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Survey of the cosmetic use of lasers and other strong optical radiation sources

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Abstract

A survey was undertaken regarding the extent to which optical radiation is used in cosmetic treatments and the compliance with national regulations. Questionnaires were sent to 65 clinics, and 23 of these were later inspected. Only one of 41 class 4 lasers had been reported to the authorities according to the regulations prior to the survey. Among sources other than lasers, intense pulsed light (IPL) sources were the most frequent. Although qualified health personnel should be in charge of the treatment, it was observed that 30% of the clinics did not fulfil this requirement. Deviations with respect to personnel training, availability of written procedures, protective equipment and warning signs were frequently observed. The results give rise to concern about the safety of patients and employees.

1. Introduction

Optical radiation has been used in medical treatment and diagnosis for decades. In recent years several new applications have been developed taking advantage of specialised optical sources and photobiological principles (see Goldberg 2005 and Calzawara-Pinton *et al* 2001). In a number of cases the same modalities are used for cosmetic purposes based on a medical indication, e.g. laser removal of traumatic tattoos, as well as for purely cosmetic purposes, e.g. removal of unwanted decorative tattoos.

Although a trend towards more extensive use of optical sources was expected, the number and types of clinics that employ such sources were unknown to the Norwegian Radiation Protection Authority (NRPA) prior to the study. Information on the number of treatments and the different indications, medical and cosmetic, was also incomplete.

Safety, for the therapist as well as the client, is of great concern when new modalities are launched. Different classes of sources have different safety standards. Laser safety is covered by a comprehensive set of international standards (EN 60825-series; see CENELEC 2007) and safety standards for other optical sources have also been established (CENELEC 2008).

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National legislation and practices seem to vary between countries (see e.g. Crawley and Weatherburn 2000).

New radiation protection regulation came into force in Norway from 1 January 2004 (Ministry of Health and Care Services 2000). Some central points are:

- The NRPA shall be notified about the use of class 4 lasers.
- Lasers shall be constructed, classified and labelled according to the European standard EN-60825-1.
- Medical use of radiation shall be justified and optimised.
- Therapy with optical radiation for the purpose of curing disease or relieving symptoms shall be performed in accordance with professionally proper and documented procedures.
- Registered nurses, nursing auxiliaries and children's nurses with special training in radiation protection in the context of light therapy are entitled to operate light therapy apparatus.
- All intended exposure of humans with class 3B or 4 lasers shall be performed under the responsibility of a medical practitioner, dentist or ophthalmologist.
- Accidents and suspected over-exposure shall be reported to the NRPA.

A guideline (Christensen and Nilsen 2006), suggesting good practice was produced and posted on the Internet in 2006.

The aim of the present work was to obtain information about the use of lasers and strong optical sources for cosmetic purposes in Norway, e.g. number of clinics, exposure conditions and risk factors. It was also of interest to assess to what extent national regulations were followed. A brief description is given of a few cases where inspections of radiation users were followed by orders to make improvements or to discontinue the treatment.

2. Methods

The study was performed in the period 2006–2008. Information about potential participants in the survey was obtained from telephone registers, the Internet and advertisements. Users within the National Health Service of Norway were not included.

2.1. Questionnaire

A questionnaire supplemented by information about the regulations and guideline was sent to 65 clinics immediately after the publication of the guideline on the Internet in July 2006. The main queries concerned the following:

(1) List of sources, including registration numbers or a new report of all class 4 lasers.
(2) Risk of accidental exposure.
(3) Qualifications, instructions and responsibility; questions about health professionals and auxiliary personnel.
(4) Description of procedures including risk analysis.

Two written reminders were sent to participants who did not answer within 1 month. After 4 months 36 participants had answered the questionnaire and the answers were evaluated. At that time non-responders were contacted by telephone. The data presented in table 1 (on training and procedures) were based on evaluation of all questionnaires irrespective of response time.

Table 1. Information about training of the personnel and about written procedures available in the treatment room. Data was taken from a collection of 40 questionnaires where information about these subjects was given.

