

SUMMARY

USE OF CLASS 3B AND CLASS 4 LASERS AND INTENSE PULSED LIGHT SOURCES FOR COSMETIC PROCEDURES IN NON-MEDICAL SETTINGS

Introduction

Body image has always preoccupied people across time and cultures. Today, the search for beauty can be fulfilled with high-power technologies that are relatively easy to use, such as Class 3b and Class 4 lasers and intense pulsed light (IPL) sources. Lasers are devices that amplify light, emitting it in a narrow, coherent optical beam; the beam produced is near-monochromatic, the particles all move in the same direction, and the waves are in phase with one another. Intense pulsed light is based on different physical and technological principles. Unlike lasers, IPL sources emit polychromatic light (non-coherent, between 500 and 1,200 nm), and selected wavelengths are obtained by means of filters. These technologies are used for various cosmetic purposes and applications, including some that clearly come under activities reserved to physicians, while others fall into the grey areas surrounding medicine.

Based on the definitions of the different fields of medical activity and on the laws and regulations governing the practice of medicine, this report has limited its scope to examining laser and IPL procedures that do not require medical diagnosis and that may be performed in Québec by operators other than physicians or health professionals, without medical supervision. This report does not purport to determine what does and does not lie within the scope of medicine. Rather, it focuses on the risks inherent in these technologies and on the qualifications required to use them, by taking hair removal as a base case and by dealing more briefly with skin resurfacing and tattoo removal, without ruling on the field of activity to which these practices belong.

Research methods

Medline (National Library of Medicine) via PubMed and the Cochrane Library were searched.

The grey literature was also examined to take into account the contextual aspects that prompted the request for this report, especially the legal and regulatory provisions framing the use of lasers and IPL by non-physician operators in various countries and regions. In addition, local experts were consulted to validate the contextual evidence and the applicability of the ensuing recommendations. These experts are key actors in the following organizations: *Association des dermatologistes du Québec*; *Collège des médecins du Québec*; *Comité sectoriel de la main-d'œuvre des services de soins personnels* [sector committee on personal services workers]; *Ministère de l'Éducation, du Loisir et du Sport*; *Ministère de l'Emploi et de la Solidarité sociale*; and *Ministère de la Santé et des Services sociaux*.

Scientific evidence

Adverse effects linked to the cosmetic use of Class 3b and Class 4 lasers or IPL sources may be caused by factors inherent in the technology or by personal characteristics such as phototype, dark skin and medication use. Although there may be infrequent cases of permanent sequelae such as scarring, the most common adverse effects of varying frequency and intensity are erythema, edema, blistering and pigmentary changes.

Two systematic reviews dealing specifically with the adverse effects of laser or IPL hair removal, including one from the Cochrane Collaboration, have been published. The Cochrane review includes 11 randomized controlled trials. While most (9 of 11 studies) were designed to assess the efficacy of this treatment, they also provided evidence on its adverse effects. The authors concluded that erythema, edema, blistering and pigmentary changes are infrequently reported. Available case series studies yielded mostly the same outcomes with all the various types of

lasers and IPL sources. However, these studies were of poor methodological quality and very heterogeneous, which excludes all possibility of meta-analyzing the efficacy and safety outcomes for these technologies. Furthermore, adverse effects were not clearly described, which prevents assessment of their severity.

No systematic reviews on tattoo removal or non-ablative skin resurfacing were retrieved. However, a few narrative reviews dealt with tattoo removal by presenting the outcomes of primary studies. Skin colour alteration, scarring and allergic reactions may result from interactions between lasers and tattoo dyes. Chrysiasis, although infrequent, may be a problem. The studies identified on the adverse effects of non-ablative skin resurfacing were case series and had the same methodological limitations as the studies on hair removal. Adverse effects were similar, although others, such as purpura, were documented, but only very infrequently.

