Assessment of the anterior loop of the inferior alveolar nerve in a Sample of Egyptian Population using CBCT: An Observational Cross-Sectional Study

Submitted for partial fulfillment of the PHD requirements in Oral and Maxillofacial Radiology department, Faculty of Dentistry, Cairo University

By

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I-Administrative Information

1-Title: Assessment of the anterior loop of inferior alveolar nerve in a sample of Egyptian Population using CBCT: An Observational Cross-Sectional Study.

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5-Roles and responsibilities of the authors:

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- Identifying the need for sub-recipient agreements.
- Ensuring that the used procedures are consistent with sound research design and do not unnecessarily expose subjects to risk/harm.
- Being responsible for all required actions to manage and complete the scientific and programmatic aspects of the project (including data collection and assessment).
- Ensuring the integrity and safeguarding of notebooks and scientific data. Ensuring the completion, accuracy and timeliness of programmatic (technical) reports.

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- Establishing a research plan with the investigator, in which the work is completed.
- Discussing the work done through meetings or exchanging email messages if the candidate is in a remote location, at least once per month.Assisting the candidate by regularly checking the records of data and observations and suggesting improvements where appropriate.

- Providing constructive criticism and advice on submitted written drafts within agreed time frames.
- Supporting the candidate in the preparation for thesis defense.
- Facilitating timely completion of the candidate's study and ultimate completion of the thesis.

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- Performing the blind assessment during the data collection stage.
- Giving detailed advice on the necessary completion dates of successive stages of the work so that the thesis can be submitted within the relevant maximum registration period.
- Reading and commenting on the whole of the final draft of the thesis, provided that this is presented within a reasonable and agreed time frame, and ensuring that the research student is aware that the thesis must comply with all relevant regulations, including those on word length, format, and binding.

II-Introduction

6. a. Scientific Background: The proper knowledge of anatomical structures and their precise position is of a paramount importance for different dental specialties. The inferior alveolar nerve (IAN) canal is one of the most important anatomical landmarks in the mandible ***Shaban et al., 2017.*** By definition the inferior alveolar nerve (IAN) is a terminal division of the mandibular branch of the trigeminal nerve, it is confined within the mandibular canal and innervates all the mandibular teeth. The IAN initiates from the mandibular foramen and goes obliquely downward and forward in the ramus, and then horizontally within the body of the mandible. The IAN gives off the mental nerve, which exits the mandible through the mental foramen, supplying sensory branches to the chin, lower lip, mucous membranes and the gingiva; from the midline to about the second premolar region. It then continues its path anteriorly and turn into the mandibular incisive nerve, which innervates the mandibular canines and incisors ***Siddiqui et al. 2018***. Before leaving the mental foramen and branching into the incisive nerve, the IAN may continue anteriorly and form an anterior loop (Al). This anterior loop is the part where the IAN directs mesially and occlusally before reversing direction and coursing distally towards the mental foramen ***Ragu et al., 2019.*** During implant planning and other surgical procedures knowing the presence of the anterior loop and its length is very crucial to avoid its injury. Specially concerning implantology where the location of the mental foramen and anterior loop determines the most distal point for implant placement in the

interforaminal area; in order to avoid any injury resulting in sensory disturbances in this area ***Panjnoush et al., 2016***

Recently, several studies have been published discussing the prevalence and length measurement of the anterior loop in many populations. However, no published researches were done on the Egyptian population. Therefore, this study is designed to assess the presence of the anterior loop and its length in a sample of Egyptian population using CBCT.

PO question

P: mandible quadrants in Adult Egyptian Population.

O: Presence of the anterior loop of the inferior alveolar nerve; and its length in the mandibles of adult Egyptian population

	Outcome Measured	**Measuring Device**	**Measuring Unit**
Primary Outcome	Prevalence of the anterior loop	CBCT axial cuts (Ondemand 3D software)	Categorical nominal data Percentage (%)
Secondary Outcomes	length of the anterior loop	Built in measuring tools (axial cuts) in Ondemand 3D software "MPR* module"	mm
	Mesial extension of the anterior loop	Cross-sectional cuts on Ondemand 3D software "DVR** module"	mm

* MPR: Multiplanar Reformatting

** DVR: Direct Volume Rendering

Research question:

How frequent is the anterior loop and how long its mesial extension is in a sample of Egyptian population?

