APPROACHING RADIOGRAPHIC PATIENT EXPOSURE AND STERILISATION QUALITY ASSURANCE IN DENTAL MEDICINE PRACTICE IN GREECE

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Abstract: The free-air exposure caused in routine position for 52 dental radiographic units, aged less than four years in operation, has been measured and the occurring exposure variation among them has been studied. Further, the dental sterilisation methods and the equipment employed by 63 private dental facilities in Greece have been thoroughly investigated.

Introduction

Dental patient-doses hazards and risks related to the quality of the sterilisation procedures of instruments and other materials constitute two systematic technology-related danger sources in dental medicine practice.

In dental radiography, the part of the head that receives the greatest dose is the skin in the area where the X- rays enter. The dose to the thyroid gland from a single, intraoral exposure such as a bitewing was investigated very early [1] and was found to be approximately 0.003 mSv (0.3 mrem). Probably the most accessible, extensive report on radiation exposures is the UNSCEAR 2000 Report [2], where a comparison of estimated doses from medical and dental x-ray examinations can be found. For populations that have a high level of medical care, like in Europe and the United States, the annual per caput effective dose is 1.2 mSv from diagnostic medical sources, compared with 0.01 mSv from dental sources. These doses vary somewhat from different machines, depending strongly on the equipment generation and on the existence of a quality assurance program for the dental radiographic units.

Therefore, we have tried to compare the dental radiography patient exposures among 52 relatively new dental radiographic equipment, aged under four years in operation, in order to determine the range of the exposure variation among comparable new generation equipment and define the extend of the contribution of the primary hardware-bound indicator, that is the exposure caused under identical or similar overall settings, from each examined model.

The second much more important and potentially much more dangerous hazard source is the dental instruments sterilisation equipment, employed by each practising dentist. Poor sterilisation procedures may lead to the transmission of severe or even lethal diseases, such as the viral infections caused by HBV, HCV and HIV. There are almost no statistically significant data, concerning these hazard sources, for the private dental-medical facilities in Greece. Therefore, we attempted to investigate the means and methods employed, for the quality assurance (Q.A.) of the dental instrumentarium sterilisation, in 63 private facilities in Greece.

Investigation of the Dental X-Ray Exposure

In order to compare the exposures caused by the 52 dental radiography equipment of various manufacturers such as Arted, Belmont-Toshiba, BlueX-IntraOs, Castellini, DeGoetzen, Fiad, Gerdex, Neodent, Satelec, Siemens and Trophy, an air ionisation chamber, calibrated against the secondary standard of the Greek Atomic Energy Commission was employed.

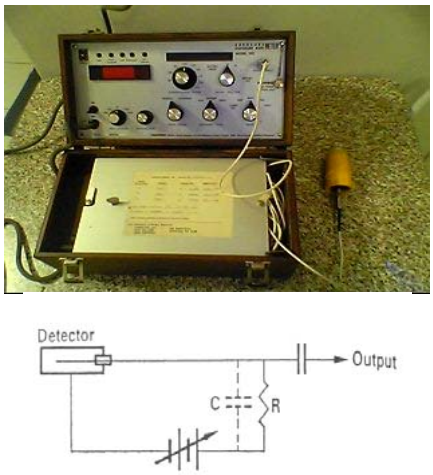

Figure 1: Photo and schematic representation of the employed ionisation chamber.

We have chosen to directly measure the relative exposure keeping all other important factors, such as geometry, current, voltage, exposure time, filtration etc. constant. The reason is that exposure is an equipment related parameter that lends itself to be employed as a comparison measure.

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Other parameters like the actually absorbed dose on the patient, first, require complicated ethical and legal issues to be settled, second, they are strongly influenced by individual anatomic and prosthetic features and, thus, lack in reproducibility. Finally, the employment of appropriate dental-phantoms is relatively expensive, inconvenient and time consuming, while is only worth, when the measurements are part of a full-scale quality assurance (QA) programme in dental radiographic units, with periodical follow-up, aiming to assess the impact of the radiographic QA guidelines by a general dentist population. An interesting study including follow-up of former investigation has appeared recently [3], covering the region of Achaia in Greece.

The free-air exposure was measured several times, at 1 cm distance from the source and for 500 ms exposure time. The mean exposure, as well as, other relevant data concerning the type and the age of the radiological unit has been also recorded.

The measurements were carried out in 52 dental practice facilities, spread out in Athens, Thessaloniki, Larissa, Trikala and Katerini. They constitute a small but representative sample of the typical, rather modern, small, private, one-dentist practice facilities that cover a huge percentage of the contemporary dental services in Greece.

