INTERNATIONAL COMMISSION ON NON-IONIZING RADIATION PROTECTION

ICNIRP STATEMENT

INTENDED HUMAN EXPOSURE TO NON-IONIZING RADIATION FOR COSMETIC PURPOSES

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INTENDED HUMAN EXPOSURE TO NON-IONIZING RADIATION FOR COSMETIC PURPOSES

International Commission on Non-Ionizing Radiation Protection (ICNIRP)[1]

Abstract—**Cosmetic devices using non-ionizing radiation (NIR) are increasingly available for people who wish to modify their appearance for aesthetic purposes. There are a wide range of NIR modalities used for cosmetic procedures, including devices that use optical radiation (laser, intense pulsed light, and light-emitting diode), electromagnetic fields, and ultrasound. Common procedures involving the application of NIR include epilation, skin rejuvenation, body sculpting and contouring, treatment of vascular and skin lesions, tattoo removal, and scar reduction. The majority of research on the use of NIR cosmetic devices has focused on the efficacy of the treatment rather than adverse effects or complications. Studies that assessed safety consisted mostly of case reports and small case series. Common adverse effects on the skin reported include mild and transient pain, erythema, swelling, and changes in pigmentation. Less common, more severe side effects include burns, blisters, scarring, persisting erythema, altered pigmentation, and eye damage. Some of the latter may have resulted from treatment errors. Particular groups of people that may be at greater risk from optical radiation include people with dark skin, with high sun exposure, and taking photosensitizing medications or supplements. There is lack of evidence for the safety profile of cosmetic NIR procedures during pregnancy. Reports of injuries to workers administering treatments with cosmetic NIR devices are rare, but inadvertent damage to the eye from optical devices may occur. Randomized controlled trials are required to fully assess potential adverse effects from the use of NIR cosmetic devices. Regulation varies worldwide and some regions apply the same safety classification and guidance as for medical devices. In order to reduce harm associated with the use of cosmetic devices, ICNIRP considers it important that regulations that cover all types and frequencies of cosmetic NIR devices are adopted worldwide and that there is greater oversight regarding their use.**
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Key words: health effects; International Commission on Non-Ionizing Radiation Protection (ICNIRP); radiation, non-ionizing; safety standards

INTRODUCTION

COSMETIC APPLICATIONS using non-ionizing radiation (NIR) are increasingly available for people who wish to modify their appearance for aesthetic reasons while avoiding invasive procedures such as surgery or injections. By definition these applications are designed to cause visible biological changes, and thus, their use has the potential for adverse physical outcomes both in those undergoing, and in those administering, cosmetic NIR treatments.

The International Commission on Non-Ionizing Radiation Protection (ICNIRP) has identified a lack of knowledge regarding possible adverse health effects from cosmetic use of NIR. In this statement cosmetic use is defined as the voluntary use of NIR to address perceived problems of appearance for purely esthetic reasons. Accordingly, ICNIRP has developed a statement regarding adverse health effects of the spectrum of cosmetic devices that employ NIR, including electromagnetic fields (EMF) with frequencies up to 300 GHz (wavelengths down to 1 mm in vacuum), optical radiation with wavelengths from 1 nm to 1 mm, and ultrasound with sound frequencies of 1–40 MHz.

The specific aims of this statement are to:

- Review the range of cosmetic devices employing NIR that are currently in use.
- Describe potential risks to the health of persons undergoing cosmetic procedures with these devices as well as to the health of persons administering cosmetic NIR-based treatments.
- Identify situations of potentially high NIR exposure during cosmetic procedures where protection may not be adequate.

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- Document regulations and guidelines for protection of clients who are treated with such cosmetic devices and of workers who administer cosmetic NIR treatments.

In developing this statement, we conducted systematic literature searches for the period 2007–February 2019 in PubMed, Scopus, Web of Science, and Cochrane databases for relevant studies on human subjects (meta-analyses, systematic reviews, randomized clinical trials, case-control studies, and case series; case studies were also accessed to obtain further technical information on devices or adverse effects) (see the Appendix for search terms). Relevant technical reports, manufacturers' information, and international regulation or guidelines were also identified via web searches and were supplemented by consulting regional experts. The statement does not necessarily provide an exhaustive list of all papers identified for all modalities; rather it discusses the adverse health effects in general terms. Data on guidelines and regulations were collected and summarized for the larger (blocs of) industrialized countries where information was available which included Australia, the European Union, China, Japan, South Korea, Russia, and the United States.

Clinical conditions such as severe acne or varicose veins were deemed medical rather than cosmetic, and therefore their treatment lay outside the scope of this statement. With regard to treatment modality, devices that combined NIR with non-NIR agents such as cold or pressure were excluded. Direct application of electric current to the body (e.g., galvanic electrolysis, radiofrequency current) was not considered specifically but was considered as a combination treatment with NIR. Indoor tanning devices employing artificial ultraviolet radiation were not included as these have been reviewed in separate ICNIRP publications.

This statement does not address the efficacy or effectiveness of cosmetic devices using NIR. The focus is on evidence that suggests that current regulations may not adequately protect against demonstrable hazards and the nature and magnitude of the risks. Finally, the statement points to gaps in current evidence that warrant future research.

COSMETIC TECHNOLOGIES BASED ON NIR

Cosmetic devices use NIR of varying wavelength and frequency, including devices that use optical radiation (laser, intense pulsed light, and light-emitting diode [LED]), EMF, and ultrasound (Table 1). The mechanisms of action of the different classes of devices and evidence of adverse health effects, categorized as either transient and minor, or as permanent and severe (Al-Niaimi 2016), are reported below.

Lasers

Cosmetic lasers are high-energy, optical radiation sources that emit a single wavelength of light in either the visible or infrared region which can be focused onto a small area. Lasers have a wide range of cosmetic applications including epilation, tattoo removal, skin rejuvenation, vascular lesion treatments, laser lipolysis, and scar reduction (MHPRA 2015). The types of lasers and applications have expanded significantly as the demand for noninvasive light-based cosmetic procedures to improve appearance has steadily grown since their initial mainstream use in the 1980s (Van Buren and Alster 2009).

Lasers achieve a desired cosmetic outcome based on the concept of selective photothermolysis (Anderson and Parrish 1983). This means that the optical energy deposited by the laser specifically targets the problem area while having a minimal effect on the surrounding normal tissue. The target is generally a chromophore such as melanin, hemoglobin, or tattoo ink; however, other cosmetic laser procedures deliver energy to fatty tissue and intracellular and extracellular water to produce the desired outcome (Husain and Alster 2016).

Lasers can be categorized by their mode of operation as either pulsed or continuous wave. Pulsed lasers deposit large amounts of energy in ultrashort pulses, some capable of emitting pulses with durations of nanoseconds to picoseconds (Husain and Alster 2016). Continuous wave lasers deliver energy over time until the desired fluence (energy per unit area or energy density measured in J cm^{-2}) is achieved based on an observable effect. Although continuous wave lasers have applications in some cosmetic treatments, the reviewed literature indicated most cosmetic treatments are applied with pulsed lasers (Paasch et al. 2017; Husain and Alster 2016; Alexiades-Armenakas et al. 2008). Further, lasers can be separated into ablative or nonablative types where the former vaporize surface skin tissue and the latter deposit thermal energy into the skin (Preissig et al. 2012).