6b. Review of literature

List of main databases used in search:

- ✓ Pubmed
- ✓ Google Scholar

Keywords:

Anterior Loop, Mandibular Canal, Mental Foramen, CBCT, Maxillofacial Anatomy, Dental Implants.

In ***1994 Solar et al*** classified the mental nerve path of the IAN canal into three types; where type I is defined as a Y-shaped anatomy of the incisive branch & the mental branch with absence of the anterior loop, while type II is a T-shaped anatomy with the incisive branch being perpendicular to the mental branch still with the anterior loop's absence, and finally type III is defined as a Y-shaped anatomy with the presence of the anterior loop (Figure 1).

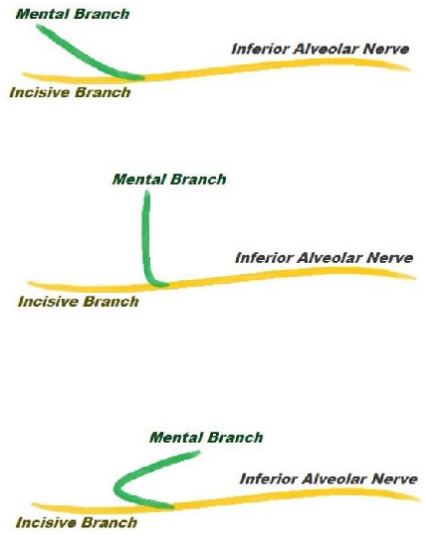

Figure 1: IAN Types ***(Demir et al 2015)***

According to ***Bavitz et al. 1993 & Misch 1999*** the IAN's anterior loop is defined as the structure where the mental neurovascular bundle passes inferior and anterior to the mental foramen then loops backwards to exit the mental foramen (Figure 2).

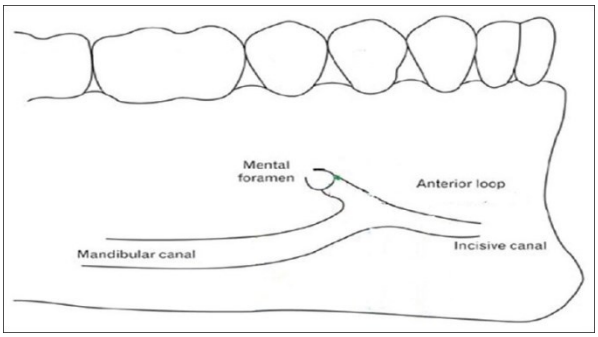

Figure 2: Schematic diagram showing key image of anterior loop of IAN ***(Siddiqui, et al 2018)***

Different methods were used to assess the anterior loop including cadavers, dry skulls, panoramic radiographs, medical CT and CBCT; which is the reason behind the considerable variation of the prevalence and average length of the anterior loop mentioned in the literature where the mean length ranges between 0.1 mm & 6.92 mm ***Patterson 2015.*** In addition to the effect of different races, age and gender. ***Ngeow et al 2009*** stated that several authors have suggested the limitation of panoramic radiograph regarding the visualization of the anterior loop for the purpose of implant planning due to the high percentage of false-positive and negative findings compared to cadaveric dissection data owing to its limitation as a two dimensional radiographic method. Bringing us to the fact that three dimensional imaging techniques such as medical CT, Magnetic Resonance Imaging (MRI) and Cone beam CT evade this draw back ***Ngeow et al 2009 & Nair at al 2013.***

Nair et al 2013 stated that CBCT surpasses medical CT in its significantly lower dose with producing high resolution, superimposition and magnification free undistorted 3D images of the maxillofacial anatomy.

Therefore it is the method of choice for assessment of the anterior loop before surgical intervention as mentioned by ***Demir et al 2015, Moghddam et al 2017 & Siddiqui et al. 2018.***

6c. <u>Statement of the Problem</u>

A high percentage of iatrogenic damage to the mental nerve occurs due to the unawareness of dental clinicians with the presence of an IAN's anterior loop in the interforaminal area during implant placement or other surgical procedures such as tumor or tooth impaction removal; leading to its injury. Therefore, dental clinicians should know the prevalence of the anterior loop in different populations in addition to having a proper case examination and planning using CBCT.

