RESEARCH

The status of Spain's dental practice following the European Union directive concerning radiological installations: 11 years on (1996–2007)

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Objectives: The aim of this study was to assess the influence of European Union legislation on dental radiology practice in Spain and the reduction in doses administered in dental radiological installations 11 years after its introduction.

Methods: A total of 19 079 official reports on dental surgeries from 16 Spanish autonomous regions published between 1996 and 2007 were studied. We analysed the physical characteristics of the X-ray units, anomalies, film processing, exposure times and mean radiation doses administered in clinical situations.

Results: The dose applied to obtain a radiograph of an upper second molar had decreased by 37% up until 2007, the mean dose being 2.7 mGy, with 81.1% of installations using a dose of less than 4 mGy, with a reference dose for the 3rd quartile of 3.6 mGy. Of note was the incorporation of digital systems (50.1%), which are gradually replacing manual processing systems (45.3%). There were significant differences between the systems: direct digital radiology < indirect digital radiology = Insight = Ektaspeed = Ultraspeed ($P < 0.001$). In installations with digital systems, 6.3% used more than 4 mGy (20.5% with direct radiology and 3.2% with indirect radiology) and 7.4% a dose of less than 0.5 mGy, with a mean dose of 1.8 mGy and a reference dose for the 3rd quartile of 2.3 mGy.

Conclusion: There has been a gradual improvement in dental radiology practices; however, the incorporation of digital systems has not resulted in all the benefits hoped for, and mistakes are frequent. Besides the physical parameters that have been established, anatomical and clinical image quality criteria should be established to convince dentists of the real benefits of incorporating quality guarantee procedures in their practices.

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Introduction

In Spain, the use of ionizing radiation in dental clinics is supervised by the Spanish Nuclear Safety Council (CSN). Since 1996, all radiological installations in Spanish dental practices are required to undergo annual quality control according to the European Union (EU) Medical Exposure Directive 97/43 EURATOM¹ and Directive 84/466 EURATOM,² incorporated in Spanish legislation by Royal Decree (ROD 2071/1995),³ which is

carried out by a private company specializing in radiological protection and approved by the CSN.

The annual inspection of dental installations, including the use of quality control procedures, is thought to be an effective means of reducing possible overexposures in dental radiology.⁴ There are no anatomical criteria for assessing dental radiological images, although a reference dose value of 4 mGy, as proposed in the European guidelines on radiation protection in dental radiology,⁵ has been adopted for intraoral dental radiology purposes.

The objectives of this study were to determine the current state of dental radiology in Spain and to

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demonstrate the changes in intraoral radiology practice that have occurred during the 11 years following the introduction of the EU directive on radiological quality control and radiological protection.

Materials and methods

A total of 19 079 official reports on radiological standards in private dental surgeries, universities and hospital dentistry units covering the period 1996–2007 were examined. All the dental clinics had been previously checked by official radiological protection units, approved by the CSN to use radiographic equipment. The installations covered in the reports encompass 16 Spanish autonomous regions (40 Spanish provinces) and represent approximately 25% of the total number of dental practices in Spain.^{4,6}

All Spanish installations with oral radiography equipment must undergo an annual inspection. This is carried out by private companies approved by the CSN, which forward a quality control report giving permission for the clinics to use radiological equipment. The variables analysed are described in Royal Decree 2071/1995.³ The variables analysed are encoded for statistical analysis and include geographical location, physical characteristics of the radiographic units, any anomalies found in the equipment and film processing. Also analysed are the mean radiation doses used for a periapical radiograph of the second upper molar, second lower molar, upper incisor and lower incisor in each dental surgery or centre, taking into account legislation concerning radiological protection and the normal work practices of each clinic.³

The quality control reports describe an anomaly as any variation measured during five consecutive exposures that exceeded $\pm 10\%$ of the tube potential and the mA stated by the manufacturer. The reports also describe anomalies in behaviour, reproducibility and linearity when these exceed $\pm 10\%$, whether or not a trigger exists and, if so, its type and any alterations in the acoustic–luminous signal (not audible or not visible). Information on the conditions in which the film is developed and the type of development (manual, automatic, digital systems or self-developing) is also included in the reports, as is the temperature of the developing liquids and renewal frequency, development times, film type, whether the film is stored inside or outside the exploration room and, if present, the use of the negatoscope.

