RADIATION EXPOSURE TO THE SURGEON DURING AXILLARY SENTINEL LYMPH NODE BIOPSY

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CANDIDATE'S DECLARATION

I, Nadine Harran, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of General Surgery in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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.....day of....., 20.....

DEDICATION

To my family:

Warren- for your patience and support and in giving me time (the most precious gift)

Oliver – for always asking to play Thomas the Tank Engine whenever I was seated at a computer

Zack – for sleeping ;-)

Marmie – for your endless editing, support and ability to make me sound intelligent

PUBLICATIONS AND PRESENTATIONS

The abstract of this work was presented as a prize paper for the Association of Surgeons South Africa at the 9th Congress of the European Hepatopancreatobiliary Association in Cape Town on the 16th of April 2011.

The abstract was presented at the Surgical Research Society, June 2011, Pretoria.

The abstract was presented as a poster at the International Surgical Week 2011 in Yokohama, Japan in August 2011.

The project was presented as a prize protocol at South African Society Endoscopic Surgeons Congress in October 2011.

The abstract of this work won third place in the annual Bert Myburgh Research Forum in the Department of Surgery, University of the Witwatersrand, November 2011.

ABSTRACT

Introduction

To measure the radiation exposure to the surgeon during axillary sentinel lymph node biopsy using the radioactive isotope technetium-99m.

Method

A prospective analysis of 36 patients undergoing axillary sentinel lymph node biopsy using technetium-99m, between 15th January 2013 to the 20th February 2013..

Results

The exposure to the surgeon during axillary sentinel lymph node dissection was measured in 36 patients by placing a thermoluminescent dosimeter (TLD) on the surgeon's finger. The TLDs recorded the total radiation exposure to the surgeon.

The recommended occupational dose limit for non radiation workers extremity exposure is less than 500 µSv. The analysed and extrapolated data showed an average exposure dose to the surgeon per patient of 2.7 µSv.

Conclusion

One surgeon would need to perform more than 85 such procedures per year in order to exceed the advised annual extremity dose limit. The data also suggests that regular measurements of radiation exposure and radiation protective measures need not be undertaken in theatres where surgeons are working with radioactive isotope for axillary sentinel lymph node biopsies.

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NOMENCLATURE

ALARA – as low as reasonably achievable

APRPANSA – Australian Radiation Protection and Nuclear Safety Agency

BRET – background radiation estimate time

CMJAH – Charlotte Maxeke Johannesburg Academic Hospital

Ci – Curie

ERCP – endoscopic retrograde cholangio-pancreatogram

Gy- gray

MCF - Machine Calibration Factor

mBq – millibecquerel

NMISA - National Metrology Institute of South Africa

RPS – Radiation Protection Services

µSv - micro-Sievert

MP – medical physics

^{99}Tc – technetium-99m

TLD - thermoluminescent dosimeter

1.0 INTRODUCTION & BACKGROUND

As regional nodal status is the most powerful predictor of recurrence and survival in women with breast cancer (Dupont *et al.*, 2001), the management of patients with breast cancer requires accurate staging of the lymph nodes in the axilla, namely, to the sentinel lymph node. Non-invasive assessment of the axilla has proved to be inadequate in accurately assessing malignant spread to the axillary lymph nodes. The standard of care was either a full or modified axillary lymph node dissection until the introduction of sentinel lymph node assessments.

The concept of evaluating the sentinel lymph node with the use of blue dye for staging was first proposed for penile cancer in 1977 by Ramon Cabanas (Waddington *et al.*, 2000). The technique of gamma probe-guided sentinel lymph node biopsy was first developed by Alex and Krag in 1993 as an alternative for blue dye localisation. The pilot study done by Krag *et al.* (1993) set about proving the accuracy of localising the sentinel lymph node in the axilla with radio-localisation. The study by Albertini *et al.* (1996) was the first to combine the two techniques and proved that the histological characteristics of the sentinel lymph node probably reflect the histological characteristics of the rest of the axillary lymph nodes. This analysis was followed by Vernosesi *et al.* (1997) which showed that a sentinel lymph node biopsy could adequately replace the axillary lymph node dissection in assessing the axilla for metastatic breast cancer. The latter group concluded that patients without clinical involvement of the axilla should undergo sentinel lymph node biopsy routinely, and may be spared of complete axillary dissection when the sentinel node is disease-free.

Where the injection of patent blue dye intra-dermally five minutes pre-operatively enabled 65.5% of sentinel lymph nodes to be identified (Guiliano *et. al*., 1994), further studies revealed that by including lymphoscintigraphy, where a radioactive isotope, specifically technetium-99m (^{99m}Tc), is bound to a protein and injected into the tissue, the success in locating the sentinel node approached 100% (Albertini *et al.*, 1996; Lineham *et al.*, 1999; Cody *et al.*, 2001; Tsugwa *et al.*, 2000; Dupont et. al., 2001; Doting *et al.*, 2007).

The accuracy in reviewing the sentinel lymph node by this dual method has enabled the surgeon to reduce the number of full axillary lymph node dissections performed unnecessarily and therefore decrease patient morbidity (Jakub, Pendas & Reintgen, 2003).

Timing is of importance in locating the sentinel lymph node. Shortly after the patent blue dye is injected into the subcutaneous tissue around the nipple areola complex of the affected breast, the dye is absorbed by the lymphatics. The lymphatics then drain to the regional lymph nodes which are, initially, the first echelon or sentinel lymph node. By timing the surgery correctly, the sentinel node in the axillary chain can be identified by its luminescent blue colour (Babiera *et al.*, 2005). Possible limitations of this procedure are when the tumour saturates the lymphatics, preventing the dye from traversing the regular lymph channels, or if the cancer drains medially to the internal mammary lymph nodes or to a set of nodes deep in the axilla which are not easy to see or access. A delay in the timing of the surgery may result in a further complication if more than one lymph node stained blue, the identity of the sentinel node may be obscured. These constraints have resulted in the use of ^{99m}Tc-labelled nanocolloid as well as patent blue dye injection to increase the sensitivity of locating the important node.

Lymphoscintigraphy involves the injection of radioactive ^{99m}Tc-labelled nanocolloid into the tissues and monitoring it as it is taken up by the lymphatics, and follows the chain of lymph nodes draining from the particular area being studied (Alazraki *et al.*, 1977). However, there are concerns regarding the best way to practise lymphoscintigraphy with regard to radiation exposure to the surgeon.

The method of using a gamma probe to identify isotope in relation to axillary sentinel lymph node biopsies has been widely studied, albeit not in South Africa. However, the optimal methods to achieve the highest sensitivity with the lowest morbidity to the patient have been intensely debated. The last 8 studies performed over a period from 1999 to 2011 have highlighted the following issues:

- Amount of ^{99m}Tc-labelled nanocolloid injected
- Anatomical position where the isotope is injected
- Time from injection to surgery
- Position of the thermoluminescent dosimeter (TLD)
- Methods used to measure radiation exposure to the surgeon and staff

Table 1.1 provides an overview of the various studies that investigated the impact of dose of ^{99m}Tc-labelled nanocolloid injected, length of time from injection to surgery, method of ^{99m}Tc-labelled nanocolloid injection and position of and device used to measure radiation exposure to the surgeon. These 8 studies are also briefly discussed below.

