

Official Title of the Study:

Effect of variations of Field of view (FOV) and milliamperere (mA) on metal artifacts in Cone Beam Computed Tomography. (In vitro study)

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I. Administrative information:

1. Title:

Effect of variations of Field of view (FOV) and milliampere (mA) on metal artifacts produced by dental implants in Cone Beam Computed Tomography image quality.
(In-vitro study)

2. Protocol registration:

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4. Funding:

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5. Roles and responsibilities:

Investigator:

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Responsibility:

She is responsible for:

- Recruitment of bio models and dental implants.
- CBCT image analysis.
- Interpretation of data.
- Writing the protocol.
- Writing final report of the research.
- Responsible for Thesis writing.

Main supervisor:

Dr. Noha Issa

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Responsibility:

Main supervisor.

The one responsible for:

- Study selection
- Data managing,
- Monitoring and auditing
- Analysis of CBCT images.
- Thesis revision.

Co-supervisor:

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Responsibility:

Co-supervisor

The one responsible for:

- CBCT image analysis.
- Data monitoring and auditing.
- Interpretation of data.
- Revision of final report of the research.
- Responsible for Thesis revision.

II. Introduction:

Cone Beam Computed Tomography (CBCT) is considered an important valuable imaging technique in the diagnosis and treatment planning in oral and maxillofacial surgery as well as implant dentistry by means of three dimensional images which provide extra information about the buccolingual dimension of the alveolar bone with more details for bone anatomy and inclination (**Venkatesh & Elluru, 2017**).

To make an accurate diagnosis and treatment planning, we have to obtain images with more details, good resolution and quality which could be achieved by CBCT. However, there are some issues in scanned areas that can affect their quality such as presence of metals (metallic restorations, orthodontic appliances, dental implants, crowns) which result in artifacts which can be considered as an important cause of poor image quality which will lead to poor diagnosis (**Bechara et al., 2012**).

There are many types of artifacts which can be observed on CBCT images. Beam hardening artifact is considered a common one which occurs when an x-ray beam comprised of polychromatic energies passes through an object, resulting in selective attenuation of lower energy photons. The effect is conceptually similar to a high-pass filter, in that only higher energy photons are left to contribute to the beam and thus the mean beam energy is increased ("hardened") (**Shokri et al., 2019**).

Research question:

Can change of milliamperage (mA) and field of view (FOV) reduce the metallic artifacts in CBCT that result from metallic structures?

The aim of this study is to evaluate the effect of exposure parameters as milliamperage (mA) and field of view (FOV) in CBCT on metal artifact of dental implant.

Review of literature:

Databases used: PubMed – Google scholar – Cochrane.

Keywords: CBCT - Metal artifacts - Beam hardening artifact - Dental Implants - MAR–Metal artifacts reduction- metal artifact reduction protocols – mAs - FOV

The first development of Cone beam Computed tomography (CBCT) was originally in 1982 for medical use specially for angiography (**Patcas et al., 2012**).

Then in 1998 the CBCT was introduced for craniofacial scanning, moreover it generates 3D image with a lower cost and lower radiation doses than that in Computed Tomography. The technique of CBCT is depending on a cone-shaped beam of x-ray which is centered on a 2D detector and rotates around the object, providing hundreds of 2D scans of a defined volume of anatomy instead of the slice by slice scanning which was carried out in conventional Computed Tomography (**Alshehri et al., 2012**).

CBCT offers more options for image quality improvement by more than one software and most of these are user- friendly and easy to use with 3D imaging tools. Third party software are available at a wide range of cost, which offer a lot of tools for easy and good diagnosis, analyzing and making appropriate treatment plan. Moreover, third party software are also of help in virtual studying, preparing surgical guides ,etc.... **(Venkatesh & Elluru, 2017).**

The use of CBCT became more common in implant treatment planning as it provides help in minimizing implant complications due to its injury of anatomical structures by offering more accurate details about them **(Alawaji et al., 2018).**

Implant placement has now become part of everyday dental practice and CBCT makes it easier and quicker by providing more accurate detailed images for preoperative treatment planning and evaluation of alveolar ridge morphology (height and width), quality (according to the density of the remaining structure of the bone) and quantity of the available bone for proper implant placement in the most appropriate position to achieve optimum phonetic, esthetic, and masticatory function. Also, CBCT can provide accurate diagnosis of lesions and anatomical structures (inferior alveolar canal, mental foramen, nasal fossa and maxillary sinus) that may limit the placement of osseous implant **(Albelbeisi et al., 2016).**

Despite all advantages of CBCT over multi-slice CT, there are some disadvantages that can interfere with the diagnosis and accurate vision of the images produced. Artifacts can be considered as one of the most important disadvantages of CBCT and when we talk about CBCT and implant we must consider metal artifacts that result from titanium implants in radiation path which can deteriorate the diagnostic image quality significantly **(Parsa et al., 2014).**

