

A comparison of radiation doses to selected vital organs in the maxillo-facial region using three different settings on the Galileos CBCT machine housed in the Wits Dental Hospital

A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in partial fulfillment of the requirements for the degree of MSc (Dent)

DECLARATION

I, Dimcho Lubomirov Dimtchev declare that this Research report is my own work. It has been submitted in partial fulfillment of the degree of MSc (Dent) at University of the Witwatersrand, Johannesburg. It has not been submitted for any other degree or examination at this or any other University.

..... (Signature)

Student number 0617083G

24th of August 2014

DEDICATION

This report is dedicated to my family who has been most supportive throughout this overwhelming task.

ABSTRACT

A comparison of radiation doses to selected vital organs in the maxillo-facial region at three different settings on the Galileos cone-beam computed tomography (CBCT) machine in the Wits Dental Hospital, was conducted with the courtesy of the Department of Medical Physics of the Charlotte Maxeke Johannesburg Academic Hospital. The study made use of the RANDO phantom and TLD- 100 detector chips, which provided detailed mapping of the dose distribution from the Galileos CBCT machine. Sixty-two Sanford® lithium fluoride dosimeters- (TLD- 100) were irradiated using a calibrated known x-ray source after having undergone a recommended annealing cycle.

The data showed great consistency in the results. Association between the different imaging modalities was further investigated using Kruskal-Wallis equality-of-populations rank test and Chi-squared test. A p-value of <0.05 was considered statistically significant. Since there do not appear to be major differences between the radiation doses for the different settings of the Galileos CBCT machine, the author recommends the use of the combined setting at all times for optimum image quality.

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ABBREVIATIONS

TLD chips	- thermo-luminescence detector chips
CBCT	- Cone Beam Computed Tomography
Galileos	- Cone Beam equipment produced from SIRONA Germany
ICRP	- The International Commission on Radiological Protection
RANDO phantom	- Latest version of Alderson radiation therapy Phantom

CHAPTER 1 INTRODUCTION AND LITERATURE REVIEW

The first cone-beam computed tomography (CBCT) scanner to obtain approval was the New Tom in March 2001.¹ The number of cone beam units for dental usage is currently on the increase in both private practices and academic institutions. The reason for this is the comparatively low cost and relatively low radiation dose as compared with conventional CT units.² In 2012 CBCT was used for the study of the *foramen tympanicum* because of the small effective dose.³

The commonest use of the cone beam machine currently has been for implant planning, orthodontic appliances and to a lesser extent for the diagnosis of pathoses in the maxillofacial region.^{4 5 6} This newly-found idea of using cone beam as a single primary technique, however, harbours risks of over-exposing patients to excessive radiation together with a possible misdiagnosis. The reason for the latter is the fact that the new dimension provided by a cone beam image requires advanced expertise in diagnosis, often beyond the scope of a general dentist. It must therefore be emphasized that a cone beam image must not constitute a routine radiographic view but should require a definite indication for its use.

As part of the strategy for high quality holistic dental services, institutions and healthcare providers are obligated to possess properly functioning equipment and to keep the radiation dose As Low As Reasonably Achievable (ALARA).⁷

Cone-Beam Computerised Tomography (hereafter referred to as CBCT) may ultimately contribute to improvement of patient care, but users must be aware of their adherence to ALARA principles to prevent latent untoward effects of radiation.

Radiation risk is frequently spoken about but all too often not taken seriously. A study done by Buch and Fensham in 2003 using thermoluminescent dosimeters and a female RANDO phantom showed that a panoramic X-ray examination from a Siemens Orthophos machine imparted to the thyroid no more than ten days of additional background radiation and to the eyes a mere two and a half days.⁸ Buch et al. in 2009 compared absorbed doses to the eyes, thyroid and uterus imparted by a Gendex panoramic machine with those from a full-mouth intraoral X-ray examination using films and digital technology. They found that the dose to the eyes from a full-mouth intraoral examination using films

was higher than that from the panoramic machine although the dose to the thyroid was half that of the panoramic examination. These doses were much reduced when using digital technology. Doses to the uterus were similar in all cases and were unchanged when a lead apron was used.⁹