Table 1.1: International Studies Evaluating Radiation Exposure during Sentinel Lymph Node Biopsy

Author and year	Number of patients (n)	*Method* and dose of isotope injection (MBq)	Time to surgery post-injection (hours)	Position and equipment	Mean absorbed dose
Stratman *et al.*, (1999)	20	*Peritumoral* 25.9-40.7	1.5-3	Geiger counter 3cm injection site	342.5 µSv/hr
Miner *et al.*, (1999)	10	*Peritumoral* 37.0	0-9	TLD in glove of left ring finger	102.0 µSv
Waddington *et al.*,(2000)	19	*Peritumoral & Intratumoral* 10.0-15.0	18-24	TLD on palmar surface of the distal phalynx of the index finger on the dominant hand	90.0 µSv
Morton et al, (2003)	32	*Peritumoral* 20.0 40.0	Same day Next day	TLD tip both index fingers Left hand exposure > Right hand exposure	13.0 µSv (less in next day)
De Kanter *et al.*, (2003)	12	*Peritumoral* 30.0	4	TLD to both hands (no exact site mentioned) Left hand exposure>Right hand exposure	Left hand 61.0 µSv
Law *et al.*, (2004)	20	*Peritumoral* 18.0 74.0	Day 0: 6 Day 1: 24	TLD dorsum left index finger	17.8 µSv
Nejc *et al.*, (2006)	13	*Peritumoral* 37.0	24	TLD palmar aspect of distal phalynx on the non-dominant index finger	7.1 µSv
Bekis *et al.*, (2009)	2 1	*Peritumoral* 29.6 44.4	3	Geiger counter at 50 cm from patient's chest	Whole body dose: 2-4.7 µSv

MBq, Mega-Becquerel; µSv, micro-Sievert.

Stratman *et al.* (1999) used a Geiger Miller counter at 3 cm from the injection site to measure exposure to the surgeon's hand during the breast procedures. This method is limited in its accuracy but still provides a reasonable assumption of exposure. His analysis showed an average rate of exposure of 342.5 µSv per hour. This study concluded that the primary surgeon can perform 2190 hrs of surgery before surpassing annual operational safety limits. However, their author extrapolated his annual allowable exposure based on an annual extremity exposure of 500 000 µSv per annum. This is the advised allowable exposure of a radiation worker, not exposure to the general public, as recommended by the United States Nuclear Regulatory Commission (USNRC)'s "*Reactor Concepts Manual*" for surgeons and other non-nuclear medicine personnel working in health or medicine. The advised allowable annual exposure for non-radiation workers or the general public is 500 µSv.

Waddington *et al.* (2000) analysed the radiation exposure to two surgeons. One surgeon performed the sentinel lymph node biopsy and the other the mastectomy. The mean finger dose for the surgeon doing the sentinel lymph node biopsy was 60.0 µSv and for the surgeon performing the mastectomy was 120.0 µSv per patient. The combined mean dose per surgery was 90.0 µSv. An interesting observation in this study was that the finger dose for a surgery performed at 4 hours post injection was not significantly different at 70.0 µSv. The authors fail to mention the length of time of surgery in this particular study. Waddington *et al.* (2000) quotes the different annual dose limits for radiation workers, as well as members of the public, and states that surgeons fall into the realm of members of

the public, however their extrapolations were also based on radiation worker extremities dose limit i.e. 500 000 µSv.

Morton *et al.* (2003) compared the radiation exposure to surgeon and staff working with patients who were operated on either day 0 or day 1. The dose per patient to the surgeon for day 0 surgery was 1.9 µSv and for day 1 was 0.5 µSv. Their reasoning for this was related to the radioactive decay of the ^{99m}Tc-isotope. The measured level of activity within the tumour went from 40 MBq to 2.5 MBq for the day 1 surgeries compared to 20 MBq to more than 10 MBq for the day 0 surgeries. The absorbed doses to the fingers on the dominant hand were low at 13 µSv and higher on the non-dominant hand as the surgeon would handle tissue with the non-dominant hand and use the dominant hand for instrumentation. Again, a radiation worker dose limit of 500 000 µSv was used to extrapolate data.

De Kanter *et al.* (2003) also had a higher total exposure dose at 61 µSv. The authors stated that their relatively short time from injection to theatre (4 hours) and the longer theatre times (1:56 hours ± 0:38 hours) accounted for the dose. The longer theatre times were due to the procedures performed: seven of the total 12 patients had mastectomies whilst the remaining five had breast-conserving surgery. They concluded their article by saying "*Radiation dose levels are less than the established dose limits for (nonexposed) workers if the number of procedures is restricted to about 100/person/year*".

The study done by Law *et al.* (2004) measured exposures to the surgeon and also found that the non-dominant hand exposure was higher. They had a day 0 and day 1 protocol but unfortunately the values were not separated out and the combined exposure dose of 17.8 µSv was reported. An annual dose limit of 500 000 µSv was used in this study to extrapolate the annual exposures and the authors stated that, depending on the workload, all surgeons should be designated radiation workers.

Nejc *et al.* (2006) measured the exposure to the hands with numerous TLDs on different sites of the surgeon, theatre sisters and medical staff. A full 24 hour delay post injection to surgery (day 1 surgery) was standard for all 13 patients in this study. The total exposure to the medical staff was much lower than to the surgeon, which was anticipated due to proximity of the surgeon to the source. The highest reading was obtained on the palmar aspect of the distal phalynx of the index finger of the dominant hand. The author contributes the lower absorbed dose of 7.1 µSv, when compared to those reported by Miner's, de Kanter's and Waddington's groups, primarily to the time delay from injection to surgery. Annual dose limits set for radiation workers were also used in this study.

Bekis *et al.* (2009) conducted a poorly constructed study with only 3 patients who received different doses of isotope, were operated on day 0 (within 3 hours of injection) and exposure to the surgeon was measured with a Geiger Muller counter at 50cm from the breast of the patient in theatre. The surgeries were lengthy at 100 minutes each, and included sentinel lymph node biopsy and mastectomy. The author compares the

measurements of this study with the body measurements in the studies of Stratman, Waddington, De Kanter, and Brenner. Their results are lower but the methods in obtaining data did not take into account the position of the surgeon, the site of the source and the decrease in penetration of the isotope at a distance from the source. Furthermore, Bekis' group used whole body dose limits as set for the general public and stated that "*the radiation risk to the surgical staff is low, and the classification of the personnel in the operating room as occupational radiation workers is not necessary*".

Important factors to consider when studying radiation exposure to the surgeon include radiation and ALARA ("as low as reasonably achievable") principles, the method and site of measuring radiation exposure, the method of injection, the timing and dose of injection, the length of time of radiation exposure and radiation concepts in general. With reference to the literature, these are discussed below.

Radiation and ALARA principles

Radiation is a process through which energy is released by one object and absorbed by another. The nucleus of radioactive isotopes changes structure by losing energy, causing energy to be emitted as radiation. The three main forms are alpha, beta and gamma rays. This process is called radioactive decay. A process called ionization results when these rays interact with the surroundings and produce positively- or negatively-charged particles, hence the term ionizing radiation (Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), 2011). Natural background radiation comes from cosmic, solar,

terrestrial, radon sources and man-made sources. Occupational exposure to radiation is classified as low dose exposure, specifically chronic low dose exposure. All chronic low-dose recommendations are based on extrapolations from high-dose exposure as the former is harder to study and the health risks are not well understood.

Although radiation may cause cancers at high doses and high dose rates, currently there is no data to establish unequivocally the occurrence of cancer following exposure to low doses and low dose rates – below about 10,000 millirem (100 000 μSv). Even so, the radiation protection community conservatively assumes that any amount of radiation may pose some risk for causing cancer and hereditary effect, and that the risk is higher for higher radiation exposures. A linear, no-threshold (LNT) dose response relationship is used to describe the relationship between radiation dose and the occurrence of cancer. This dose-response hypothesis suggests that any increase in dose, no matter how small, results in an incremental increase in risk. The LNT hypothesis is accepted by the NRC as a conservative model for determining radiation dose standards, recognizing that the model may overestimate radiation risk.