Specific Objectives:

To detect the prevalence of anterior loop and measure its length in relation to gender effect in a sample of the Egyptian population.

Hypothesis: null

III -Methods

A) Study design and setting

7- Study Design: An observational Cross-sectional Study

8- Setting and Location:

The CBCT data of this study will be obtained from the CBCT data base available at a private radiographic centre "ORASCAN Oral & Maxillofacial Imaging Centre" located in Cairo, Egypt. Being a retrospective study, CBCT images of Egyptian patients who have already been subjected to CBCT examination as part of their dental diagnosis and/or treatment planning during the years 2018-till present will be included according to the proposed eligibility criteria.

B) Participants:

Based on sample size calculation, a sample of 192 CBCT images of mandible quadrants belonging to Egyptian individuals will be examined. The selection of the scans to be included will be based on the following eligibility criteria.

9- Eligibility criteria and selection method:

- ✓ **Inclusion criteria:**

- CBCT scans of adult Egyptian patients, males and females.
- CBCT scans with unilateral or bilateral anterior mandibles; with minimum 2 mm length distal to the mental foramen (mental foramen & anterior mandible are clearly delineated) ***Moghddam et al, 2017.***

- ✓ **Exclusion criteria**

- CBCT images of poor quality or artifacts interfering with the assessment of the anterior loop of IAN.
- Scans showing any pathosis in the interforaminal area (tumor or impaction).

10- Matching criteria and allocation ratio:

Not applicable in the study

C) Variables:

11- Details about variable

1. Length of anterior loop's mesial extension if present.
2. Sex of the patient will be identified and addressed as the prevalence of the anterior loop of the IAN and its length may show sex predilection.

12- Data Sources / Measurements:

- Retrospective Data Analysis will be performed after the CBCT images are pooled from the computer database.
- Exposure parameters of the scans were as following; scanned using Cranex® 3DX SOREDEX, 0.2 voxel resolution, 8 × 6 cm FOV, 90 kVp, 10 mA and 6 seconds exposure time
- CBCT images will be analysed using OnDemand3D ® App (Cybermed, Seoul, Korea); using the 3D module, reference lines are modified to confine with the buccolingual orientation of the inferior alveolar loop, to obtain a modified axial cut showing the inferior alveolar loop and mental foramen opening on the same plane.
  In scans with an anterior loop, on the corrected axial cut the distance between the most mesial point of the mental foramen and the maximum mesial extension of the anterior loop will be measured ***Von Arx et al 2013*** (Figure 3).

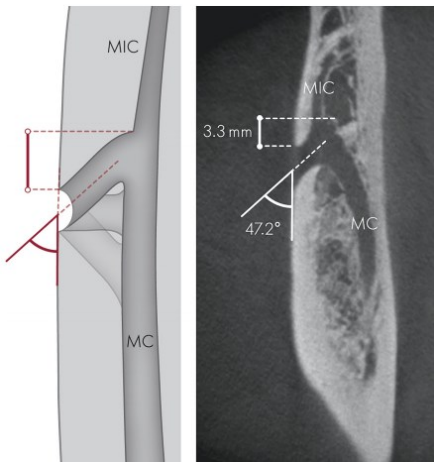

Figure 3: the distance between the most mesial point of the mental foramen and the maximum mesial extension of the anterior loop will be measured ***Von Arx et al 2013***

- Using the DVR module; an arch line will be drawn on the axial plane to obtain a reformatted panorama; then the mesial extension of the AL will be detected and its length will be measured by counting the number of the consecutive adjacent vertical cuts on cross-sectional view between the slice showing the anterior border of the mental foramen and the anterior border of the loop using slice interval of 1mm ***Apostolakis et al 2012*** (Figure 4).