Furthermore in all the above experiments (with one exception) a RANDO phantom was used. The Alderson RANDO phantom has been in use for over 30 years. The male phantom is 173 cm tall, and weighs 73.5 kg. It consists of a human skeleton surrounded by tissue-equivalent material. Such material approximates the average radiation density of human tissues. In fact a study published in 2001 concluded that the tissue equivalence of a RANDO phantom does not differ by more than 15% from that of a cadaver.¹⁰ The phantom is transected horizontally into 2.5 cm thick slices. Each slice has holes with plugs, which can be replaced with TLD chips.¹¹

Current studies provide comparative measurements of doses from different CBCT equipment, but do not take into account dose differences, which may occur at different settings of the machine. In 2006 Ludlow et al used TLDs and a RANDO phantom to determine radiation doses of three different CBCT machines.² This study has clearly shown that considerable differences exist between the various makes of CBCT machines. Furthermore in 2008 Palomo et al. modified CBCT equipment to allow for different mA and kV choices. For this experiment TLD chips, a RANDO phantom and a fresh cadaver were used.^{12,13} Although the radiation dose in this instance was comparatively low, it resulted in a low quality image.

A systematic review¹⁴ has revealed that no comparative doses corresponding to the different settings on the Galileos CBCT appear to be available. Doses quoted by the manufacturer are average full-body doses, which have no relevance to specific vital organs at the different settings. Inter-unit variability too is a parameter, which has not as yet been assessed. Increased popularity and interest in CBCT has led to increased numbers of presentations at conferences, a multitude of brochures from manufacturers, but no real evidence-based exchange of information with regard to radiation doses. Most purchasers of CBCT machines in South Africa are dentists. The limited imaging and technical knowledge of this group of users is largely accountable for the confusion encountered in clinical literature. Technical device settings and properties of those settings were not constant in the abovementioned studies. Apart from the lack of

evidence-based data for CBCT radiation doses, there was inconsistency of terminology associated with those studies. The use of CBCT will undoubtedly improve patient care in the long term, but practitioners must be aware of their responsibilities in holistically interpreting the data collected at each examination.

In 2003 Mah et al. used a tissue-equivalent humanoid phantom and TLDs to measure the whole-body effective dose. The unit under investigation was the New Tom 9000. The study compared CBCT with CT and panoramic units with respect to full-body dose. It also compared doses to bone marrow, bone surfaces, salivary glands and thyroid gland in combined settings, but did not measure effective doses in different fields of view.¹⁵

In 2005 Tsiklakis et al. published a study in which seventy-five TLD-100 dosimeters and a male RANDO phantom were used to compare radiation doses imparted by the New Tom 9000 CBCT machine with those from a standard panoramic machine. A p-value of <0.05 was used to determine the statistical significance for the experiment. The result was that CBCT appeared to have a three to seven times higher risk compared to a panoramic examination.¹⁶

In all the above experiments thermo-luminescent dosimeter chips were used to monitor radiation doses. Thermo-luminescent dosimeter chips (TLD) constitute the primary mode of radiation exposure monitoring today. The reliability of the method was studied by Buch and Keddy in 1987 and was proved to be a reliable instrument for the purpose. The authors showed that TLD chips provide an acceptably accurate measurement of doses of absorbed radiation to certain areas of the body for dental x-ray examinations.¹⁷ TLD dosimeters allow for the determination of a wide range of absorbed doses. This makes them useful in dose detection from μGy to several Gy. TLD's are easy to transport, can be mailed and can be used for many different applications.¹⁸ TLD 100 dosimeter chips made from lithium fluoride (LiF) material have a wide potential in radiation dosimetry.¹⁹ They are accurate for X-, gamma, beta, electron and neutron radiations, are reusable and are nearly tissue- equivalent.

LiF material when irradiated undergoes changes in the physical properties and the energy is stored. Electrons in some solids can exist in two energy states, a lower energy state called the valence band and a higher energy state called the conduction band. The difference between the two bands is called the band gap. Normally in solids no electrons exist in energy states contained in the band gap. When impurities are added to LiF, the forbidden region i.e. the band gap can trap electrons. Those trapped electrons represent

the energy acquired in the process of irradiation. When the chips are heated with a laser the electrons return to the valence band and light is emitted. The emitted light is measured in a photomultiplier tube. Interpretation of the emitted light is done by algorithms contained in computer software.