The Exposure caused by the various X-ray equipment and the corresponding periods of employment (age) of the equipment examined are presented in Table 1.

Table 1: Exposure caused by various X-ray equipment.

Age months	dQ/dm mR	Age months	dQ/dm mR	Age months	dQ/dm mR
9	1,279	3	1,406	40	2,077
42	2,240	6	1,406	12	1,605
0	1,515	8	1,451	14	1,596
0	1,487	6	1,497	9	1,614
0	1,542	15	1,678	15	1,632
3	1,451	28	2,014	19	1,642
3	1,587	12	1,669	10	1,551
3	1,596	19	1,624	10	1,460
7	1,678	17	1,642	12	1,487
4	1,587	15	1,515	12	1,487
8	1,632	13	1,497	16	1,497
6	1,859	14	1,515	14	1,551
5	1,524	14	1,415	13	1,415
18	1,923	17	1,497	48	2,277
20	2,268	12	1,487	36	2,023
9	1,587	12	1,478	42	1,995
10	1,832	12	1,469	26	1,823

We have consciously chosen to recall in service the ancient unit R (Roentgen) instead of the non attractive to medical professionals SI unit C/kg (Coulomb / kilogramme) (1 R = 2,58 x 10^{-4} C/kg).

We have avoided the use of relative exposure units, because it is important to demonstrate that although, first, dental examinations represent approximately 25% of the radiological examinations performed in the European Union, and, second, almost every dental practice in Greece is equipped with an X-ray tube, the achieved exposures are and can be kept relatively low [4], [5].

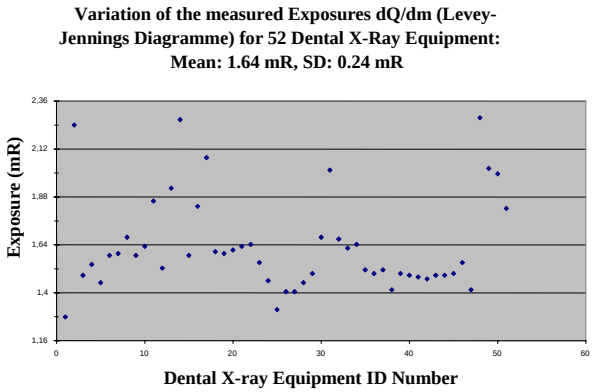

Figure 2: The Variation of the measured Exposures dQ/dm for the 52 Dental X-Ray Equipment in a Levey-Jennings Diagramme. Mean: 1.64 mR (4.23x10^{-7} C/kg) and SD: 0.24 mR (0.62x10^{-7} C/kg).

Concerning the variation of the measured Exposures dQ/dm for the 52 Dental X-Ray Equipment around the Mean Exposure of 1.64 mR (4.23x10^{-7} C/kg), 94% of the obtained experimental data are within the ± 2 SD and 81% are within the ± 1 SD intervals.

The reproducibility of the results is rather remarkable, if it is taken into account that there are various models of eleven different manufactures involved in the experiment.

The equipment history expressed as number of items versus months is presented in Figure 3. The mean length of service at the time of the investigation was 13.7 months.

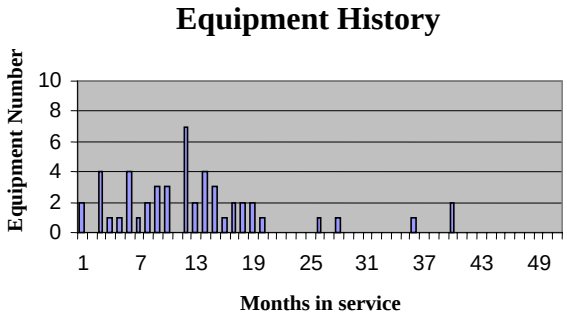

Figure 3: The equipment history expressed as number of items versus months in service for the 52 investigated Dental X-Ray Equipment.

The Correlation between the Exposure and the Months in Operation for the 52 investigated Dental X-Ray Equipment has been investigated and the results are presented in Figure 4.

The mean exposure measured for equipment with a length of service over the mean of approximately 14 months was found to be 1.79 mR. Further, the mean exposure measured for equipment with a length of service over 20 months was found to be 2.09 mR, since

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the corresponding value for equipment with less than a year in service was found to be 1.53 mR. Finally, a slightly increasing trend concerning exposure versus time in service appears to be present in Figure 4.

