Aesthetics
MONTHLY JOURNAL FOR MEDICAL AESTHETIC PROFESSIONALS
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The Last Word

Dr Selena Langdon discusses her concerns with the regulation and marketing of body contouring treatments in the UK and what she believes needs to change to ensure patient safety

The global market for body contouring treatments was estimated by market research company IMARC Group to be valued at US $5.3 billion in 2016 and is forecast to grow at a compound annual growth rate (CAGR) of around 7% during 2017-2022 to reach US $8 billion.[1] Many practitioners will notice the number and type of devices available is growing to meet this demand.

I believe that like many other aesthetic treatments and devices in the UK, there is a lack of appropriate regulation in regards to product safety and pre-market testing. This has led to a growing number of devices being marketed to the public, many of which have little or no evidence of either efficacy or safety. As well as this, many users are implementing misleading marketing messages and using devices, whether they are appropriately regulated and tested or not, in settings with no medical oversight.

An unregulated device market – the root of the issue

The Medicines and Healthcare Products Regulatory Agency (MHRA) is charged with regulating medical devices in the UK to ensure they work and are acceptably safe.[2] If aesthetic devices make no medical claim, they are currently outside the current scope of regulation.[3] The Care Quality Commission (CQC) as the healthcare regulator for England, only licenses and regulates cosmetic treatments that involve surgical procedures and does not regulate the non-surgical sector.[4] This leaves body contouring devices and their operation currently outside the scope of any direct regulation.

In my own practice, I rely on Food and Drug Administration (FDA) clearance as it requires evidence of both safety and efficacy before a device can be marketed in the US.[5,6] In contrast, the current European equivalent for medical devices is the CE Mark, which does not subject the device to a comparable level of scrutiny.[7] As body contouring devices are not, at present, classed as medical devices in Europe and instead are classed as electrical devices,[8] the CE Mark applied to these devices only relates to the Low Voltage Directive (LVD) 2014/35/EU[9] and the Electromagnetic Compatibility (EMC) Directive 2014/30/EU.[10] Both of these require no certification or testing of patient safety, treatment efficacy or post-market surveillance, monitoring or reporting of complications.[9,10] Even if body contouring devices were classed as medical, the requirements for a Class II medical device only differs in that a Notified Body is required to carry out a conformity assessment to approve the manufacturer's declaration.[11] While medical device distributors are required to report adverse events to a competent authority (MHRA), there is no obligation for clinical investigation data to be provided as part of the approval submission for body contouring devices.[11]

Non-medical operators compound the risks

I believe there is an issue with non-medical professionals performing body contouring treatments without the oversight of a medically trained and regulated practitioner. While side effects, complications and other problems can potentially arise from most treatments, the ability to properly assess contraindications such as male gynaecomastia, hernias, tumours, diastasis recti, lymph node enlargement or lipomas is extremely important. Offering body contouring treatments with devices which have not been subject to sufficient scrutiny in a setting where no medical oversight is available only compounds the risks and using such devices when the patient has a contraindication can lead to serious post-treatment complications.

As an example, in 2017 the *Journal of Wound Care* (JWC) reported a complication case that involved a 53-year-old woman. She sustained a significant frostbite injury following a 60-minute unnamed cryolipolysis treatment performed by a beauty therapist in a beauty salon. A few hours after the treatment, it was reported that two painful skin blisters developed with progressive associated erythema. The salon owner did not recommend the patient seek immediate medical attention and the injury progressed to full-thickness frostbite injuries after one week.[12] Unlike non-medics, who do not have

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any professional guidelines to follow, medical operators of body contouring devices have a responsibility to follow professional guidelines and are subject to professional standards such as those laid down by the General Medical Council in its 'Guidance for doctors who offer cosmetic interventions'.[13]
From my personal experience, I am aware that several major body contouring manufacturers and their distributors carry out a process of due diligence on those seeking to purchase and operate their devices. I am told by the manufacturers that the reason for this is to ensure that a medical practitioner is sufficiently engaged in the consultation and treatment process, as they believe that outcomes and safety of the treatment is, in part, operator dependent.

Holding professionals to a higher standard does not guard the public against those not subject to oversight by a professional body. While professional oversight helps to raise standards within a professional setting, it does not capture all operators of the devices. Without sufficient regulations being in place to control the sale and use of the devices, or make medical oversight compulsory, then risks to the public remain.

Marketing

I believe the marketing of body contouring devices is also an issue. The marketing of body contouring treatments is subject to certain standards such as the Cosmetic Interventions Advertising Guidance, and monitoring of compliance with this guidance is the responsibility of the Advertising Standards Authority (ASA).[14,15,16]

The ASA's Cosmetic Interventions Advertising Guidance states, among other requirements:

- advertisements must not mislead by exaggerating the capability or performance of a product or service
- objective claims must be backed by evidence, if relevant, consisting of trials conducted on people

For the ASA to pursue an advertiser for a false claim, it is likely that a patient would need to raise an issue with the ASA and will probably only do so once they become aware that the claims made in the advertising are false. This would occur most likely after a failed treatment or having sustained injury. Advertisers who fail to remove misleading or inaccurate advertisements can be referred by the ASA to the National Trading Standards (NTS). The NTS is the legal backstop for the ASA and can prosecute an advertiser to an unlimited fine or up to two years in prison.[17,18] However, such penalties are used as a last resort and, in most instances, the ads are amended or withdrawn, with more severe penalties applied only to repeat offenders. The incentives for advertisers to make false or misleading claims are therefore high and consumers are afforded only modest protection from false or misleading claims about treatment efficacy and safety.[19]

A change to regulation

An important change in regulation took place on 25 May 2017, with the introduction of EU Regulation 2017/745, which becomes applicable from 25 May 2020.[21] This specifically includes equipment intended to be used to reduce, remove or destroy adipose tissue. The devices will need to undergo clinical evaluations which shall be based on relevant data concerning safety, including data from post-market surveillance, post-market clinical follow-up, and, where applicable, specific clinical investigation. Manufacturers will also have to report serious incidents and other reportable events, as well as supporting the coordination of the evaluation of such incidents and events by competent authorities.[21] The reporting of adverse incidents is important because adverse incidents can occur due to a malfunction, unclear instructions, poor user practises or servicing and maintenance issues. This change in regulation will bring the EU more in line with the standards and practices of the FDA in terms of regulation, monitoring and consumer protection. Although the extent to which the UK regulations will reflect the EU Regulations post-Brexit is difficult to ascertain; I believe this is an extremely positive step forward for aesthetics in the UK.

Where to from here?

The demand for body contouring treatments is growing and the new EU Regulation will increase oversight of body contouring devices. The question is the extent to which the UK will incorporate the new regulation into its own, post-Brexit. I am hopeful that the UK chooses to harmonise with the EU on medical device regulation, which will improve patient safety by providing more oversight, better pre-market testing and more control over the body contouring devices available in the market. Assuming an improved regulatory framework for these devices, clinical evaluation prior to certification and mandatory reporting of adverse incidents to a competent authority (the MHRA in the UK),[21] I expect the market for body contouring treatments to develop in a positive way post 2020. In the meantime, I believe it is necessary for medical practitioners to help patients understand the treatment choices and risks associated with the various methods for body contouring available, provide effective oversight of the treatment and to advertise treatments in line with professional standards and ASA guidance.

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