There have only been two studies (Cardis *et al.*, 1995; Brenner *et al.*, 2003) which have attempted to determine the effect of chronic low dose radiation exposure on humans. These studies both showed that the estimates were lower than what would have been expected with a LNT extrapolation from high dose exposure data, proving that there is still risk with chronic low dose exposure, albeit substantially lower. Notably, among the non-

cancer causes of death, circulatory diseases were significantly associated with radiation dose (Cardis *et al.*, 1995). Also noteworthy is that the latter study excluded subjects with exposure levels above the annual limit of 500 000 μSv.

Table 1.2 illustrates the annual effective doses to which human populations are exposed from different background radiation sources. When comparing all the sources of background radiation, it is evident that the annual exposure from natural sources is the highest (2400 μSv). This value is variable depending on the location and radon concentration. Radon is produced by the decay of radium-226 which is present wherever uranium is found. Radon is a gas which seeps out of uranium-containing soil and is the largest and most unpredictable contributor to background radiation.

Table 1.2: Annual per Caput Effective Doses in the Year 2000 from Natural and Manmade Sources

Source	Worldwide annual per caput effective dose (μSv)	Range or trend in exposure
Natural background: Radon, solar, cosmic, external terrestrial etc	2400	Typical ranges from 1000-10000 μSv, depending on circumstances at particular locations, with sizeable populations also at 10000-20000 μSv
Diagnostic medical examinations	400	Ranges from 40-1000 μSv at lowest and highest levels of health care
Atmospheric nuclear testing	5	Has decreased from a maximum of 150 μSv in 1963. Higher in the northern hemisphere.
Chernobyl accident	2	Has decreased from a maximum of 40 μSv in 1986 (average in northern hemisphere). Higher at locations nearer the accident site
Nuclear power production	0.2	Has decreased with expansion of programme but decreased with improved practice

From: Report of the UN Security Council on the effects of the atomic radiation to the General Assembly

However, measurement of ionizing radiation is quite complex as measurements depend on radiation activity or exposure. The Australian Radiation Protection and Nuclear Safety Agency defines these concepts as:

1. Radiation activity: how much radiation is coming out of something
2. Radiation exposure: measures the effect of radiation on substances that absorb it.

Measuring the dose of radiation absorbed by the body and determining the risk associated with the absorbed dose are important factors for radiation protection. Where the Curie (Ci) is the common unit of radioactivity, the Becquerel (Bq) is the SI derived unit of radioactivity. The absorbed radiation dose is measured in Gray (Gy) and the assessment of biological risk,

or the effective dose and equivalent dose, is expressed in Sievert (Sv). Table 1.3 gives the definitions of these different radiation units.

Table 1.3: Definitions of Radiation Units

Unit:	Definition:
Curie (Ci)	A unit of radioactivity produced by the disintegration of unstable elements
Becquerel (Bq)	SI unit of radioactivity, defined as the quantity of a radionuclide that undergoes one disintegration per second
Gray (Gy)	SI unit of absorbed radiation dose defined as the transfer of 1 joule of energy per kilogram of absorbing material
Sievert (sV)	SI unit of radiation absorbed dose equivalent, producing the same biological effect in a specified tissue as 1 gray of high-energy x-rays

The radioactive isotope ^{99m}Tc is the gamma ray emitting isotope used in lymphoscintigraphy. ^{99m}Tc is well-suited because it emits readily detectable 140 keV gamma rays (these are about the same wavelength emitted by conventional X-ray diagnostic equipment), with a half-life for gamma emission of 6.02 hours (Miner *et al.* 1999; Bekis *et al.*, 2009). This short half-life keeps the patient's total radiation exposure low. The isotope is bound to a carrier protein, often albumin, and this combined molecule is preferentially absorbed by the lymphatics and concentrates in the sentinel lymph node. The rate of isotope transport is strongly linked to the carrier particle size (Alazraki *et al.*, 1997). The smaller the carrier particle size, the higher the likelihood that it will be absorbed into the systemic circulation and hence not provide a lymphatic "route map". Conversely, the larger particle will not be able to migrate from the injection site as it will not be able to be absorbed by the blood or the lymphatics. The ideal sized carrier particle needs to allow absorption by the lymphatics,

but not the capillaries, and it must not clear too rapidly from the lymphatics, thus to allow retention in the lymph node and allowing identification with a gamma camera in theatre. Almost 80% of the particles in the ^{99m}Tc-labelled nanocolloid are less than 30 nm, allowing lymphatic vessel absorption, and about 20% of the particles range from 30 and 80 nm which enables prolonged lymph node retention (Valdés Olmos *et al.*, 1999).

Medical equipment such as a gamma camera can be used in theatre to detect the gamma rays emitted by the injected ^{99m}Tc-labelled nanocolloid. Higher readings on the gamma camera indicate a higher concentration of gamma irradiation at that specific point, thereby identifying the position of the sentinel lymph node (Doting *et al.*, 2007).

The recommended dose limits for radiation workers are based on the principles and dose limits specified in Report No. 116 of the National Council of Radiation Protection (NCRP) (2009). The limits are based on estimates of fatal cancer risks and an assessment of the risk that should be tolerated by workers who are occupationally exposed (Kase, 2004). These principles have been updated as information about radiation effects on human populations became available. The recommended dose limits for the public are different. A radiation worker is defined as an individual who is likely to receive an occupational dose in excess of 100 millirem in a calendar year. Table 1.4 illustrates minimum occupational dose limits set by the NCRP and the Reactor Concepts Manual (USNRC) for different anatomical region exposure for radiation and members of the public. Once again one should recognize that these limits have been based on extrapolations from high dose exposure studies.

Table 1.4: Annual Occupational Dose Limits for Radiation Workers and members of the public

Region	Annual dose limit per for radiation workers (µSv)	Annual dose limit for non-radiation workers (µSv)
Whole body	50 000	50
Extremities	500 000	500
Lens of eye	150 000	150
General public	1 000	1

Evident from Table 1.4, there are different dose limits set for radiation workers compared to members of the public. According to the definition of a radiation worker mentioned above, such an individual is likely to receive an occupational dose in excess of 100 millirem (1000 µSv) in a calendar year and medical personnel who work with isotopes on a regular basis should be classified as radiation workers. However, according to NCRP they are not. As such, extrapolations of annual exposure are based on different annual dose limits in the literature and as a result these studies cannot be accurately compared.

Devices used to measure radiation exposure are called dosimeters. There are a few available and each has its own particular advantages. The Geiger Mueller counter is easy to use and inexpensive, however there is difficulty in translating data gathered into the daily practice of the surgeon as it measures exposure from a distance (Yun, 2009). With regard to extremity exposure, the TLD is more reliable than the badge dosimeter as it has a larger

range and can measure background radiation levels greater than 5 – 10 Gy (Cameron *et al.*, 1991).

ALARA is a radiation safety principle for minimising radiation doses and releases of radioactive materials by employing all reasonable methods. ALARA is not only a sound safety principle, but is a regulatory requirement for all radiation safety programmes (Radiation Safety and ALARA). It states that the three major principles to assist in maintaining as low as reasonably achievable doses are:

1. *Time*: by minimising time exposed to the radioactive substance, the exposure dose is directly decreased
2. *Distance*: by doubling distance from the source of the radiation decreases gamma radiation exposure by four times (inverse square law)
3. *Shielding*: using any source of protective clothing or equipment is an effective way to reduce radiation exposure.