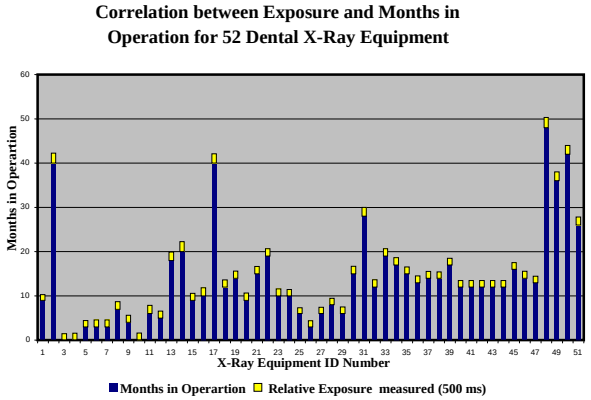

Figure 4: The Correlation between the Exposure and the Months in Operation for the 52 investigated Dental X-Ray Equipment.

However, the confirmation of this assumption, although plausible, would require a follow up study, for the same group of equipment, after about 5 years.

Investigation of the Dental Sterilisation Conditions

Dental infection control practices across developed countries are very common in order to give answer to the main question: Do dentists follow the associated recommendations? Even in pioneer countries in the field like Canada the question is not satisfactorily answered and ongoing studies attempt to investigate provincial and territorial differences in dentists' compliance with recommended infection control practices.

According to a large scale investigation [6], questionnaires were mailed to a stratified random sample of 6,444 dentists, of whom only 66.4% responded, significant provincial and territorial differences were found that included testing for immune response after hepatitis B virus (HBV) vaccination, HBV vaccination for all clinical staff, use of infection control manuals and post-exposure protocols, biological monitoring of heat sterilisers, hand washing before treating patients, using gloves and changing them after each patient, heat-sterilising hand pieces between patients, and using masks and uniforms to protect against splatter of blood and saliva. Excellent compliance with a combination of 18 recommended infection control procedures ranged only from 0% to 10%. Finally, the best predictors were more hours of continuing education on infection control in the last two years, practice location in larger cities (> 500,000) and sex (female).

Chemical Process Indicators are convenient paper strips, adhesive-backed labels or inks that change colour permanently when exposed to sterilant. These sterilisation indicators are used on unit packages to aid tracking and inventory of sterilised versus non-sterilised products, thus providing the end-user with visual verification of processing. There are indicators suitable for all methods of sterilisation, such as Radiation, Ethylene Oxide (EO), Steam, Dual EO/Steam, Chemical Vapour, Dry Heat, and Hydrogen Peroxide.

For dental use the most important are *Steam Sterilisation Integrator*, usually integrating all 3 critical parameters of sterilisation time, temperature and saturated steam that usually require a minimum exposure of 10 min at 121°C or 2 min at 134°C, appropriate for use in all steam systems, that is: gravity, vacuum and flash, and the *Dry Heat Sterilisation Indicators* that require exposure up to 160°C, resulting in colour change.

Biological indicators offer consistent purity and resistance between lots. They may be used for sterility tests during release testing procedures. All products are labelled with certified population, D-value, Z-value, survival/kill data and expiry date and are supplied with instructions for use. Organisms include Geobacillus Stearothermophilus, Bacillus pumilus and Bacillus atrophaeus. They are available in various formats, such as spore strips, discs, dots spore suspensions and threads. Some Chemical Process Indicators are certified to perform equally to a biological indicator.

Figure 5: Several commonly employed sterilisation indicators: a) Attest Biologic Indicator, b) Mini spore-strips and c) Bowie-Dick type test Indicators.

There are almost no statistical data, concerning these hazard sources, for the private dental-medical facilities in Greece, especially concerning the employment of Biological Indicators, which constitute the quality control of choice applicable to sterilisation cycles. However, it is not compulsory for dentists to biologically verify sterilisation cycles, since the various

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national and international standards [7], [8] are not yet being enforced by law.

Therefore, in order to attempt to investigate a side of the quality assurance procedure of the sterilisation, a random sample including 63 private dental-medical facilities in Greece has been examined. The measurements were carried out in several Dental practice facilities, spread out in Athens, Thessaloniki, Larissa, Trikala and Katerini.

During the investigation, a visual inspection and registration of the available equipment and accessories was the first step. A typical test-run of the steriliser, employing the various quality assurance materials available was the second step. Finally, a questionnaire (Table 2) was filled, concerning the type and the age of the equipment, the method of sterilisation, the sterilisation indicators employed and the frequency of their employment, and the confidence to the indicators used.

