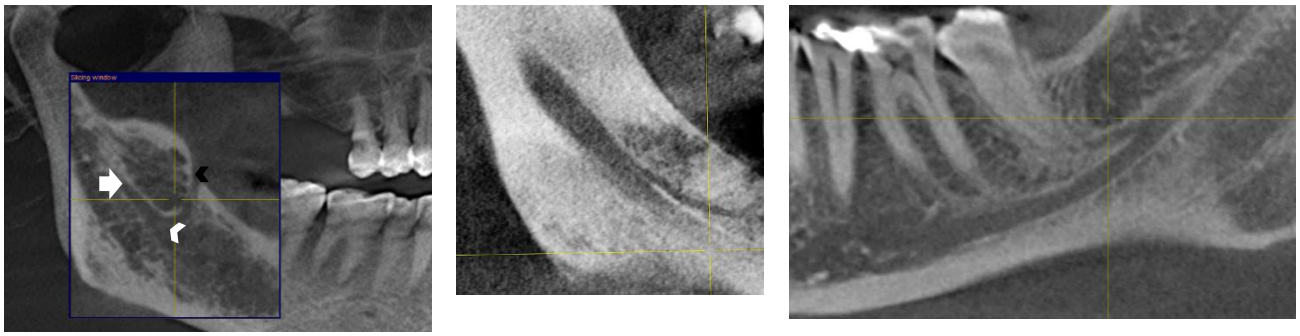
CHAPTER 6: RESULTS

A total of 800 CBCT images were included in the present study of 347(43.38%) male and 453(56.62%) female patients. The mean and median age were 39.18 years ± 12 SD and 39 years respectively, ranging from 19 to 67 years of age.

6.1 DOUBLE IANC

6.1.1 Occurrence and types of double IANC observed

Double IANC were observed in 26 (3.25%) of the 800 CBCT images (29 of 1600 sides, 1.81%). The most frequently encountered type of double IANC was type 1 (23 / 29, 79.31%), followed by type 3 (4 /29, 13.79%) and then type 2 (2 / 29, 6.9%) (Figure 2).



a b c

Figure2: Panoramic reconstructions (tangential views) of mandibles (a, b, c) showing double IANC type 1, type 3 (without confluence) and type 2 respectively. In Figure 2a, the white arrow shows a main IANC while the white arrowhead shows the point of separation/bifurcation of a double IANC that terminates at a point indicated by the black arrowhead.

Intergroup differences (row-column) among the various types of IANC were estimated at 95% CrI and are shown in Table 1. The rate of occurrence of double IANC was in the descending order of type1, type 3 and then type 2.

Table1: Intergroup differences between various types of double IANC (at 95% CrI)

	Type 2	**Type 3**
Type 1	0.69[0.49, 0.84]	0.62 [0.42, 0.80]
Type 2		-0.06 [-0.24, 0.097]

6.1.2 Location of the double IANC within the mandible (body, angle or ramus)

Double IANC were more common in the angle region (25(86.21%)) of the mandible as shown in Table 2.

Table2: Location of the double IANC within the mandible

Region of mandible	**Right side n (%)**	**Left side n (%)**
Ramus	0(0%)	2(6.9%)
Body	2(6.9%)	0(0%)
Angle	16(55.17%)	9(31.03%)

6.1.3 Association between side of the mandible (right or left) and the presence of various types of double IANC (Proportion difference and the 95% CrI)

Fifteen (57.69%) of the double IANC were on the right side, while eight (30.80%) were on the left side. In three (11.53%) patients, double IANC were observed on both the right and the left sides. Overall, double IANC were more on the right side (0.61 [0.44, 0.78]) than on the left side (0.39 [0.22, 0.55]). The probability of more IANC being observed on the right side was estimated at 96.7%. This finding was however not statistically significant (right - left: 0.23 [-0.012, 0.46]).

More of type 1 double IANC were observed on the left side while type 2 and type 3 were more on the right side as shown in the results of a Bayesian binomial test done to estimate the proportions in each of the sides (Table 3). These differences were however not statistically significant. The differences in the rate of occurrence of the various types of double IANC are shown in Table 4.

Table3: Distribution of the various types of double IANC on the right and left mandible (at 95% CrI)

Type of double IANC	Right	Left
Type 1	0.71 [0.51, 0.89]	0.86 [0.67, 1.0]
Type 2	0.14 [0.017, 0.30]	0.056 [5.9e-06, 0.22]
Type 3	0.19 [0.049, 0.37]	0.14 [0.0072, 0.34]

Table4: Side and types of double IANC inter-group differences (row - column) (at 95% CrI)

Side/Type of IANC	Right type 2	Right type 3	Left type 1	Left type 2	Left type 3
Right type 1	0.56 [0.29, 0.78]	0.51 [0.23, 0.75]	-0.15 [-0.41, 0.13]	0.64 [0.38, 0.84]	0.56 [0.28, 0.81]
Right type 2		-0.05 [-0.29, 0.18]	-0.71[-0.92, -0.45]	0.07 [-0.15, 0.29]	0[-0.26, 0.24]
Right type 3			-0.66[-0.89, -0.4]	0.12 [-0.11, 0.35]	0.05[-0.21, 0.31]
Left type 1				0.79 [0.54, 0.97]	0.71 [0.43, 0.93]
Left type 2					-0.07 [-0.33, 0.15]

6.1.4 Association between gender and the presence of various types of IANC (Proportion difference and 95% CrI)

There were more double IANC observed in females (0.86 [0.73, 0.97]) than males (0.24 [0.11, 0.42]). The probability of this observation was estimated at 99.9%. This difference was statistically significant (Males - Females: -0.61 [-0.8, -0.4], at 95% credible interval). Type 1 double IANC were mainly observed in females while type 2 and type 3 were more in males as shown in the results of a Bayesian binomial test (Table 5) done to estimate the proportions in each of the genders. None of these findings were statistically significant.

Table5: Distribution of various types of double IANC between the genders (at 95% CrI)

Type of double IANC	Males	Females
Type 1	0.50 [0.18, 0.81]	0.85 [0.69, 0.96]
Type 2	0.23 [0.0095, 0.52]	0.068 [0.0023, 0.18]
Type 3	0.36 [0.081, 0.68]	0.11 [0.017, 0.25]

Table6: Intergroup differences (row-column) among types of double IANC with respect to gender (at 95% CrI)

Gender/Type of IANC	Male type 2	Male type 3	Female type 1	Female type 2	Female type 3
Male type 1	0.25[-0.19, 0.66]	0.13[-0.19,0.66]	-0.34 [-0.19, 0.66]	0.42[0.086, 0.75]	0.38 [0.029, 0.71]
Male type 2		-0.13 [-0.56, 0.28]	-0.61 [-0.88, -0.28]	0.15 [-0.11, 0.48]	0.11 [-0.15, 0.45]
Male type 3			-0.48 [-0.8, -0.13]	0.29 [-0.0094, 0.63]	0.25 [-0.056, 0.6]
Female type 1				0.77 [0.58, 0.92]	0.73 [0.53, 0.89]
Female type 2					-0.04 [-0.22, 0.11]

6.1.5 Diameter of the double IANC

A summary of the mean diameter and length of double and main IANC is provided in Table 7 and Figure 3.