The necessary mean radiation dose (10 exposures, in mGy) to obtain a radiographic image of the designated teeth in the normal operational conditions of each installation was determined using a PMX I WA Kit detector or PMX III QA system (RTI Electronics, Mölndal, Sweden) and occasionally a thermoluminescence dosimeter (TLD) (GR-200r; Conqueror Electronics Technology Co, China) supplied and read by the Environmental Energy and Technological Research Council of the Spanish Ministry of Industry and Technology (CIEMAT). A backscattering factor of

1.1 was applied to the values obtained for the years 2002–2007, following the Spanish norm.

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

Results

The radiation dose necessary to obtain an image of an upper second molar in normal working conditions of Spanish installations has reduced gradually since 1996, to reach a reduction of 37% in 2007. Since 2001, the official doses should add the backscattering factor (1.1), which implies an increase of 10% in the real doses determined by physical procedures (Figure 1). For this reason the mean official dose used to obtain the above-mentioned radiograph was 2.7 mGy in 2007; 81.1% of installations used less than 4 mGy and complied with the recommendations described in 2004.⁵ The 3rd quartile of the installations analysed showed a reference dose of 3.6 mGy.

The physical characteristics of the radiological equipment used did not change significantly in the 5 years leading up to 2007 (Table 1), although there was a slight increase in the number of sets working at 70 kVp and the use of 2.5 mm Al filtration. No rectangular collimators, adapted to the form of the film, were observed, the 20 cm long by 6 cm diameter cone having become standard. The number of radiological sets with important faults that needed to be repaired before passing an inspection also remained constant. The findings show that every year almost a third of the sets examined needed to be repaired because of a serious fault (Table 1).

Statistical analysis indicated significant differences ($P < 0.05$) between the dose of radiation and the make

Figure 1 Evolution of mean doses administered during the years studied (1996/7–2007) (with and without backscattering factor (BF))

Table 1 Evolution of some characteristics in Spanish dental installations (%) (1996/7–2007)