Table 2: A typical portion of the questionnaire form. Multiple answers were allowed.

Steriliser Type/Date	Sterilisation Indicator	Equipment Settings	Confidence to:
Dry	Steam	Pressure	Sterilisation Indicator
Wet	Bowie-Dick	Temperature	Equipment Settings
Wet+V	Biological	Time	Steriliser Type
Rest	Other	Other	Other

Concerning the employed methods of sterilisation, 74 % of the used equipment was found to be hot-air dry sterilisers, followed by steam sterilisers without vacuum (15 %) and with vacuum (7 %), as indicated below in Figure 6.

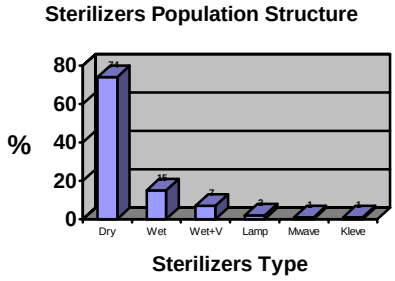

Figure 6: The structure of the 63 Dental Sterilisers investigated, concerning the employed sterilisation method.

Another important issue for the quality assurance approach is the age of the sterilisation equipment. The sterilisers' age distribution, expressed in years in service, is shown in Figure 7. About 40 % of the items are 5 – 10 years in service, 27 % are 10 – 15 years in service, and only 22 % are 1-5 years in service.

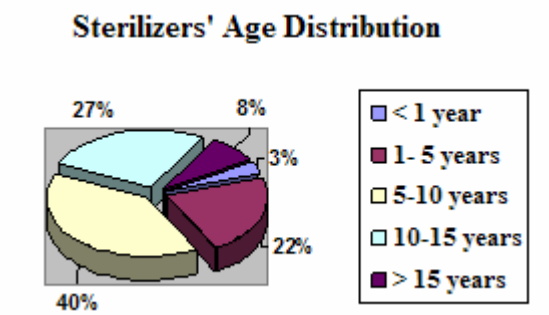

Figure 7: The sterilisation equipment age distribution expressed in years in service.

A very important question is whether the dentist employs a sort of quality assurance monitoring procedure for the in-house sterilisation. The evaluation of the completed questionnaires has disclosed various interesting and controversial information. 58 out of the 63 dentists interviewed express their confidence for the employment of the various types of sterilisation indicators (Figure 8).

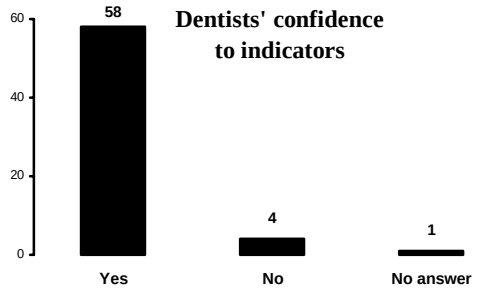

Figure 8: The confidence of the 63 interrogated Dentists to the employment of various indicators.

However, the frequency of the employment of some kind of sterilisation indicator, as presented in Figure 9, shows that only approximately 32 % of the dentists monitor always or almost always the sterilisation procedure.

Figure 9: Sterilisation indicator employment frequency.

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The use of indicators seems to be strongly depending on the sterilisation method, equipment and even sterilisation programme employed. The most usual temperature, pressure and time settings for the various frequently used sterilisation programmes, in most commercially available sterilisation equipment, are presented in Table 3.

Table 3: The most usual temperature, pressure and time settings for the various sterilisation programmes.

Method	Temperature ^{0}C	Pressure Bar	Time min
Unwrapped	134	2.16	3
Wrapped	134	2.16	12
Packs	121	1.15	30
Liquids	121	1.15	30
Special	101-135	0.00-2.16	1-90

The necessity of the employment of some kind of indicators, according to the questionnaire evaluation data, is presented in Figure 10.

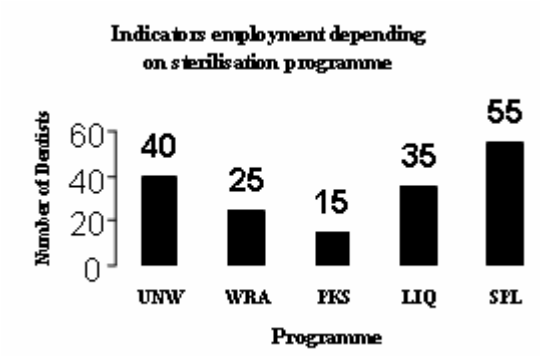

Figure 10: The use of indicators depending on the sterilisation method and programme employed.

