

The increasing use of cosmetic non-ionising radiation applications – types of procedures, potential risks to consumers and regulation in Australia

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Key points

- Cosmetic procedures using non-ionising radiation (NIR) have become very popular, however reports of avoidable injuries from inappropriate or incorrectly performed procedures are continually highlighted in the media
- More research is needed on the health risks of cosmetic NIR applications in order to determine the overall public health impact
- Regulation of cosmetic NIR procedures is limited and inconsistent in Australia. To mitigate the impacts of this gap in oversight, national advice has been published for consumers and treatment providers

Abstract

In recent years, there has been a large increase in cosmetic applications using non-ionising radiation (NIR). These applications use various types of NIR such as lasers and ultrasound for numerous cosmetic outcomes such as epilation, skin rejuvenation and tattoo removal. Cosmetic NIR procedures are marketed as a low-cost and low-risk alternative to more invasive procedures. However, treatments with these devices always result in high NIR exposure to targeted tissue in order to ensure efficacy of treatment. Consequently, there is always a risk of adverse health effects from these procedures, which may be temporary or longer lasting. Research on the health risks of cosmetic NIR applications is lacking, particularly on the extent of poor treatment application or misuse. In Australia, except for the banning of solarium, there is no national regulation for the use of NIR devices for cosmetic purposes and only three states have established regulatory controls for certain optical cosmetic applications. To mitigate the impacts of this gap in oversight, the Australian Radiation Protection and Nuclear Safety Agency has published national advice for consumers and service providers that give information on cosmetic NIR treatments and the potential risks involved.

Introduction

Cosmetic procedures using non-ionising radiation (NIR) have grown significantly in popularity and availability in recent years in Australia. They are used for the elective treatment of perceived problems in appearance for purely aesthetic reasons such as epilation, skin rejuvenation and tattoo removal.¹ NIR is distinguished from ionising radiation as not carrying enough energy to ionise atoms or molecules (i.e. remove electrons from their orbit) which can change the chemical composition of material. NIR has less energy but can still excite molecules and atoms causing them to vibrate faster which can lead to a range of biological effects.²

There is a common public perception that cosmetic NIR procedures are quick, easy, painless and low risk, and are often marketed as such. However, many of these procedures are complex and require a high level of application skill and experience, and after-treatment care. In Australia, cosmetic NIR procedures may be performed by medical professionals as well as non-medical providers such as beauty and dermal therapists. The lack of consistent regulation and poorly defined training requirements across different Australian jurisdictions have resulted in service providers having various levels of training and expertise.³ Further, cosmetic NIR procedures can also be performed using home-use devices.

Reports of injuries, increased media coverage and industry calls for greater regulation of non-surgical cosmetic procedures using NIR have led health authorities to consider these potential problems within the cosmetic industry. The aim of this paper is to increase awareness of the possible risks associated with cosmetic NIR applications, present an overview of the regulatory framework for these procedures in Australia and provide information and advice to the wider community.

Types of cosmetic procedures using non-ionising radiation

There are different types of cosmetic NIR applications, which can be broadly classified according to the type of radiation that is used, including optical radiation (laser, intense pulsed light, and light-emitting diode), low frequency and radiofrequency electromagnetic fields, and ultrasound. There are also solarium devices employing artificial ultraviolet radiation for tanning, but their commercial use is banned in Australia because there is strong evidence of skin cancer induction following exposure^{3,4}; so these devices are not covered here. The different types of NIR modalities achieve the various cosmetic outcomes via specific biomechanisms and these are described in detail elsewhere.¹ In general, cosmetic NIR applications achieve their desired outcomes through the deposition of energy into specific target tissues. The different types of NIR modalities and typical cosmetic procedures are summarised in Table 1.

There are also cosmetic procedures that combine different types of NIR in an attempt to achieve a better cosmetic result, for example combining optical radiation with radiofrequency. In addition to cosmetic NIR procedures being performed in commercial settings by treatment providers, home-use devices are also available for purchase by consumers. The home-use devices typically employ lower power than devices used in commercial settings, however, they are also often lower cost and poorer build quality with less robust safety features.⁵

What are the possible risks of cosmetic non-ionising radiation treatments?