		1996/7	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	Evolution
Physical characteristics of X-rays tubes	kVp (70 kVp)	61.1	64.8	67.5	70.4	72.8	75	77.3	78.2	75.2	71	67.7	+6.6
	mA (8 mA)	75.7	76	78.4	80.3	79.8	79	80.7	80.1	76.1	70.3	66.2	−9.5
	Filtration (2.5 mm Al)	36.5	39.6	58.5	61.4	62.2	65.7	69.4	68.1	65.2	60.1	57	+20.4
	Exposure inside room	15.3	1.6	0.7	0.9	1.2	5.7	17.8	9.7	4.3	2.7	2	−13.3
Anomalies intraoral sets	Cone of 20 cm	88	87	88.6	90.1	90.1	91.3	89.6	91.4	91	90.5	90.7	+2.7
	kVp	9.9	10.8	11.4	11.2	8.9	5.6	4.3	2.9	3.7	4.3	3.7	−6.2
	Exposure time	6.7	7	11.7	11.9	14.2	3.7	3.5	2.2	2.2	1.8	1.4	−5.3
	Tube efficiency	9.4	8.5	4.5	4.5	4	32.6	22.1	13.9	18.8	23.8	20.2	+10.8
Film	Linearity	3.9	4.8	1.7	3.9	3.3	1.8	2.4	1.8	1.6	1.1	0.8	−3.1
	Acoustic-luminous	7	3.7	1.4	0.6	1.2	4.5	0.9	0.1	0.1	0.3	0.1	−6.9
	Total	36.9	34.8	30.7	32.1	31.6	48.2	33.2	20.9	26.4	31.3	26.2	−10.7
	Ultra-speed	72.6	87.3	79	80.8	79.2	82.9	82.3	83.2	84.7	82	83.3	+10.7
Type of film processing	Insight	0	0	0	0.4	4.5	11.1	12	11.1	9.8	12.3	12	+12
	Dentus M2	5.1	2	4.2	3.9	4.1	3.7	4	3.3	3.8	3.7	3.2	−1.9
	Manual	87.3	87.7	85.2	86.1	81.3	75.1	75	71	61.5	50.3	45.3	−42
	processing												
Characteristics of film processing	Digital system	4.4	6.5	8.1	10.3	12	16.1	19.5	23	44.1	44.1	50.1	+45.7
	Automatic	6.7	4.8	5.7	4.6	5.8	8.3	5.1	5.5	5.6	5	4.3	−2.4
	processing												
	Self-developing films	1.5	1	0.9	0.4	0.9	0.5	0.4	0.5	0.4	0.6	0.3	−1.3
Negatoscope	Without control temperature	97.7	98.1	99.7	99.1	99.7	89.1	90.2	96.1	97.2	99.3	99.6	+1.9
	Without control times	80.2	73.6	69.1	73	76	29.5	28.8	27	29	27.1	27.5	−52.2
	Changes solutions weekly	71	82.2	77.3	77.5	80.6	86.7	90.5	97.5	97	98	98.1	+27.1
	Storage film inside of room	48.9	23.5	19.5	12.7	17.6	12.5	6.4	4.5	4	3.3	1.3	−47.6
	Glass processing manual	—	—	—	—	—	—	—	95.2	94.7	97.2	96.7	+1.5
	There is negatoscope	—	—	—	—	—	67.9	78.8	81.2	80.7	67.7	62.7	−5.2
	It never uses negatoscope	—	—	—	—	—	0.5	0	5.3	6.1	21.9	30.9	+30.4
	It is needed to repair box	—	—	—	—	—	32.7	38.9	27.1	27	22.4	16.9	−15.8

of the equipment used; machines made by Castellini (SPA; Bologna, Italy) and Villa (Sistemi Medicali; Milan, Italy) emitted higher doses than other makes. Significant ($P < 0.05$) differences were observed between the doses administered by the equipment complying with official EU recommendations (70 kVp, 1.5 mm of Al and collimating cylinder of 20 cm) and the doses administered by other standardized equipment, which used significantly more radiation. Similarly, there were statistically significant ($P < 0.05$) differences between the doses administered by radiographic equipment that showed alterations in the acoustic–luminous signal and equipment where this safety device worked well. Equipment emitting significantly higher doses and those with a cone length of less than 20 cm, needle or pointed cones and machines with no acoustic–luminous signal have gradually been replaced.

The main differences concerned the way in which the radiological images were processed. The number of installations that use manual processing has decreased by 51.9% (87.3% in 1996–7 to 45.3% in 2007), while the number of digital imaging sets reached 50% in 2007

(Table 1 and Figure 2). In the installations that use radiographic film and manual processing, little change occurred over the 11 years; most used Ultraspeed (Kodak, Valencia, Spain) (83.3%) and manual processing in a 100 ml glass or plastic container for the processing liquids (96.7%). The solution is changed once a week (98.1%) and, although some measures to control the time have been introduced, the manufacturer's recommendations are not followed and temperatures are not controlled (99.6%) (Table 1).

Only 62.7% of dental installations possessed a negatoscope (dental light box) in 2007, and of these 15.8% showed serious alterations that needed repair; 30.9% of the installations never use a negatoscope.

Statistical analysis pointed to significant differences between the doses administered and the type of processing and films used. The lowest doses were observed for digital systems and were significantly lower than both manually and automatically processed films ($P < 0.001$) and conventional radiographic films as a whole ($P < 0.001$). However, no statistical differences were observed between manual and automatic processing or

Figure 2 Type of film processing found in the study (1996–2001) (manual, automatic, digital and self-developing films)

between the radiation doses used by the different films themselves.