Image artifact defined as a visualized structure in reconstructed data which is not visible in the object under investigation. Which interfere with the final diagnostic process, so must know about these artifacts and how to reduce them. These artifacts include extinction artifacts, beam hardening artifacts (metal artifact and cupping artifacts), partial volume effect, aliasing artifacts, ring artifacts and motion artifacts (misalignment artifacts) **(Jaju et al., 2013).**

Beam hardening is considered as one of the most encountered sources of artifacts that are produced when lower-energy photons in the polychromatic x-ray beam are absorbed by a higher attenuating or radiopaque material in preference to high energy photons. The attenuated x-ray beam exits this material with a higher mean energy than the incident or primary beam as it becomes harder or more intense when it reaches the detector. This results in distortion of the attenuated x-ray beam because of differential absorption by the material and produces streaks and dark bands on the image **(Jaju et al., 2013).**

So, beam hardening considered as two different artifacts on the reconstructed images, the appearance of streaks or dark bands and a cupping artifact. Cupping artifacts resulted from passing of x-rays through the large object center which become harder that through the edges due to the greater amount of material that

the beam has to penetrate. So, the final profile of linear attenuation coefficients appears as a cup. But the dark streaks and bands between dense objects which can be seen between two implants in close relation to each other as the beam becomes harder when it passes through both objects than when it passes through only one object (**Jaju et al., 2013**).

Metallic objects in the dental field as implants can produce dark artifacts, induced by scattering, and streak artifacts, making anatomical structures mysterious and affecting the contrast between adjacent areas at region of interest. As this metallic material highly attenuates the x-ray beam, the attenuation values of objects behind the object are incorrectly high. Due to the cone shaped beam of CBCT, the metallic streak artifacts occur in all directions from the high attenuation object (**Parsa et al., 2014**).

Many types of software and imaging protocols have been developed trying to solve the problem of the effect of the artifacts on the final CBCT image. So, manufacturers tried to minimize beam hardening by using filtration, anti-scatter grids, calibration correction, and beam hardening correction software. (**Jaju et al., 2013**).

A lot of parameters such as X-ray beam quantity and quality, rotation arc, field of view (FOV) and pixel size can affect the CBCT image quality and image characteristics that may include artifacts, contrast resolution and noise. Metal artifact is considered as one of the most factors that degrading the image quality (**Panjnough et al., 2016**).

Field of view is one of the most important hardware tools that must be determined carefully to get more reliable and accurate measurements (**Abdelkarim, 2019**).

FOV must be determined according to the needs of the case.

Small FOV devices range normally from 5 to 10 cm, which give a 3D view of a single tooth unit and its surrounding anatomy. They are used for individual tooth assessment (e.g; impacted teeth, root morphology, supernumeraries, sites for placement of dental implants, and temporary anchorage devices). Medium FOV provides single jaw anatomy, whereas the maxillomandibular FOV gives the clinician an understanding of two-jaw anatomy, temporomandibular joint (TMJ), and occlusion. They are used for more information on facial asymmetries, bilateral TMJ evaluations and occlusal relationships.

In addition, Large or craniofacial FOVs include the cranial base, cranium and all associated structures. The large FOVs involve most of the whole head which help clinicians to assess relationships between skeletal bases, between teeth and skeletal bases, and also can be significant for anomalies in patients requiring orthognathic surgery or those with craniofacial anomalies (**Kau and Ortho, 2014**).

In a study done by **Shokri et al**, to evaluate the effect of exposure parameters of milliampere (mA) and field of view (FOV) of CBCT image on a metal artifact of dental implants by using of 27 bone blocks with different densities (nine were type 1, nine were types 2 and 3, and nine were type 4). These blocks were placed in mandibular wax models. Then scanned after drilling and implant placement using Cranex3D imaging system with a $4 \times 6 \text{ cm}^2$ and $6 \times 8 \text{ cm}^2$ FOV and 4 and 10 mA. Gray value of the bone blocks was

recorded before and after placement of implants. And the result was that the amount of artifacts was lower in small FOV compared to large FOV ($P < 0.05$). Change of mA had no effect on metal artifacts ($P > 0.05$). Artifacts in type 4 bone were greater than in other bone types ($P < 0.05$). Difference between type 1 and types 2 and 3 was not significant ($P > 0.05$).

Study objectives and hypotheses:

Study objectives:

The objective of this study will be the evaluation of the effect of variation of the exposure parameters FOV & mA on the produced metallic artifact induced by dental implants that affect the CBCT image using linear measurements of dental implant dimensions.

Study hypotheses:

Is the variation of Field of view (FOV) and milliamperere (mA) can affect the CBCT image quality with metal artifacts?