Studies have been done in the past to ensure that the radiation exposure to the surgeon does not exceed the minimum dose limits. As surgeons have no formal training for working with radioactive substances, education and research is crucial to prevent excessive exposure and to institute best-practice or ALARA principles. An extensive radiation study was undertaken across three continents with over 95,673 nuclear industry workers to assess the effects of low dose on cancer mortality (Cardis *et al.*, 1995). The aim of the study was to obtain more precise direct assessment of the carcinogenic effects of prolonged low-level to

predominant gamma radiation. The outcome showed no evidence of any association between radiation dose and mortality from all radiation causes and all cancers.

The limitations of this study were the exclusion of anyone exceeding an annual exposure of 500 000 µSv or more, and there were no lifestyle risk factors included in the study as it was a retrospective study and thus the influence of tobacco could not be weighed. However, among the non-cancer causes of death, circulatory diseases were significantly associated with radiation dose (Cardis *et al.*, 1995). With protracted low-dose exposure there were conflicting statistically significant results about leukaemia, but what was evident was that the younger age at which the exposure commenced (<5 years) the greater the incidence of solid organ cancer, such as that of the thyroid (Cardis *et al.*, 1995; Brenner *et al.*,2003).

Method and site of measuring radiation exposure

Stratman *et al*. (1999) and Bekis *et al*. (2009) used the Geiger-Muller counter to measure exposure to the surgeon at 3 – 50 cm. This is a large hand held device that cannot be sterilised and, as such, measures radiation exposure at a site up to 30 cm distant from the surgical field. The results obtained from these studies are not accurate enough to truly represent the exposure to the surgeon. A TLD, which can be placed directly onto anatomical component that is to be measured, is a far more accurate method as it measures the exposure to the human tissue handling the radioactive tissue.

The placement of the TLD is important to calculate maximal exposure accurately. Placements were discussed in Miner *et al.* (1999), Waddington *et al.* (2000) and de Kanter's

et al. (2003) studies who established that the non-dominant hand had the highest exposure. Nejc *et al.* (2006) recorded the highest readings on the pulp of the index finger in comparison to other sites on the hand, but his study recorded the highest exposure to the dominant hand. Vanhavere *et al.* (2008) reported that there was a higher level of exposure to the tip of the finger as opposed to the base of the same finger, indicating a TLD placed at the tip of the finger would accurately determine the true level of exposure to the surgeon.

In our study we used a small extremity dosimeter taken out of its plastic casing, this was then placed under the glove. The TLD was placed on the palmar surface of the distal phalynx of the index finger on the non-dominant hand in order to accurately analyse the highest exposure to the surgeon as the surgeon tended to handle the ^{99m}Tc-labelled nanocolloid-filled tissue with the non-dominant hand and use the dominant hand for dissection. This placement of the TLD did not interfere with the surgeon's ability to operate.

Method of radioisotope injection

The method of ^{99m}Tc-labelled nanocolloid injection has also been debated (Valdés Olmos *et al.*, 1999) as it can be injected in four different quadrants or injected at one point. It can also be injected into the tumour (intratumorally) resulting in early visualisation of the sentinel node. Specifically, visualisation after 30 min post injection occurred in 40% of patients (Valdés Olmos *et al.*, 1999). Therefore, these patients need early surgery post injection to locate the node with the gamma camera. The ^{99m}Tc-labelled nanocolloid can also be injected around the tumour (peritumorally). Peritumoral injection has a slower rate

of uptake and as such allows for later visualisation of the sentinel node. This is understandable as the tumour site may be drained differently from the nipple areolar complex (Stratmann, McCarty & Kuhn, 1999). Injecting of the bound isotope around the nipple areolar complex showed a lower rate of uptake by the node especially for the internal mammary node but it is an easier technique as it avoids the need for image guided injection (Jakub, Pendas & Reintgen, 2003). In our study the ^{99m}Tc-labelled nanocolloid was injected subcutaneously peritumorally.

Timing and dose of radioisotope injection

The timing and dose of radioisotope injection prior to theatre is also critical (Doting *et al.*, 2007; Stratman, McCarty, Kuhn, 1999; Miner *et al.*, 1999; Chok *et al.*, 2003; de Kanter *et al.*, 2003; Bekis *et al.*, 2009). Timing considerations include whether the patient injected with isotope in the morning is operated on that same afternoon. Day 0 surgery was thought to be the most accurate method of locating the sentinel node as the gamma camera is able to pick up higher readings from the emitted gamma rays over the node making the accuracy in locating it higher. However, more recent work has revealed that the isotope injection can occur a day prior to surgery, i.e. day 1 surgery. With an increased dose of isotope on day 0, the sentinel lymph node still emits sufficient gamma rays for the gamma camera to detect them on day 1 (Waddington *et al.*, 2000; Miner *et al.*, 1999; Chok *et al.*, 2003; Morton *et al.*, 2003).

The study by Chok's group in 2003 investigated whether a day 0 protocol was better than a day 1 protocol. Their findings showed no difference in accurately localising the sentinel

lymph node (92 vs. 98% for day 0 and 1 surgery, respectively) if the isotope was given 30 min to 24 hours pre-operatively. Similarly, McCarter's group showed no difference between day 0 and 1 protocols. However, they highlighted the logistical advantages of day 1 surgery, specifically with regards to time constraints of both surgeons and nuclear medicine physicians (McCarter *et al.*, 2001). Even though their dose of isotope for the day 1 protocol was 5- times greater than that for day 0, i.e. 18.5 MBq (0.5 mCi) versus 3.7 MBq (0.1 mCi), respectively, they argued that although they used a higher dose for day 1 injections it was so trivial that it should not raise radiation safety issues.

The issues regarding day 0 versus day 1 operations were also addressed by Morton *et al.* (2003), Law *et al.* (2004) and McCarter *et al.* (2001). All these studies concluded that by operating on patients injected the previous day (i.e. day 1 surgery), a surgeon would be practising ALARA principles. Law *et al.* (2004) stated that the low mean exposure coupled with the slightly-higher injection dose of isotope left the issue of lower exposure to the surgeon on day 1 surgery unanswered. He concluded that depending on the workload, a surgeon should possibly be considered as a "radiation worker". As the low exposure is presumably associated with the length of time from injection to surgery, Nejc *et al.* (2006) concluded that day 1 procedures were safer to medical staff from a radiation exposure point of view.

By increasing the time between injection and surgery the irradiation to the surgeon is lower as the isotope undergoes decay. During a 24-hour period, four physical half-lives of the

radio-tracer pass, resulting in 1/16th of its initial radioactivity remaining. The activity is further diminished due to clearance of the radiotracer from the blood (Nejc *et al.*, 2006). The dose of isotope injected also varied from study to study (Babiera *et al.*, 2005). Of relevance was that when a larger dose of isotope was used on patients having surgery on day 1 or day 2, the exposure to the surgeon was lower compared to a smaller dose given to patients with day 0 surgery. Again, this is due to the exponential degradation of the radioactive isotope per unit time (decay). The higher doses given to patients for day 1 protocols are still trivial doses from a patient safety perspective.

