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# Aesthetics

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## Defensive Strategies CPD

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# Implementing Efficient Defensive Strategies

Expert witnesses Dr Godfrey Town and Dr Ross Martin consider options for defending yourself against patient claims related to lasers and other energy-based devices

**The practice of defensive medicine is not a new concept to the medical profession.** The incidence of complaints that turn into allegations of negligence is certainly on the increase,[1,2] and many aesthetic practitioners may not be aware of how vulnerable they can be to such allegations. There is undoubtedly a need for help and advice on how to stay protected against the commonest occurrences. This article will explain how aesthetic practitioners using lasers and other energy-based devices can ensure they can mitigate their chances of a claim being held against them, as well as defend themselves should they be faced with a claim.

## Legal responsibility

All aesthetic professionals have a 'duty of care', which is a legal obligation not to cause a patient injury while in their care.[3] To mount a legal case successfully against a clinic, a breach of duty, often referred to as negligence, must be suggested by the circumstances surrounding the patient's concern. Contrary to popular perception, the legal test of negligence is actually quite hard to achieve, as a direct act or culpable omission by the defendant has to be demonstrated. This must result in injury to the claimant as a reasonably foreseeable consequence of the act or omission of the defendant. Sometimes insurers will resolve cases by simple negotiation or as a result of mediation on what are called 'settlement terms' rather than by a court, so as to limit their exposure to costs.[4]

The lawyers managing these cases will have some knowledge of the techniques that are being used in clinics, but beyond that they rely on the opinion of experts to decide whether to pursue a case. Insurance companies and defence organisations also employ experts for the same reasons. Ultimately, of course, it is for a court to decide where negligence may or may not lie, but one must remember that few of these cases ever get anywhere near a court.

## Professional responsibility

Additionally, healthcare professionals are also answerable to their licensing bodies regarding the way they carry out their professional duties. Where the conduct of a medical professional is governed by a complex set of rules laid down by regulatory bodies such as the General Medical Council (GMC), it is possible for complaints to reach the attention of these organisations in addition to civil litigation. There are several areas of practice where risks will occur in an aesthetic setting, but this article will focus on those associated with energy-based devices.

## Risks of energy-based devices

Fortunately, in the use of lasers and other intense light sources (ILS) in aesthetic procedures, serious injury is a rare occurrence. In the US, the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) data on complications confirms only eight reports of eye injury with ILS and laser amongst 1,257 medical device reports between 1991-2013.[7] Although it is extremely rare to get an ocular complication, injury to the skin is much more common and must be considered by all practitioners.[8-11]

## Developing defensive strategies for energy-based devices

### Evidence of minimum prior educational requirements

Many new laser and other EBD devices can be operated by the medically-trained healthcare professional or delegated under supervision to 'physician extenders' who have been suitably trained.[12] In November 2015, Health Education England (HEE) published a recommended qualification framework for delivery of cosmetic procedures, providing the indicative content and knowledge elements of training and education for practitioners. The recommended framework is now owned by the newly formed Joint Council for Cosmetic Practitioners (JCCP) and has been adopted and amended. However, the JCCP recognises that its two registers are voluntary and therefore not a legal requirement.[13,14]

The manufacturer or supplier of devices is only responsible for providing the user with basic training in the safe use of the device. In our experience of the aesthetic sector, this rarely includes specific application coaching or preceptorship training.

Increasingly, IPL devices are being operated by personnel from differing professional backgrounds. This makes it very difficult to generalise about the type and quality of training that might be considered adequate. In addition, the professional background and training of operators required by the various regulatory and licensing agencies varies from country to country within the UK.[15-18] In our

## The effect of claims on the practitioner

An area often neglected in discussions on this subject is the effect that this whole process has on the practitioner. Litigation and all the unpleasantness of the process, including the language used by lawyers and the vast amounts of paperwork to be dealt with, can increase levels of stress. Data confirms that practitioners have taken their own life whilst awaiting these proceedings.[5,6]

opinion, a suitable apprenticeship model with both learned theory and a qualified mentor to ensure that workplace skills are developed is the ideal. This will allow for variations in regional rules and provide reassurance to the public that the operator was properly trained. As a general rule, compliance with whichever regulation or licensing requirement is in place in a particular jurisdiction will confer a level of protection for the operator, should a complaint arise. The opposite is that if guidance is available and is ignored, the point will be seized upon by any expert asked to look at the complaint.