Table7: Mean (SD) (range) of measurements of the double and main IANC (mm)

	Mean	SD	Min	Max
Diameter of double IANC right side (n=18)	1.56	0.46	0.79	2.47
Diameter of double IANC left side (n=11)	1.59	0.39	1.11	2.37
Length of double IANC right side IANC (n=18)	13.44	4.48	6.39	25.43
Length of double IANC left side IANC (n=11)	13.55	4.42	9.48	26.08
Diameter of main IANC right side (n=26)	3.15	0.64	2.02	4.39
Diameter of main IANC left side (n=26)	3.19	0.67	2.28	4.50

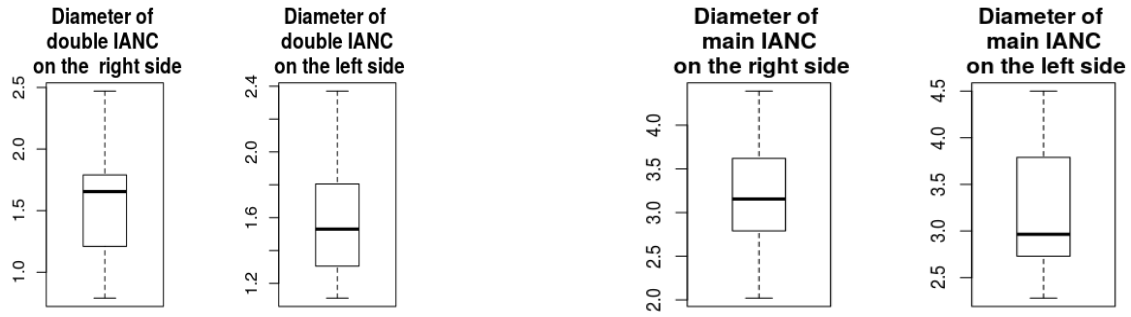


Figure3: Box and whisker plots of diameters of double and main IANC (all measurements are in mm).

The overall mean diameter of double IANC was 1.57mm ±0.41SD while that of the main IANC was 3.16mm ±0.63SD. The main IANC were always greater than the double IANC with an effect size of 2.83 as shown in Figure 4 below.

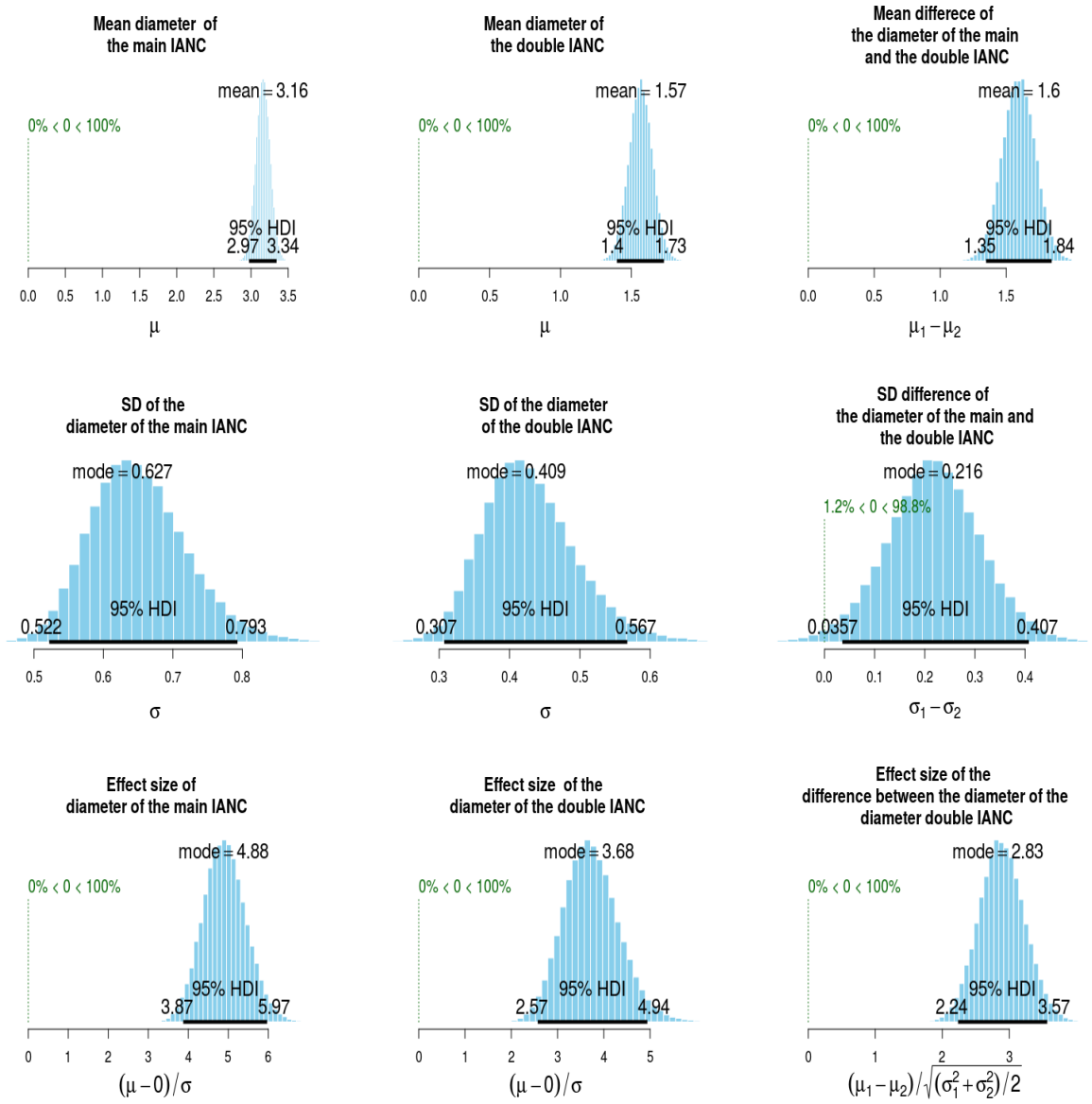


Figure4: Histograms showing the posterior distributions of the means, standard deviations and effect sizes (Main IANC, double IANC and mean difference). HDI – highest density interval.

The mean diameter of the main IANC on the left sides with double IANC was less than that of the right sides without double IANC. There was a probability of 61.8% of the diameter of the right main IANC being greater than the left when a double IANC was present on the right side (Figure 5).