The issue of assessing the safe use of lasers and IPL sources by non-physician operators, without medical supervision, cannot be resolved given the current state of scientific evidence. No scientific study attempted to determine whether there was an association between the frequency and severity of adverse effects and the types of operators using these technologies (physicians vs non-physicians) for any of the three indications studied.

Regulatory oversight outside Québec

Overall analysis of the regulatory situation prevailing outside Québec showed that laser and IPL use is a topic of controversy characterized by the grey areas between what is strictly cosmetic and what comes under the purview of medical practice, and by the divergent positions of different jurisdictions about authorized activities and their operating conditions.

Under their respective medical laws, France, Switzerland and several U.S. states restrict the cosmetic use of lasers and IPL to physicians. However, a number of U.S. states authorize people other than physicians to operate these devices, provided that they do so under medical supervision. Still other U.S. states, along with England, Belgium, Queensland (Australia), British Columbia

and Alberta, permit the use of these technologies without medical supervision. In Alberta and British Columbia, any cosmetic procedure not regulated by medical legislation is not subject to any prohibitions. In England, this practice is restricted to hair removal and skin resurfacing, while only hair removal is authorized in Queensland. In Belgium, the senate is in the process of regulating laser or IPL hair removal.

The U.S. states that authorize the cosmetic use of lasers or IPL by non-physicians have implemented a series of measures to prevent the risks of complications. All the jurisdictions studied have directed high-level decision bodies to determine licensing requirements for cosmetic care establishments or businesses not part of the health and social services system. Some of these organizations base licensing on safety issues (Director of Radiation Health, Alberta; Australian Radiation Protection and Nuclear Safety Agency, Queensland), while others extend it to public health considerations (Healthcare Commission, England; Department of Public Health, Belgium; Ministry of Health and Ministry Responsible for Seniors, British Columbia).

Some governments also monitor the credentialing of laser and IPL operators. This is carried out through various government measures: a mandatory training program (England), evaluation of predetermined laser operator knowledge (British Columbia), and issuance of operating licences determining the level of medical supervision required (Queensland, Australia).

Furthermore, some jurisdictions have established good practice rules, along with measures to audit compliance with these rules, such as public safety standards and compliance inspections (Alberta), regulation of personal services and provision of practice guidelines (British Columbia), and implementation of practice standards and annual establishment inspections (England).

Québec context

In Québec, the cosmetic use of lasers and IPL by non-physician operators without medical supervision is widespread, although no data are available either on the particular types of technologies used or on the cosmetic procedures

provided. This practice is characterized by a regulatory gap resulting from the fact that:

- the current Medical Act (R.S.Q., c. M-9) does not stipulate that the cosmetic use of Class 3b and Class 4 lasers and IPL sources is an activity reserved to physicians, nor does it define the boundary between aesthetic procedures and medical cosmetic procedures;
- the Act respecting Health Services and Social Services (R.S.Q., c. S-4.2) does not apply to strictly cosmetic procedures;
- there is no professional order or regulatory association capable of oversight on the practice of estheticians or electrologists;
- the *Comité sectoriel de la main-d'œuvre des services de soins personnels* and the *Ministère de l'Éducation, du Loisir et du Sport* have developed their own training programs in laser hair removal, but these programs are not mandatory and do not cover other cosmetic laser applications or the use of IPL.

Yet, the Act respecting Workforce Vocational Training and Qualification (R.S.Q., c. F-5) could fill this regulatory gap in part by standardizing the required occupational skills, establishing vocational training and qualification programs, and determining occupational eligibility requirements for laser or IPL operators working in non-medical settings.

Conclusion and recommendations

Analysis of the scientific and contextual evidence leads to these findings:

- Class 3b and Class 4 lasers and IPL sources are high-power technologies entailing risks for operators and their customers.
- The use of these technologies leads to adverse effects that, although minor and transient for the most part, may in some cases be serious; however, scientific evidence does not allow us to determine their frequency or severity, or to link them with the types of professionals using them.
- Some cosmetic procedures may overlap with activities reserved to physicians when these

procedures are applied to areas of the skin with an underlying medical condition or with the risk of complications requiring medical expertise.

