DEVELOPMENT OF INTRA-ORAL DENTAL RADIOLOGY AFTER THE ESTABLISHMENT OF NEW QUALITY CONTROL LEGISLATION IN SPAIN.

M. Alcaraz¹, Y. Martínez-Beneyto¹, S. Jódar¹, A.M. Saura-Iniesta¹, E. Velasco²

¹Radiology and Physical Medicine Department. University of Murcia. 30100-Murcia. Spain. E-mail: mab@um.es

Abstract. Dental radiology is the most frequent radiological diagnosis examination in the industrialised world and it represents almost 25% of all radiological examinations carried out in the European Union. New regulations were established in 1996 which set forth quality criteria in diagnostic radiology to improve medical radiology and to avoid inappropriate exposures. This work contains the first quantitative analysis of the parameters controlled in these compulsory quality control reports, which mean checking the process of obtaining radiological images, as well as development after five years since the establishment of said regulations.

Material and Method: 7,176 official quality control reports in diagnostic radiology of dental clinics using intra-oral radiology were studied. The developmental study refers to the first 5 obligatory quality control checks carried out by the UTPR [Technical Unit of Radiology Protection] Asigma S.L. in the second half of 1996 to December 2001, and which mainly concern private facilities.

Results: The results show a quantitative analysis of the parameters stated in those reports, with special reference to physical characteristics (kVp, mA, filtration, collimator, length of the exposure switch), as well as operation deviations detected (31% of facilities/year). The characteristics of the process of obtaining radiological images in these facilities was determined (type of developing, control of developing times, replacement of liquids, type of radiographic film, storage and expiry of film) and the average dose of ionising radiation used in the facilities to obtain the radiological image of a same dental part in the usual working conditions of every one of the rooms. All of this in the developmental process during the five years after the establishment of quality control regulations. In short, the results show a decrease of 18.75% in the average doses administered in these five years of the study. 97.98% of the dental radiological facilities studied use doses the same as or less than 7 mGy to carry out the examination analysed. However, only 72.79% of the radiological facilities could comply with all of the European Union’s recommendations on the operation characteristics of this equipment.

Conclusion: Although the degree of compliance with official recommendations on radiological protection is not satisfactory, significant improvements were observed in dental radiological performance by professionals throughout these five years of development. Therefore, the establishment of legal regulations is leading to a slow but progressive improvement in dental performance in Spain.

1. Introduction
The use of X-rays in medical diagnosis should only be undertaken if it is clinically justified; it should expose the patient and practitioners to the lowest doses of radiation reasonably acceptable and the maximum dose administered should be limited (1). Dental radiology represents about 25% of all radiological examinations carried out each year more than 200 million in the member states as a whole (1,2).

Although the dose of ionising and the possible risks to health are very small when considered individually, the collective dose is not to be underestimated, especially when most explorations are made in children and adolescents (1). Furthermore, many x-rays are made on old equipment and following incorrect procedures both in the exposure and film processing. With the consequence that 25-33% of panoramic x-rays are, according to some authors, of insufficient quality to enable correct diagnosis (1,3,4,5,6). This situation is repeated in the case of intraoral radiology, where 49-54% of all periapical x-rays were considered unacceptable in studies carried out in the United Kingdom and Greece due to the incorrect application of the procedure and mistakes made in processing film (4,7,8).

The annual inspection of dental installations, including a control of the whole process of obtaining the X-ray image, is though to be an effective means of avoiding possible overexposure in dental radiology.
A recent study carried out in the United States describe the radiological dental practice in some schools of dentistry (9) but there are few studies in Europe. Since 1996 all radiological installations in Spanish dental surgeries are required to undergo an annual control of quality according to European Union (UE) directive (Royal Decree 2071/1995), which is carried out by a Radiological Protection Unit, a company approved by the Spanish Nuclear Safety Council.

The objectives of the present study were to determine the incorrect parameters that affect the radiation dose to which patients are exposed, to examine any changes in intraoral radiology practice during the five years following the introduction of the EU norm concerning radiological quality control and to evaluate the extent to which the recommendations are followed.