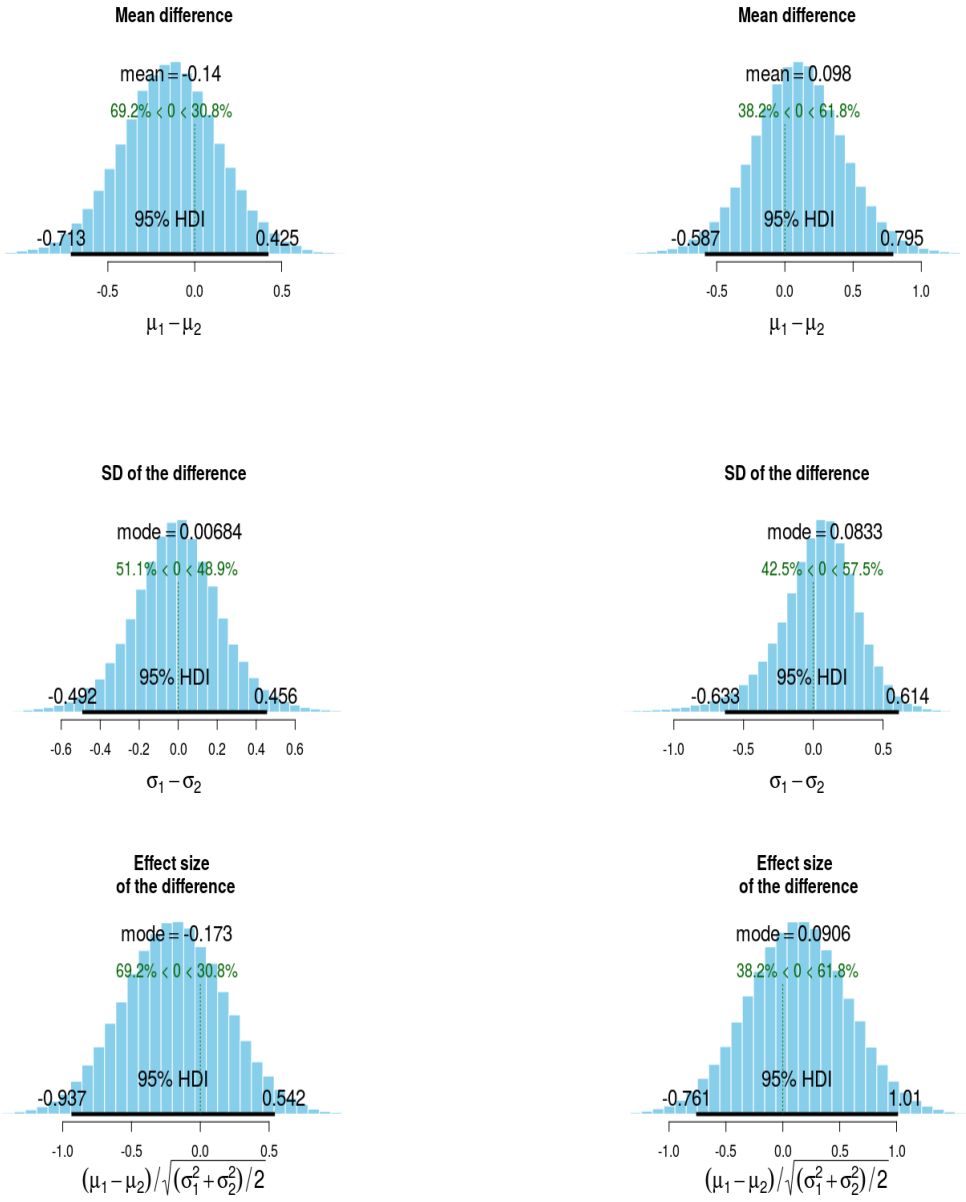


Figure5: Posterior distributions of the difference in diameter of main IANC between sides with and without double IANC. This difference was estimated by subtracting the mean diameter of the main IANC on the side without double IANC from that of the side with double IANC. Left and right columns correspond to when the double IANC is on that side. HDI – highest density interval.

6.1.6 Length of double IANC

The mean length of double IANC was 13.1mm ±3.45SD and effect size (ES) of 3.42 as shown in the posterior distributionsin Figure 6.

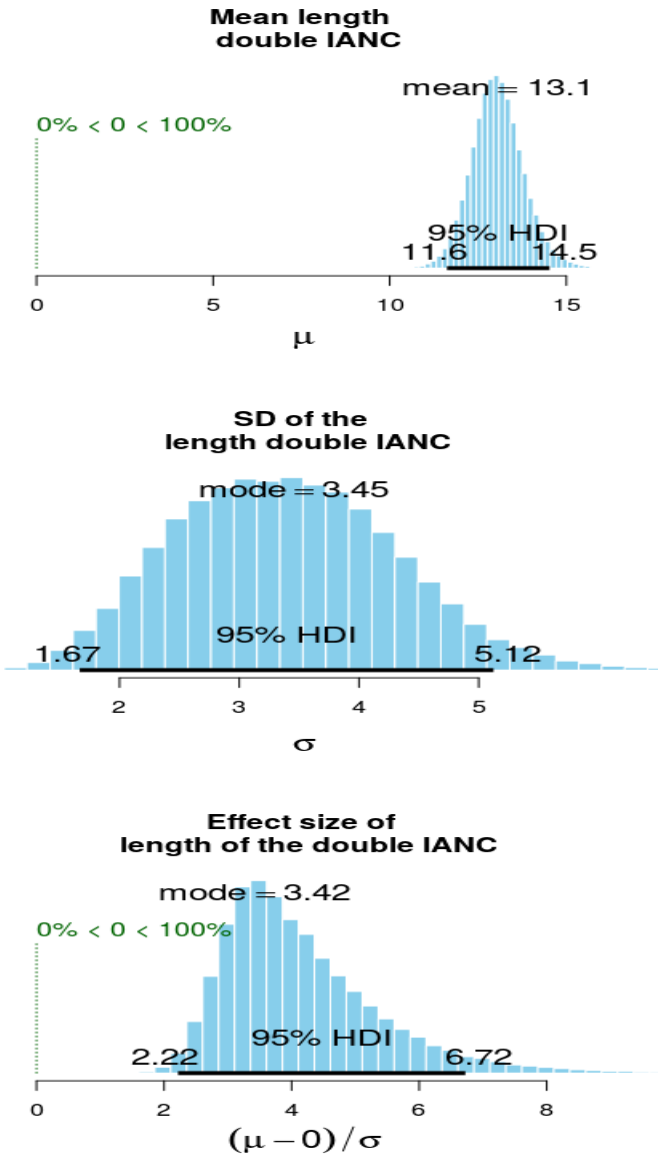


Figure6: Histograms showing the posterior distributions of the means, standard deviations and effect sizes (Length of IANC). HDI – highest density interval.

The distribution of length of the double IANC in the study population is shown Figure 7 below.

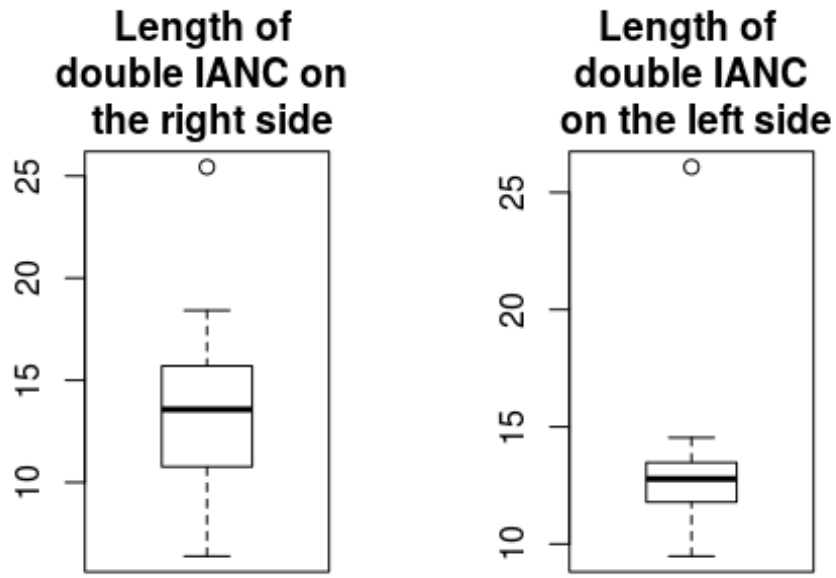


Figure7: Box and whisker plots of length (mm) of the double IANC on right and left sides

6.2 DOUBLE MF

Main MF were observed on both sides of the mandible in all the 800 CBCT images.