There are risks associated with the use of NIR in cosmetic procedures because the application of energy to biological tissue at levels high enough to cause an effect presents a potential for adverse health effects to occur.¹ The potential health risks of cosmetic NIR applications have not been well investigated, with the majority of research consisting of uncontrolled, nonrandomised studies with small sample sizes. Further, the available research has mainly focused on the efficacy of the desired aesthetic outcomes rather than adverse effects or complications.⁶

From the available research, the possible adverse effects can vary by the type of NIR modality and procedure and they can be either transient or permanent; however, permanent adverse effects are rare.¹ The more common and less serious adverse effects include pain, temporary erythema, swelling and changes in pigmentation. More severe adverse effects, which are less common but can be longer lasting, include burns, blisters, scarring, persisting erythema, altered pigmentation and eye damage. Many of the severe adverse effects may be preventable with good application technique, however, gaps in the oversight of industry practice may contribute to the occurrence of preventable injuries. Specific research is required on the frequency of adverse effects and how they relate to particular NIR cosmetic procedures and the training and experience of the service provider.

There are also a number of other factors that could increase the risk of adverse effects from cosmetic NIR treatments, and particularly from applications using optical radiation.¹ These include having dark skin (Fitzpatrick skin type IV to VI)⁷, high sun exposure, using photosensitising medications or supplements, damaged or compromised skin, and certain medical conditions. For people with active implanted medical devices such as pacemakers, there is the risk of interference when undergoing cosmetic treatments using electromagnetic fields and ultrasound. It is important for individuals to provide information about any of these factors to the treatment provider before starting any cosmetic NIR procedure. Further, this information should form part of the service provider's risk assessment of the client, either as a regulatory requirement or as part of industry best practice.

Although it has been suggested that pregnant women may be more susceptible to various adverse effects, there is no scientific evidence to support this.⁸ Medical advice should be sought by pregnant women considering cosmetic NIR procedures. There is limited research on children, therefore parents or guardians should consider cosmetic NIR treatments on children to be conducted

Table 1. Types of NIR cosmetic procedures, possible adverse effects and existing regulation in Australia^{1,3}

Non-ionising radiation modality	Typical procedures	Possible adverse effects	Regulation in Australia
Optical radiation			
Laser	Epilation, skin rejuvenation, tattoo removal, vascular lesions and pigmented lesions, scar reduction	Pain, erythema, edema, burns, pigmentary alterations, blistering, crusting, scarring	Tasmania, Queensland and Western Australia
Intense pulsed light	Epilation, skin rejuvenation, vascular and pigmented lesions	Pain, erythema, pigmentary alterations, crusting, eye injuries	Tasmania
Light-emitting diode	Skin rejuvenation, mild acne, hair growth	Erythema	None
Electromagnetic fields			
Low frequency	Skin rejuvenation	Pain, erythema	None
Radiofrequency	Epilation, body shaping	Pain, erythema, edema, blisters, burns, scarring	None
Ultrasound			
	Skin rejuvenation, body shaping	Pain, erythema, edema, burns, bruising	None

under the supervision of medical professionals. Further research is needed on whether pregnant women and children are at greater risk and whether specific regulatory controls are required to limit NIR cosmetic applications for these groups.

There have also been reported incidents of avoidable injuries received by consumers from the misuse of cosmetic NIR applications.⁹ However, current information on the extent of inappropriate or incorrectly performed procedures in Australia is limited. The causes of injuries can include:

- Untrained service providers
- Inappropriate use of a device (e.g. incorrect energy settings or wrong device for indication)
- Contraindications not considered or not disclosed by the client
- Safety procedures not followed (e.g. use of protective eyewear)
- Poor equipment design or function.

There are specific gaps in the knowledge of how often avoidable injuries occur and how the possible causes described above contribute to reported injuries. More research is therefore needed on the effects of cosmetic NIR applications, particularly on the extent of poor treatment application or misuse, to determine the overall public health impact.