Common types of lasers used in cosmetic treatments include the neodymium-doped yttrium aluminum garnet (Nd:YAG, 532, 1,064, 1,320, and 1,440 nm); erbium-doped YAG (Er:YAG, 2,940 nm); Q-switched alexandrite (755 nm); pulsed dye laser (PDL, 585–595 nm); potassium titanyl phosphate (KTP, 532 nm); pulsed carbon dioxide (CO_2, 10,600 nm); and diode lasers emitting at a range of wavelengths (Preissig et al. 2012; Husain and Alster 2016). The choice of laser is determined by the specific cosmetic treatment and may be further influenced by the client's skin type, where longer wavelengths have been shown to result in less severe complications when treating dark-skinned clients (Van Buren and Alster 2009). The fluence of cosmetic laser treatments depends on the particular treatment. For most superficial treatments the fluence is in the range of 5–15 J cm^{-2} (Royston et al. 2008; Gregório et al. 2013). However, another study indicated heterogeneity in energy delivered, reporting fluences of up to

Table 1. List of technologies applying NIR for cosmetic purposes and their reported adverse effects.

Modality	Treatment	Wavelength/ frequency	Applied energy/ power of device	Adverse effects reported
Laser				
Nd:YAG	Vascular lesions, pigmented lesions, tattoo removal, epilation, ablative skin resurfacing	532, 1,064, 1,320, 1,440 nm	5–15 J cm^{-2} for superficial procedures (e.g., epilation), ~40 J cm^{-2} for vascular lesions and up to 20,000 J of deposited energy for lipolysis	Transient pigmentary alteration (hypo- and hyperpigmentation), systemic allergic or localized granulomatous tissue reactions, ignition of explosive particles in traumatic tattoos, atrophic scars, blistering, crusting, dyspigmentation, and rarely scarring
Er:YAG	Ablative skin resurfacing	2,940 nm	150 J cm^{-2}	Erythema and edema, postinflammatory hyperpigmentation
Q-switched alexandrite	Vascular lesions, pigmented lesions, tattoo removal, epilation	755 nm	5–15 J cm^{-2} for superficial procedures, ~40 J cm^{-2} for vascular lesions	Transient pigmentary alteration (hypo- and hyperpigmentation), systemic allergic or localized granulomatous tissue reactions, ignition of explosive particles in traumatic tattoos, atrophic scars, blistering, crusting, dyspigmentation, and rarely scarring
PDL	Vascular lesions, hypertrophic and keloid scars	585–595 nm	5–15 J cm^{-2} for superficial procedures, ~40 J cm^{-2} for vascular lesions	Postoperative purpura, transient dyspigmentation, and rarely vesiculation, crusting, scarring
KTP	Vascular lesions	532 nm	~40 J cm^{-2} for vascular lesions	Erythema, edema, and crusting
CO_2	Ablative skin resurfacing	10,600 nm	150 J cm^{-2}	Intense erythema and edema, milia and mild acne, postinflammatory hyperpigmentation, and infection
Diode laser	Vascular lesions, epilation, ablative skin resurfacing, lipolysis	Various	10s–100s of J cm^{-2} depending on procedure; up to 2,500 J of deposited energy for lipolysis	Blistering, crusting, dyspigmentation, and rarely scarring, edema, burns
IPL				
	Epilation, skin rejuvenation, improvement of pigmentation problems (e.g., sun damage, age spots), improvement of appearance of vascular lesions	500–1,300 nm	Up to ~56 J cm^{-2}	Pain, erythema, hypo- or hyperpigmentation, crusting, vesicle formation, and eye injury (visual loss, pain, photophobia, pupil distortion, and iris defects)
LED				
	Mild acne	415 nm or 415 nm + 633 nm	415 nm: up to 48 J cm^{-2} 633 nm: up to 126 J cm^{-2}	None or mild erythema
	Skin rejuvenation	633 nm or 633 nm + 830 nm	633 nm: up to 150 J cm^{-2} 830 nm: up to 66 J cm^{-2}	None or mild erythema
Low-frequency and radiofrequency EMF				
	Skin rejuvenation	15 Hz, pulsed, combined with radiofrequency electric current (1 MHz)	1.5 mT peak Unknown SAR, device power 80–200 W, tissue temperature 42–46°C	Transient heat sensation, pain, erythema, edema likely related to radiofrequency current Transient heat sensation, tenderness, erythema, hyperesthesia; incidents of burns, blisters, scarring, nodules or lumps Transient discomfort, edema, tingling; incidents of altered sensation/neuropathy, burns, blisters, necrosis, ulceration, abscess, scarring, nodules, or lumps
	Body shaping	27.12 MHz	Unknown SAR, device peak SAR without cooling 10^5 W kg^{-1}	
	Epilation	5.8 GHz		

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Table 1. *(Continued)*

Modality	Treatment	Wavelength/ frequency	Applied energy/ power of device	Adverse effects reported
Ultrasound				
	Skin tightening, wrinkle removal, body sculpting, and reshaping	MFU: 4–10 MHz HIFU: 0.2–7 MHz	0.4–1.2 J mm^{-2} 40–350 J cm^{-2}, often delivered in several passes of around 30–55 J cm^{-2} per pass	Mainly transient: mild pain during and after treatment, erythema, edema, bruising, skin burns (2 cases, one of which second-degree burn)
Combined				
Optical (laser, IPL, infrared) + RF current	Epilation, skin rejuvenation, body shaping, wrinkles, scars	Laser: 900 nm IPL: 400–1,200 nm IR: 680–1,500 nm RF: 1MHz	Optical: 10–50 J cm^{-2} RF: 10–100 J cm^{-3}	Common effects include varying levels of transient erythema, edema, irritation, and discomfort/pain; less common effects include blistering, crusting, and pigmentary changes
Optical combinations	Skin rejuvenation	Laser: various IPL: 550–950 nm IR: 780–1,000 nm	Laser: up to 1,500 J cm^{-2} IPL: up to 30 J cm^{-2}	Mild transient effects, including erythema, edema, and hyperpigmentation
Ultrasound (US) + RF current	Body shaping	US: 0.2 MHz RF: 0.8 MHz	US: 141 W RF: 35 W	Mild transient effects, mainly erythema and edema
Home use				
Laser	Hair loss, epilation, skin rejuvenation, wrinkles, scars	Hair loss: 630–680 nm Epilation: 800–810 nm Antiaging: 400–1200 nm	Up to 24 J cm^{-2}	Mild transient effects, including erythema, edema, discomfort/ pain, blistering, and crusting.
IPL	Epilation	400–2000 nm	Up to 23 J cm^{-2}	In a clinical setting mild transient effects, including erythema, edema, and discomfort/pain; when self-administered, greater incidence and severity of adverse effects when the device was used by a subgroup of darker-skin types
LED	Mild acne, skin rejuvenation Stimulation of hair growth	405–860 nm	Up to 126 J cm^{-2} Up to 67 J cm^{-2}	Usually no effects reported; occasional reports of transient effects, including mild erythema and minimal skin dryness and hyperpigmentation

36 J cm^{-2} for the treatment of vascular conditions (Meesters et al. 2013). Lasers used for skin resurfacing can deliver fluences up to 150 J cm^{-2} (Alexiades-Armenakas et al. 2008). In the case of laser lipolysis, the total energy delivered is much greater, ranging from hundreds to thousands of joules accumulated in the treatment area (Tagliolatto et al. 2012).

Most of the information available on adverse health effects comes from case studies that assessed the efficacy of treatment while documenting complications arising from the laser exposure. Many of the studies were conducted by clinicians and consultants who were directly involved in providing treatment. These studies generally had a higher emphasis on the efficacy of treatment while maintaining established safety controls and safe industry practice.