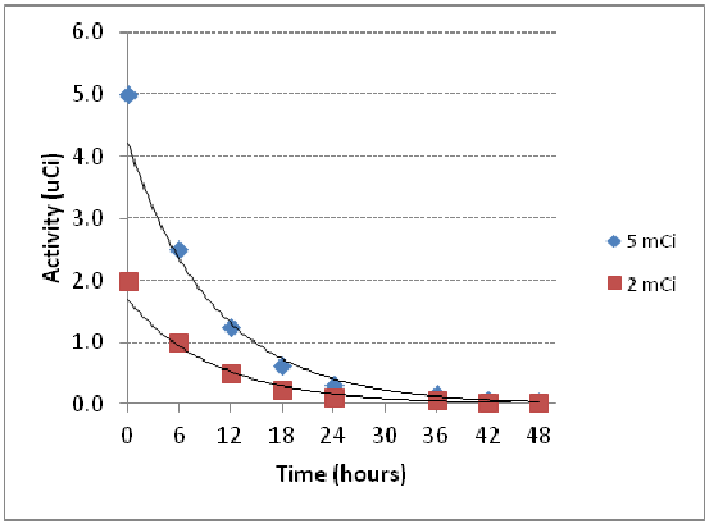
Figure 1 (A and B) shows the radioactive decay of ^{99m}Tc for the two different doses used in this study over time. The higher dose of 185 MBq (5 mCi) for day 1 operations enables adequate isolation of the sentinel lymph node with the gamma camera, but the emissions of the isotope remain minimal so that exposure to the patients and accumulative exposure to the surgeon remains low. With the lower dose of 74 MBq (2 mCi) for day 0 surgery, the emitted gamma rays are higher at the time of surgery and, consequently, the exposure to the surgeon is greater. When comparing the decay of the two doses of isotope over time the emissions at 15 hours for the 185 MBq (5 mCi) dose are equivalent to that of the 74 MBq (2 mCi) at 6 hours. As most day 1 surgeries occur between 18-24 hours post injection, the exposure to the surgeon is less. In addition, this significantly broadens the window from injection to surgery, allowing for any delays in theatre.

The current recommendations (Nejc *et al.*, 2006; Waddington *et al.*, 2000) state that even though the radiation to the surgeon is low with ^{99m}Tc-labelled isotope injection on the same

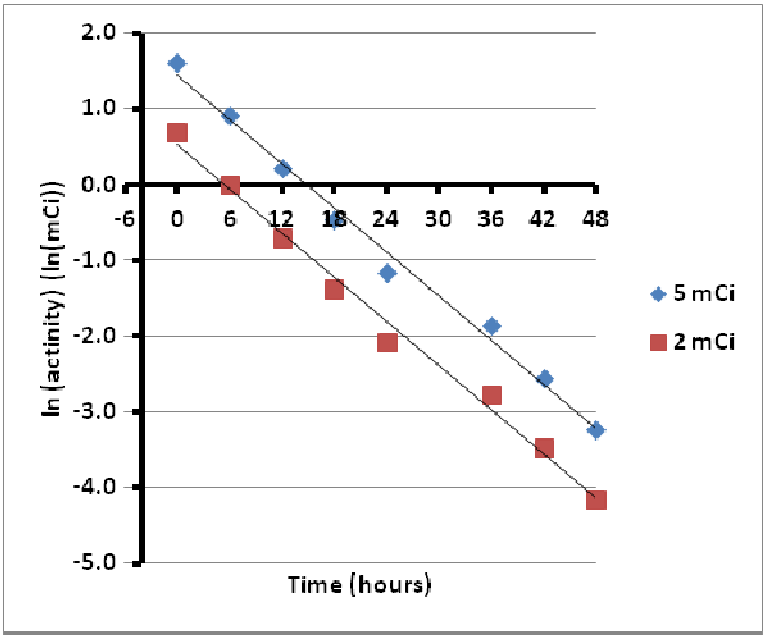
day as the surgery, the best practice with regards to radiation exposure principles is to follow 2-day protocols, i.e. day 0 and day 1. Day 1 operations allow for accurate localisation whilst decreasing the surgical team's exposure. By using a smaller dose on day 1 the time frame during which the surgeon is able to accurately identify the sentinel lymph node is much smaller. With the unpredictable issues resulting in delays in theatre lists this could result in that window being missed and the node not being found.

Figure 1: Radioactive Decay of Technetium-99m (^{99m}Tc) over Time

A



B



A. The radioactive decay of ^{99m}Tc per unit time. **B**. The log of the radioactive decay of ^{99m}Tc per unit time.

Length of time of radiation exposure

The longer a procedure takes, the greater the radiation exposure to the surgeon. Where studies included mastectomy or wide local excisions with the sentinel lymph node biopsy, the average exposure to the surgeon was higher than with sentinel lymph node biopsy alone. In addition, when handling the cancer specimen with residual ^{99m}Tc-labelled nanocolloid, the exposure to the surgeon was higher due to the combination of the isotope within the tumour and the sentinel lymph node (de Kanter *et al.*, 2003; Nejc *et al.*, 2006).

From the review of the literature above, it is evident that only a few studies have investigated the effect of chronic low dose radiation exposure on humans and concluded that the risks of solid-organ cancer and circulatory disorders are associated with radiation dose. This dose-response hypothesis suggests that any increase in dose, no matter how small, results in an incremental increase in risk.

Breast surgeons are continually exposed to low dose radiation and, as surgeons have no formal training for working with radioactive substances, education and research is crucial to prevent excessive exposure as well as institute ALARA principles. Currently there is no published data from South Africa investigating low dose radiation exposure to breast surgeons during axillary sentinel lymph node biopsy. We therefore have no information on the radiation dose and/or exposure dose to our surgeons during any given year and can make no assumptions as to whether we are nearing the annual occupational dose limits for radiation exposure.

Furthermore, the earlier international studies evaluating radiation exposure to the surgeon highlighted the lack of consistency in the timing of isotope injection and surgery, the dose of isotope injected, and the method used to measure exposure to the surgeon. Also, these studies were small in sample size.

This study aims to investigate radiation exposure to the South African surgeon performing sentinel lymph node biopsies on patients in a South African environment with a standardised method in patients who have received an isotope injection from a single nuclear medicine department in a single hospital. Results from this study would inform us whether our surgeons are within the annual occupational dose limits for radiation exposure, as well as enable us to compare our radiation injection dose and surgeon's exposure dose to other international groups.

2.0 STUDY AIM AND OBJECTIVES

The aim of this study is to investigate the radiation exposure to the South African surgeon performing sentinel lymph node biopsies on patients who have received a ^{99m}Tc-labelled nanocolloid injection prior to surgery.

The specific objectives of this study are:

1. To measure the radiation exposure to the surgeon during a sentinel lymph node biopsy.
2. To extrapolate the mean radiation exposure into daily, weekly, monthly and annual exposure rates.
3. To establish if minimum extremity exposure limits could be breached in daily surgical practice.

3.0 METHODS AND MATERIALS

This study investigates the accumulative extremity radiation exposure to one surgeon during an axillary sentinel lymph node dissection in South Africa, in a total of 36 patients.

3.1 The patients

The study sample comprised of 36 patients who required injection with the ^{99m}Tc-labelled nanocolloid prior to their surgery. Patients were analysed from the 15th of January 2013 until the 20th of February 2013. All these patients were female. The average age was 51.5 years and the average injected radioactivity dose was 185 MBq for day 1 surgery and 74 MBq for day 0 surgeries.

The timing of injection is discussed in section 3.3 and the TLDs are discussed further in section 3.4.

3.2 The surgeon

Dr Carol Benn, a surgeon in Johannesburg, who has a special interest in breast disease, was selected as the surgeon because she performs between two and eight operations using the ^{99m}Tc-labelled nanocolloid per week.