	Interpretation of answer						
	Training				Written procedures		
	Some form of training	Training from the equipment supplier	Training by co-workers or courses	No details about the form of training	Some form of written procedures	Written procedures, other than technical equipment manuals	No information about written procedures
% of participants	92	50	25	17	68	22	32

2.2. Inspection

24 clinics were selected for inspection in November and December 2006. Two of them could not be inspected due to practical considerations and one of the undertakings owned two clinics that operated independently. Thus, 23 inspections were performed. The selection criterion was based upon location: two geographical areas were selected and all eligible users of optical radiation within the two areas were inspected. A standardised check-list containing the same main issues as in the questionnaire was used during interviews with the manager and the employees. The inspections started with an introductory meeting (20 min) with the clinical and administrative personnel. Visual inspections of the radiation sources, protective material, written instructions etc were carried out and the inspections ended with a concluding meeting. In small clinics, with one or two employees, a less formal schedule was followed. A written draft-report was presented to the manager shortly after the end of the inspection.

When deviations from the regulations were found, they were characterised as minor or major. The *minor* deviations (e.g. incorrect labels on equipment) were commented upon during the inspection process, but no formal steps were taken. However, the participants were urged to correct the deviations. *Major* deviations (e.g. lack of health professionals) required that the participants provided a written response to the authorities about the correction of the deviation(s) in question. If a report was not received or corrections were not reported correctly, the participant was ordered to make the corrections. The use of optical radiation was stopped in situations where a serious health risk might exist as a result of non-compliance with the regulations. In one case the participant was inspected twice after the clinic had been ordered to stop using lasers.

3. Results

3.1. Information obtained from questionnaires

3.1.1. Sources. The total number of different optical sources reported in the 36 answers to the questionnaire and the distribution between them can be seen in figure 1. Each participant had 2.6 sources on average. Only one of a total of 41 class 4 lasers had been reported to the authorities before the study started.

3.1.2. Risk analysis. The respondents characterised the risk connected to the use of sources as low or non-existent, provided that protective equipment was used (emphasised by 50% of

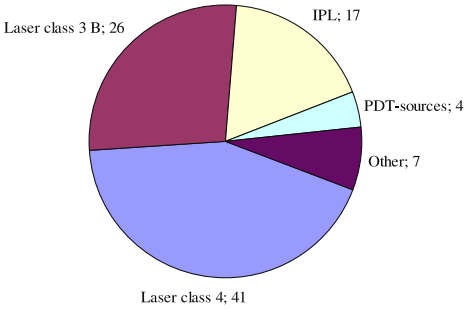

Figure 1. The types and number of different optical sources reported by the 36 participants responding to the questionnaire.

(This figure is in colour only in the electronic version)

the users). They reported that the employees were the group at highest risk. Nevertheless, four of the 36 clinics reported having experienced injuries to patients/clients. The injuries were characterised as superficial skin lesions, i.e. burns and pigmentation changes.

3.1.3. Competent personnel. Thirty per cent of the clinics that offered treatment with class 4 and 3B lasers lacked a responsible medical practitioner or dentist. Similarly, 40% of the clinics reported that treatment with optical radiation was performed by other types of employees than qualified health personnel (registered nurses, nursing auxiliaries and children's nurses with special training in radiation protection in the context of light therapy).

3.1.4. Education and procedures. Most personnel had some form of training. Thirty participants (75%) reported training from suppliers, co-workers or courses (table 1). Only nine (22.5%) of the participants indicated that written procedures in addition to technical manuals for the instruments were provided for the operators (table 1).

3.2. Inspections

Figure 2 summarises the occurrence of deviations from the regulations. Some particularly important results from the inspections are as follows:

(1) Lack of responsible medical practitioner for the operation of strong lasers, class 3B and 4, was noted in four of the inspected clinics.
(2) Four clinics totally lacked written procedures for treatment and radiation protection. They were all cosmetic clinics with no medical practitioner among the staff.
(3) In six clinics it could not be determined if the eye protection was designed to protect against radiation from the sources present in the treatment area.
(4) The authority demanded discontinuation of the use of optical radiation in three clinics due to serious health risks. Two of the clinics corrected the deviations and were re-opened, while one did not respond, and the closure order was still effective as of August 2009.