A review of the literature describing various cosmetic laser treatments in clinical settings reported permanent adverse health effects were comparatively rare (Husain and Alster 2016; Al-Niaimi 2016). Transient adverse health effects included erythema, edema, crusting, pain, infections, skin pigmentation changes, and allergic reactions to disrupted tattoo ink (Husain and Alster 2016). Transient effects such as mild erythema, edema, and pain usually resolved within hours to days. For other side effects such as infections, purpura, milia, etc., the resolution time was found to be longer, ranging from days to months (Husain and Alster 2016). Permanent effects, some characterized as major, were generally restricted to various types of scarring and skin pigmentation changes (Al-Niaimi 2016). Adverse effects were generally more common in darker-skinned individuals due to higher concentrations of melanin in the skin resulting in greater absorption of the optical energy (Fitzpatrick skin type IV to VI) (Fitzpatrick 1988). Risks also appeared higher in patients taking photosensitizing drugs due to the target chromophore being more sensitive to the optical energy (Paasch et al. 2017). Complications were highly dependent on the treatment applied and the wavelength used (Husain and Alster 2016; Paasch et al. 2017). Hammes et al. (2012) reported that, overall, the

delivery of excessively high energy for the indicated treatment could be considered the primary cause of most unexpected side effects.

Overall, there were very few large studies specifically focusing on adverse health effects from cosmetic laser treatments. Case studies were generally limited to subjective measures of adverse health effects such as during treatment. Other studies were limited by small sample sizes and focused on inappropriate treatment for the indication or misuse of the laser (Hammes et al. 2012). Complications and adverse health effects of cosmetic lasers were transitory in nature and could be managed with sufficient posttreatment care (Husain and Alster 2016; Lim and Lanigan 2006).

Intense light source (ILS) devices

ILS devices used for cosmetic procedures include intense pulsed light (IPL) and LED devices. IPL devices have been used since the 1990s to treat vascular lesions (Babilas et al. 2010). IPL devices use pulsed (typically in the millisecond range) xenon flash lamps which are filtered to generate visible light and infrared radiation in the 450 to 1,300 nm wavelength range. The size of the treatment site ranges from 1 to 6 cm^2 (Town and Ash 2009). IPLs usually come with optional filters to further customize the emission spectrum. Similarly to lasers, IPL devices operate on the absorption of photons by endogenous or exogenous chromophores within the skin, thus generating heat. In the common IPL application of hair reduction, this heat eventually destroys the targeted tissue, i.e., the hair follicle (Town and Ash 2009). IPLs are available that emit a range of wavelengths, pulse duration, pulse intervals, and energy levels up to 45 J cm^{-2}, depending on the condition being treated (Goldberg 2012). Besides hair reduction/removal, IPLs are also used in the treatment of wrinkles and scars, and other skin conditions. In all applications, IPLs are normally used in conjunction with an optical coupling gel for optimum results. The use of this gel reduces light reflection from the skin, allowing for a more efficient treatment. The IPL hand piece must be slowly moved across the treatment area, which leads to an unavoidable overlap of sequential pulses. This overlap can lead to overtreatment of the overlapped area, resulting in burns. This is especially true if the spatial distribution of the light output is nonuniform (Town et al. 2012).

Intense pulsed light. There have been many reports of adverse side effects associated with the use of IPLs, such as edema, erythema, blistering, hypopigmentation, hyperpigmentation, atrophy, scarring, keloid formation, and infection (Zelickson et al. 2014). Most of the more serious side effects have been associated with the higher-power professional-use devices and associated with operator error (Zelickson et al. 2014). Other causes of error include inaccurate calibration and other device malfunctions (Zelickson et al. 2014). There have also been reports of irreversible eye damage when the IPL device was used close to the eye; even, in some cases, when protective eyewear was reported to have been used (Ricci et al. 2015; Lee et al. 2011; Jewsbury and Morgan 2012; Javey et al. 2010; Pang and Wells 2008; Sutter and Landau 2003). It is also critical to assess the skin type of the client receiving treatment prior to use as darker skin types are particularly at risk of unexpected, adverse events (Babilas et al. 2010). It is important for the client to avoid ultraviolet (UV) exposure immediately before and in the weeks following IPL treatment to avoid unexpected pigmentation effects (Babilas et al. 2010). Before starting the full treatment, an initial test exposure is also recommended to evaluate any ill effects several weeks later (Babilas et al. 2010). For hair reduction/removal, treatments are typically administered at 1 to 2 wk intervals with up to a total of 4–5 treatments (Juhász et al. 2017).

Light-emitting diodes. LEDs have gained popularity in recent years as a safer source for light therapy (Hession et al. 2015), making them especially well suited for use in the home or other nonprofessional settings. The action of nonthermal LED light is called photobiomodulation or low-level light therapy (Wunsch and Matuschka 2014). Exposure to visible and near-infrared light from LEDs is thought to trigger intracellular photobiochemical reactions through absorption by chromophores/pigments such as porphyrins, flavins, and other absorbing entities within the mitochondria and cell membranes (Barolet and Boucher 2008). Absorption in the mitochondria is thought to affect cell metabolism which leads to modulation of reactive oxygen species, increase of blood flow, and prevention of apoptosis (Barolet and Boucher 2008). LEDs emitting in the 600 to 1,300 nm range have been shown to be useful in promoting wound healing, tissue repair, and skin rejuvenation, mainly through stimulation of collagen production (Wunsch and Matuschka 2014). Blue LED devices have been marketed for the improvement of mild acne, using energy levels up to 126 J cm^{-2}. Red LEDs have been marketed for reducing the inflammatory response in inflammatory mild acne, for improving the appearance of wrinkles/signs of photoaging (Wunsch and Matuschka 2014), and for treating alopecia (Lanzafame et al. 2013, 2014; Kim et al. 2013). Infrared (830 nm) LEDs have also been used in combination with red (630 nm) LEDs to treat wrinkles (Lee et al. 2007). In general, LED devices have gained widespread acceptance for use in skin rejuvenation, using energy levels up to 150 J cm^{-2} but much lower irradiance (50–70 mW/cm^2) when compared to lasers and IPLs (peak irradiance >100 W/cm^2) in clinical settings with low risk of side effects (Ablon 2018; Opel et al. 2015; Hession 2015).

In summary, ILS devices are being marketed to treat a multitude of cosmetic concerns, and demand for these devices is expected to grow in the future. The risk of adverse

side effects from IPLs is high, though most of these will resolve with time. Irreversible eye injuries during IPL procedures are of particular concern. These have occurred due to the lack of appropriate protective eyewear in some cases. In other cases, these injuries were caused because the optical energy from the laser or IPL traveled through the skin to the eye, usually when the laser/IPL was used on the eyebrow or very near to the eye. The risk of adverse side effects from LEDs is quite low, but precautions such as the use of protective eyewear are still necessary (ISO/IEC 2019).

Devices applying electromagnetic fields (up to 300 GHz)

A limited number of cosmetic applications use magnetic fields or EMF with frequencies up to 300 GHz. There is an extensive literature on so-called "radiofrequency" devices for cosmetic purposes, but the vast majority of these concern direct application of radiofrequency alternating current to the body (Sadick and Rothaus 2016). Although these devices have considerable potential for adverse effects (Tremaine and Avram 2015), they do not employ NIR as a treatment modality and thus fall outside the scope of this ICNIRP statement. However, electrodes and cables can act as secondary sources of radiofrequency EMF with a strength that may exceed ICNIRP occupational reference levels (Stam and Yamaguchi-Sekino 2018; ICNIRP 1998). Virtually all of the peer-reviewed publications identified for devices applying EMF are uncontrolled, nonrandomized case series, and the majority of these were supported by the manufacturer or had one or more authors that were paid consultants or board members of manufacturers.