**Seeking patients' consent**

It is a general legal and ethical principal that valid consent must be obtained before commencing any physical examination, treatment or personal care for a patient.[19] This principle reflects the right of patients to determine what happens to their own bodies and is a fundamental part of good practice. A healthcare professional (or other healthcare staff) who does not respect this principle may be liable both to legal action by the patient and to action by their professional body.[20]

While there is usually no statute setting out the general principles of consent, case law (common law) in England has established that touching a patient without valid consent may constitute the civil or criminal offence of battery.[21] Furthermore, if healthcare professionals (or other healthcare staff) fail to obtain proper consent and the patient subsequently suffers harm as a result of treatment, this may be a factor in a complaint against the healthcare professional involved. Failing to respect this principle may expose a health professional to both legal action and disciplinary action by their professional body.

Failure to warn a patient of a risk of injury, however small the probability of the risk occurring, denies the patient the chance to make a fully informed decision. It is therefore necessary for healthcare practitioners to give information about all significant possible adverse outcomes and make a record of the information given.[22,23] In the absence of specific guidance for non-medical aesthetic practitioners, this approach should be adopted as best practice.

The legal case of Montgomery in England[24] has been seized upon enthusiastically as 'the most important medical negligence case in the last 30 years' by lawyers looking for new business. In our experience, before this case, it was considered acceptable in the UK only to warn a patient about side effects of treatment that were reasonably common. New case law puts the onus on the practitioner to warn of all side effects that the particular patient might be expected to be made aware of.

According to the GMC, patients attending a consultation must be provided with written information (e.g. patient education brochure) about the proposed procedure or treatment and the patient must be given a verbal explanation of the procedure by a practitioner who is familiar with the treatment, its possible complications and side effects, and any available alternatives. They must have adequate opportunity to read, review and understand the consent form and other material, and have time to reflect on the nature and purpose of the treatment, before reaching a voluntary and informed decision before proceeding with a proposed intervention.[25]

A good technique, and one which we have used, is to leave the room while a patient considers the form in front of them. In our experience, all too often complainants claim that the practitioner sat over the patient watching them sign the form and were given no opportunity to reflect or ask questions.

For consent to be valid, the GMC states that it must be taken, preferably by someone who is competent to perform the procedure, and given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question (normally this will be the patient or someone with parental responsibility for a patient under the age of 18). Acquiescence where the person does not know what the intervention entails is not 'consent'.[26]

Case law puts the onus on the practitioner to warn of all side effects that the particular patient might be expected to be made aware of

Different jurisdictional requirements may apply in regards to consent from 'young people' e.g. aged 16 or 17, but where they are presumed to be capable of consenting to their own medical treatment, consent will only be valid if it is given voluntarily by an appropriately informed young person, capable of consenting to the particular intervention.[27]

Consent must be given voluntarily and freely, without pressure or undue influence being exerted on the person either to accept or refuse treatment. Such pressure can come from partners or family members, as well as commercial pressure from other clinics/practitioners. Practitioners should be alert to this possibility and where appropriate should arrange to see the person on their own to establish that the decision is truly their own.[28]

Some people may wish to know very little about the treatment that is being proposed. If information is offered and declined, it should be recorded in the notes.[29]

Where prospective patients have language difficulties, patients will be asked to bring a trusted relative or friend to translate and ensure that the consent form is fully understood before signing. However, if the staff member giving information is not confident about the adequacy of the translation, treatment should be declined.[29]