6.2.1 Association between the presence of double MF and gender (Proportion difference and 95% CrI).

Double MF were observed in 19 (2.4%) patients; 11 (0.57 [0.37, 0.77]) males and 8 females (0.43 [0.23, 0.60]). This prevalence was always higher in males by a probability of 0.825 but was not statistically significant (male - female: 0.14; 95% CrI [-0.14, 0.43]).
In one male patient (5.3%), one double MF was observed on the right side and two on the left side (Figure 8a).

Figure 8a.

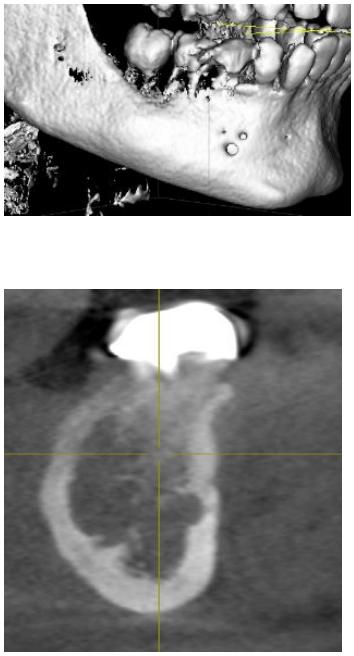


Figure 8b.

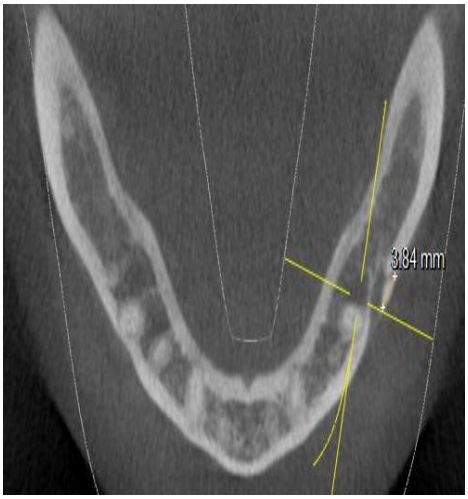


Figure 8c.

Figure8: CBCT three dimensional (3D) reconstructions and cross-sectional views of the mandible showing double MF

8a: Three-dimensional reconstruction (upper image) and coronal (lower image) views of two double MF positioned anterior superior to the main MF on the left mandible of a male patient. Note that all the foramina show continuity with the IANC. They were thus all considered double MF.

8b: 3D reconstruction (upper image) and coronal (lower image) views of double MF anterior superior to main MF on right side of a male patient. Only two foramina show continuity with the IANC. The rest were nutrient foramina.

8c: Axial view of a mandible depicting the distance (3.84mm) between double MF and the main MF.

6.2.2 Association between the side of the mandible (right or left) and the prevalence of the double MF (Proportion difference and the 95% CrI)

There were more double MF on the left side (11/21, 52.4%) than on the right side (10/21, 47.6%). This difference was however not statistically significant (estimated group difference (right side- left side: -0.05; 95% CrI [-0.33, 0.25]). On the right side, double MF were mainly found posterior-inferior to the main MF, while on the left side, they were mainly anterior-superior to the main MF (Figure8a, Figure 8b and Table 8). Altogether, double MF were mainly on the left side and were either anterior-superior or posterior-inferior to the main MF (Figure 9).

Table8: Position of double MF in relation to main MF and their distribution on the left and right side of the mandible

Relation of double MF to main MF	**Right Side n (%)**	**Left Side n (%)**
Anterior superior	2(9.5)	4(19)
Anterior inferior	0(0)	1(4.8)
Posterior	2(9.5)	0(0)
Posterior superior	1(4.8)	2(9.5)
Posterior inferior	3(14.3)	3(14.3)
Superior	2(9.5)	1(4.8)
TOTAL	**10 (47.6)**	**11 (52.4)**

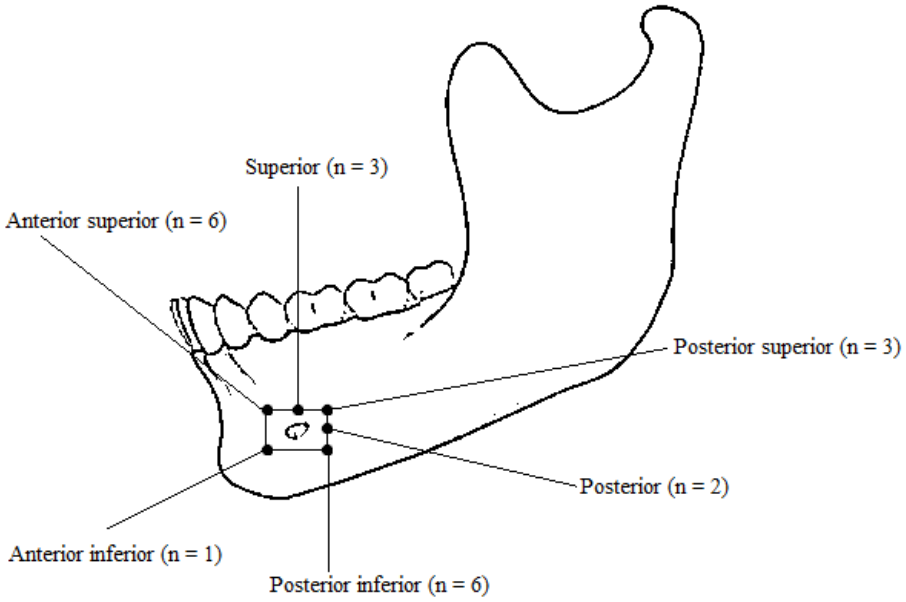


Figure9: Schematic representation of various positions where the double MF (black dots) were found in relation with the main MF (in the center of rectangle) in this study population. This drawing is not to scale.

6.2.3 Diameter of double MF and its distance from main MF

A summary of the mean diameters of double and main MF and mean distances of double MF from main MF is provided in Table 9.

Table9: Mean (SD) (range) of measurements of the main and double MF (mm)

Morphometric measurement	Mean	SD	Min	Max
Diameter of first double MF right side (n=10)	1.49	0.47	0.77	2.13
Diameter of first double MF left side (n=10)	1.07	0.24	0.69	1.38
Diameter of second double MF left side (n=1)	0.89	NA	0.89	0.89
Distance of first double MF from main MF (Right side) (n=10)	5.43	2.45	1.6	8.57
Distance of first double MF from main MF (Left side) (n=10)	4.02	2.49	1.4	8.72
Distance of second double MF from main MF (Left side) (n=1)	8.72	NA	8.72	8.72
Diameter of main MF (Right side) (n=19)	2.66	0.88	1.26	4.71
Diameter of main MF (left side) (n=19)	2.82	0.93	1.14	4.4

Distribution of the diameters of the main MF in the study population is shown in the box-and-whisker charts below (Figure 10).