Pulsed low-frequency magnetic fields are used for the treatment of skin laxity or wrinkles but usually in combination with radiofrequency current, which is a likelier source of the observed adverse effects (temporary heat sensation, pain, erythema, and edema) (Krueger et al. 2012; Few et al. 2016). The pulse repetition frequency is 15 Hz, and a peak magnetic flux density of 1.5 mT per pulse has been reported (Krueger et al. 2012). This exceeds ICNIRP's occupational reference level at the equivalent frequency of 1,000 Hz for a pulse duration of 0.5 ms (Jokela 2000; ICNIRP 2010). This also indicates that there is at least a potential for health risks for clients (nerve stimulation). Recently, pulsed low-frequency magnetic fields with an average repetition frequency of approximately 10 Hz have also been applied for abdominal muscle stimulation and fat reduction (body shaping) (Jacob and Paskova 2018; Jacob et al. 2018; Kinney and Lozanova 2019). Information on the exact magnetic flux density and pulse duration or induced electric field strength are lacking. Since the magnetic pulses are reported to be strong enough to cause muscle contractions, their strength would certainly be expected to exceed ICNIRP occupational reference levels at the position of the client. The only reported side effects were muscle soreness or fatigue and mild discomfort.

Radiofrequency EMF devices at the diathermy frequency (27 MHz) are used for subcutaneous fat reduction (body shaping), primarily in the abdomen and thighs. The applied radiofrequency power of up to 200 W results in tissue heating (up to 46°C in fat and 44°C in skin), but the exact dosimetry in terms of local specific absorption rate (SAR) has not been reported. The adverse effects reported in peer-reviewed papers are relatively mild and last up to an hour (warmth, tenderness, erythema) or up to a week (discomfort, hyperesthesia) (Fajkosova et al. 2014; Key 2014; McDaniel and Samkova 2015; Moradi and Palm 2015; Pumprla et al. 2015; Fritz et al. 2016; Hayre et al. 2016; Fritz and Salavastru 2017; Suh et al. 2017). In addition to the aforementioned mild adverse effects, the MAUDE database with reported adverse events involving medical devices of the US Food and Drug Administration (FDA) for the period 2007–2018 includes reports of burns, blisters, scarring, nodules, or lumps for this particular radiofrequency EMF device, which had cleared away within 7 wk (US FDA 2018).

A device that generates EMF in the microwave range (5.8 GHz) was originally developed for the treatment of severe hyperhidrosis (excessive sweating), which is classified as a medical condition and therefore outside the scope of this ICNIRP statement. It has, however, also been applied for a cosmetic purpose, namely axillary hair reduction (Brauer et al. 2017). Peak local SAR can reach 10^5 W kg^{-1}, but surface cooling is applied to the skin to limit potential damage (Johnson et al. 2012). Local anesthesia is applied during the treatment, but the reported side effects can be more severe than those reported for body shaping at diathermy frequencies. Published short-term adverse effects days after treatment include discomfort, edema, or tingling in 26% to 55% of subjects. Rarer adverse effects lasting 1 wk to 6 mo in up to 18% of subjects include edema, altered skin sensation, or ulnar neuropathy (Brauer et al. 2017). In addition, US FDA's MAUDE database for the period 2007–2018 includes multiple reports of burns, blisters, or necrosis lasting up to 3 wk, and ulceration, abscess, scarring, nodules, or lumps lasting up to 1 y (US FDA 2018). Since the treatment aim was often unrecorded, it is possible that these were related to the device's use for hyperhidrosis. However, the authors state that the device was used for hair removal in the same manner as the technique cleared by the US FDA for hyperhidrosis treatment (Brauer et al. 2017).

For all cosmetic devices using EMF with frequencies lower than 300 GHz, there is a distinct lack of measurement data of field strengths experienced by the client or by the worker who administers the treatment and also a lack of dosimetric studies of the resulting induced electric field strengths and specific absorption rates. More information

on these parameters would help to improve the risk assessment for these devices.

In summary, radiofrequency devices have the potential for serious adverse effects in at least a subpopulation of treated clients. Incident reports submitted to the US FDA tend to list more severe and longer-lasting adverse effects than peer-reviewed publications.

Ultrasound

The two main types of ultrasound for cosmetic applications are microfocused ultrasound (MFU) and high-intensity focused ultrasound (HIFU). MFU is mainly used for skin tightening and for removal of wrinkles, but also for body sculpting. HIFU is mainly used for body sculpting or reshaping through fat reduction, but also for skin tightening. Both types of applications are popular because they are noninvasive. This statement does not consider ultrasound applications combined with procedures involving skin penetration, such as liposuction.

MFU treats the superficial layers of the skin using relatively low levels of energy, i.e., 0.4–1.2 J mm^{-2}, a frequency of 4–10 MHz, and focal depths of 1.5–4.5 mm (Alam et al. 2010; Fabi 2015). By adjusting energy and focal depth of the emitted ultrasound, treatment can be adapted to the physical characteristics of individuals. MFU achieves its effects by heating the tissue (above 60°C) to produce small thermal coagulation points within the mid-to-deep reticular dermis (at 3.0 mm) and subdermis (4.5 mm). Overlying dermal and epidermal layers are spared (Laubach et al. 2008; Wulkan et al. 2016). The stated aim is to briefly elevate the local temperature to at least 65°C. Collagen contraction begins to occur at this level. In addition to local coagulation, the application of heat causes collagen in the subcutaneous fat layer to denature and contract, resulting in shorter, thicker collagen fibers. New viscoelastic collagen also forms in areas of tissue coagulation to obtain lifting and tightening of lax skin and decrease visible wrinkling, e.g., on the face including around the eyes, neck, elbow, or behind the knee.

No randomized controlled trials evaluating MFU were found. Many of the studies and reviews of MFU (e.g., Fabi 2015; Wulkan et al. 2016) have investigated treatment effectiveness and appear to have been associated with manufacturers of an FDA-approved device (conflicts of interest and sources of support were often unstated). There is no available official documentation of equipment or treatment regimens (Toivo et al. 2017). Reviews of safety have also been industry sponsored (e.g., Teitelbaum et al. 2007; Hitchcock and Dobke 2014). Existing evidence suggests that most side effects are short lived (up to 10 d); however, long-term follow-up beyond 6 mo is lacking. Many commercial websites describe mild side effects such as transient mild pain and erythema. Pretreatment analgesia or anesthesia (e.g., nerve-block) has usually been administered. Consistently reported common adverse effects are erythema and edema (Hitchcock and Dobke 2014); pain, bruising, increased skin pigmentation, numbness, and transient paralysis also occur (Wulkan et al. 2016). Acute heat-induced eye injury, namely acute increase in intraocular pressure and accommodation spasm, has been reported after tightening of the eyelid with MFU (Chen et al. 2018).

In cosmetic procedures, HIFU is used mainly for ablating subcutaneous adipose tissue for body contouring. The frequencies of devices vary from 200 kHz up to 7 MHz with energies reaching over 1,000 W cm^{-2}. The fluence varies around 40–350 J cm^{-2} and is delivered in several passes. One device, for example, targets fatty tissue using a total energy of around 165 J cm^{-2} at a frequency of 2 MHz, often delivered in several passes of around 30–55 J cm^{-2} per pass, at a focal depth of 1.1–1.8 cm (Fatemi 2009). The actual energy per pass depends on the degree of pain an individual can tolerate. This is performed across a varying number of sessions (e.g., from 1–8 over 4 wk). HIFU ablates fat cells (e.g., of abdomen, thighs, back, buttocks), sparing the epidermis and dermis above and tissues and organs below, by the same mechanism as MFU; viz., heat causing focal coagulation and necrosis of fat cells with subsequent inflammation and repair and diffuse collagen fiber retraction. Cavitation is also considered part of the destructive effect; eventually adipocytes rupture under the rapid alternance of positive and negative pressures (Bani et al. 2013). These broken-down fat cells are then cleared through normal metabolic processes. In addition, some shearing effect is thought to occur with production of small bubbles as a result. These bubbles react by either moving back and forth (noninertial cavitation) or by expanding and shrinking until they implode (inertial or transient cavitation), thereby creating new bubbles as well as heat and, possibly, free radicals (Holland et al. 1996). HIFU has also been described as a method to reduce hyperpigmentation by reducing melanin deposition in the epidermis. In a small study, UVB-induced skin hyperpigmentation was significantly reduced after 2 wk of HIFU treatment with 0.2 J cm^{-2} and 3 wk after HIFU with 0.1 J cm^{-2} (Choi et al. 2016).