Patients may over a period of time receive multiple CT scans for different reasons and the cumulative radiation dose over the years may exceed the doses received by the Hiroshima survivors.

In a retrospective cross-sectional study performed on 1119 adult patients in USA, the overall effective dose for the head and neck using conventional CT was shown to be 2 mSv, and that for the abdomen about 31 mSv.²⁰ This data was analysed using TLD chips and a RANDO phantom.

Risk of developing cancer has been identified in long-term survivors of Nagasaki and Hiroshima, who received exposures in the range of 10 to 100mSv.

Radiation received is cumulative throughout life. It is therefore essential to reduce the number of radiographs taken and to choose the most appropriate imaging modality. The International Commission on Radiological Protection (ICRP) provides tissue-weighting factors, which represent the relative contribution of that organ or tissue to the overall risk.²¹ Salivary glands, thyroid gland and eyes are the most susceptible to radiation in the head and neck region. Tissue-weighting factors are not being taken into consideration by the author, as the purpose of this study is to measure accurately and compare doses using different settings of the CBCT Galileos.

Diagnostic quality improves with an increase in contrast. This in turn increases the radiation dose.²² Diagnostic quality also improves with the increase of the field of view. This is what the different settings of the Galileos CBCT aim to achieve. The most pertinent question is where this is achieved, by simple shedding of the sensor, or by collimation of the x-ray beam and shedding of the sensor. Different clinicians use different parameters to achieve a desired result.²³ The use of mandibular, maxillary or a combined setting of Galileos CBCT appears to be subjective rather than for any good reason. Such subjectivity enables the operator to believe that the patient is exposed to less radiation if a modality is used that provides half of the complete view. The practice thereof, however is questionable.

A study done by Ludlow et al. in 2008 compared ten different CBCT, 3D and CT devices.²⁴ However the researcher did not embark on any other studies, which compared different exposure settings of the same equipment.

In today's world patients can be quickly assessed and treated thanks to sophisticated computed x-ray equipment. However, the concern about radiation risks are being addressed in many research publications.^{8, 9} Many emphasize the responsible approach of weighing up the value of the X-ray examination against the potential risk.

Many studies refer to full-body dose, but the researcher has come across no study with doses for vital organs in the head and neck accurately measured for Galileos CBCT settings and the present study aims to demonstrate this. Furthermore the risk of exposure to ionizing radiation should be balanced with the potential benefit to the patient. An important strategy of any dental radiologic service is to ensure that a revised or newly developed radiographic protocol, in line with the latest national radiological policy should be implemented at all training institutions.

This study was undertaken following a discussion between the researcher and the supervisor. It was agreed that there was a need for a study, which would provide a guideline for more effective and responsible use of the CBCT machine at the Wits Dental Hospital. The Radiology section of the Wits Dental Hospital admits 12 000 patients annually for radiographic examinations. During the first seven months of its installation, 168 CBCT examinations were performed on the Galileos machine which is accessible to all registrars in the various fields of dentistry but whose expertise in the use of this new equipment is limited.

CHAPTER 2 AIMS and OBJECTIVES

AIMS

- To measure the effective doses of radiation imparted by the Galileos CBCT using the maxillary setting only.
- To measure effective doses of radiation imparted by the Galileos CBCT using the mandibular setting only.
- To measure effective doses of radiation imparted by the Galileos CBCT using the combined maxillary and mandibular setting.
- To compare the effective doses in all three settings.
- The results thereby obtained may justify the use of the combined setting for the attainment of improved diagnostic information.

OBJECTIVES

- Effective doses of radiation imparted by the Galileos CBCT as mentioned above will be measured using new Sanford square TLDs placed within a RANDO phantom.
- Absorbed doses obtained from three different exposures of the Galileos CBCT will be compared.
- The statistical significance of the different settings will be established.

CHAPTER 3 MATERIALS AND METHOD

A set of sixty-six Sanford square TLD 100 detector chips (dosimeters) to be used in this study were purchased from Sanford Dosimeters in the USA. These are accurate for X-, gamma, beta, electron and neutron radiations and are composed of lithium fluoride material (LiF). Dosimeters are reusable and are nearly tissue- equivalent. The study utilized the principle of thermo-luminescence.

Thermo-luminescence is the phenomenon by which information is stored in the TLD chips. When heated with a laser the electrons return to the valence band and emit light. The light emitted, which is proportional to the radiation dose received is measured in a photomultiplier tube. The interpretation of that emitted light is done by algorithms contained in a computer software.