- Current Canadian safety standards regulate the sale and importation of these devices and their use in health-care facilities, and the safe use of lasers is governed by laws and regulations intended to protect workers' health and safety in all work settings. However, Québec has no law or regulation to protect the health and safety of the public undergoing laser or IPL procedures in non-medical settings.
- The use of Class 3b and Class 4 lasers and IPL sources is widespread in beauty care centres, but the specific types of devices used are not known.
- There is no professional order regulating the practice of estheticians or other types of personnel working in the personal services sector and likely to use laser or IPL devices, and the Office des professions du Québec has already denied the application by the Association des électrolystes du Québec to establish a professional order.
- The Comité sectoriel de la main-d'œuvre des services de soins personnels and the Ministère de l'Éducation, du Loisir et du Sport have already developed their own non-mandatory vocational training programs in laser hair removal, but these programs do not cover other cosmetic laser applications or the use of IPL.
- The Act respecting Workforce Vocational Training and Qualification (R.S.Q., c. F-5) could fill this regulatory gap in part by standardizing the required occupational skills, establishing vocational training and qualification programs, and determining occupational eligibility requirements for laser or IPL operators working in non-medical settings.

In light of these findings, this report is not able to rule either on the safety of laser or IPL procedures by non-physician operators working without medical supervision or on the scope of activities that could be authorized to them in the Québec context. However, given that these technologies present hazards and may lead to adverse effects that are potentially serious when used for

cosmetic procedures, and given that there is a serious possibility of interference with the field of medicine, AETMIS has reached the following conclusions, which define the major issues to be dealt with:

- The boundary between the procedures restricted to the field of medicine and the cosmetic procedures that may be performed by non-physician operators must be clearly established.
- The cosmetic procedures performed with Class 3b or Class 4 lasers or with IPL that are not defined as activities restricted to physicians must be subject to minimum quality-assurance measures so that these procedures cause no physical harm to the people undergoing them.
- A fundamental measure ensuring safe practice is to oblige all people wishing to use Class 3b or Class 4 lasers or IPL for cosmetic procedures to take a comprehensive and recognized training program to allow them to acquire and maintain the necessary occupational qualifications.
- Consumers who personally choose to make use of these beauty care services must be made aware of the risks inherent in these technologies and the potential complications stemming from their use.

Consequently, AETMIS recommends that:

- The Collège des médecins du Québec should define which cosmetic procedures should come under the Medical Act either directly (based on the type of condition being treated) or indirectly (conditions requiring prior diagnosis or evaluation).
- The Ministère de l'Emploi et de la Solidarité sociale should establish, jointly with its partners, vocational training and qualification programs for all people working in the personal services sector who, in performing their trade or profession, use Class 3b or Class 4 lasers, IPL or any other high-power energy source for non-medical cosmetic purposes, and should propose regulatory provisions to ensure that the programs are implemented.
- The Ministère de l'Éducation, du Loisir et du Sport, jointly with the Ministère de l'Emploi et de la Solidarité sociale, should adapt its vocational training programs in esthetics and hair removal to comply with said regulation for all procedures performed with Class 3b or Class 4 lasers, IPL or any other high-power energy source.
- The Comité sectoriel de la main-d'œuvre des services de soins personnels, jointly with the Ministère de l'Emploi et de la Solidarité sociale, should adapt its current training program in electrolysis to comply with said regulation and should develop mandatory vocational training programs for all the procedures not under the Medical Act and requiring the use of Class 3b or Class 4 lasers, IPL or any other high-power energy source.
- The Ministère de la Santé et des Services sociaux, jointly with the other government authorities concerned, should inform the public of the risks associated with beauty care services involving the use of Class 3b or Class 4 lasers or IPL sources, including the risks inherent in these technologies.