Reported studies of HIFU have often been associated with industry; although for many, authors have not made any declarations about conflicts of interest or sources of support. There have been no randomized controlled trials, although a few clinical studies have compared treated and untreated sites, like the thighs, within the same individuals (e.g., Nassar et al. 2015). The majority of reports have been based on single-center case series ranging in size from 6 to 152 subjects. Use of analgesia (e.g., with paracetamol) or of anesthesia has been sporadically reported.

Adverse effects reported for HIFU range from mild pain, erythema, and edema of skin lasting a few days in a

study of 46 people treated for fat reduction of the flanks (Gold et al. 2018) to more prevalent and wide-ranging effects in a study of 152 volunteers treated for abdominal adiposity with different energy levels (range 47–331 J cm^{-2}) (Gadsden et al. 2011). These included pain after treatment (~75%), edema (~75%), bruising (~66%), pain during treatment (~66%), tingling (60%), erythema (45%), and two people experienced skin burns, which were second-degree for one (Gadsden et al. 2011). Pain scores were higher when higher energy levels were used (Robinson et al. 2014). Blood lipids have not been perturbed in studies that have assessed this (Shek et al. 2009).

In summary, most reported adverse effects from cosmetic ultrasound procedures have been temporary and resolved in a week or so, but no documentation exists, to our knowledge, on long-term follow-up beyond 6 mo.

Combined devices

There are a number of devices that combine different modalities in an attempt to achieve a better cosmetic result. These devices are used for various cosmetic treatments including epilation, skin tightening/rejuvenation, and body shaping, and to treat wrinkles, mild acne, and scars. The most widely used combination is the application of radiofrequency current together with optical energy from laser, IPL, and/or infrared. Although the direct application of radiofrequency current is not NIR, its widely used combination with optical radiation was considered important to include in this statement. In these devices, the optical energy is used to preheat the target tissue. This creates small temperature differences between the target and the surrounding tissue, which lowers the tissue's impedance. The lower impedance makes the tissue more susceptible to the RF current so that it can be selectively treated (Lolis and Goldberg 2012). A variety of combined optical sources are used (IPL: 400–1,200 nm; laser: 900 nm diode laser most common; infrared: 680–1,500 nm) with energy fluences ranging from 10 to 50 J cm^{-2}. The devices mainly combine a bipolar radiofrequency current source (monopolar and fractional radiofrequency sources are also used) operating at 1 MHz with radiofrequency energies ranging from 10 to 100 J cm^{-3} (Lolis and Goldberg 2012). Several reviews have reported that these devices use lower optical energy levels than those used in traditional light-based systems, thereby enabling potentially safer treatments (Lolis and Goldberg 2012; Goldberg 2013). Further, it is claimed that these combined devices can be used on a wider range of skin types because radiofrequency energy is not readily absorbed by the melanin abundantly found in the epidermis of darker skin types, theoretically sparing it from damage (Nouri 2011).

There were no randomized clinical trials (up to 2017) that investigated the safety of devices combining optical and radiofrequency modalities. There have been quite a number of case series investigating the efficacy of these devices, which also reported side effects. It is important to note that these studies were often financed by the cosmetics industry, and the authors of many of the studies had professional interests with the cosmetics industry. In general, these studies did not report serious adverse effects but did report transient, less serious adverse effects, including varying levels of erythema, edema, irritation, and discomfort/pain. Less common were reports of blistering, crusting, and pigmentation changes (both hypo- and hyperpigmentation). It is difficult to discern from these studies whether the side effects were due to the optical energy or due to the RF current. Given that the optical energy in combined devices is lower than in traditional optical treatments, it may be likely that the RF current is responsible for the side effects. In some studies, subjects were treated with both combined and optical-only sources and reported more side effects with the combined treatment (Sochor et al. 2011; Ryu et al. 2013; Verner and Kutscher 2017), although this could have been due to the increased energy from the combination rather than the RF alone.

A smaller number of devices combine different optical modalities, with fluences up to 30 J cm^{-2} for IPL (Alma Laser 2019) and 1,500 J $cm^{-2}$for laser (DEKA 2019), used mainly for skin rejuvenation. Only a few case series studies have reported mild transient adverse effects from therapies that have combined laser, IPL, and/or infrared, including erythema, edema, and hyperpigmentation (Ruiz and Rivero 2014; Tao et al. 2015). Kearney and Brew (2012) compared a laser combined with IPL treatment to laser-only and IPL-only treatments and found no statistically significant difference in adverse reactions between the different treatment groups.

There are also devices that combine ultrasound with other modalities, mainly radiofrequency current, for body contouring and ablation of adipose tissue (Lindberg and Martensson 2013). These devices first apply the radiofrequency current in order to preheat the target tissue, thereby increasing local blood circulation and creating mild edema. This in turn is claimed to enhance the cavitational mechanical effects of the subsequent focused ultrasound treatment (Mulholland et al. 2011). Exposure information on these devices is scarce, but one study reported the application of RF at a frequency of 0.8 MHz and power 34.5 W and ultrasound at 0.2 MHz and 141 W (Chang et al. 2014); no energy fluence information was available. There are only a handful of case series studies investigating the combined RF current and ultrasound devices. These studies reported only mild transient effects, mainly erythema and edema, which were most likely due to the thermal damage from the RF current rather than secondary to thermal or mechanical effects of the ultrasound waves (Mulholland et al. 2011).

In general, combined devices have not been shown to produce serious adverse effects, and the limited research has reported only mild to moderate transient effects.

Home-use devices

Home-use cosmetic devices are becoming increasingly popular, with numerous products available to consumers for purchase at retail stores, beauty salons, and on the internet (Hession et al. 2015). The majority of home-use devices use laser and intense light sources and are marketed for cosmetic applications, such as epilation, skin tightening/rejuvenation, hair growth, and mild acne treatment (Town and Ash 2010; Hession et al. 2015; Juhász et al. 2017). Several companies also sell ultrasound devices (ultrasound cavitation slimming machines) for home use. The lack of any specific regulations controlling the operation of home-use devices has allowed a number of such products to be sold in some international markets without reliable evidence-based data on safety (Town et al. 2012). Furthermore, the proliferation of home-use devices demonstrates a movement from professional oversight to individual consumer use, which may further raise safety concerns (Thaysen-Petersen et al. 2012). Potential safety issues include unintentional misuse in darker skin types and treatment of sun-tanned skin, moles, or pigmented tattoos, which increases the risk of skin damage. Further, accidental exposure to the eye may cause reversible or irreversible ocular damage (Thaysen-Petersen et al. 2012).

Home-use devices operate at a variety of wavelengths including laser (630–680 nm for hair growth, 800–810 nm for epilation, and 400–1,200 nm for antiaging), IPL (400–2,000 nm for various procedures), and LED (405–860 nm, mainly used for mild acne and antiaging) (Thaysen-Petersen et al. 2012; Hession et al. 2015; Juhász et al. 2017). Many of these devices include a contact sensor to reduce the chance of eye exposure by switching off the optical exposure when the sensor registers a loss of contact with the skin. Some devices also have a built-in skin type/color sensor because treatment is often contraindicated in very dark skin types. Given that home-use devices are designed for personal use without medical supervision, they often operate at lower exposure levels, with a recent review estimating five times less energy delivered (Juhász et al. 2017) compared to professional devices. Reported fluences include up to 24 J cm^{-2} for laser and IPL, and up to 126 J cm^{-2} for LED (Thaysen-Petersen et al. 2012; Hession et al. 2015; Juhász et al. 2017).