All sixty-six TLD chips were annealed in a PTW-LTDO oven driven by the Mecer Prelude computer loaded with Windows 7 and Theldo oven software. Vacuum tweezers were used to transfer the TLDs at the time of measurements and calibration. The prescribed annealing procedure recommended by the manufacturer was followed: The chips were placed in each of sixty-six wells contained within a metal slab and preheated to 400°C. They were kept at this temperature for 3 hours. Thereafter they were kept at 100°C for an hour before being left to cool down to room temperature. TLDs were kept in the metal slab and covered with a metal lid between the annealing and irradiation processes.

Since lithium fluoride chips vary from one to another in their responses to the same dose of radiation, a method of selection and calibration of discs was necessary.⁹ All sixty-six annealed dosimeters were placed on a polymethyl-methacrylate (PMMA) phantom and exposed to a known dose of radiation i.e. 1Gy in a Linear accelerator Siemens. The TLDs were then read in a HARSHAW QS 3500 TLD reader. A specific calibration factor was programmed into the reader. A 15% tolerance was considered acceptable for the measurement of absorbed doses. Fifty-seven TLDs, which gave similar readings, were selected for the experiment. The position of the chips remained unchanged in the reading plate during the experiment. Each chip was allocated a unique code- A1A, A2A etc. Each of those procedures as well as the subsequent reading of the chips was carried out in the Department of Medical Physics.

The next phase of the experiment involved the use of the RANDO phantom. The phantom consists of a human male skeleton surrounded by tissue-equivalent material and transected horizontally into 2.5 cm thick slices. Each slice contains a series of wells obturated by plugs. The plugs can be removed and replaced with TLD chips. The latter could fit snugly in the above-mentioned wells thereby eliminating any possible drift of the TLD's during their transportation between the two departments.

The chips were then placed within the head of the phantom in positions corresponding to the eyes, the thyroid and the parotid glands. The phantom head had initially been scanned in a CT scanner in order to determine the exact position of the TLD detector chips. The phantom head was then transported to the Radiology section of the Wits Dental Hospital and placed in the Galileos CBCT machine for subsequent exposure. Eight chips were used each time for all 9 exposures. The position of the chips was as follows:

- Thyroid gland- thyroid anterior (superficial) and thyroid posterior (deep).
- Parotid gland- right parotid deep, right parotid superficial, left parotid deep and left parotid superficial.
- Eyes- right eye (at the position of the lens), left eye (at the position of the lens).

The Galileos CBCT was set to VO1 HC, 85 kV, 42 mAs, for all nine exposures.

The constant position of the phantom head in the CBCT for all exposures was ensured by means of laser markers. Three different settings of the Galileos CBCT were used i.e. mandibular exposure only, maxillary exposure only and combined maxillary and mandibular exposure. Each set of exposures was repeated three times giving a total of nine exposures.

At the completion of all exposures the TLD detector chips were read in the HARSHAW TLD reader housed in the Department of Medical Physics.

An additional three annealing cycles and sequential readings were performed in order to determine the background radiation on all 57 TLD detector chips.

Data was entered on to an MS Excel spread sheet and analyzed using Stata under the guidance of two statisticians. The analysis included descriptive analysis of the study population; Cross-tabulations were also used to investigate associations between readings of the TLD detector chips for the different modalities. Association between the different imaging modalities was further investigated using Kruskal-Wallis equality-of-populations rank test and Chi-squared test. A p -value of <0.05 was considered statistically significant.

Study design

This study is an analytical comparison.

The following characteristics of the Galileos CBCT were included:

- the maxillary settings for males
- the mandibular settings for males
- the maxillary and the mandibular settings together for males

The settings of the Galileos CBCT used for the females and the children were excluded.

The phantom head only was used in this study, which limited the amount of scattered radiation. Exact orientation of the chips was not taken into account.

Validity and reliability of the study:

Validity related to the above tests evaluated the extent to which the data was plausible, credible and trustworthy.

A measurement is considered reliable if a score on the same test performed twice produces a similar result. The study compared results from an initial test with repeated measurements. The results were found to be reliable.