There was a significant difference between the doses administered in digital systems and where radiographic film was used: direct digital radiology < indirect digital radiology = Insight = Ektaspeed = Ultraspeed ($P < 0.001$) (Figure 3). However, we also found significant differences between the different types of digital sets. Figure 4 shows the annual mean dose used to obtain an image of an upper second molar with direct digital radiography (DR) (charged coupled device (CCD) and complementary metal oxide semiconductor (CMOS)) and indirect or computerized digital radiography (CR) (phosphor plate system). DR < CR ($P < 0.05$); while DR used a lower dose, no appreciable differences were observed between the CR system and the radiographic film used.

Figure 4 shows the distribution of the radiological doses used by the dental installations with digital systems during the last year of the study (2007). Of note is the fact that 6.5% exceed the maximum dose of 4 mGy recommended by the EU (20.5% of installations with CR and 3.2% of those with DR). Furthermore, 7.4% of the digital systems (8.2% of DR and 3.5% of CR) use a dose of less than 0.5 mGy to obtain an image of a second upper molar in normal working conditions. The reference dose corresponding to the 3rd quartile in installations with digital systems was 2.3 mGy in 2007.

Discussion

During the revision made 5 years after the directive came into force (in 2001) we observed that the doses used in Spanish dental installations had fallen by

18.7%. We attributed this decrease to the replacement of old, unapproved and/or faulty radiography machines; the disappearance of filtration problems; the increased kVp of modern sets; and the correction of the most serious errors involved in processing radiographic film (unsuitable solutions, out of date film, etc.).^{4,7}

The results we obtained for 2003 suggested that errors in manual processing were the cause of the lower than expected fall in dose measured^{7–9} and of the almost imperceptible fall in doses used with the most sensitive films,¹⁰ although, as some authors have recently mentioned,¹¹ we did not identify statistically significant differences between the different methods used to process the radiographic film (manual or automatic).

We have mentioned how Spanish legislation,¹² together with the quality controls described, oblige dentists and dental auxiliaries to follow a course (Directors and Operators of Dental Radiodiagnostic Installations), which, on successful completion, provides the operator with a licence to operate dental radiological equipment. All the professionals concerned had fulfilled this obligation. Therefore, one would have expected the errors associated with the equipment, the handling of the equipment and processing to have been resolved, and consequently the doses to have been reduced;^{13,14} however, this was not the case.

The present study, carried out 11 years after the directive was approved, has revealed that the most significant parameters (type of film used, development time and frequency of changing liquids) have remained constant, and only a few parameters have improved (for example, storage of films and remote control for exposure outside exploration room). This reflects a reluctance on the part of dentists to follow the quality

Figure 3 Evolution of mean doses (mGy) and types of films used in Spanish dental installations during the period 2004–2007. CR, radiology digital indirect; DR, direct digital radiology

control programme, at least in those installations where radiographic film continues to be used.^{7,14}

The equipment used in Spain can be regarded as very similar to that used in the rest of the industrialized world in terms of kVp, mA and filtration since it is generally manufactured by the same multinational companies.^{4,9} Our results show that for many years companies tended to manufacture equipment that worked at 70 kV and 8 mA; however, the gradual incorporation of digital technology from 2004 onwards has led to the appearance of apparatus using higher tube potential, values other than 8 mA and increased filtration.

Figure 4 Distribution of the doses used by the dental installations with digital radiological systems (DR, direct digital radiology; CR, radiology digital indirect) in 2007 ($n = 1166$ installations, DR in 967 and CR in 199 installations)

According to our results obtained in 2003, when only 19% of Spanish dental installations inspected used some type of digital imaging, we postulated that the increasing adoption of digital systems was probably the best way of attaining any significant reduction in the radiation dose administered to patients.^{9,10,14} Indeed, the great increase in the number of installations using digital systems has led to a substantial drop in the radiation doses used (37% decrease in 2007) and has removed the errors associated with the manual processing of films. For this reason, given the high number of installations that still use manual processing (47%) and the gradual substitution of digital systems, it is foreseeable that further reductions in the doses administered may be achieved.