According to the evaluated data, the necessity of the employment of some kind of indicators is higher for the *special* programmes, where the settings are free chosen by the dentist (87 %), followed by the Unwrapped (64 %), the rather rare Liquids (56 %), the Wrapped (40 %) and finally the Packs (24 %) that is logical, since the packed materials usually include an indicator in the packing material (e.g. tape).

The 63 Dentists' Opinion about the necessity of the employment of Sterilisation Indicators is presented in Figure 11. Although 60 % of the participants regard the use of some kind of sterilisation indicator somehow necessary, the remaining 40 % are of the opinion that the employment of sterilisation monitoring is hardly ever or not at all useful. But the most amazing finding out of the questionnaire is that, 84% of the dentists, even if they use frequently indicators, consider their employment as superfluous, trusting more or exclusively the choice of the right programme and the correct autoclave settings.

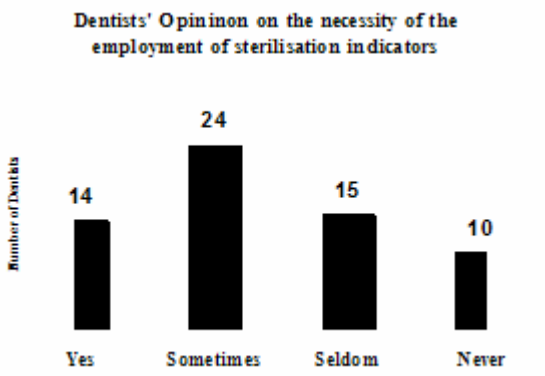

Figure 11: The 63 Dentists' Opinion about the necessity of the employment of Sterilisation Indicators.

Conclusions

The above presented investigation leads to several useful conclusions concerning Dental patient-doses hazards and risks related to the quality of the sterilisation procedures of instruments and other materials that constitute the two main technology related danger sources in dental medicine practice. Further, there are some first answers emerging, regarding the compliance of the Greek dentists to the rules of sterilisation bound Hygiene, and Radiation Protection in their own practice.

Regarding the Exposure caused by the 52 dental radiological units examined, there were no substantial exposure differences among modern dental radiographic equipment, especially if the positioning uncertainty of the ionisation chamber is considered. The reproducibility of the results is remarkable, if it is taken into account that there were various models of eleven different manufactures involved in the experiment. A slightly increasing trend concerning exposure versus time in service appears to be present, however, the confirmation of this assumption, although plausible, would require a follow up study, for the same group of equipment, after about 5 years.

It should be kept in mind that although the behaviour of the X-ray tubes seems to be predictable, the actual patient dose depends strongly also on various other settings, such as film quality and development method, positioning of the film and the patient, the employment of radiation protection aprons for the patient, in order to reduce the genetically significant exposure and other conditions. Although the application of digital imaging techniques has seen tremendous growth in recent years over traditional methods such as film, none of the examined dental facilities employed digital equipment.

However, it seems that in the near future, digital imaging systems driven by consumer and security products, and by cost reductions and performance enhancements due to miniaturisation and technology advancement, such as the adoption of hybrid pixel technology, derived from high energy physics, will offer great advantages in ultimate sensitivity and device functionality.

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Concerning the equipment and the Quality Assurance of sterilisation in private dental medical practice in Greece, it seems that further attention and improvement is required. Concerning the employed methods of sterilisation, 74 % of the used equipment was found to be hot-air dry sterilisers. Only 22 % of the sterilisers of all types employed are new, that is they are between 1-5 years in service, since the rest are already or will be in the next years in age of replacement. However, it was observed that new technology equipment, replace the old ones with very slow rhythms.

Although 60 % of the participants regard the use of some kind of sterilisation indicator somehow necessary, the remaining 40 % are of the opinion that the employment of sterilisation monitoring is hardly ever or not at all useful, and 84% of the dentists, even if they use frequently indicators, consider their employment as superfluous, trusting more or exclusively the choice of the right programme and the correct autoclave settings. The younger and fresh in the profession dentists seems to be the ones who more often meet the terms of material and tool sterilisation.

The decision on how to sterilise dental medical instruments is dependant on many factors such as cost, speed, the availability of a technology, and the level of customer support that is provided. However, improvements in infection control seems to be desirable for dentists, and extending continuing professional education initiatives to include infection control may promote better compliance with current trends and recommendations.

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