

I. Administrative information:

Title:

Accuracy of linear measurements of ultra-low dose Cone Beam Computed Tomography and Digital Panoramic Radiography Performed on mandibular anaesthetic landmarks Versus Real mandibular measurements (Diagnostic Accuracy Study)

II. Introduction:

Background:

One of the important mandibular anatomical landmarks is the inferior alveolar Nerve which can be damaged during surgical procedures such as third molar extraction, management of trauma and surgical removal of tumors. Therefore the dentist must be able to localize it prior to any dental procedure (Patil et al 2015).

The mandibular foramen represents the entrance of the inferior alveolar nerve, which passes through the mandibular canal throughout the body of the mandible till it reaches the mental foramen where it divides into mental nerve and incisive nerve (Salinas et al 2016).

In the past, the anterior region of the mandible was regarded as a safe area for implant surgery due to the absence of neurovascular structures. However, recent studies have shown haemorrhage and hematoma formation in the floor of the mouth due to injury to the vessels of the mandibular lingual foramen (Rosano et al 2009).

Panoramic radiography is simple, inexpensive, and widely used, in addition to offering low radiation exposure to the patient. Kaffe et al 1994 found panoramic radiographs to be beneficial in locating mandibular foramen. In another study performed by Kositbowornchai et al 2007 it was found that there is a high accuracy between the distances measured on panoramic radiographs and real measurements on dry mandibles (Kaffe et al 1994) and (Kositbowornchai et al 2007).

Ultra-Low Dose CBCT technology is a recommended option for clinicians due to the decrease in radiation exposure to patients. Patients must not be exposed to a higher dosage than needed to acquire images of sufficient diagnostic quality (Kusnoto et al 2015)

Review of literature:

Resources: PubMed, Science direct.

In a study performed on dry mandibles the comparison of linear measurements made with digital caliper and CBCT showed no significant differences for 95% of the distances measured. The 5% discrepancy is considered acceptable (Kamburoglu et al 2011) and (Sanjana et al 2017).

A study was performed to evaluate the accuracy of panoramic radiographs in the localization of mandibular foramen on dry mandibles, where the position of mandibular foramen in relation to the ramus width and height was noticed. The results showed that there were statistically significant differences between distances measured on dry mandibles and radiographs except for the upper anterior ramus height (**Kositbowornchai et al 2007**) and (**Patil et al 2015**).

Another study was conducted on dry mandibles for the localization of the mental foramen. Measuring the distances from the crest of the ridge to the center of the mental foramen and from the inferior border of the mandible to the center of the mental foramen in addition to the location of the mental foramen relative to its' alignment with mandibular teeth. For mental foramen measurement from crest of the ridge till its' center did not show a significant difference for laterality, while the distance from the inferior border of the mandible till the center of the mental foramen the results showed a significant difference. Studies have shown that the most common location of the mental foramen is aligned with the second premolar, followed by between the first and the second mandibular premolar (**Lopes et al 2010**).

A study was performed for the localization of the lingual foramen using CBCT. Linear measurements were made including their diameter, the distance between the lingual foramen and the crest of the ridge and the distance from the inferior border of the mandible to the lingual foramen. Lingual foramina were classified according to their location into midline type, Para median type or posterior type. (**He et al 2016**).

CBCT and panoramic radiographs have been used to detect and measure lingual foramina. It has been proposed that CBCT provides highly accurate data of the mandibular anatomy (**Ludlow et al 2007**) and (**Stratemann et al 2008**).

III. Methods:

A. The pre-analytical phase: Mandibular anaesthetic landmarks will be identified on each dry mandible and will be marked using gutta percha.

B. The analytical phase. The ten human dry mandibles will be submitted for:

1-Digital Panoramic Radiography.

Panoramic radiographs will be obtained using the SOREDEX CRANEX™ 3Dx unit. The exposure parameters will be 8Ma, 63kVp and 16.4 sec exposure time.

2-Cone Beam Computed Tomography (CBCT).

SOREDEX CRANEX™ 3Dx unit will be used in this study. Images will be acquired at a single rotation. SOREDEX® MiniDose parameters will be used. The exposure parameters will be 3.2 Ma, 90kVp and 2.3 sec exposure time to take the advantage of 3D data in dose sensitive cases like children, or reduce the radiation dose for the patient.

The real linear measurements will be measured in millimeter on dry mandibles using digital caliper and will be compared with measurements obtained from both techniques.

C. The post analytical phase. Images will be evaluated by two experienced radiologists of ten years of experience. Each one will evaluate the images separately twice with a period of two weeks in-between the two reading sessions. The researcher will measure out the real linear measurements on the dry mandibles using digital caliper.

D) Statistical analysis

Sample size calculation and how it was determined

Sample size calculation was done using R statistical package, version 3.3.1 (21-06-2016). Copyright (C) 2016. The R Foundation for Statistical Computing.

One-way analysis of variance power calculation for more than two groups was used to detect the proper sample size. Means and standard deviations were determined according to Patil et. al (2015) based on the difference in distances measured on dry mandibles between different radiographic techniques.

The results showed that, at a power of 80% and a two-sided significance level of 5%; a total sample size of 10 dry mandibles will be adequate to reject the null hypothesis that the group means are equal; i.e there's no difference between radiographic techniques.

Sample Size Calculation statistical output

Name of the test: One-way analysis of variance (ANOVA) power calculation for more than two groups.

Source use for calculation:** Patil et. al, 2015

Output:

```
> m1=15.27
> sd1=1.57
> m2=16.93
> sd2=1.54
> n1=n2=25
> k=2
> within.var=(sd1^2+sd2^2)/2
> m=((n1*m1)+(n2*m2))/(n1+n2)
> between.var=(((m-m1)^2)+((m-m2)^2))/(k-1)
> power.anova.test(groups = 3, between.var = between.var, within.var =
within.var, power=0.80, sig.level=0.05)
```

Balanced one-way analysis of variance power calculation

groups = 3

n = 9.52841

between.var = 1.3778

within.var = 2.41825

sig.level = 0.05

power = 0.8

NOTE: n is number in each group