2. Materials and Methods

A total of 7,176 official reports on radiological standards in private dental surgeries, universities and hospital dentistry units covering the period 1996 to 2001 were studied. All the dental surgeries had been checked by officially Radiological Protection Units and were approved by the Spanish Nuclear Energy Council to be used as x-rays sets.

The variables studied prior to their encoding for statistical treatment were: geographical location, physical characteristics of x-rays equipments, any anomalies in the way the equipment worked, film processing, and mean dose of radiation used to take an X-rays exploration of the upper second molar in each surgery or centre, taking into account legislation concerning radiological protection (10, 11). The first report referring to 1996-97 served as reference for comparing subsequent annual reports up to 2001.

The degree of dependence and correlation between variables was assessed by an analysis of variance, complemented by a contrast of means using the minimum significant difference method (p<0.05). Quantitative means were compared by regression and lineal correlation analysis.

3. Results and Discussion

The installations covered by the reports examined are found in 37 Spanish provinces and represent about 25 % of the total according to UNSCEAR report (12,13).

Sixty-three different types of x-rays equipment for intraoral radiology were recorded in the last year of the study, of which 65.88% were from Trophy (Kodak, Germany). The tube potentials ranged from 50 kVp to 70 kVp, the number using the recommended 70 kVp increasing during the five-year study. In 1996-97, only 61.67 % of the equipments worked at 70 kVp, rising to 72.79 % in 2001, an increase of 11,12 %. In 2001, the milliamperage used by the equipment was 8 mA in 79.8 % of the cases, representing an increase of 4.11 % in the five years studied.

Filtration thickness during the first year of the study varied from 0 mm Al to 3.4 mm Al, although 98.97 % of the equipment used more than 1.5 mm Al. In 2001, 62.16% had 2.5 mm Al. In 1996, 88.02 % of the equipments had tube length of 20 cm, a figure which had risen to 90.11 % in 2001. Nearly 9.92 % of the x-rays machines surveyed in 1.996-7 showed variation in excess of 10 % as regards the kVp described by the manufacturer, 6.7 % did not accurately measure the exposure time and 9.4 % showed a variation in x-rays tube performance exceeding ± 20%. Other faults were less common: deviations in the reproducibility of the radiological dose and time (0.7 % in both cases) and alterations in the alignment of the x-rays tube (3.94 %). In 2001, 8.92% of machines showed differences from the kVp mentioned by the manufacturer, 14.24 % showed variations in the exposure time, 4.1% variations in tube efficiency and 3.34% in anomalies of alignment.

During the first year of the study, 14.05 % of installations had a fixed exposition button outside the room used for raking the x-rays, although some had extension leads of less than a metre, remote controls and even fixed exposition button in the exposure room and 62.22% fulfilled the European recommendations of an extension lead of 2 metres.

Most clinics (87.31%) used manual processing of films during the first year, while only 6.72% did so automatically, 4.45% using digital techniques. In the last year revised, the number processing the film
manually had decreased to 81.27% due mainly to the increased use of digital systems (11.95%), while only 5.81% had automatic processing equipment.

In 1996, 65.62% of the installations renewed the processing liquid on a weekly basis, 20.83% fortnightly and only 7 installations renewed it each time. Five years later, 80.61% renewed the liquid weekly, 5.81% fortnightly, and 4.94% monthly. In a few installations (0.9%) the liquid was renewed every 45 days and in two cases (0.12%) every three months. The number of clinics not strictly following the manufacturer’s processing times changed very little during the study period (80.13% in 1996 and 75.95% in 2001).

As regards the type of film used, 72.58% used D-Speed (Ultra-speed, Kodak®) in 1996, a figure that had risen to 79.19% in 2001. More sensitive film (E-speed, Ekta-speed, Kodak®) was used in 17.02% of installations in 1996, falling to 10.24% in subsequent years. In the last year studied higher velocity emulsion type film (Insight, Kodak®) was used in 4.53% of the cases.

In half of the clinics inspected during 1996 the x-rays film was stored in the exposed room, although this had fallen to 17.62% in 2001.

As regards the radiation dose used for an upper second molar, 92% already fulfilled the EU recommendations in 1996-97 and did not exceed 7 mGy on average per shot. Indeed, the mean dose was 3.015 mGy. Five years later, 97.98% used doses below 7 mGy with a mean of 3.123 mGy, representing a drop of 18.75% per exposure (see Figure 1).