The validity of consent does not depend on the form in which it is given. Written consent merely serves as evidence of consent. Although completion of a consent form is, in most cases, not a legal requirement,[21,30] the use of such forms is generally accepted as good practice where an intervention is undertaken. In addition to the actual consent form, the operator may wish to consider making hand or type-written records of the consenting process to support contemporaneously what is stated in the consent form.[31]

Alternatively, or additionally, the use of check-boxes next to the most salient points, to be initialled by the patient, also makes a very clear statement to somebody looking for evidence of consent that it has actually been obtained and is recommended. The use of such defensive techniques has become even more important in England with the introduction of new Montgomery case law.[32] The practitioner has a 'duty of candour' to be honest and open with patients both when explaining a proposed course of treatment, during the procedure and

## Top tips

1. **Appropriately select patients**. Obsessive complaints or unrealistic expectations should certainly 'ring alarm bells'. Full-blown body dysmorphic disorder is well described.[42] You do not have to treat these patients – use a polite excuse like 'this treatment is not really suitable for you'.
2. **Be careful what you say to those around you** whilst performing procedures. The patient may remember and misinterpret statements that you have made.
3. **Decline to comment** on the care provided by other practitioners until you are in full possession of the facts and circumstances.
4. **Use mediation techniques.** If you do find yourself in the position of having a discussion with your patient regarding an untoward incident, it is always best to firstly try techniques that a mediator might use. Determine what the complainer's ideas of what has gone wrong are, why they are upset, correct any misconceptions as far as possible and seek what they are trying to gain from the process.

in the event of an untoward incident. This includes communicating clearly with patients and treating them with respect and dignity. Any misrepresentation of these elements will invalidate consent.[33] The completion of the consent form is only part of the consent process and should only be carried out in the context of an informed discussion with the person giving consent, with more detailed explanation given where necessary. The practitioner providing the treatment is responsible for ensuring that the person has given valid consent before treatment begins. The law does not set any timescale for the validity of consent to an intervention so it remains valid indefinitely as long as it would appear to be reasonable that it is still valid i.e. until completion of the treatment or unless consent is withdrawn by the person.[34]

### Clinical governance and oversight/supervision

The degree of medical supervision required for a laser or other EBD intervention will vary according to jurisdiction. In certain regional areas of England, namely the London boroughs, Nottingham and some Essex boroughs, a licensing scheme exists for establishments that provide 'special treatments', which includes laser and ILS interventions and where the degree of clinical governance is specified.[26] In Scotland, Wales and Northern Ireland this is regulated by Healthcare Improvement Scotland (HIS), Health Inspectorate Wales (HIW) and the Regulation and Quality Improvement Authority (RQIA), respectively. However, the abiding principle to reduce the risk of a complaint, is that there must be an appropriate degree of medical oversight. In particular, a current written treatment protocol should be followed that has been issued by an expert in the procedure using the laser or other EBD and that the protocol's authorship and credentials be identified clearly and be subject to evidence of periodic review.[16-18]
Specific predesigned stationery, adapted to a particular procedure taking place, is often useful in ensuring that the correct parameters for light-based treatments are being recorded as used. For instance, in a typical case of tattoo removal, we would expect to see recorded as a minimum: the wavelengths of laser used, the spot size/energy output (or fluence), pulse duration and the number of pulses or repetition rate of the laser. In the event of an adverse incident, anything less than this would, in our opinion, not allow an investigating expert to make a judgement based solely on the notes about whether the operator had fully understood the principal underlying the use of the machine with which he, or she, was treating the patient. In the UK, a number of organisations, including BAAPS, BAPRAS, BCAM, BAD and the BACN publish ethical guidelines which their members are obliged to follow. Specific treatment-related guidelines published by specialist bodies in the international peer-reviewed press may also serve as a 'benchmark' for best clinical practice.[35,36] When advertising your services, you must follow advertising regulations or codes in your particular jurisdiction. In particular you must be certain that the information that you publish is factually correct and can be checked, and that it does not exploit patients' vulnerability or lack of medical knowledge. Additionally, claims should not be made for the superiority of one practitioner over another.[37,38]