3.3 The ^{99m}Tc-labelled nanocolloid

The ^{99m}Tc-labelled nanocolloid was injected by the nuclear medicine department in the Netcare Milpark Hospital. The ^{99m}Tc-isotope solution was pre-mixed and linked to an albumin colloid called Nanocoll, which was injected subcutaneously peritumorally. Most of the international studies use a peritumoral injection technique as this allows for a slower uptake of the isotope by the lymphatics and a late lymph node uptake which allows adequate isolation of the sentinel node up to 24 hours post injection. A different method is to inject the isotope intra-tumorally allowing the node to be visualised within 30 min (Valdés Olmos *et al.*, 1999). The intra-tumoral injection is associated with a higher radiation exposure to the staff as the isotope has not had sufficient time to decay as the surgery needs to be performed sooner after injection and as such there is a higher concentration of gamma radiation emitted by the tissue.

Different doses of isotope were injected depending on the length of time prior to surgery. An average isotope dose of 185 MBq was injected the day before if the patient was scheduled for early morning surgery, day 1. However, 74 MBq was injected on the morning of the operation, if surgery was scheduled for that afternoon, day 0.

The same two nuclear medicine physicians who administered the isotope injections on all of the patients recorded the time of injection as well as the dose injected on a data sheet supplied for the data collection.

3.4 The thermoluminescent dosimeter (TLD)

The TLDs were small enough to fit into the surgeon's glove and did not inhibit her sensation or capability during surgery. Before surgery, the TLD was placed on the palmer aspect of the distal phalanx of the index finger on the non-dominant hand of the surgeon. The fingertips of a latex glove were cut off and one of these 'tips' was placed over the TLD and secured to the distal phalynx the surgeon's finger with Sleek® adhesive. She then scrubbed as usual and donned her usual size 7 Biogel® gloves over the TLD and latex fingertip. The reason for selecting this site for the TLD placement was to enable the maximal measured dose exposed to the surgeon to be recorded. As the surgeon would be directly handling the isotope filled tissue, this was the site in contact with the radiation source and hence the area of maximal exposure.

The TLDs used to record exposure data were extremity badge dosimeters. These were supplied by SABS and given to the Medical Physics (MP) Department of the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH). These TLDs were calibrated by irradiating them using a Cs-137 beam at the SABS. They were then irradiated with a beam dose ranging from 4.25 mSv, 6 mSv and 31 mSv, and were then processed after 24 hours of irradiation for fading purposes. In theatre, the TLDs were taken out of their plastic casing and placed on the surgeon's finger. The MP department was consulted on the removal of these TLDs from their casing and they confirmed that removing the TLD from casing would not impact on the device's functionality. After the operation the TLDs were taken to the MP department at CMJAH and sent through to SABS via the MP department where they were analysed. These measurements are traceable to the National Metrology Institute of South

Africa (NMISA). For quality control, the SABS has a Cs-137 source in the Panarad irradiator at CMJAH. It is used for irradiating the control TLDs which are used to perform the machine calibration (MC), MC factors (MCF), in-house TLD calibration (ECF) and weekly standards dosimeters. RPS performs MCF every day before processing the TLDs. The TLDs are irradiated with the following beam dose. 4.15 mSv (called low dose) and 3.07 mSv (called high dose). If the reader did not pass MCF then it will not be used for processing TLDs for that day. Every Monday SABS perform weekly standards: TLDs are irradiated with 3 mSv dose using Cs-137 source. They also run dosimeters calibration, or ECF, only when the dosimeters are new or when the calibration period is due. The system sets up the date for the next ECF calibration for each of the TLDs.

3.5 In theatre

Once in theatre, the data sheet was completed with the patient's name, age, hospital number and the type of surgery being performed. During surgery, either the study investigator (N.Harran) or a research assistant would record the length of time the surgery took and the values obtained by the gamma camera on the skin, in the axilla and the specimen on the data sheet. The start time was recorded when the surgeon made the first incision in the axilla and the end time was recorded when the surgeon unscrubbed. The length of surgery was documented in this way because the surgeon did not close the wound herself. Thus length of time exposed was essentially only during the handling of the node.

3.6 Statistical methodology

Data analysis was done using STATISTICA 9 software. Descriptive statistics were used and results were reported as means and standard deviations (SD).

4.0 RESULTS

The raw data was analysed and Table 4.1 illustrates the descriptive data captured for all the study patients.

Table 4.1: Descriptive Statistics of TLDs

	Age (years)	Dose of Isotope (MBq)	Injection time to Surgery (Hours)	Total time per Surgery (minutes)
Mean*	51.5 ± 10.4	111.0 ± 52.5	9.32 ± 7.31	12.6 ± 7.2
N#	22	36	36	36

*Value ± SD; N#=36, however incomplete data from some variables.

On average the time from isotope injection to surgery was less than 10 hours. This indicates that there were more same-day (day 0) operations performed throughout the study period.

The average time for the procedure was 12.6 minutes. This is consistent in that mostly sentinel lymph node biopsies alone were being performed throughout. Notably, the surgeon's preference (also see the next paragraph below) is to do the sentinel node biopsy as a single initial operation for staging; dual operations were the result of a patient's choice, controversial previous sentinel lymph node results or completed neoadjuvant chemotherapy.

In the study's practice, 'isolated' sentinel lymph node biopsy is performed as the initial staging surgery, because the time delay involved in evaluating the node under frozen section is not practical. The patients are staged on the paraffin-embedded histology of the sentinel lymph node biopsy and can then either proceed with completion surgery or neoadjuvant chemotherapy.

The TLD's were analysed by SABS and the methods used have been described above in section 3.4. As mentioned above, the discrepancies between the different TLDs are due to the different surgical procedures performed, ranging from mastectomies and wide local excisions with sentinel lymph node dissections to sentinel lymph node biopsies alone.

From the data in Table 4.2 we were able to calculate that the average radiation dose exposure to the surgeon per patient and this was 2.7 µSv, with a total exposure of 98.25 µSv over a total of two months.

Extrapolation into annual figures, depending on how many theatre days the surgeon had per week with an average of 2.5 patients per day, showed annual exposure of 2 464 µSv for a 7-day week and 1 755 µSv for a 5-day week. All the readings exceed the advised annual extremity dose limit of 500 µSv for members of the public. Table 4.3 illustrates the extrapolation of patient and dose exposures relevant to the surgeon.

Table 4.2: Finger Dose Exposure from Sentinel Node to the Surgeon

TLD Number	Number of Patients	Calibrated reading of TLD (µSv)	Total Time in Surgery per TLD (hh:mm)	Average of total time in Surgery per patient (mm:ss)	Average of total time from injection to surgery per patient (hh:mm)
A	9	28.68	02:36	17:20	06:15
B	6	13.33	00:55	9:10	12:30
C	5	15.93	00:59	11:48	08:08
D	3	27.20	00:20	6:40	14:07
E	13	13.11	02:43	12:32	08:47
TOTAL	**36**	**98.25**	**07:33**	**12:35**	**09:19**

Table 4.3: Comparing results of International Studies with this Study

Author and year	Number of patients (n)	*Method* and dose of isotope injection (MBq)	Time to surgery post-injection (hours)	Position and equipment	Mean absorbed dose
Stratman *et al.*, (1999)	20	*Peritumoral* 25.9-40.7	1.5-3	Geiger counter 3cm injection site	342.5 µSv/hr
Miner *et al.*, (1999)	10	*Peritumoral* 37.0	0-9	TLD in glove of left ring finger	102.0 µSv
Waddington *et al.*,(2000)	19	*Peritumoral & Intratumoral* 10.0-15.0	18-24	TLD on palmar surface of the distal phalynx of the index finger on the dominant hand	90.0 µSv
Morton et al, (2003)	32	*Peritumoral* 20.0 40.0	Same day Next day	TLD tip both index fingers Left hand exposure > Right hand exposure	13.0 µSv (less in next day)
De Kanter *et al.*, (2003)	12	*Peritumoral* 30.0	4	TLD to both hands (no exact site mentioned) Left hand exposure>Right hand exposure	Left hand 61.0 µSv
Law *et al.*, (2004)	20	*Peritumoral* 18.0 74.0	Day 0: 6 Day 1: 24	TLD dorsum left index finger	17.8 µSv
Nejc *et al.*, (2006)	13	*Peritumoral* 37.0	24	TLD palmar aspect of distal phalynx on the non-dominant index finger	7.1 µSv
Bekis *et al.*, (2009)	2 1	*Peritumoral* 29.6 44.4	3	Geiger counter at 50 cm from patient's chest	Whole body dose: 2-4.7 µSv
Harran *et al.*, (2013)	36	*Peritumerol* *74* *185*	9.19	TLD on palmer surface of index finger of non-dominant hand	2.7 µSv

MBq, Mega-Becquerel; µSv, micro-Sievert.