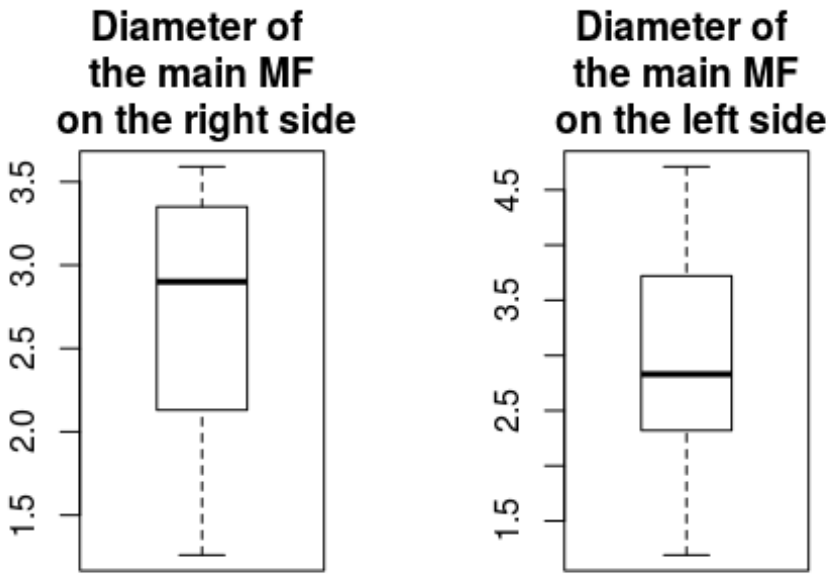


Figure10: Box and whisker plots of diameters of main MF on the right and left sides.

Distribution of the diameters of the double MF in the study population is shown in the box-and-whisker charts below (Figure 11).

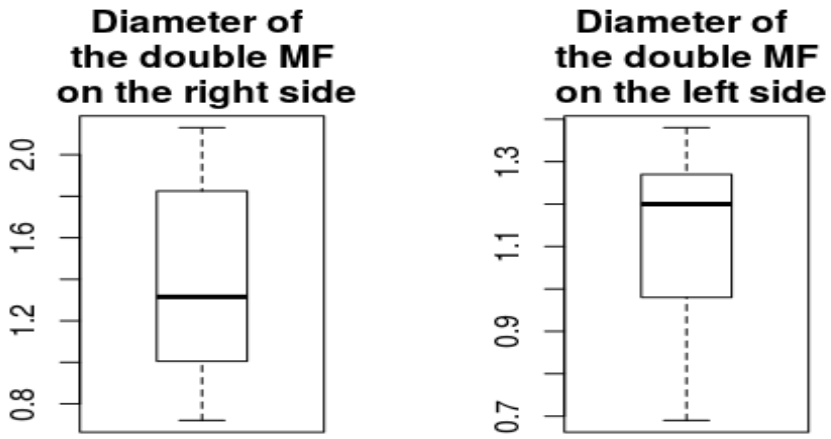


Figure11: Box and whisker plots of the diameter of double MF on right and left sides.

The overall mean diameter of double MF was 1.27mm $\pm$0.41SD while that of the main MF was 2.81mm $\pm$0.84SD. The main MF were always greater than the double IANC (effect size = 2.23) as shown in Figure 12.

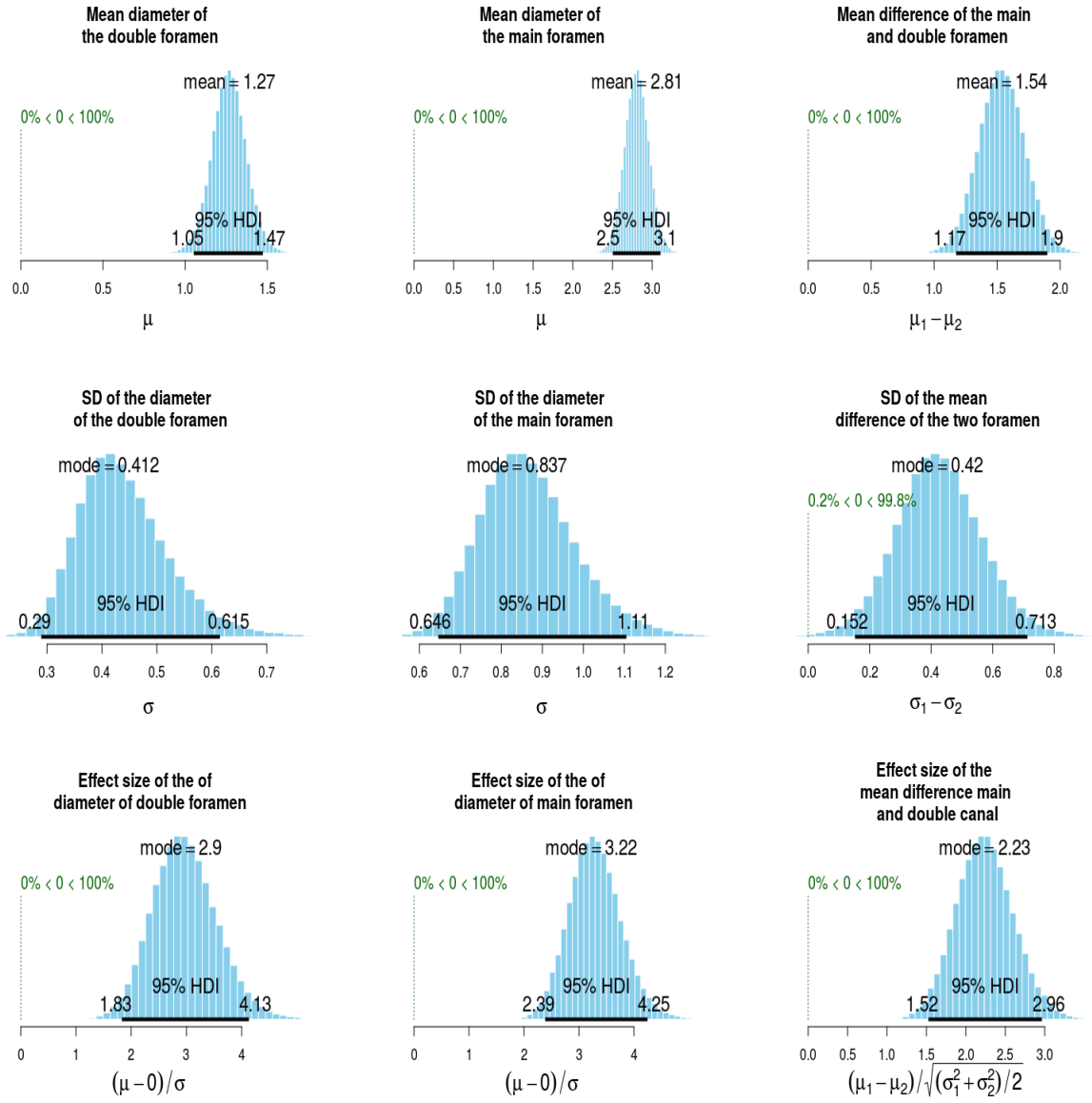
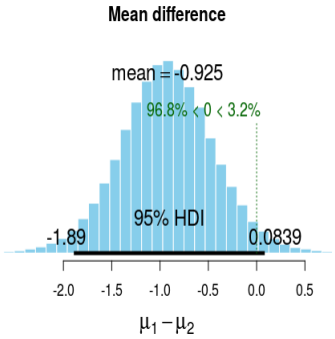
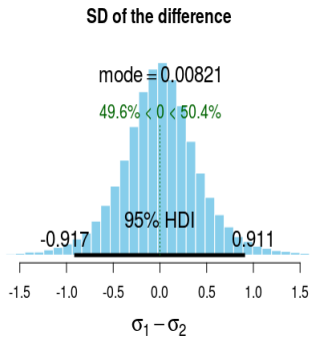


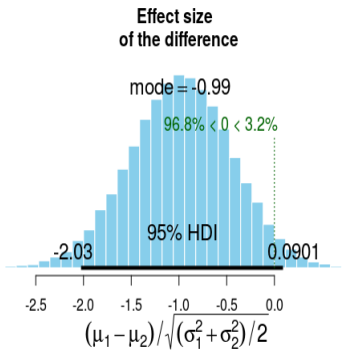
Figure12: Histograms showing the posterior distributions of the means, standard deviations and effect sizes (Main MF, double MF and mean difference). HDI – highest density interval.