## Good practice

To help keep patients safe, follow guidance on establishing and participating in systems and processes that support quality assurance and service improvement.[39] In particular:

- Comply with any statutory reporting duties in place
- Contribute to national programmes to monitor quality and outcomes, including those of any relevant laser or other EBD registries
- Routinely monitor patient outcomes, and audit your practice, reporting at least annual data
- Report product safety concerns to the relevant national regulator

You should share insights and information about outcomes with colleagues who offer similar interventions, to improve outcomes and patient safety. You must tell patients how to report complications and adverse reactions.[39]

## Resolving disagreements

Generally, patients become annoyed when they perceive that they are not being listened to or feel that they are being 'fobbed-off'. A degree of openness involving a discussion about the patient's own ideas about what has gone wrong, together with their long-term worries and what they consider can be done to redress the balance, is a good course of action. It is important, however, that medical indemnity providers are kept in the loop before this process starts. Procedures would normally be conducted in-house at the initial stage or possibly, in large organisations, by someone designated to this role. Unless this preliminary procedure fails, and again with the permission of the insurer, a form of alternative dispute resolution could be considered. The UK judiciary is keen to reduce the burgeoning number of claims and is looking increasingly towards alternative dispute resolution such as mediation to fill the gap. This is already happening in higher courts.[40,41] Laser and ILS practitioners should also be aware that under the Equality Act 2010, several every day situations encountered routinely in the clinic such as, but not limited to, HIV/AIDS and pregnancy have 'protected' status. In the event of disinclination or refusal to treat a person with any of these conditions could imply a breach of the Act and expose the clinic, its staff and professional consultants to liability claims.[42]

## Conclusion

The incidence of complaints that turn into allegations of negligence is increasing and practitioners are often unaware of their vulnerability to potential litigation. Compliance with regional regulation and licensing provisions will confer a level of protection for the operator, should a complaint arise. Valid patient consent and the practitioner's duty

to be honest and open with patients is vital, as any demonstrated misrepresentation may invalidate consent and expose the practitioner to the risk of prosecution for battery. In the event of a personal injury claim, alternative dispute resolution is encouraged.

## Reflection questions

1. **Which of the following is a useful approach with patients?**
   - **a.** Use of mediation techniques when discussing an untoward incident with a patient
   - **b.** Commenting on the care provided by other practitioners
   - **c.** Treating patients with unrealistic expectations
   - **d.** Chat casually to those around you while performing procedures

2. **Which of the following is NOT an absolute requirement of informed consent?**
   - **a.** Taken by someone competent to perform the procedure
   - **b.** Given voluntarily and freely by an informed person
   - **c.** Honesty when explaining a proposed course of treatment
   - **d.** Written consent

3. **Which of the following is NOT 'Best Practice' guidance?**
   - **a.** Routinely monitor patient outcomes
   - **b.** Focus patient information only on the procedure you offer
   - **c.** Report product safety concerns to the national regulator
   - **d.** Share information with those who offer similar procedures

**Dr Godfrey Town PhD** is an RPA2000 certified laser protection adviser and holds a PhD in light-based therapy from the University of Wales, Swansea and has an Expert Witness Certificate from Cardiff University Law School. He is a registered clinical technologist and has published more than 25 peer-reviewed scientific and clinical papers. He sits on several international laser and light safety standards committees.

**Dr Ross Martin MB, ChB** has worked widely in the cosmetic industry as a practitioner, adviser and expert witness for the last 24 years. He has a special interest in medical and surgical aesthetics and is a recognised laser expert medical practitioner, working with lasers since 1993. He is a qualified mediator. He has owned clinics in Nottingham, Hull and Sheffield and has worked in laser clinics across the country.

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**Answers**

1. Use of mediation techniques when discussing an untoward incident with a patient
2. Written consent
3. Focus patient information only on the procedure you offer