3.2.1. Follow-up. One of the clinics was re-inspected twice after the initial visit. The first follow-up was unsuccessful, since the inspector could not gain access to the premises, while the second was aided by the local police and resulted in confiscation of essential parts of more

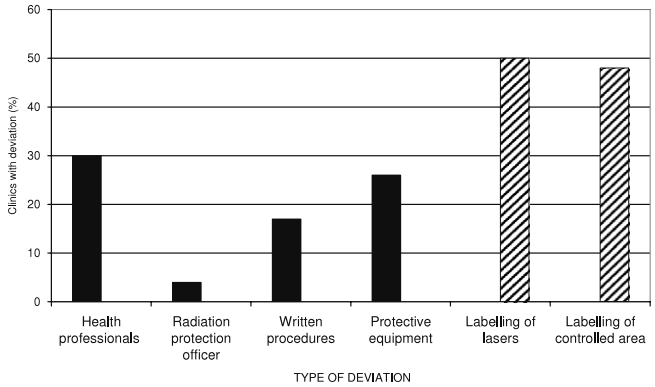

Figure 2. The main types and relative number of various deviations found during inspections of 23 clinics. Major deviations, requiring follow-up in writing are indicated with black bars. Minor deviations that were remarked upon during the inspection but that did not require a report after correction are indicated with hatched bars. Four of the 23 participants had more than one deviation from the regulations.

than 10 lasers. Later the clinic was re-opened as a result of documented improvements, the most important being:

(1) Class 4 lasers were reported.
(2) A contract with a medical doctor agreeing to be responsible for the laser treatment was presented.
(3) Written procedures were prepared.

In a second clinic, an order of discontinuation of the treatment was given due to lack of competent personnel, but the clinic presented a written agreement with a medical doctor a few days later. The third clinic where the use of optical radiation was stopped was unable to present documentation on the education of the staff responsible for the treatment.

4. Discussion

4.1. Selection of participants

A preliminary survey including experienced users representing different specialities was performed. From the background of the results of the preliminary study two conclusions about the continuation of the project were drawn: eye clinics offering correction of vision were excluded since the risk of radiation damage to the client and operator was judged to be small and the laser operations are only performed by ophthalmologists. Likewise, the use of sources that are unable to cause significant adverse effects was excluded from the project. The use of light and lasers in dentistry was also excluded. The preliminary survey included one dentist. Dental clinics were not picked up in our search in telephone registers, on the Internet or as a result of advertisements because the use of optical radiation is normally not specified among the various treatments offered by the dentist. The use of optical radiation in dental offices has been the subject of separate investigations (Bruzell *et al* 2007, 2009).

An evaluation of 36 questionnaires out of 65 was made. The group of 36 represented the clinics that responded within 3–4 months. A few answers were received at later times and 10 of the original 65 participants reported that they did not use optical sources and these were excluded from the evaluation. Therefore it is concluded that the evaluation was based

on analysis of 75% of the eligible participants and that it may be assumed that this group is representative. On the other hand speculations over the fact that some participants did not answer, may indicate that the non-responders pay particularly little attention to regulations and have difficulties satisfying the requirements of safe use.

4.2. Sources

This project shows that a number of laser owners did not report their class 4 laser before they were directly asked to do so by the authorities. According to figure 1 many other sources are used for treatment as well, ranging from class 3B lasers to low power conventional lamps. A particular concern is raised by the frequent use of sources of intense pulsed light (IPL). These sources have power and potential risks in the same range as many class 4 lasers in addition to independent risk factors (Ross 2006). We found 17 IPL sources in the investigated clinics, but the total number nationwide can be assumed to be much higher: IPL sources are typically used in beauty parlours not included in the survey.