CHAPTER 4 RESULTS

Tables 4.1, 4.2 and 4.3 represent the data collected from all the 9 exposures. The data shows great consistency in the results. However this raw data cannot be used for any assumptions before is statistically calculated.

Table 4.1 Mandibular/Maxillary readings for the different settings of the Galileos CBCT (μSv).

	Man/Max 1 st	Man/Max 2nd	Man/Max 3rd
Thyroid Anterior	277.9	64.23	132.2
Thyroid Posterior	313.3	105.01	255.6
Right Parotid Deep	181.1	120.9	107.8
Right Parotid Superficial	104.6	57.57	85.69
Left Parotid Deep	77.91	83.53	89.42
Left Parotid Superficial	87.70	80.73	81.37
Right Eye	54.05	38.45	21.83
Left Eye	44.27	39.05	42.05

Table 4.2 Maxillary readings for the different settings of the Galileos CBCT (μSv).

	Max 1 st	Max 2nd	Max 3rd
Thyroid Anterior	114.7	305.7	58.76
Thyroid Posterior	148.7	152.1	232.1
Right Parotid Deep	125.2	123.21	129.7
Right Parotid Superficial	140.5	154.8	72.59
Left Parotid Deep	89.91	108.2	73.32
Left Parotid Superficial	82.33	69.41	83.70
Right Eye	39.91	36.85	41.51
Left Eye	45.50	38.38	40.66

Table 4.3 Mandibular readings for the different settings of the Galileos CBCT (μSv).

	Man 1 st	Man 2 nd	Man 3 rd
Thyroid Anterior	133.5	347.7	90.88
Thyroid Posterior	151.9	471.0	100.9
Right Parotid Deep	50.71	192.3	53.35
Right Parotid Superficial	32.44	59.09	23.71
Left Parotid Deep	36.50	29.71	25.45
Left Parotid Superficial	28.19	27.18	19.12
Right Eye	15.54	15.59	10.55
Left Eye	11.74	15.53	11.39

Table 4.4 Background exposure (μSv) of the TLD chips in the reading plate.

TLD Position letter →	A	B	C	D	E	F	G	TLD position No: ↓
	Mean value out of 3 background exposures	Mean value out of 3 background exposures	Mean value out of 3 background exposures	Mean value out of 3 background exposures	Mean value out of 3 background exposures	Mean value out of 3 background exposures	Mean value out of 3 background exposures	
1	14.86	6.252	5.205	6.361	5.786	8.009	7.095	1
2	11.39	8.553	5.209	7.292	9.194	9.636	10.02	2
3	7.719	3.983	4.886	5.059	8.004	9.881	7.186	3
4	5.394	15.61	3.818	5.883	6.553	6.418		4
5	4.353	6.789	6.103	9.369	6.129	4.474		5
6	20.41	6.686	7.734	9.509	5.754	6.325		6
7	6.171	8.683	5.416	6.249	9.648	5.219		7
8	5.526	5.785	3.811	6.666	5.434	5.268		8
9	9.351	5.583	4.652	5.510	4.066	5.126		9

Most of the background radiation where the experiment took place emanated from the surrounding concrete structures of the building.

Table 4.5 Median exposure values for the different settings of the Galileos CBCT (μSv).

	Mandibular/Maxillary Exposure – 85 kV/42 mAs/HC	Maxillary Exposure – 85 kV/42 mAs/HC	Mandibular Exposure – 85 kV/42 mAs/HC
Thyroid Anterior	131.00	152.9	133.5
Thyroid Posterior	196.55	192.1	151.9
Right Parotid Deep	114.35	124.205	53.35
Right Parotid Superficial	88.44	114.395	32.44
Left Parotid Deep	85.405	83.775	29.71
Left Parotid Superficial	82.49	81.77	27.18
Right Eye	33.68	40.71	15.54
Left Eye	40.55	39.52	11.74