Statistical analysis pointed to significant differences (p<0.05) between the dose of radiation and the make of x-rays equipment used, the machines made by Castellini and Villa emitting higher doses than the other makes found in clinics (Trophy, Gendex-Philips, Satelec, etc).

Significant (p<0.05) differences were observed between the doses administered and physical characteristics of the equipment complying with official EU recommendations (70 kVp, ≥1.5 mm of Al and focus-Skin distance of 20 cm) using significantly lower doses than non-standardised equipment. Similarly, there were statistically significant (p<0.05) differences between the doses administered and the use of x-rays equipment showing alterations in the acoustic-luminous signal, such machines emitting significantly higher radiation doses.

There were also significant differences (p<0.001) between the doses administered and the type of development used, the lowest emission being measured in digital systems, which used significantly lower doses than both manual and automatic development and compared with conventional radiographic films (Ultraspeed®, Ektaspeed®, Dentus®, etc.).

![Mean doses](image)

**FIG.1:** Evolution of radiation doses used in dental radiology (mGy).
Nowadays, 25,058,622 (629/1,000 inhabitants) of radiological examinations are annually carried out, of which approximately 20.85% (5,226,823) correspond to dental examinations (12, 13). The Spanish rate of dental radiological examination (131/1,000 inhabitants) is lower than in most other EU member states. For example, in the United Kingdom some 16 million per year were mentioned by Horner (1994), a figure that had risen by another 2 million by 2001 (14).

It is precisely because of this tendency for the annual number of radiological examinations to increase that effort should be made to minimise the radiological dose administered (1, 2, 15, 16, 17). The promulgation of Royal Decree 2071/1995 (10) which made annual quality assurance checks of x-rays equipment compulsory in Spain has made such a study as this possible and also led to measures being introduced to limit the amount of radiation to which both patients and workers are exposed (18).

The x-rays equipment used in Spain for intraoral examination has similar physical characteristics (kVp, mA and filtration) to those found throughout the developed world since they are normally manufactured by multi-national companies (19, 20, 21). Our findings point to a slightly better situation than that mentioned by other authors (22, 23), whose describe extreme values of 45 and 90 kVp. This cannot only be attributed to the difference in the years of the respective studies since such figures are still described for Dental Schools in the USA (9). Other studies describe that 45% of Syrian dentists still use x-rays equipments that works with kilovoltagess below 50 kVp (24).

Our study shows that only 72.79 % of dental x-rays equipment works at the 70 kVp recommended by the EU, although there has been an improvement of 11.12 % in this respect during the five years analysed. In more industrialised countries, such as USA and Canada, 88 % of the equipment in Dental Schools has been seen to work at 70 kVp (9).

Intraoral x-rays devices are manufactured, as mentioned above, by large multi-national companies that offer simple machines considered suitable for dental practice radiography. However, there seems to be little in the way of post-sale service offered by these companies, which means that any anomaly tends to persist. Indeed, almost a third of the equipment examined annually showed potentially serious malfunctioning as regards kVp, exposure timing, tube efficiency, alignment, acoustic signal, etc., at the time they were inspected. This apparent lack of interest on the dental practitioners part to solve such technical problems could well result in patients being exposed to higher radiation levels than necessary. However, the data may also be interpreted as meaning that a third of all x-ray sets suffer a serious fault at least once a year.

The renewal of dental x-rays equipment during the five years studied has led to the improvement in another parameter: the length of the cone. Since 90.11 % of the machines now have a 20 cm cone, replacing the 10 cm cones which were common before. This situation is not observed in some other countries considered as developed (9, 25).

One of the most notable aspects of our study is the absence of a rectangular collimator adapted to the size of radiological film. In other countries, Canada for example, 8 % of dental surgeries (23), have been reported as using such a device, while in America this percentage is 5-47% (9, 26) and in Sweden 29-36% (27, 28). It is widely accepted that the replacement of round collimator by rectangular models reduces exposure to ionising radiation by a factor of four (29, 30), making it possible to reduce the dose administered to the patient by up to 60% (1). Both the American Dental Association (ADA) and several european institutions cite the joint use of rectangular beam limitation and speed films as being of use in reducing radiation (1, 23, 27, 29, 31, 32, 33). In Spain we have found no distributor selling rectangular collimator, so that it is extremely difficult for Spanish dentists to obtain such an equipments.