Research on the safety of various home-use devices is limited and has been previously reviewed by Hession et al. (2015) and Juhász et al. (2017). The available studies are primarily industry-sponsored case series with small sample sizes and a lack of long-term follow-up (Hession et al. 2015). In these studies, where cosmetic home-use devices were applied under clinical conditions, mild to moderate transient erythema was the most consistently reported adverse effect followed by varying levels of discomfort or pain; other common effects included edema, blistering, crusting, and pigment changes. There is a paucity of information on the prevalence of self-treatment with home-use devices where there is a greater chance of adverse effects given the uncontrolled setting. In a study by Wheeland (2007), where a home-use epilation device was self-administered, mild to moderate transient erythema and slight pain during treatment were reported; however, there was greater incidence and severity of adverse effects when the device was used by a subgroup of people with darker skin types. One article about a home-use IPL device for tattoo removal reported that a user developed severe keloids after attempting self-treatment for tattoo removal and warns that these types of devices are unsafe for home use and should be completely avoided (Friedmann et al. 2017). In addition, there are concerns that the eyes of the client may not be sufficiently protected, especially in the home or other nonmedical settings, e.g., salons or esthetic clinics. However, as noted previously, eye injuries have occurred even when the treatments were performed by a medical professional (Ricci et al. 2015; Lee et al. 2011; Jewsbury and Morgan 2012; Javey et al. 2010; Pang and Wells 2008; Sutter and Landau 2003). These results highlight the importance of product information including appropriate package labeling (see the Regulation section).

There are also various home-use devices that use ultrasound for skin tightening/rejuvenation and wrinkle treatment, but no studies were found on the safety of these devices.

In general, the limited research on the safety of home-use devices has reported mild to moderate transient adverse effects on the skin when devices are used properly, but an increase in adverse effects in darker skin types has been shown. Many home-use devices are now equipped with skin-sensing technology that limits use on darker skin types, tanned skin, or pigmented lesions such as nevi or tattoos (Juhász et al. 2017). No ocular damage has been reported in the small amount of research into safety of these devices (up to February 2019).

ADVERSE EFFECTS FROM MISUSE OF COSMETIC DEVICES

Reports of adverse effects from cosmetic laser and IPL devices that are directly attributable to misuse are rare, but there have been some documented cases of problems when incorrect settings or the incorrect device for the indication was used. The reports of eye injuries during laser and IPL use near the eye are most likely due to failure of the practitioner to apply appropriate eyewear to the patients during the procedure as mentioned earlier (Ricci et al. 2015; Lee et al. 2011; Jewsbury and Morgan 2012; Javey et al. 2010;

Pang and Wells 2008; Sutter and Landau 2003; Huang et al. 2018).

One retrospective survey (Hammes et al. 2012) demonstrated severe and unexpected adverse health effects such as burns and scarring caused by inappropriate application of lasers by untrained service providers using both photographical and statistical evidence. Hammes et al. (2012) reported that, overall, the delivery of excessively high energy for the indicated treatment could be considered to be the primary cause of most unexpected side effects.

Another study of twelve cases of adverse effects from tattoo removal using lasers, IPLs, and a radiofrequency device indicated that the equipment parameters chosen for treatment were inappropriate to minimize thermal damage to surrounding skin tissue (Wenzel and Landthaler 2009). The adverse health effects included extensive scar formation and pigmentation changes. Except in the case of the radiofrequency device, the authors attributed the adverse health effects to incorrect settings or unsuitable cosmetic devices for the treatment. This resulted in excessive energy delivered to the treatment area being dissipated thermally into surrounding tissue, causing effects such as burns and scarring. The practitioners in this study included medical practitioners and medical laypersons.

Another case series examined probable causes of the adverse health outcomes from optical treatments, based on the practical experience and professional medical credentials of the treatment providers (Greve and Raulin 2002). These included incorrect diagnosis of the conditions treated resulting in improper treatment, use of the wrong laser type (wavelength, pulse length), inappropriate or incomplete consultation with the patient to inform on risk and gather lifestyle data, no test treatments being performed, and most commonly, inappropriate energy settings (i.e., fluence too high).

It has been identified that the treatment of pigmented skin lesions with NIR for cosmetic purposes may present a serious indirect risk to the health of patients. Based on a small number of case reports, treating pigmented lesions like melanocytic nevi (moles) with NIR without prior histopathological diagnosis to exclude melanoma could be especially hazardous and worsen prognosis (Gottschaller et al. 2006; Zipser et al. 2010). However, there is no evidence that laser or IPL treatment of benign lesions such as nevi or lentigo maligna causes malignant transformation (Hibler et al. 2017).

Most of the studies that examined the negative outcomes of misuse of light-based cosmetic devices identified a fundamental lack of competency in one of two key areas of safety in performing cosmetic treatments. These were an appropriate level of clinical knowledge of human physiology and response (understanding the biophysical mechanisms of light interaction with target pigments) and the knowledge of the physics and properties of the equipment used to deliver treatments (Hammes et al. 2012; Greve and Raulin 2002).

Despite some assertions that misuse is more prominent when nonmedical persons perform cosmetic treatments, a study examining cases of litigation in the United States for adverse health effects due to negligence from laser cosmetic treatments reported that over 50% of the personnel conducting the treatment were physicians (Jalian et al. 2013).

Further research is required to compare cosmetic light-based treatment application by medically trained vs. untrained providers. This may provide useful information on whether the nature of adverse health effects is inherent to laser use in all settings or a function of treatment providers' level of competence.

For devices employing EMF or ultrasound, no data were found that indicated that the observed adverse events resulted from misuse of the device or inadequate protection measures.

OCCUPATIONAL EXPOSURE

No studies were found that examined direct health risks from NIR exposure to workers administering treatment with cosmetic NIR devices. For optical devices, hazards are possible to workers carrying out cosmetic procedures (or to those in the vicinity) from inadvertent exposure (Smalley 2011). A worker exposed to a direct or reflected laser beam, for example, may suffer an injury to the eye and/or the skin. The eye is generally regarded as the organ at greatest risk from accidental exposure to light-based cosmetic treatments. Recommendations have been published on the safe use of light-based cosmetic treatments for operators (Smalley 2011; FPTRPC 2011a)

Another possible occupational hazard related mainly to ablative laser treatment is the generation of airborne contaminants such as toxic gases, biological materials, and even viruses (Smalley 2011). Studies have shown that high-powered lasers used in cosmetic procedures release various environmental toxins and suspected carcinogens into the workplace (Eshleman et al. 2017; Chuang et al. 2016). Chronic exposure to gaseous and particulate matter has been linked to detrimental health effects, including lung cancer and other cardiopulmonary diseases (Eshleman et al. 2017; Chuang et al. 2016). It has been suggested that an effective local exhaust system equipped with chemical extraction and particulate capture be used by practitioners who regularly perform cosmetic procedures using powerful lasers (Eshleman et al. 2017; Chuang et al. 2016).

For cosmetic devices using EMF, given that ICNIRP occupational reference levels can be exceeded at the client level by pulsed low-frequency magnetic fields

(Krueger et al. 2012), they could potentially also be exceeded at the level of nearby workers. Similarly, since thermal effects are induced in clients being treated and given the maximum occupational exposures reported for similar devices with medical therapeutic use (Stam and Yamaguchi-Sekino 2018), it is possible that ICNIRP occupational reference levels can also be exceeded near cosmetic devices using radiofrequency EMF. In countries that already apply ICNIRP reference levels and basic restrictions, existing regulation should be adequate to protect workers administering the treatments against EMF-related risks of cosmetic devices.

There is very little information on occupational exposure to ultrasound used for cosmetic procedures. The attenuation of ultrasound in air is very high, specifically at the very high frequencies used in clinical ultrasound, but the main reason for the lack of effect of ultrasound traveling through air is the 99.9% reflection when it reaches the skin surface (NCRP 1983). The technique, therefore, does not pose any direct risks to workers who apply it to patients or clients.