III. Methods

A) Samples, intervention and outcomes

7. Calculated sample size

A power analysis was designed to have adequate power to apply a statistical test of the null hypothesis that there is no difference between tested groups. By adopting an alpha level of (0.05) a beta of (0.2) i.e., power=80% and an effect size (f) of (0.38) calculated based on the results of a previous study¹; the predicted sample size (n) was a total of (80) cases. Sample size calculation was performed using G*Power version 3.1.9.7²

8. Description of study sample

- 4 dry human mandibles will be obtained from faculty of medicine from Cairo University.
 - Layers of dental wax for soft tissue stimulation from dental store of El-Kasr El-Einy, faculty of dentistry, Cairo University.
 - 8 dental implants will be obtained from Roots Company.
 - Each dry human mandible with implant will be scanned in the Oral and Maxillofacial Radiology Department, Faculty Dentistry, Cairo University using CBCT machine Planmeca ProMax® 3D Mid.
 - Produced CBCT images will be analyzed by using Romexis ® software (planmeca Helsinki-Finland) for measuring dental implant dimensions (length and width) using linear measurements on software and real measurements of dental implants as a reference standard.
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9. Intervention for each group

- Each mandible will be prepared and drilled for implant placement at the middle of the bone at the area of interest
- Two layers of wax will be applied over them for soft tissue stimulation.
- Then each mandible will be scanned by using CBCT machine Planmeca ProMax® 3D Mid in the Oral and Maxillofacial Radiology Department, Faculty Dentistry, Cairo University 4 times with 4 different protocols of FOV (40 × 50 mm & 100 × 60 mm) and mA (8 and 10) by the following:
 - First:
 - mA 8 and FOV 40 × 50
 - mA 8 and FOV 100 × 60
 - mA 10 and FOV 40 × 50
 - mA 10 and FOV 100 × 60
 - Second:
 - mA 8 and FOV 40 × 50
 - mA 8 and FOV 100 × 60
 - mA 10 and FOV 40 × 50
 - mA 10 and FOV 100 × 60
 - Third:
 - mA 8 and FOV 40 × 50
 - mA 8 and FOV 100 × 60
 - mA 10 and FOV 40 × 50
 - mA 10 and FOV 100 × 60
 - Fourth:
 - mA 8 and FOV 40 × 50
 - mA 8 and FOV 100 × 60
 - mA 10 and FOV 40 × 50
 - mA 10 and FOV 100 × 60
- Each CBCT image Produced will be analyzed for metal artifact by using Romexis ® software (planmeca Helsinki-Finland) for measuring dental implant dimensions (length and width) using linear measurements

10. Outcomes

The primary outcome of this study will be the assessment of Implants dimensions measurements that will be measured by using linear measurement on Romexis® software (Planmeca-Helsinki-Finland) for each scan to evaluate the effect of FOV and mA on artifacts induced by dental implants.

Prioritization of Outcome	Method of Measurement	Unit of Measurement
Assessment of implants dimensions measurements accuracy	Linear measurements	Millimetres (mm)

B) Assignment to intervention

The randomization will be applicable.

11. Sequence generation

Mechanism used to implement the random allocation sequence is that mandibles will be sequentially numbered.

12. Allocation concealment

Opaque sealed envelopes will be used to conceal the sequence until intervention is assigned.

12. Implementation:

The main supervisor will be responsible for the random allocation sequence and enrolling mandibles, but the co-supervisor and the researcher will be responsible for assignment for intervention.

C) Blinding

14. Blinding

The Co-supervisor and investigator will be blinded.

D) Statistical methods

Handling of numerical/ quantitative variables:

Numerical data will be explored for normality by checking the data distribution, calculating the mean and median values and using Kolmogorov-Smirnov and Shapiro-Wilk tests. If the data was found to be normally distributed, it will be presented as mean and standard deviation values. If the assumption of normality was found to be violated, the data will be presented as median and range values.

Handling of categorical/ qualitative variables:

Categorical data will be represented as frequency (n) and percentage (%).

Statistical methods:

Categorical data will be represented as frequency (n) and percentage (%) and will be analyzed using chi square test. Numerical data will be explored for normality by checking the data distribution, calculating the mean and median values and using Kolmogorov-Smirnov and Shapiro-Wilk tests. If the data was found to be normally distributed, it will be presented as mean and standard deviation values and one-way ANOVA followed by Tukey's post hoc test will be used for the analysis.

If the assumption of normality was found to be violated; the data will be presented as median and range values and will be analyzed using Kruskal Wallis test followed by multiple Mann-Whitney U tests with Bonferroni correction.

The significance level will be set at $p \leq 0.05$ for all tests. Statistical analysis will be performed with IBM® SPSS® Statistics Version 26 for Windows.

IV- Ethics:

16. Research ethics approval

V- References:

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