The official EU recommendations establish point out that the use of a constant potential of 70 kVp, 8 mA, a 20 cm focal-skin distance and filtration thickness of at least 1.5 mm of Al considerable reduce patient exposure to radiation (1, 15, 34). According to the latest quality assurance reports in our study, we can say that 72.8 % of Spanish dental installations comply with these recommendations. We have mentioned that 81.27 % of dental surgeries develop films manually and only 5.81 % automatically. These results are similar to the situation in Finland ten years ago (22) and in Greece at the present time (20). In Denmark 50 % of films are processed automatically (19), 88% in Sweden (28) and 93 % in Canada (23). Almost all authors who have described the manual processing of x-ray film agree with our findings of development times that vary widely from the manufacturers’
recommendations, greatly varying times for changing the processing liquids and the absence of any temperature control for the same, all deficiencies that will be reflected by increased radiation doses for the patient (19, 22, 28, 35, 36, 37).

Traditionally it is accepted that rapid emulsion films reduce radiation doses, type E speed film decreasing up to 50 % radiation compared with type D (38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49,50,51). The results regarding the use of E speed films in Spain differ from those published for other countries: 25 % in Denmark and Canada (19, 43), 66 % in Greece (20) and 86 % in American and Canadian dental schools (9). The fact that the more sensitive film is not used in 79 % of the installations inspected is presumably due to the persistence of habits acquired in the Schools of Dentistry where practising dentists were trained (1). This shows the need for instituting in-service training courses for practitioners, so that they are kept abreast with developments in the field of radiological protection and quality assurance. It seems that commercial suppliers are little interested in the matter and a recent report shows that 85 % of dentists in USA use the same type of film throughout their professional lifetime and that this type is the same as they used in their training at Dental Schools (9).

Manual film processing needs tight control of the following parameters: the time taken to develop the film, the renewal of developing-fixing liquids, the temperature of these liquids and the correct storage of x-ray film. If such control is not exercised the resulting image may not be of sufficient quality to be of diagnostic use, indirectly increasing the dose administered to the patient. In fact, the literature consulted suggests that 49-54% of periapical films are unacceptable for clinical diagnosis (4, 8).

Recent years have seen a considerable increase in the use of digital systems and almost 12 % of the installations inspected are now digital, tripling the number in 1996. The dose of radiation used by such systems may be 40-60 % less than is necessary for rapid emulsion films such as Ektaspeed®) (34,36, 52, 53, 54). However, this type of radiological system has its drawbacks in the size and lack of sensor flexibility compared with traditional film. This means that more than one exposure is frequently necessary to cover the same area that could be exposed with one shot using conventional film, and there are zones (e.g. the palate) that need a more flexibility device. There are plans to incorporate larger sensors but, until then, digital systems may even increase the radiological exposure of patients because multiple exposures are frequently necessary. Despite these disadvantages, to which may be added their relatively high cost, the number of digital systems used in Spain has steadily increased (33, 37).

Our findings show that the radiation dose to which patients are exposed during the radiography of an upper molar is less than 10 mGy in 99.57 % of the installations examined during 2001. Taking the EU recommended dose of 7 mGy as standard, 97.98 % of installations are in compliance. Our study points to an average dose of 3.12 mGy in Spanish dental practice, however another study carried out in Spain described mean doses of 3.5 mGy (17). In other European countries, studies have pointed to similar or slightly higher mean radiation doses: between 3.8 mGy (20) and 6.9 mGy (8) in Greece, 3.9 mGy in UK (55) and 4.2 mGy in Germany (56).

In conclusion, certain anomalies in some parameters (kVp, mA, film type, processing system, change of liquids and the use of circular collimator) are evident, which may increase the radiation dose to which patients are exposed. If these problems were tackled, the doses could well be reduced. Although EU recommendations concerning radiological protection in dental clinics are not met in all cases, the introduction of legislation has resulted in a gradual improvement in dental radiology practices.

4. References