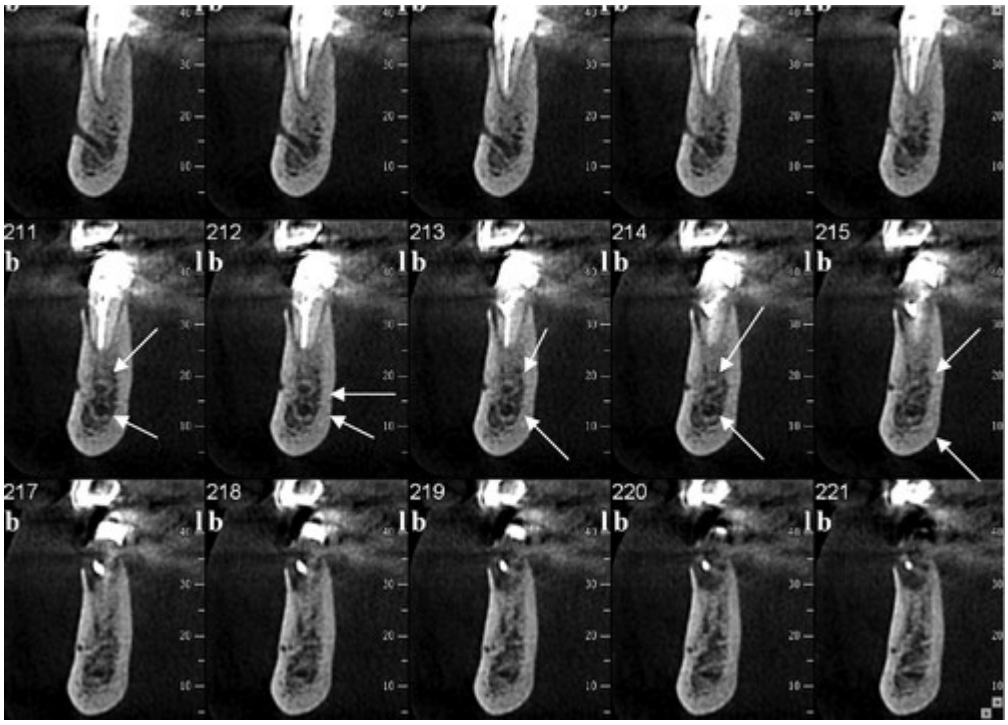

Figure 4: Cross-sectional reconstructions showing the AL ***Apostolakis et al 2012***

- CBCT images will be interpreted by two oral radiologists independently; blinded from demographic data of the patients and from the results of each other.
- Each radiologist will evaluate the images for detection of the anterior loop and measuring its length. Then one of them will re-evaluate the images with two weeks interval between the two reading sessions.
- Intra-observer and inter-observer and variability between the observers will be evaluated.

13- Addressing potential sources of bias:

No source of bias. CBCT images will be interpreted by two oral and maxillofacial radiologists independently blinded from demographic data of the patients and from the results of each other.

D) Study Size:

14- Study Size:

The aim of this study is to detect the prevalence and length of the anterior loop among a sample of Egyptian population. Based upon the results of ***Shariati et al 2017***, the prevalence of the anterior loop= 24.3%. Using alpha (α) level of (5%), acceptable margin of error = 6%, the minimum estimated sample size was 192 subjects. Sample size calculation was performed using Epi Info 7.2.2.2

E) Quantitative variables

15- Handling of quantitative variables in analyses:

The number of CBCT scans of Egyptian individuals with an anterior loop of the IAN will be counted and its length will be measured to estimate the variations in the Egyptian population. The length of the anterior loop will be handled as mean and standard deviation.

F) Statistical methods:

16- Statistical methods:

Data will be analyzed using IBM SPSS advanced statistics (**Statistical Package for Social Scienceaszxs**), version 21 (**SPSS Inc., Chicago, IL**). Numerical data will be described as mean and standard deviation or median and range. Categorical data will be described as numbers and percentages. A p-value less than or equal to 0.05 will be considered statistically significant. All tests will be two tailed.

IV. Ethics and dissemination

17a. Research ethics approval: The Study protocol will be submitted to the Ethics commute in Faculty of Dentistry- Cairo University for approval .

17b. Protocol amendments: Any amendments in the protocol will be reported to the main and co-supervisor.

17c. Access to Data: Investigator, Co-supervisor and main supervisor will have access to the final trial data set .

17d.Dissemination Policy: The Investigator will communicate her results with other participants and healthcare providers through publication of the protocol and the research final results and recommendations. This will be done through publication websites and journals concerned Oral and Maxillofacial Radiology specialty, For Sharing the recommended clinical application obtained from the final results of the research.

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