Table 4.4: Averages and Annual Extrapolation of Patients and Dose Exposure Relevant to the Surgeon

Average number of patients/theatre day	**2.5 patients**
Average daily exposure/theatre day (Surgeon)	6.75 µSv
365 days (7 day week)	2 464 µSv
260 days (5 day week)	1 755 µSv

Based on the averages in Table 4.3, we are able to estimate the conditions needed for the surgeon to exceed the recognised annual dose extremity limits of 500 µSv and 500 000 µSv for members of the public and radiation workers per annum, respectively. Table 4.4 illustrates these conditions.

Table 4.5: Needed to Exceed the Annual Extremity Dose Limit

	Member of the Public: Annual extremity dose limit of 500 µSv	**Radiation worker: Annual extremity dose limit of 500 000 µSv**
Theatre Hours per Annum *(based on 12.6 min per patient)*	38.85	38 850
Theatre Days per Annum *(based on 6.75 µSv per day)*	74	74 074
Patients per Annum *(based on 2.7 µSv per patient)*	185	185 185

5.0 DISCUSSION

5.1 Interpreting the results

During the period 15th January 2013 to 20th February 2013, data was collected from 36 patients who had ^{99m}Tc-labelled nanocolloid injected for their operations. These patients were given isotope injections to increase the sensitivity in locating the sentinel lymph node to establish any evidence of metastasis of the cancer. This information is crucial in staging the cancer and planning further individual patient treatment.

After analysing the data from 36 patients recorded on a total five TLDs, we cross-referenced this data with the raw patient data collected to enable the study objectives to be obtained.

The TLDs were analysed by SABS, from the MP Department at the CMJAH. These TLD's were analysed under reference conditions and as such did not need to be corrected by a calibration factor or corrected for background radiation. The results from these TLDs showed a total exposure to the surgeon of 98.25 µSv. The mean exposure to the surgeon per patient was calculated as 2.7 µSv.

This mean absorbed dose value is lower than exposures measured by all of the previous studies (Stratman et al., 1999; Miner et al., 1999; Waddington et al., 2000; Morton et al., 2003; Law et al., 2004; Nejc et al., 2006; Bekis et al., 2009). Possible reasons for lower levels are discussed below. Having said that, when the data is extrapolated to annual exposures

based on the surgeon's level of activity, this lower reading exceeds the annual dose limits for extremity exposure in members of the public as stipulated by the Reactor Concepts manual (USNRC).

The importance of TLD calibration prior to use to measure total exposure has been highlighted by one of the examiners on this study and subsequently addressed. If a TLD is not correctly calibrated and this calibration method is not standardised and controlled, the results obtained will be unreliable. Readings from such TLDs could either over or under estimate the exposure to the index case.

While most background radiation comes from natural environmental sources, a small percentage of the radiation in the environment is manmade, considering the use and testing of nuclear weapons is especially important. Nuclear power plants and recycling of nuclear fuels also contribute to environmental radiation. Radioactive medical devices, such as x-rays, make a small contribution to the background radiation levels. Background radiation is evaluated by using the Background Radiation Equivalent Time (BRET) (Nickoloff *et al.*, 2008). One BRET is equivalent to one day's worth of average human exposure to background radiation. BRET is used to measure low radiation exposure only, not in areas where there is known high radiation source or an accident has occurred. The BRET unit is not standardised as the value for average background radiation exposure differs from country to country, but the 2000 UNSCEAR estimate for worldwide background radiation dose is 2 400 µSv. This is the value we used in this study to take background radiation into account.

For this study, the total radiation exposure was then analysed and extrapolated according to the total exposure to the surgeon per patient, per unit time and per annum, as well as the annual minimum theatre hours, theatre days and patient number. This analysis revealed that, if the surgeon was considered as a non-radiation worker or member of the public, the annual extremity dose limit in number of hours, patient cases and theatre days during which operations using the ^{99m}Tc-labelled nanocolloid were performed, was 38 hours, 74 days or 185 patients. The only international study which extrapolated their data to annual figures was the Stratman group (1997) who concluded that the primary surgeon can perform 2190 hrs of surgery before surpassing annual operational safety limits, but this was for a an annual dose limit of 500 000 μSv, a limit set for radiation workers.

Low-dose exposure can be quantified as an acute exposure (such as atomic bomb explosion) or a protracted exposure (such as occupational or therapeutic exposure). As there was a significant increase in solid organ cancer in the dose category 5 000 - 125 000 μSv in comparison to those with <5 000 μSv in acute exposure, the question posed by Brenner's group: "*What is the lowest dose for which there is good evidence of increased carcinogenic risk?"* (Brenner *et al.*, 2003) remains unanswered. The study conducted by Cardis' group across three continents with a sample size of over 95 000 patients could not prove an effect of chronic low dose radiation on cancer mortality (Cardis *et al.*, 1995).

Occupational low-dose radiation exposure to medical professionals is predominantly by gamma irradiation during fluoroscopy. Doctors who fall into this category include

radiologists (especially intervententional radiologists), cardiologists (Dash&Leanman, 1984; Andreassi, 2004), orthopaedic surgeons (Barry, 1984; Riley *et al.*, 1989) and gastroenterologists performing endoscopic retrograde cholangio-pancreatograms (ERCP) (Cohen *et al,* 1997). All studies showed that minimum dose limits were not breached if ALARA principles were practised. However, SABS does not classify doctors who work regularly with fluoroscopy as radiation workers.

During this study the surgeon received a total absorbed dose of 98.25 µSv over the 2 month period. This is equivalent to an annual dose of 590 µSv. This dose exceeds the annual threshold of 500 µSv per annum and as such radiation protection methods or ALARA principles should be instituted in these breast theatres. Therefore, surgeons performing procedures/operations involving ^{99m}Tc-labelled nanocolloid and handling of ^{99m}Tc-labelled nanocolloid-filled specimens require additional radiation protective measures during their daily theatre practices. To practise best principles, the following ALARA principles could be applied in the surgical setting so as to lower the annual exposure dose:

- *Time*: More day 1 surgeries could be scheduled and direct node handling limited during theatre exposure.
- *Shielding*: Protective clothing, such as lead gloves and goggles, and possibly lead aprons should we worn. Although the latter will not protect the extremities, vital organs will receive the benefit. Another method would be to rather use instruments to handle tissues thereby reducing direct exposure and increasing the distance from the radiation source even if it only by a few centimeters.

The extrapolation of this data to annual figures shows that breast surgeons performing regular sentinel lymph node biopsies should either be limiting the amount of procedures they perform per annum or potentially be reclassified as radiation workers.