GROUPS AT PARTICULAR RISK

It has been suggested that pregnant women may be more susceptible to postinflammatory hyperpigmentation and hypertrophic scars and have reduced wound healing (Gontijo et al. 2010) though there are no scientific data supporting this. Due to the lack of evidence available for the safety profile of cosmetic NIR procedures during pregnancy, experts recommend that these procedures should not be performed during pregnancy (Gontijo et al. 2010; Lee et al. 2013; Trivedi et al. 2017). Low-frequency and radiofrequency EMF generated by cosmetic devices can exceed both occupational and general public reference levels for clients and can penetrate the body to a depth sufficient to reach internal organs (see, for example, Mohammed and Saber 2014). Additional safety measures may therefore be necessary for pregnant clients who undergo cosmetic treatment with devices using EMF and for pregnant workers who operate such devices.

As previously mentioned, dark-skinned individuals (Fitzpatrick skin type IV to VI) are at greater risk of negative side effects from light-based cosmetic treatments. (Paasch et al. 2017). This is due to the higher concentration of melanin within these darker skin types. Although the skin may not be the target of the treatment (epilation, vascular lesion treatments, etc.), the melanin in the incidentally exposed skin absorbs the optical energy delivered by these devices and will either undergo photothermolysis in the same way as other pigments or alternatively, absorb large amounts of energy resulting in collateral damage during dissipation into surrounding tissue. Darker-skinned individuals are therefore at greater risk of adverse effects including burns and postinflammatory hyperpigmentation and hypopigmentation. One study comparing IPL and laser epilation on dark-skinned subjects demonstrated that the laser treatment resulted in less severe observed side effects than the treatment conducted with the IPL device (Goh 2003).

There are a number of other factors that could increase the risk of adverse effects from cosmetic NIR procedures, including sun exposure, medication or supplement use, compromised skin, and certain medical conditions. After a cosmetic NIR procedure, it is recommended that a person avoid sun exposure to prevent postinflammatory hyperpigmentation (Drosner and Adatto 2005). There is little evidence to support this recommendation; however, it is considered "good advice" (Thaysen-Petersen et al. 2015). There is also a lack of evidence on whether taking photosensitizing medications (e.g., isotretinoin) and supplements (e.g., St John's wort) increases the risk of adverse effects; however, they remain possible risk factors (Kerstein et al. 2014; Waldman et al. 2017). Damaged or compromised skin from a number of conditions (including eczema and oral herpes) has been reported as contraindications for light-based cosmetic treatments from industry sources (Consumer Services Industry Authority 2003; Australian Skin Clinics 2015); however, there are no data on the specific effects. Particular medical conditions including diabetes, autoimmune diseases, and disease that can result in reduced wound healing or excessive blood loss could be contraindications to cosmetic NIR treatments (Paasch et al. 2017). There are industry recommendations in the United Kingdom for people with these conditions to consult with a medical practitioner prior to undertaking any cosmetic procedure (Consumer Services Industry Authority 2003). Overall, there is a lack of evidence for the above contraindications for cosmetic NIR procedures, and further evidence is needed to evaluate possible risks.

Cosmetic NIR devices combining pulsed low-frequency magnetic fields with radiofrequency current may cause interference with active implanted medical devices such as pacemakers (Boston Scientific 2017). Cosmetic NIR devices operating at diathermy and microwave frequencies generate EMF that may constitute a potential risk for wearers of active medical devices and for passive metallic implants (Boston Scientific 2017; Medtronic 2016; St. Jude Medical 2018). Risks for clients wearing active medical devices may also occur if they undergo ultrasound treatment, unless precautionary measures are taken (Medtronic 2016; St. Jude Medical 2018).

GLOBAL REGULATION

Cosmetic applications typically require exposures to humans that are far higher than would be permitted by the

ICNIRP guidelines; they are thus not compliant with them. Strict application of guidelines that preclude any harm would represent one solution to the issue. However, these would also exclude any benefits from cosmetic applications as described above. Further regulations may offer a more effective means of preventing serious harm associated with the use of cosmetic devices, as well as of ensuring transparency regarding potential limited harm that is intended to ultimately result in a beneficial effect. Accordingly, current regulation practices are described below.

Regulation of NIR from cosmetic devices can be subdivided into regulation governing device marketing and consumer safety (safe design, protection of clients and users) and regulation governing the health and safety of workers in clinics and beauty institutions that operate the devices. There is some variation globally in the extent to which cosmetic devices are regulated in a similar way to medical devices.

Regulation of device marketing and consumer safety

In the European Union, the safety of medical devices is governed by the regulation on medical devices. The regulation determines that certain classes of cosmetic devices that work on the same principle as the equivalent medical device are also subject to the requirements of the regulation on medical devices. The cosmetic devices in question include devices to reduce, remove, or destroy adipose tissue and devices employing high-intensity NIR for skin resurfacing, tattoo or hair removal, or other skin treatment. Common specifications list the key elements in the risk management and clinical safety evaluation of these cosmetic devices. Individual EU member states can have more specific regulation of, or guidance for, the professional groups using the devices.

In the United States, the US FDA has the authority for the regulation of medical devices and all electronic devices emitting radiation on the market. The US FDA can also take action against devices that are marketed without FDA review, clearance, or approval. The devices regulated by the US FDA include lasers, IPL sources, radiofrequency devices, and ultrasound devices. The US FDA does not make a distinction between devices used for medical purposes and those used for cosmetic purposes. As long as they are deemed to affect the structure or any function of the body of humans or animals, they are considered to be medical devices. With regard to professional use, some states have no oversight, some states require licensing, and in some states only medical practitioners can attain a license for the use of lasers and IPLs in cosmetic applications. Medical practitioners are allowed to delegate procedures based on training, depending on circumstance or jurisdiction.

In China, NIR devices are approved and classified in a similar way to the United States by the China Food and Drug Administration. There are strict rules for training and qualification requirements for health care professionals using these devices. However, any technology registered as a medical device is prohibited for use by the beauty therapy sector.

In Japan and South Korea, there is no specific national regulation for the use of NIR-emitting devices for cosmetic purposes. Cosmetic devices, including energy-based devices such as high-power lasers and IPL sources, are considered medical devices, which are regulated by law. There is no separation in the definition of medical or cosmetic devices.

In the Russian Federation, regulation for the registration and marketing of medical products applies, among others, to any medical devices used for modification of anatomy or physiological functions of the body. ICNIRP was unable to ascertain to what degree this regulation also applies to cosmetic devices. In addition, all medical devices and activities must comply with a federal regulation that lists fixed emission limits for NIR (EMF, thermal radiation, visible optical radiation, and ultrasound).

In Australia, there is no uniform national regulation for the use of NIR-emitting devices for cosmetic purposes. Three out of eight Australian states and territories license the use of lasers for cosmetic applications, and one state licenses the use of IPL devices. The federal government's Therapeutic Goods Administration may be involved in approval and safety reports of imported lasers for cosmetic purposes. No regulation of radiofrequency or ultrasound cosmetic devices exists. There is no radiation protection standard for home-use devices. In 2019, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), through collaboration with the states and territories of Australia, published advice for the use of light-based cosmetic treatments performed by lasers, IPLs, and LED phototherapy. The advice promotes safety in the delivery of cosmetic services by focusing on good practice for cosmetic treatment providers and risk awareness for consumers.

International standardization organizations, such as the International Electrotechnical Commission (IEC) and International Organization for Standardization (ISO), and in Europe the European Committee for Electrotechnical Standardization (CENELEC), have developed technical standards with specifications for safe design and assessment of exposure of clients or workers to NIR from medical and cosmetic devices. These can be harmonized with government regulation to provide a means of assessing compliance with the regulatory requirements, for example, those of the EU regulation on medical devices.