Table 4.6: Kruskal-Wallis equality of population rank test

	Thyroid anterior		Thyroid posterior		Right Parotid Deep		Right Parotid Superficial		Left Parotid Deep		Left Parotid Superficial		Right Eye		Left Eye	
Type	Observations	Rank- Sum	Observations	Rank- Sum	Observations	Rank- Sum	Observations	Rank- Sum	Observations	Rank- Sum	Observations	Rank- Sum	Observations	Rank- Sum	Observations	Rank- Sum
Mandibular	3	21	3	17	3	14	3	7	3	6	3	6	3	6	3	6
Man/ Max	3	22	3	23	3	23	3	26	3	30	3	32	3	27	3	31
Maxillary	3	23	3	26	3	29	3	33	3	30	3	28	3	33	3	29
Chi-squared	0.386		0.144		1.076		5.589		6.000		6.182		6.409		6.045	
P-value	0.8243		0.9306		0.5840		0.0609		0.0498		0.0455		0.0406		0.0487	

Rank-Sum test is a standard test for testing the difference between populations.²⁵

CHAPTER 5 DISCUSSION

Despite the fixed position of the phantom for every set of exposures, small differences in dose readings for the various organs are apparent for the same machine settings. Some of these differences may be related to scatter- radiation, which is unpredictable and are not necessarily related to the accuracy of the reading method, the annealing procedure or the stability of the TLD-100 detector chips. Nevertheless a minimum error of 10% in the accuracy of any single chip must be allowed for.⁸

There is also a possibility that many of these small discrepancies are due to background radiation. Much of the background radiation in the premises where the experiment took place emanates from the heavy surrounding concrete structures of the building.

Table 4.4 represents the mean values of three background exposures of the TLD chips in the reading plate. These readings are mostly in the range between 3.811 μSv and 15.61 μSv and are very unlikely to significantly affect the result of the experiment.

Table 4.5 illustrates the median exposure values for the different settings of the Galileos CBCT machine. The readings for the thyroid (anterior) for all three different settings does not differ more than 14.8% in the median value. For the thyroid (posterior) this value differs only between the mandibular and the combined maxillary/mandibular exposures by 26%. A study done by Ruben Pauwels et al. also showed that the largest deviations in radiation doses were seen in the thyroid gland.²⁶

The median values for maxillary and maxillary/mandibular exposures are similar. These similarities are explained by the fact that CBCT scanning of the facial structures relies on a rotation center for the scanning motion that approximates to the rami of the mandible for scanning of the posterior section of the jaws and to the center of the floor of the mouth for scanning of the anterior section. These rotation centres absorb more radiation than do transiently exposed anatomical structures. Continuously exposed rotation centres are in very close proximity to the thyroid gland, resulting in the highest radiation doses as measured in this experiment. This conforms to a study by Ludlow et al. who thoroughly investigated these rotation centres.² The calculated *p*-values for the three different settings for the thyroid are 0.82 (superficial) and 0.93 (deep). Statistically this is not considered significant.

Table 4.5 further illustrates that the values for the right parotid are higher than those for the left. This paradox has been mentioned in a number of studies² and is due to fact that the rotation of the CBCT machine appears to have a bias, the right side being more heavily exposed than the left. As a result the calculated *p*-values for the three different settings for the deep parotid are 0.58 right and 0.05 left. Statistically this is not considered significant.

The same applies to the superficial parotid as illustrated in Table 4.5, the radiation values on the right side being higher than on the left. There is a 25% difference between maxillary and combined maxillary/mandibular exposures on the right side and almost no difference on the left. Mandibular exposures on both sides are about 2.5 times less than both maxillary and combined exposures. However, the calculated *p*-value for the right side is 0.06 and that for the left is 0.0455 (0.05 if rounded). These two *p*-values are considered statistically non significant.

The lens of the eye, one of the most radiation-sensitive anatomical structures in the head region appears to be well protected owing to the engineering design of the Galileos CBCT machine. The radiation dose to the eye for the mandibular setting is equivalent to background radiation and for both the maxillary and combined settings is about two to two and a half times the background dose. It may appear surprising that the calculated *p*-value for the right eye is 0.0406, which is statistically significant, whereas 0.0487 for the left eye (rounded to 0.05) is statistically non significant. This very small difference could be due to the higher exposure on the right side and a greater amount of scatter radiation.

Reproducibility of the results of this study can be confirmed, there being no greater an overall variation than 15% between repeated examinations. There were, however, significant deviations in the TLD readings for specific locations, especially in the region of the thyroid gland. Similar deviations were reported in 2006 by Ludlow et al.² The actual surface orientation of the TLD chips was not taken into account as the TLDs were placed in the existing holes in the phantom, their position being constant for all the experiments.

