

Burn Injury Following Noninvasive Radiofrequency Lipolysis: A Rare Complication Highlighting Regulatory and Medico-legal Issues

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ABSTRACT

OBJECTIVES: The escalating demand for nonsurgical body contouring and skin rejuvenation has led to a surge in the use of radiofrequency techniques. Despite their popularity, scientific investigations of devices and parameters remain inadequate, resulting in a lack of evidence-based clinical trials. In this case report, we have highlighted the potential hazards of noninvasive radiofrequency fat reduction by presenting a severe burn case. Our objective was to underscore the importance of scientific rigor in establishing treatment parameters and the need for regulatory oversight in the aesthetic industry.

MATERIALS AND METHODS: A 47-year-old female underwent radiofrequency therapy at an unregulated aesthetic clinic, resulting in a full-thickness deep tissue burn. We have outlined the patient's history, treatment details, and subsequent care, emphasizing the absence of medical supervision during the procedure.

RESULTS: The patient developed a 6 cm × 6-cm full-thickness burn, necessitating operative management. Despite initial nonoperative measures, the burn progressed, leading to a permanent scar and contour irregularity.

CONCLUSIONS: This case highlights the urgent need for improved regulation, training, and safety protocols in the aesthetic industry, especially concerning radiofrequency devices. The Montgomery principle emphasizes the necessity

of informed consent, and the complexities of medical device regulations and indemnity considerations warrant increased regulatory oversight. Collaborations among legal experts, regulatory bodies, medical professionals, and nonmedical practitioners are essential to ensure patient safety in an evolving aesthetic landscape.

KEY WORDS: *Aesthetic industry, Deep tissue burn, Fat reduction and skin tightening*

INTRODUCTION

The increasing demand for body contouring and skin rejuvenation has led to an upsurge in the use of nonsurgical techniques, especially radiofrequency techniques, for fat reduction and skin tightening.¹ Radiofrequency-assisted lipolysis employs electromagnetic radiofrequency to induce controlled heating in adipose tissues, promoting neo-collagenesis and achieving fat reduction and skin tightening without skin ablation.² However, despite its growing popularity, the safety parameters of these devices remain insufficiently studied, with settings often determined by marketing priorities rather than scientific evidence.³

The gap in scientific rigor on use of electromagnetic radiofrequency creates a substantial risk, especially as unregulated aesthetic practices can administer these treatments. Although they are generally considered safe, improper use of radiofrequency devices can result in severe complications, including burns requiring surgical intervention. Here, we present a patient who developed a full thickness burn after noninvasive radiofrequency fat reduction. We also discussed the need for enhanced regulation, training, and safety measures in the aesthetic industry to prevent similar burn injuries.

CASE REPORT

A 47-year-old female patient presented to the emergency plastic surgery clinic following radiofrequency therapy to

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bilateral hips for fat reduction and skin tightening at a private aesthetic clinic. The patient had no significant medical history, was a nonsmoker, and used over-the-counter multivitamins but took no other regular medications. She had undergone a single session of radiofrequency treatment on both thighs at an unregulated cosmetic establishment without medical supervision. Unfortunately, information could not be obtained on the exact technology used and the associated settings. During the procedure, she experienced a sudden burning sensation on her right thigh, which lasted approximately 1 minute. Blistering ensued, and, after initial first aid with tepid water for 10 minutes, she sought medical attention.

On the following day, the patient developed substantial swelling; a superficial blistering partial-thickness burn, measuring 6 cm × 6 cm, was evident over the right hip. The burn exhibited a pink, sensate, blanching base, accompanied by indurated subcutaneous fat (Figure 1). Although no collections were noted, substantial swelling was present under the burn area. The patient had no evidence of burns or injury on her left thigh. Conservative management with silver-based dressings (UrgoTel SSD) was performed for 3 weeks, followed by honey dressings (L-Mesitran) for 2 weeks. After 6 weeks, the wound had progressed to a full-thickness burn with underlying fat necrosis encompassing a 6 cm × 6-cm area (Figure 2). At this point, a decision was made for operative management.

The patient underwent debridement under general anesthesia before primary closure of her wound with 20 PDS, 30 Monocryl, and 30 Prolene sutures. After the procedure, the patient required weekly dressing changes for 4 weeks. Sutures were removed at 2 weeks. The patient achieved complete wound healing after 5 weeks but was left with a permanent scar and contour irregularity (Figure 3). She was discharged from acute care with scar management guidance.