The mean diameter of the main MF on the side with the double MF was always smaller than the side without the double MF (Figure 13). The mean distance between a double MF and the main MF was estimated at 4.69mm+2.46SD and had an effect size of 1.82 (Figure 14).

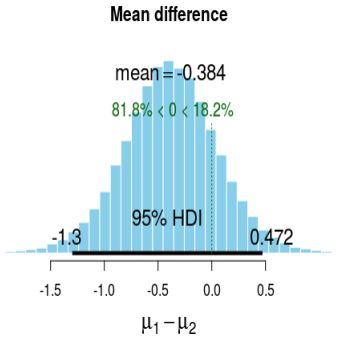
Mean diameter difference: Right side

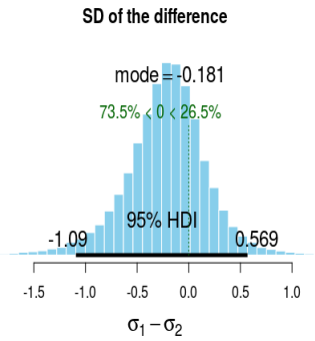






Mean diameter difference: Left Side





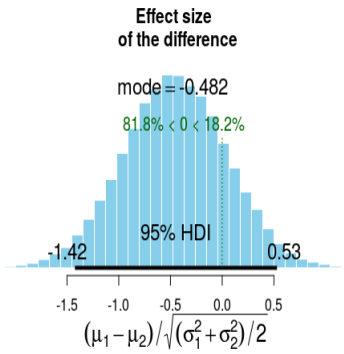


Figure13: Histograms showing the posterior distributions of differences in mean diameter, SD and ES; between main MF on the sides with and those without double MF. This difference was estimated by subtracting the mean diameter of the main MF on the side without double MF from that of the side with double MF. HDI – highest density interval.

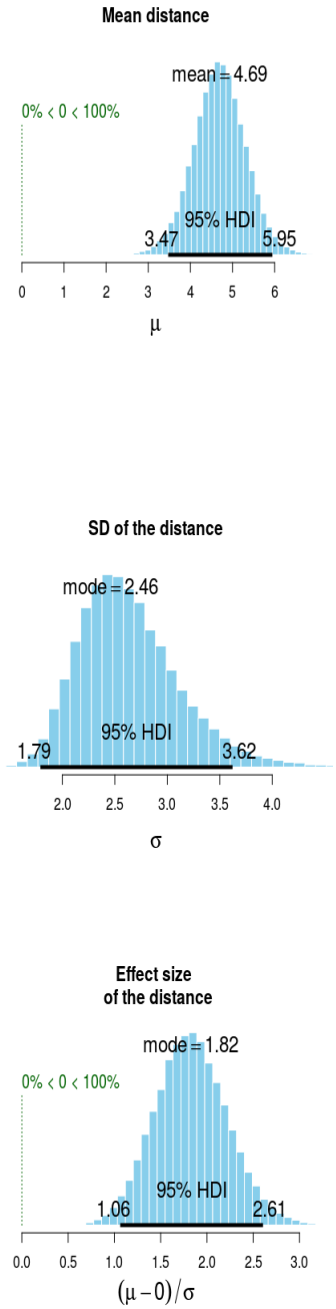


Figure14: Histograms showing the posterior distributions of the mean, standard deviation and effect size of the distance between double MF and main MF. HDI – highest density interval.

CHAPTER 7: DISCUSSION

7.1 Double IANC

The IANC is the bony channel through which the inferior alveolar neurovascular structures run within the mandible starting at the mandibular foramen and ending the mental foramen.[9] It is formed during the seventh week of intrauterine development because of intramembranous ossification along the lateral border of Meckel's cartilage.[13] Although commonly assumed to be a single canal,[2,6,9,12,14,15,16,17] double and triple[3,18]variations of the IANC have been reported.

Gross anatomical and histological studies have confirmed that double canals contain a nerve bundle accompanied by an artery.[9,17]The neurovascular contents of a retromolar double IANC that ends in a retromolar foramen may be at risk of damage during bone harvesting in the retromolar region[1] or may be traumatized by a denture that extends to this area.[21,22] They may also be at risk of damage during the alignment of bones during fracture reduction.[22]Paresthesia, bleeding during surgery and failure to achieve anesthesia have been associated with the presence of double IANC.[1,2,3,15,22]

Previous, studies based on at least 1,000 panoramic radiographs based on populations from different geographical locations, reported less than two percent prevalence of double IANC.[5,20,21,22] This modality has however been found to underestimate the presence of extra canals.[23,25] CBCT scans are the recommended modality of choice for detailed 3D analysis of double IANC when the same are observed on panoramic radiographs.[15,18,24,25] The current study showed that double IANC were found in 3.25% of the individuals whose CBCT scans were analyzed. In earlier similar studies, a higher incidence ranging from 10.2% to 66.5%, with no age or gender predilection, was reported.[1,6,14,23,24] Conversely, the present study established a statistically significant difference in the occurrence between genders, as more females than males had double IANC (occurrence in males less the occurrence in females = -0.61, 95% CrI -0.8 to -0.4). No statistical significant difference between the right and left sides was elucidated.

In studies done in Korea, Onyuntugs et al.[24] reported that the retromolar canal (type 1) accounted for 71.3% of the identified double IANC while Ju-Han et al.[14] found the same canal in 52.5% of their study participants. In the two studies, a forward canal[24] (type 3) (4.1%) and buccolingual[14] (type 4) (2.0%) types of double IANC were the least prevalent.

In a retrospective study conducted in Turkey, the commonest type was the forward canal (29.8%) and the least was the dental type (type 2) (8.3%).[1] Kuribayashi et al.[23] studied 301 subjects of Japanese origin and found that the dental canal (85.1%) was more common than retromolar canal (10.6%). Conversely, Naitoh et al.[6] established the following occurrences of double IANC on the same (Japanese) population; forward canal (59.6%), retromolar canal (29.8%), dental canal (8.8%) and buccolingual canal (1.8%). There was no buccolingual canal (type 4) found in the present study.

In the current study, it was established that the most frequently encountered type of double IANC was the retro-molar canal (79.31%), followed by forward canal (13.79%) and then dental canal (6.9%). Cleary, the prevalence of the various types of double IANC differ from one population to the other and even within the same population. This could be due to differences in the study methodologies used. It therefore implies that clinicians must radiographically investigate each case on its own merit and not generalize based on reported prevalence.