4.3. Medical competence

Our findings show that a medical practitioner was responsible for laser treatment in 70% (16 of 23 participants) of the cases, but that another person was acting under his/her directions in a number of these cases. In a Danish investigation of 28 clinics utilising lasers and IPL for cosmetic use, it was found that only three of the clinics offered the clients a medical examination prior to the procedure and never by a dermatologist (Beyer *et al* 2006). This number is lower than the percentage of clinics with a medical practitioner in our study, but we did not specifically ask whether the doctor examined the client before the treatment. The medical supervision may in some cases be a legal construction to fulfil the requirements in the regulation. It is also worrisome, as indicated by Crawley and Weatherburn (2000), that a few medical practitioners give medical cover for a large number of clinics across the country. In our material there were several cases where the same doctor was responsible for more than one clinic, even in different parts of the country (data not shown). Physicians have a crucial role in, for example, long term safety when using lasers and IPL (Burkhart 2007). Indeed, the availability of medical competence was the most important decision factor among patients considering undergoing a cosmetic procedure in Taiwan (Tzung *et al* 2007).

Our investigation indicated that the availability of radiation protection officers was satisfactory, since a majority of the respondents (22 of 23 participants that were visited for inspection, figure 2) stated that they had a person with this duty. It is possible that the respondents had given overly positive answers and pointed to a responsible person during the interview/inspection who in many cases may not have had the right qualifications or even been aware of the responsibility or required competence.

The importance of proper knowledge has been underlined by several investigators since operator errors are the most common cause of laser accidents (see Barat 2003 and Moseley 2004). The staff can receive training from several organisations. In our investigation courses and introduction to new equipment offered by the supplier or manufacturer was the only reported training in 50% of cases. One may suspect that training arranged by companies with economic interests in the equipment may not fulfil the regulatory demands and otherwise be of variable quality. As a direct result of the observations made in this project a continued education programme in safety of light and laser therapy is now offered by Buskerud University College near Oslo (Stranden 2007). The role of several medical doctors in charge of the laser treatment in Norwegian laser clinics will be further evaluated in cooperation with the Norwegian Board of Health Supervision.

4.4. Written procedures

When staff were asked about treatment procedures during the inspections on site, a frequent answer was that the operator was dependent on the information provided with the equipment. This information was often in electronic form and only available for the user during operation of the equipment. In a preliminary report on the use of light in dermatological clinics it was found that written procedures were actively used when present in the clinic (Huldt-Nystrøm 2007). Therefore it can be concluded that improvements in the availability and quality of written materials will be used and appreciated by staff.

4.5. Report of incidents

Reporting of incidents with optical sources was also a subject of the present investigation. Four uncomplicated cases of over-exposure of the skin were reported in the questionnaires. A number of participants left the answer to this question open. In Norway it is compulsory to report any incident involving radiation to the NRPA within 3 days, and none of the above-mentioned incidents had been reported prior to the present investigation. The true number of incidents cannot be determined from our data due to probable under-reporting. Other countries may have different routines for reporting incidents (Barat 2003) and improvements in reporting systems have been suggested (Clark *et al* 2006).

4.6. Labelling of equipment

Figure 2 shows that deviations with respect to labelling of equipment, treatment room and protective equipment were frequently reported. Such deviations can easily be corrected by the undertaking itself and no further action from the authority was taken to control improvements with respect to labelling.

5. Conclusions

It is worrying that the safety of cosmetic laser treatment and other optical methods was lower than required for a number of participants. Lack of health professionals and medical control are regarded as serious deviations from national regulations and international standards causing concern about the safety of patients and staff. Compulsory notification of class 4 lasers was rarely done unless requested by the authorities. Suppliers of equipment were found to be the main source of information about procedures and safety measures. This information may not be sufficient for safe use. Information about correct application and safety is already provided by the authorities, but communication of this information could be improved. However, in order to achieve justified, optimised and safe use of lasers and other strong optical radiation sources the owner of each clinic must take responsibility.

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