Surprisingly, when the distribution of radiation doses administered in digital systems in 2007 (Figure 3) was compared with doses administered in 2002–3⁸ when most installations used radiographic film, the results were not all that different, suggesting that the conversion from conventional to digital simply involved the replacement of the film processor and the viewing box, while almost the same radiation dose was maintained.¹⁵ In other words, dentists use the same exposure times with new digital systems as with the previous radiographic films.

Other aspects of our study worth mentioning are that 23% of installations with indirect digital systems (CR) and 3.2% of those with direct systems exceeded the 4 mGy recommended by the EU. This has not previously been mentioned in other studies, presumably because it was assumed that digital systems can reduce exposure times by 50%, and so the radiation dose would also be reduced by 50% or more.¹⁶ Most installations with digital systems used a dose of 1–3 mGy, the same

as used for radiographic film. Finally, 7.4% of the installations with digital systems use doses of less than 0.5 mGy to obtain an image of an upper second molar. However, in tests carried out by the authors using different machines, we observed that such doses do not provide images of sufficient diagnostic quality. Once again, this supports the case for establishing quality controls based on certain image standards, if possible clinical or anatomical, and not only taking into account radiophysical parameters.¹⁷

Several authors have established reference dose levels (DRLs) for the 3rd quartile in intraoral radiology,^{6,9,10,18–21} even differentiating references for different systems, proposing, for example, a dose of 0.9 for digital systems and 1.5 mGy for film systems.²¹ However, in our study, these reference doses were 2.3 mGy for digital systems and 3.6 mGy for films, which underlines the fact that the use of digital systems does not necessarily have such a clear effect on the radiation dose administered to the patient¹⁹ and that *in vitro* studies on dose reduction and digital manufacturers' claims of dose reduction were probably overstated compared with the clinical situation.^{15,22}

It is important to ascertain why results obtained in controlled conditions in the laboratory are not repeated in clinical practice. According to Hellen-Halme et al²³ the diagnostic image quality is the crucial parameter when determining whether an image is "good" or "no good", and certain guidelines should be provided to the practitioner. If such image quality standards are not set, the variables will be so diverse and contradictory that any statistical analysis will be pointless.

Between 1996 and 2007, the radiation dose used in Spanish dental installations fell by 37%, the dose curves shifting towards the right (abscissa axis), mainly because of the increasing use of digital systems in the last 5 years studied and owing to the technical inspections of the radiophysical parameters. This minor reduction is probably related to the fact that dentists, in general, show little enthusiasm for applying the quality guarantee programme. Despite the innovations made possible by new technology, they continue to make the same errors as they did when they used radiographic film.¹⁴

Lastly, our results can be interpreted simply as a reference to the doses administered in the clinics

inspected in normal work conditions, but not as a reference to the doses administered to patients. To consider them as such, two parameters should be considered: firstly, the rejection rate in each of the clinics (intraoral sets have no counters of radiological exposures meaning that only one estimation of the same can be made);^{11,22} and, secondly, the increase in the number of exposures needed by individual patients because of the small size of the digital sensor and the relatively short period between exposure and display of the radiograph in the monitor, which some authors have estimated to be as high as 50%. The above can contribute to annulling the potential benefits of the lower doses needed by digital systems.²²

For all these reasons, it may be that, despite the reductions in dose found by our study of dental clinics (37%), the dose administered to patients may have remained constant or even increased, as some authors have suggested.^{15,19,22} The involvement of dentists as principal players in radiodiagnostic quality control programmes is essential if greater reductions in the doses administered to patients are to be attained.^{14,18,19,23} However, the present system of external audits and inspections as carried out in Spain has the inconvenience of fomenting confrontation between the practitioner and the system of legally imposed obligations.

In conclusion, the EU directive of 1996–7 has led to a 37% reduction in the doses used by dental installations in intraoral radiology. However, the incorporation of digital imaging systems has not brought about the full benefits expected since the errors committed with radiological film are reproduced. The involvement of dentists in quality control and radiological protection in their clinics is essential. Once the physical parameters of the equipment have been established, criteria related with image quality (preferably anatomical and/or clinical) should be applied to demonstrate to dentists the real benefits to be gained from incorporating a quality guarantee system in their practice.

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