The diameter and length of double IANC have been documented in the past. Various authors reported the mean diameter of the double IANC and the main IANC (respectively) as follows; Kang et al.[14] 1.27mm (range: 0.27-3.29mm) and 2.85mm(range: 1.52-4.32mm), Rashsuren et al.[24] 2.2mm $\pm$0.5SD and 4.3mm$\pm$0.8SD, Kuribayashi et al.[23] 1.68mm (range:0.88-3.40mm) and 3.28mm (range: 2.02-4.63mm). The present study results compare well to the latter. At a credible interval of 95%, the mean diameter of the double IANC was 1.57mm [1.40mm-1.73mm] while the mean diameter of the main IANC was 3.16mm[2.97mm-3.34mm]. The presence of an extra canal did not seem to influence the diameter of the main IANC.

In aKorean population, Kang et al.[14] reported that the mean length the double IANC was 14.97mm (range: 2.17-38.8mm) while Rashsuren et al.[24] reported it as 16.9mm(SD: $\pm$6.8). This is higher than mean length of 13.1mm(SD$\pm$3.45) [95% CrI: 11.6,14.5mm], reported in the present study. The current findings concur with those from a Turkish population where it was reported as 13.6mm on the right side and 14.1mm on the left side.

Taking the standard deviation into consideration, it shows there is no difference between the findings from patients studied in Kenya and those from other geographical origins in the above studies with respect to the mean diameter and length of double IANC. It has

been speculated that if traumatized, arteries with a lumen of 1 to 2 mm internal diameter can lead to loss of up to 420 ml of blood in 30 minutes from the cut end, assuming a flow 0.2 ml per beat at 70 beats/min.[44] In this study, canals of a significant diameter (1.73mm) and length (14.50mm) were found. It is worth noting that irrespective of the type, double IANC have also been associated with difficult in achieving anesthesia in the lower jaw.[2,3]

7.2 Double MF

Mental nerve is a branch of the inferior alveolar nerve which exits the mandible at the mental foramen (MF) to give sensory innervation to the skin of the chin, mucous membrane of the lower lip and the gingiva on the ipsilateral side.[33] This foramen is found either inferior and in line with the 2nd premolar, between 2nd premolar and 1st molar, or between the two premolars (57.8%, 25%, and 9.4%, respectively) according to a study done on dry mandibles of Kenyans.[34] Double MF is an anatomical variation where an extra mental foramen is found adjacent to the main MF. Its prevalence, based on CBCT and medical CT studies has been reported to range from 4% to 10.7% and are either unilateral[26,29,33,38,39] or bilateral.[39] Absence of main MF has also been reported in literature.[4,38,40]

In the present study, all patient scans had the main MF on both sides. Double MF was observed in 19 (2.4%) patients (11 (57%) males and 8 (43%) females). In one male patient, double MF were observed on both sides of the lower jaw. There was no statistical significant difference in the occurrence between the two genders or sides of the mandible. This was a lower rate of occurrence as compared to the one reported in most of the previous studies (4% to 10.7%)[26,29,33,38,39]though consistent with that in more recent study (3%)[45] and even higher than was reported in a similar study done in Turkey (2%).[46] The discrepancy between the findings of the current study and those reported previously could be attributed to differences in sample sizes, measurement errors and the variation in methodologies adopted by these studies.

The position of double MF is reported to be mainly distal to the main MF.[29,39] Sisman et al.[46] found that in 43% of the cases the double MF was mesial to the main MF, and distal in the remaining case (57%). They further established that most of the double MF were inferior to the main MF. In contrast, the present study found that 11 double MF were posterior, seven were anterior and three were superior to the main mental foramen (MF). This observation is similar to what was established in a Caucasian population where the

double MF were in most cases superior and posterior to the main MF.[38] These differences may be due to racial and geographical origin differences as was previously established.[4,37]

At a 95% credible interval, the mean distance between double MF and the main MF was 4.69 [3.47, 5.59mm] with a standard deviation of 2.26mm in the present study. This compares closely to those by Sisman et al.[46] who reported 5mm (SD: ±2.5mm), Kalender et al.[47] who reported 5.3mm (SD: ±4.4mm) and Imada et al.[45] who reported a mean distance of 4mm (SD: ±0.7mm).[45] However, in the current study the mean diameter is less than, but comparable to that reported by Naitoh et al.[29] where they found this distance to be 6.3mm(SD: ±1.5mm). Taking the average distances reported in the literature together with the maximum distance found between the main MF and the double MF in the current study, risk of trauma to the neurovascular contents of the double MF can be greatly reduced if a safe distance of 9 mm from the walls of the main MF is observed. This would especially be useful in areas where CBCT radiography is not readily available for detailed analysis of double MF when the same is observed on panoramic radiographs. This would however only hold after the distortions in panoramic radiographs are corrected for.

The mean diameter of the double MF has also been documented in earlier studies. In a Turkish report, Sisman et al.[46] found the mean long axis of double MF to be 1.4mm (SD: ±0.4mm). Kalender et al.[47] studied mandibles in same population (Turkish) and reported that the mean vertical and horizontal dimensions of double MF were 1.4 mm (range: 0.8–2.4 mm) and 1.6 mm (range: 0.8–3 mm), respectively. In aBrazilian population, two studies reported varying but comparable mean diameters of the double MF. Imada et al.[45] reported a mean of 0.93mm (SD: ±0.4 mm), while Christiano et al.[38]reported 1.9mm (±0.7m). In two studies among the Japanese, the mean area (in square millimeters) of double MF was found to be 1.5mm[26] and 1.7mm[29] as measured on CBCT.

At 95% CrI, we estimated the mean diameter of double MF to be 1.27 [1.05, 1.47]mm with a standard deviation of ±0.41mm. Although Christiano et al.[38]observed that the presence of double MF did not seem to have a major influence on the size of the main MF; in the present study, it was observed that the mean diameter of the main MF on the side with double MF was always smaller than that of the side without the double MF. Taking the standard deviation into consideration, it shows there is no difference between the patients whose radiographs were included in this study and the subjects in the populations studied earlier with respect to the mean diameter of the double MF and its distance from the main

MF.

Toh et al.[48] established that accessory nerve fibers exited from the double MF to supply the mucous membrane and the skin of the corner of the mouth. An interesting observation in that study was that the extra mental nerve communicated with a branch from either the facial or buccal nerves. It is therefore plausible that surgical procedures may lead to trauma to the accessory mental nerves and therefore sensory complications in the areas they supply.[39,48] Identification of the position and potential variations of the MF is thus critical to minimize the risk of nerve damage. CBCT is more effective than panoramic radiography in the assessment of the MF region to detect and analyze in detail the presence of any double MF preoperatively.[45]

7.3 Strengths of this study

Bayesian methods were used in this study because they are incredibly useful for solving estimation problems, handling smaller sample sizes with greater accuracy, and incorporating prior judgment or knowledge into the estimation process.[49] Consequently, this is the first study to present measures of the magnitude of effects with their respective credible intervals. The present findings can therefore be incorporated into future meta-analyses.[50] In this study, the CBCT measuring tool measured a sub-millimeter diameter of up to 0.69mm; making the measurement results highly accurate.

7.4 Limitations of the study

Lack of extensive experience by the sole observer in this study may have introduced errors in identification and measurement of the study variables. However, training obtained from the manufacturers may have resulted in minimization of potential random measurement errors. It is also worth noting that the CBCT machine used in the current study has an inherent slice thickness of 0.3mm. In other words, any structures with a dimension smaller than this thickness were not detected.