Regulation in Australia

Regulatory frameworks for cosmetic devices using NIR are limited and inconsistent in Australia. The regulatory controls in place only cover optical devices in three jurisdictions: Tasmania, Queensland and Western Australia.^{10,11,12} All of these states regulate the use of high-emission cosmetic lasers, and Tasmania also

regulates the use of intense pulsed light devices, through a combination of licensing premises and/or treatment providers. These regulations specifically focus on qualifications of providers, compliance with standards of devices and the physical practice environment. There are no regulations that deal with devices that use electromagnetic fields or ultrasound in commercial settings and there is no oversight for home-use devices for any modality. The Therapeutic Goods Administration may be involved in approval and safety reports of some cosmetic lasers, however, there is no restriction on importing NIR cosmetic devices into Australia.¹³

A previous analysis has investigated the impact for greater regulation for optical cosmetic procedures and the costs versus benefits of its implementation.⁹ The analysis explored various aspects of a mandatory or self-regulating regime, including the appropriate level of training and qualifications as well as the specific licensing requirements of service providers and how these relate to different types of cosmetic procedures. The analysis concluded that there was not enough verifiable information on the health burden of NIR cosmetic procedures to pursue regulatory oversight. Comprehensive NIR cosmetic injury data collection and analysis are therefore required for Australian states and territories to be able to develop regulation for these applications.

Information and advice

Given the possible risks associated with cosmetic NIR procedures and inconsistent oversight across Australia, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) has published national advice for cosmetic treatments using lasers, intense pulsed light devices and light-emitting diode phototherapy.^{14,15} The

advice for consumers contains educational material to help them make informed decisions about undergoing cosmetic NIR treatments based on risk information and indicators of reputable treatment providers. The advice for treatment providers focuses on standards of service delivery, risk communication to clients, qualifications and training available to deliver cosmetic procedures and injury reporting. It contains information about treatment risk assessments such as skin type, hair colour and medical or lifestyle factors that may present contraindications to undergoing treatments, and refers to specific equipment and practice standards to promote safety.

Conclusion

With advances in technology, increasingly sophisticated devices that use NIR are being introduced for cosmetic procedures. It is important to ensure that their use does not carry unwarranted risks to health. More research and evidence of harm is required if further and consistent regulation is to be considered in Australia. As a priority, research is needed on the burden of injury resulting from NIR cosmetic treatment, including data on complaints from consumers who have experienced an injury and clinical data on injury presentations (e.g. through hospitals and general practitioners/Primary Health Networks). Specific information that is required includes data on types of injuries, how often they occur and the circumstances that led to the injury (type of NIR modality, type of cosmetic treatment, qualifications of the provider, etc). This research will inform regulatory authorities in different Australian jurisdictions whether greater regulation is required, the types of NIR treatments regulation needs to cover and the types of controls regulation needs to include (licensing requirements, qualifications of service providers, standards of treatment delivery, etc). Further to the need for more research, public awareness should be expanded on the potential risks related to NIR, both through government and industry stakeholders. Information and advice should cover all NIR cosmetic applications, with a strong focus on qualifications and training available to deliver cosmetic procedures and injury reporting.

Peer review and provenance

Externally peer reviewed, not commissioned.

Competing interests

KK, DU and RT are employed by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), which is an Australian Government organisation providing information and advice on protecting people and the environment from the harmful effects of radiation.

The International Commission on Non-Ionizing Radiation Protection (ICNIRP) is an independent body setting guidelines for non-ionising radiation protection. KK is a member of the ICNIRP main commission and chair of the project group on NIR exposure for cosmetic purposes – these are voluntary, non-paid positions

RT is a member of the World Health Organization International Advisory Committee and steering member of the Basic Safety Standard for protection of people from non-ionizing radiation exposure. These are voluntary, non-paid positions.

TW is a member of the Radiation Health and Safety Advisory Council, which advises the chief executive officer of ARPANSA on emerging issues and matters of major public concern relating to radiation protection and nuclear safety. This position is remunerated by way of a sitting fee for council meetings. TW also represents Standards Australia as the head of Delegation, Co-convenor of TC76 working 7 – high power lasers & secretary of TC76 Working group 8 – Development and maintenance of basic standards. These positions are voluntary, although travel support is available to attend international meetings. TW is the chairman of committee Standards Australia SF019, which is responsible for developing and publishing Australian laser safety standards. This is a voluntary position.

Author contributions

KK and DU wrote the manuscript with contributions from RT and TW. All authors read and approved the final manuscript.

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