CHAPTER 6 CONCLUSION

The aim of the study was to compare the effective doses in all three settings. The results obtained were used to justify the use of the combined setting for the attainment of improved diagnostic information. Since there were no major differences between the radiation doses for the different settings of the Galileos CBCT machine, the author recommends that the combined setting may be used at all times for optimum image quality.

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ANNEXURE 1

Ethical considerations

- No human participants or animals were involved in this study. An ethical clearance certificate No. M130237 was therefore obtained from Ethics Committee on the 22nd of March, 2013..
- Written permission was also obtained from the Head of the Department of Medical Physics for the use of the RANDO phantom and for assistance in the analysis of the TLD detector chips.
- Written permission was obtained from the management of WITS Dental Hospital in order to conduct the study



R14/49 Dr Dimcho L Dimtchev

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M130237

NAME:
(Principal Investigator)

Dr Dimcho L Dimtchev

DEPARTMENT:

Radiology Department
Wits dental Hospital

PROJECT TITLE:

A Comparison of the Radiation Doses to
Selected Vital organs in the Maxillo-Facial
Region using three Different Setting on the
Galileos CBCT Machine Housed in the wits
Dental Hospital

DATE CONSIDERED:

22/02/2013

DECISION:

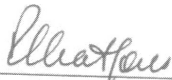
Approved unconditionally

CONDITIONS:

SUPERVISOR:

Prof Brian Buch

APPROVED BY:

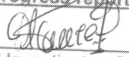

Professor PE Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 22/02/2013

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

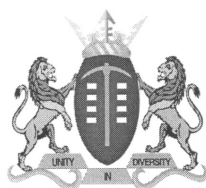
To be completed in duplicate and **ONE COPY** returned to the Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report**


Principal Investigator Signature

Date

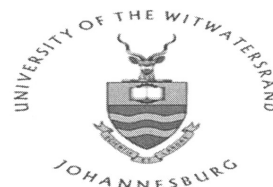
22. 03. 2013

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES



GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA



Enquiries: B Van Wyk

Tel: 0114812149

TO: WHOM IT MAY CONCERN

FROM: BP VAN WYK
ACTING HEAD OF MEDICAL PHYSICS
GAUTENG DEPARTMENT OF HEALTH

DATE: 1 FEBRUARY 2013

SUBJECT: DL DIMITCHEV

The department of radiation sciences division of medical physics have no objection to supplying Dr Dimtchev with the necessary phantom and assistance during his study.

Yours sincerely
BP Van Wyk

27 January 2013

To: The Management of WITS Dental Hospital

From: Dr DL Dimtchev

Student number: 0617083G

TO WHOM IT MAY CONCERN

Dear Sir, Madam,

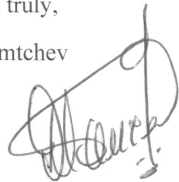
This letter is to serve a request for a written permission to conduct a study:

A comparison of the radiation doses to select vital organs in the maxilla-facial region using three different settings on the Galileos CBCT machine housed in the Wits Dental Hospital

in fulfillment for the degree of MSC Dent (Maxillo-Facial and Oral Radiology), University of the Witwatersrand, Johannesburg. The study will be conducted at Radiology department, WITS Dental Hospital and will include the detection of radiation dose of Galileos CBCT on RANDO phantom and TL detector chips.

Yours truly,

Dr Dimtchev



082 7011884

011 862 4747(w)

DR D KOTSANE

HOD: GDP

Approved subject to approval of protocol
by university research office and ethical clearance
PROF P HLONGWA  30/01/2013

HOS / CEO: WITS ORAL HEALTH CENTRE

ANNEXURE 2

Timing

- The Human Research Ethics Committee granted approval of the research protocol, on the 22nd March 2013.
- The purchase of the TLD detectors and the delivery from USA took 3 months.
- Calibrations and selection of the TLD detector chips took place in August 2013.
- Irradiations and readings of the TLD chips were from September to October 2013.
- Data analysis was done during November 2013.
- The final draft of report was submitted to my supervisor in February 2014.

ANNEXURE 3

Funding

- Cost of chips.....R 4000.00
- Cost of paper and stationary.....R 800.00
- Cost of printing.....R 900.00
- Travelling and cost of petrol.....R 300.00
- Total.....R 6000.0

The total cost of the research was funded by the researcher.