CHAPTER 8: CONCLUSION

Based on the findings reported in this study, the rate of occurrence of double IANC and double MF was typically low among the dental patients studied. The commonest site for double IANC was the retro-molar region of the mandible. Double MF were mainly superior or posterior to the main MF and were always of a lesser diameter than the main MF. There was no difference in diameter between the main IANC and MF on the side with double occurrence and the side without. No gender predilection in the occurrence of the variations existed.

There was no difference between the patients attended to in Kenya and those in the literature reviewed in the present study with respect to the morphometric measurements of double MF and IANC. A difference however existed in the location of the double MF in relation to the main MF; a difference that could be due to geographical origin or racial differences among these populations.

If the presence of a double MF or IANC is observed on a panoramic radiograph, confirmation with a CBCT scan is recommended as it can detect in detail anatomical structure of less than a millimeter as was evident in this study. Upon confirmation, utmost care should be taken by adjusting the planned surgical procedure to avoid complications that may follow damage to these variant structures. A safe distance of 9 mm from the walls of the main MF would greatly reduce the risk of injury to the neurovascular contents of the double MF whenever CBCT imaging is not available.

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11. APPENDIX 1: DATA EXTRACTION FORM

File number:

Gender:

Age:

Side of the jaw	Double IANC	Location	Diameter	Length	Orientation
Right					
Left					

Side of the jaw	Double MF	Diameter	Distance from MF	Relation to MF
Right				
Left				

12. APPENDIX 2: LETTER OF INSTITUTIONAL PERMISSION

Dental Surgeon

Dr. Sunil Vinayak

B.D.S. (NRB) FR.S.H.
FADI (USA) FPFA
Member: BOS. IAO. AOS

smile AFRICA

8th September 2015

To Whom It May Concern,

RE: PERMISSION FOR DR. JOSEPH MUTAHI GAKONYO TO CONDUCT A STUDY AT OUR CLINIC

This is to confirm that the above named dental surgeon is well known to me and will be analyzing cone beam computed tomography (CBCT) scans at our clinic.

This is part of his Master of Science degree at the University of Pretoria, faculty of dentistry. The study is titled" *Double Inferior Alveolar Nerve Canals and Mental Foramina in the Mandible: A Computed Tomography Study at a Private Dental Clinic in Kenya*"

He has my permission to do the study at our facility upon clearance by the Kenyatta National Hospital/University of Nairobi Research and Standards Committee. I wish him the best in his research and future Implantology career.

Yours sincerely,

S. Vinayak

DR. SUNIL VINAYAK
DENTAL SURGEON

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14. LETTER FROM THE STATISTICIAN

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University of Nairobi
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12th June 2015

TO WHOM IT MAY CONCERN

RE: REVIEW OF RESEARCH PROPOSAL.

Title: Double Inferior Alveolar Nerve Canals and Mental Foramina in the Mandible: A Computed Tomography Study in a Kenyan Private Dental Clinic.

Candidate: Joseph Gakonyo

I hereby wish to confirm my contribution in the development of the proposal.

In my view, it has been conceptualised with the ideal statistical considerations.

Additionally, the following points reflect the specific statistical considerations and its robustness to achieve the proposed aims:

- The proposal to use a sample size that optimizes achieving all the objectives.
- The proposal to use estimation for inference of the parameters of interest (proportions and means). The effect sizes will also be estimated.

I would be glad to discuss any concerns with you.

Yours sincerely,

12/6/2015

Dr. Edwin M. Kagereki
Lecturer - Biostatistics

15. RESCOM FORM B: LETTER OF CLEARANCE FROM THE BIOSTATISTICIAN

RESCOM B

LETTER OF CLEARANCE FROM THE BIOSTATISTICIAN

This letter is to confirm that the student(s), with the Name(s)
JOSEPH MUTAHI GAKONYO

Studying at the University of
PRETORIA

Discussed the Project with the title
"Double Inferior Alveolar Nerve Canals and Mental Foramina in the Mandible: A Computed Tomography Study at a Private Dental Clinic in Kenya"
with me.

I hereby confirm that I am aware of the Project and also undertake to assist with the Statistical Analysis of the data generated from the Project.

The analytical tool that will be used will be
Estimation methods of proportions and means (and mean differences) for statistical inference using Bayesian methods. Statistical software to be used is R and the relevant packages.

to achieve the objective(s) of the study.

Name: EDWIN M. KAGEREKI Signature:

Department of Unit: Department of Periodontology / Community and Preventive Dentistry; University of Nairobi, Kenya.

Tel nr: +254726226143 Date: 15th September, 2015.

RESCOM B

16. CLEARANCE FROM ETHICS COMMITTEE

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.
- FWA 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
- IRB 0000 2235 IORG0001762 Approved dd 22/04/2014 and Expires 22/04/2017.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee

28/01/2016

Approval Certificate
New Application

Ethics Reference No.: 6/2016

Title: Double Inferior Alveolar Nerve Canals and Mental Foramina in the Mandible: A Computed Tomography Study at a Private Dental Clinic in Kenya

Dear Dr J M Gakonyo

The **New Application** as supported by documents specified in your cover letter dated 4/01/2016 for your research received on the 4/01/2016, was approved by the Faculty of Health Sciences Research Ethics Committee on its quorate meeting of 27/01/2016.

Please note the following about your ethics approval:
- Ethics Approval is valid for 1 year
- Please remember to use your protocol number (**6/2016**) on any documents or correspondence with the Research Ethics Committee regarding your research.
- Please note that the Research Ethics Committee may ask further questions, seek additional information, require further modification, or monitor the conduct of your research.

Ethics approval is subject to the following:
- The ethics approval is conditional on the receipt of 6 monthly written Progress Reports, and
- The ethics approval is conditional on the research being conducted as stipulated by the details of all documents submitted to the Committee. In the event that a further need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

Additional Conditions:

- Our REC waives the need for individual participant informed consent.

We wish you the best with your research.

Yours sincerely

*** Kindly collect your original signed approval certificate from our offices, Faculty of Health Sciences, Research Ethics Committee, H W Snyman South Building, Room 2.33 / 2.34.*

Professor Werdie (CW) Van Staden
MBChB MMed(Psych) MD FCPsych FTCL UPLM
Chairperson: Faculty of Health Sciences Research Ethics Committee

The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

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Ref: KNH-ERC/A/70

3rd March 2017

Dr. Joseph Mutahi Gakonyo
P O BOX 54954-00100
NAIROBI

Dear Dr. Gakonyo

REVISED RESEARCH PROPOSAL: DOUBLE INFERIOR ALVEOLAR NERVE CANALS AND MENTAL FORAMINA IN THE MANDIBLE: A COMPUTED TOMOGRAPHY STUDY AT A PRIVATE DENTAL CLINIC IN KENYA (P685/09/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 3rd March 2017 – 2nd March 2018.

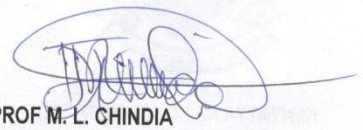
This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

"Protect to Discover"

Yours sincerely,



PROF M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH-UoN ERC
Supervisors: Dr.Tom Onyango Ochola(UON), Prof. Andre van Zyl (UOP), Prof. Johan Marnewick(UoP)