DISCUSSION

The prevalence of nonablative radiofrequency treatments in aesthetic clinics has raised concerns about the safety of these devices, particularly in unregulated environments. Despite increasing government pressures with the introduction of the Health and Care Act 2022⁴ in the United Kingdom, which aims to implement licensing requirements for anyone providing cosmetic procedures (including those involving energy devices), no licensing requirements are in place and regulatory oversight remains limited. Because radiofrequency treatment is considered to be generally safe, Paasch and colleagues⁵ highlighted that nonmedical practitioners often provide treatment without any medical supervision. Nevertheless, we have demonstrated here that radiofrequency lipolysis has the potential to cause major burns requiring surgical management. In our case, the factors contributing to the development of a burn only on one

FIGURE 1. Burn at Initial Presentation of Case Patient



FIGURE 2. Burn Area at 6 Weeks in Case Patient



FIGURE 3. Burn Area at 5 Weeks After Debridement and Closure in Case Patient



side were not clear but potentially included radiofrequency probe being incorrectly placed on the skin, inadvertent change to settings providing increased energy, not monitoring the skin temperature throughout the procedure, leaving the probe on one site too long, and not moving to the next anatomical treatment region.⁶

Few publications are available on the rate of burns associated with radiofrequency lipolysis. However, with careful use and monitoring, Fitzpatrick and colleagues⁷ reported an overall second-degree burn incidence after facial radiofrequency skin tightening procedures of 0.36%. Although our patient initially presented with a burn shown as a partial thickness burn, the burn developed into a full thickness burn requiring surgery. This was due to the burn involving the deep tissues and the zone of injury only developing gradually to involve the skin. Thus, regular, prolonged follow-up of patients with radiofrequency burns is necessary to monitor for progression.

Importantly, our patient was never informed of the potential risks of burns before treatment. The Montgomery ruling in the United Kingdom states that all practitioners are “under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment.”⁸ Incorporating the Montgomery ruling means that clinics must ensure patients are educated about the potential for burns resulting from radiofrequency interventions regardless of their rarity. Providing clear and accurate information can equip patients to make informed decisions about their treatments and to fully understand the risks involved.

Integral to this discourse is the complex realm of medical device regulations. The heightened accessibility of radiofrequency devices in aesthetic environments necessitates stringent oversight by regulatory bodies, such as the Medicines and Healthcare products Regulatory Agency (MHRA), The EU Medical Devices Regulation (EU MDR), and the UK Conformity Assessed. From July 1, 2023, the UK Conformity Assessed marking replaced the EUMDR/CE marking with regard to placement of a device on the market in the United Kingdom for all medical devices.⁹ All medical devices must be registered with the MHRA before they are placed on the UK market. The MHRA performs market surveillance of medical devices on the UK market and is able to make decisions over the marketing and supply of devices in the United Kingdom. The role of the MHRA in vetting and certifying the safety and efficacy of medical devices, including radiofrequency platforms, is pivotal to curbing potential hazards. In our case, it was not clear whether the complication was reported to the MHRA and what requirements were in place for aesthetic clinics to report device-related complications.

Of equal importance are the indemnity considerations faced by nonmedical aesthetic practitioners and the clinics offering these treatments. The intricacies of medical indemnity in these cases, and the liabilities incumbent on practitioners without medical qualifications, engender a pressing imperative for increased regulatory oversight required for nonsurgical treatments involving energy devices. Unfortunately, as the Joint Council for Cosmetic Practitioners has highlighted, “currently there is no legal requirement for non-healthcare practitioners to have medical indemnity insurance cover for non-surgical procedures that they provide to members of the public.”¹⁰ The lack of legal requirements for professional indemnity when radiofrequency treatments are performed exposes clinics and practitioners to potential litigations arising from complications such as burns.

Duty of care is also owed to patients; thus, adherence to rigorous training, standardized protocols, and best practices are required. Patients who develop complications in these clinics should be referred to the most appropriate clinic speciality to assess and manage any complications. Clinics must be attuned to evolving legal requirements, including those pertaining to advertising, disclosure of practitioner qualifications, and the delineation of roles between medical and nonmedical staff. The legal obligations extend to ensuring that nonmedical practitioners providing radiofrequency treatments possess the requisite training and skills to mitigate risks and deliver optimal outcomes.

CONCLUSIONS

With the greater use of radiofrequency devices in aesthetic clinics, improved regulation, training, and safety advice on their use are necessary. With relation to the Montgomery ruling, individuals who undergo these procedures should be appropriately consented for the rare but significant complication of burns. This case highlighted the severe consequences of unregulated radiofrequency treatments and the importance of integrating burn care into aesthetic practice. In the milieu of a growing aesthetic industry, collaborations among legal experts, regulatory bodies, medical professionals, and nonmedical aesthetic practitioners are key in ensuring patient safety.

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