5.2 Research in context

Various studies have been conducted internationally to determine the dose of radiation exposure to the surgeon, the theatre staff and the pathologist when dealing with patients who have been injected with the ^{99m}Tc-labelled nanocolloid for lymphoscintigraphy and identification of the sentinel node using a gamma probe. When we compare these studies (listed in Table 1.1) to our study, it is evident that there were more day 0 surgeries and future studies should attempt to measure the difference in average exposure to the surgeon per patient comparing the day 0 injection and surgery with the day 1 surgical patients. Unfortunately, as the patients who had day 0 or day 1 surgeries in our study were mixed on all the TLDs, it was impossible to extract that information for the analysis. However, the average time from injection to surgery in our study indicated that more day 0 operations were being done.

Radiation protection principles are not routinely practised in our theatres, results from this study has shown that the radiation exposure to the surgeon, and hence the other theatre staff, is above the recommended levels advised by the Reactor Concepts Manual (USNRC). In addition, the radiation exposure could potentially be decreased further by performing

more day 1 operations and practicing the ALARA principles more aggressively. Waddington *et al.* (2000) measured the radiation exposure to the theatre staff and the pathologist analysing the specimens in their study and found that the radiation dose exposed to the pathology staff was dependent on the timing of the operations. Exposed dose to the pathologists was ten times lower when surgery was performed 24 hours post injection, as opposed to 4 hours post injection. In a future attempt to reduce annual radiation dose exposure to our surgeons, we should rather perform day 1 surgeries.

During our study, the average exposure dose per patient to the surgeon was 2.7 µSv. This exposure was much lower than those reported by Miner's, Waddington's and De Kanter's groups of 102, 90 and 61 µSv, respectively. The average time from injection to theatre was 18-24 hours for Waddington's study (Waddington *et al.*, 2000). Taking into consideration the half-life of the isotope and, hence, the amount of gamma ray exposure to the surgeon decreasing exponentially with time, the exposure would be higher to the surgeon given a shorter interval from injection to theatre, as in our study. Our study had an average time from injection to theatre of less than 10 hours, yet our injected dose was much higher than that of Waddington's group and our absorbed dose much lower. De Kanter's group had a shorter interval from injection to theatre time, but their lower absorbed dose is probably accounted for by the lower injected dose of 30 MBq compared to 74 MBq in our study. Similarly Miner's group had a much lower injection dose at 37 MBq (Miner *et al.*, 1999, Waddington *et al.*, 2000, De Kanter *et al.*, 2003).

Our exposure dose of 2.7 µSv was however lower than those reported by Morton's, Law's and Nejc's studies of 13.0, 17.8 and 7.1 µSv, respectively (Morton *et al.*, 2003, Law *et al.*, 2004, Nejc *et al.*, 2006). These differences are possibly explained by a combination of:

1) *Anatomical positioning of TLD onto the finger tip to provide more accurate measurements of extremity radiation*. Previous international studies used a host of badge TLDs, which are not as close to the radiation source as the hands of the surgeon, and/or a TLD placed on the body or the non-dominant hand.
2) *Type of TLD*. A TLD which has been prepared in controlled conditions and is more robust not requiring correction for calibrations factors and background radiation may provide a more accurate reading.

Although Stratman *et al.* (1999) reported an inconsistent 2190 theatre hours per annum when compared to our 38 hours per annum before exposure limits are exceeded, the former group studied whole body exposure and used an annual limit set for radiation workers. Similarly Bekis *et al.* (2009) reported on whole body absorbed dosages and can therefore not be compared to our study.

In summary, our exposure dose to the surgeon is much lower than that reported by the other studies. Even though the possible reasons for the latter is discussed above, it is evident that our injected dose of ^{99m}Tc-labelled nanocolloid is much higher when compared to that in other, smaller studies. This begs the question of why we are injecting higher radioactive dosages and whether we can reduce this quantity. This may also have advantageous cost implications. Also, our average time from injection to surgery suggests more day 0 surgeries. It would be best practice and in line with the ALARA principles to perform more day 1 surgeries.

5.3 Study limitations

There are a number of limitations in the current study. The study only assessed the radiation exposure to one surgeon. This may skew the data as the methods or theatre practices used by this surgeon may not be common to other breast surgeons. Individual surgeon's technique when handling the node, the amount of instrumentation used to handle the tissues and dominant hand use may all affect time and amount of exposure.

In hindsight it would have been interesting to group the day 0 and day 1 surgery patients on different TLDs to determine if day 0 surgery resulted in higher rates of exposure to the surgeon than day 1 operations.

There would also have been benefit in using one TLD per patient to establish each patient's exposure to the surgeon individually. Unfortunately, we did not have enough TLDs to do individual patient analysis.

5.4 Future studies

Future studies could include samples of more than one surgeon to assess how radiation values vary according to surgical technique and practice. Some surgeons may handle specimens which may impact on the amount of radiation absorbed. Also, more day 1 surgeries and shorter theatre times would affect the amount of radiation to which the surgeon was exposed and, finally, if the surgeon was involved in closing the wound, this may also prolong radiation exposure.

Studies focusing on these variables would help to establish which surgical practices increase radiation exposure to the surgeon and, as such, protective principles could be established to

modify theatre practices when patients have been injected with a ^{99m}Tc-labelled nanocolloid.

It is also recommended that different TLDs are used for different doses of ^{99m}Tc-labelled nanocolloid. For example, grouping the patients injected with 185 MBq (5mCi) of ^{99m}Tc-labelled nanocolloid on the day prior to surgery separately from the those injected with 74 MBq (2mCi) of ^{99m}Tc-labelled nanocolloid on the same day as surgery in order to determine whether the delay in surgery would result in lower radiation exposure to the surgeon without affecting the sensitivity in locating the sentinel node. In addition, TLD placement on the torso would enable us to estimate whole body exposure and compare it to annual limits.

6.0 CONCLUSION

Radiation exposure is a risk to medical practitioners. With improved technology and the readily available use of radiological procedures and equipment to physicians and surgeons alike, the opportunity to be exposed to radiation, such as the extremely penetrating gamma radiation, is increased. In addition, without formal training in radiation-protection principles or a basic understanding in methods to decrease radiation exposure, doctors are at risk of not performing best-practice medical principles, to patients as well as to themselves.

This study compared data collected from a single South African hospital to that from smaller international studies done previously. Our exposure dose to the surgeon per patient is lower than other studies but exceeds the non-radiation workers' annual absorbed dose limit for the extremity (as specified by the Reactor Concepts Manual (USNRC) and shown in Table 1.4). However, it is evident that our injected dose of ^{99m}Tc-labelled nanocolloid is much higher when compared to other studies. Also, we are doing more day 0 surgeries than day 1, further increasing the exposure dose to the surgeon. Analysis of the radiation exposure to a single surgeon over the two month trial period revealed a total exposure of 98.25 µSv. When modified to per patient exposure, the surgeon would need to perform more than 185 sentinel lymph node biopsies each year to reach the non-radiation worker annual exposure limit of 500 µSv. The likelihood of this being achieved is strong and will limit the practice of any busy breast surgeon. This highlights the importance that any doctor who works with radioactive isotopes or radiation equipment should have a firm understanding of ALARA principles, as well as how to maintain low-dose exposure to themselves and the staff in their vicinity.

Finally, we should investigate reasons behind our higher injection dosages for sentinel lymph node procedures. Reducing the injected dosages to the lowest possible dose for effective intraoperative lymph node localization may result in the advantage of reducing the cost of the procedure.

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