Regulation of worker health and safety

In the European Union there is specific legislation for the protection of workers against the risks of EMF and

optical radiation with binding exposure limits based on the ICNIRP guidelines available at the time of publication (EU Directives 2013 and 2006). These apply to all worker exposure from devices for cosmetic purposes.

In South Korea, there are legal limits for occupational exposure to radiofrequency EMF based on the ICNIRP (1998) guidelines.

In Australia, ARPANSA's national advice for cosmetic treatment providers also provides information on common standards to aid in managing risks to personnel performing treatments. In Australian states where there is a regulatory framework in place, protection of workers performing laser or IPL treatments is in place and managed through the licensing process.

In China, the national standard with occupational exposure limits for physical agents in the workplace has limits for radiofrequency EMF that are lower than the reference levels in the ICNIRP guidelines for frequencies up to 300 MHz. For EMF with higher frequencies, the limits can be higher or lower than ICNIRP reference levels depending on exposure duration. The occupational limit for low-frequency electric fields equals the ICNIRP general public reference level, but there are no limits for low-frequency magnetic fields. For optical radiation, there are limits for ultraviolet and laser radiation, which are similar to (but not identical with) those in ICNIRP guidelines.

In Russia, there are federal regulations for workers with occupational exposure limits for EMF, infrared and ultraviolet radiation, and ultrasound. The occupational limits are similar to ICNIRP occupational reference levels for infrared and ultrasound, but for EMF they are stricter and depend on the duration of exposure.

In Japan, there are no legally binding limits on occupational exposure to NIR. Health and safety legislation contains a general obligation to prevent health impairment due to radiation, high temperatures, and ultrasound. The Japan Society for Occupational Health has recommended occupational exposure limits for radiofrequency EMF that are based on the ICNIRP (1998) guidelines.

In the United States, there are no legal limits for occupational exposure to EMF or optical radiation that would apply to workers near cosmetic devices. The American Conference of Governmental Industrial Hygienists has recommended exposure limits to supplement professional occupational health and safety programs. In many states, voluntary consensus standards published by the American National Standards Institute are used to protect workers from non-ionizing radiation exposure.

Does current regulation provide sufficient safety?

As described above, regulation varies substantially both within and across most countries, with the degree to which it provides adequate safety and transparency similarly variable. Indeed, in some countries there is neither regulation of NIR cosmetics devices nor requirement to comply with ICNIRP guidelines for occupational exposure. Not only does this compromise health and transparency for the consumer, but it also reduces consumer confidence in the adequacy of the science underpinning the regulations that are used. Contrary to this variability in regulation, the science underpinning regulations is independent from geography. Accordingly, in order to reduce harm associated with the use of cosmetic devices and to provide adequate transparency for consumers, ICNIRP considers it important that regulations are developed and adopted worldwide that cover all types and frequencies of cosmetic NIR devices.

CONCLUSION

Cosmetic devices that use NIR for the purposes of modifying appearance have become well established. These devices achieve their outcomes through the deposition of energy into specific target tissues. Devices can be broadly categorized by NIR modality. Light-based devices including lasers, IPLs, and LEDs are applied for epilation, tattoo removal, pigment reduction, skin tightening, and fat reduction. Devices employing EMF and ultrasound are generally used for fat reduction or skin tightening. There are also devices that combine different modalities, where one component is used to effect changes in the target tissue that assists the other component in delivering the required energy for the cosmetic outcome (Lolis and Goldberg 2012). In addition to these devices being employed in a clinical setting or by treatment providers, some are also available for purchase by individual consumers for use at home. The home-use devices are typically lower-power optical and ultrasound devices (Hession et al. 2015; Juhász et al. 2017).

By its nature, the application of energy to biological tissue at levels high enough to cause an effect presents a potential for adverse health effects to occur. The potential health effects of cosmetic NIR procedures have not been well studied, and often the available research is focused on efficacy and conducted by clinicians and consultants with direct involvement in providing treatment (Husain and Alster 2016; Al-Niaimi 2016). The majority of peer-reviewed publications identified were uncontrolled, nonrandomized case series.

The possible adverse effects of the treatments can differ based on the modality of use and on the desired effects. The adverse health effects can be either transient or permanent; however, permanent effects for all modalities are rare. Common, less serious effects include pain, temporary erythema, swelling, and changes in pigmentation. Less common, longer-lasting, and more severe side effects include burns, blisters, scarring, persisting erythema, altered pigmentation, and eye damage. There are also reports of a small number of

cases where clinical error (incorrect diagnosis) or device misuse (incorrect energy settings or wrong device for indication) resulted in avoidable and serious health complications (Wenzel and Landthaler 2009).

There is limited evidence that certain groups are at particular risk from these cosmetic treatments. These groups include people with darker skin (Fitzpatrick skin type IV to VI), pregnant women, individuals with high sun exposure, people taking photosensitizing medications or supplements, and people with particular medical conditions. This increased risk proposed for certain groups was generally specific to the use of light-based treatments.

Occupational injuries or health effects resulting from the operation of cosmetic NIR devices are rare, and there are few reported occurrences (Smalley 2011). Of highest concern for occupational exposure is injury to the eyes both from direct exposure and from reflected light (Smalley 2011). Another risk to consider is the indirect effect of air contamination when using lasers for cosmetic treatments. For cosmetic devices using radiofrequency EMF, there is the potential that occupational exposure limits can be exceeded if adequate protection measures are not applied.

Within the scope of the countries included, regulation of NIR cosmetic devices varies significantly across the world. In the European Union, United States, China, Russian Federation, Japan, and Korea, these devices are considered analogous to medical devices and are regulated accordingly in terms of their performance and risks. However, existing regulation does not always cover all types of cosmetic devices or frequency ranges identified by ICNIRP. For example, the EU medical device regulation does not cover cosmetic devices using EMF for purposes other than lipolysis or devices for cosmetic ultrasound treatment. There are also variations in oversight regarding the use of cosmetic devices, specifically regarding the levels of training or qualification of the treatment provider. In Australia, there is a general lack of consistency. Only three out of eight applicable jurisdictions in Australia regulate the use of some of these devices for cosmetic purposes. Protection of workers applying NIR treatment also varies. Where there is regulation, most countries set limits or recommendations based on ICNIRP guidelines for occupational exposure.

In summary, the majority of the identified literature regarding the use of NIR cosmetic devices was focused on the efficacy of the treatment rather than adverse effects or complications. Most of the studies that assessed health effects consisted of case reports and case series with small sample sizes. These studies have limited use in assessing the nature of any adverse effects and their prognosis. More randomized controlled trials are required to assess the full impact and potential for adverse health effects in the use of NIR cosmetic devices keeping in mind the challenge in establishing a control group among cosmetic clients. In view of the potential for adverse health effects already identified and the regulatory gaps discussed, it would be useful to explore the feasibility and likely benefit of a regulatory framework for cosmetic NIR devices.

In order to reduce harm associated with the use of cosmetic devices, ICNIRP considers important that regulations that cover all types and frequencies of cosmetic NIR devices are adopted worldwide and that there is greater oversight regarding their use.

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APPENDIX

List of search terms:

- NIR exposure—non-ionizing, optical, laser, light, ILS, IPL, LED, electric, magnetic, electromagnetic, radiofrequency, microwave, EMF, ultrasound, combined, home use, professional, occupational, worker.
- Treatment—cosmetic, esthetic, aesthetic, epilation, hair, tattoo, skin, wrinkle, scar, acne, rosacea, pigment, body, lipolysis, cellulite, bleaching, curing, vascular lesions, pigmentation.
- Studies—human, meta-analysis, systematic review, randomized clinical trial, epidemiological, case-control, cohort, cross-sectional, ecological, case series.