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LASERS

in Dermatological Practice

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CHAPTER 16

Medicolegal Aspects of Lasers in Dermatological Practice

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INTRODUCTION

The use of high energy light sources [laser, intense pulsed light (IPL)] is a booming industry. Lasers were introduced in the specialty of dermatology in the *mid-1960s*. Since then, their wide acceptance and use provide striking evidence of their extraordinary ability to treat, precisely and effectively, a number of skin diseases that were previously incapable of being managed by other medical or surgical methods. Continued evolutionary changes in both the laser IPL technology and the understanding of the mechanisms involved in the laser-tissue interaction have improved the precision with which cutaneous laser surgery can be performed and have also increased the indications for it.

TYPICAL COMPLICATIONS

Laser and intense pulsed light (IPL) treatments are, however, not without their hazards, especially at the hands of a non-specialist, as has become the trend lately. Typical complications arising from laser and IPL treatments are allergic reactions (due to unknown tattoo inks), blistering, burning, color changes (with removal of permanent make-up), contact dermatitis (after hematogeneous dissemination of the allergens), crusts, folliculitis, hypertrophic scarring/keloids, localized herpes virus infections, loss of pigmentation/hyperpigmentation (depending on laser/IPL setting, skin type, and preinterventional or postinterventional sun exposure), paradoxical hair growth (especially with IPL technology) and pruritus. The biggest problems are the treatment of pigmented lesions of uncertain benign/malignant nature without prior diagnosis or histological controls, which often leads to the appearance of an atypical postoperative recurrent nevus or pseudomelanoma. Sometimes, amelanotic melanomas may be allowed to progress without detection and may even metastasize.

Laser burns is another injury which may occur during hair removal. Although usually safe and well tolerated, with the widespread use unexpected side effects can be seen. In recent years, a new laser technology has been

introduced to aid in pain and other side effects in laser applications. Diode laser systems are produced for this technology. The major disadvantage with this laser is the gel application during procedure. Epidermal burn reactions can occur due to accumulated debris on the guide (Kacar SD).

A number of laser specific complications are detailed in a separate chapter and needless to say, the patient should be told about the complications and the course of the sequelae in advance (Table 16.1).

A list of conditions for which litigation was initiated in a study (Jalian HR) is listed in Table 16.2.

It is not surprising that as laser hair removal is the most common “out sourced” procedure, it is the most common cause of litigation. Apart from that, note that in some cases using the laser for indications that are better treated by other means can be a valid cause for litigation. The classic examples are psoriasis and vitiligo. For both, these the excimer laser/light are used which are in no way superior to other forms of therapy, including phototherapy. If not charged (as in certain institutions), it may not be an issue, but if charged, can be a “recipe” for trouble. Nonsurgical sculpting and tightening are classic examples of indications where there is a mismatch of expectations and results, unless patients are counseled well in advance.

WHO IS QUALIFIED TO DO LASER SURGERY?

This question is often asked, especially as the cosmetic laser trend continues to grow, a number of unqualified practitioners have started doing laser cosmetic procedures. Physicians are also increasingly using *physician extenders* (PE) to assist them with such procedures. A physician extender [most commonly a nurse practitioner or physician assistant] is a health care provider who is *not a physician* but who performs medical activities typically performed by a physician. Without appropriate supervision and training one can expect

Table 16.1 Injuries sustained because of laser surgery (Jalian HR, et al.)

Burns	Physical suffering	Eye injury
Scars	Erythema	Death
Pigmentation	Diminished quality of life	Disability
Disfigurement	Ulceration	Infection
Emotional distress	Embarrassment	

Table 16.2 Laser procedures performed resulting in litigation (Jalian HR, et al.)

Hair removal	Tattoo	Pigmented lesion
Rejuvenation	Neoplasm	Others *
Vascular	Scar	
Leg veins	Pigmentary disorder	

* These cases included 6 cases in which the specifics of the procedure were not disclosed, 2 cases related to fat removal, 1 case of skin tightening, and 1 case of psoriasis treatment.

a higher incidence of complications for these nonphysicians (Goldberg). At many places, most notably *wellness facilities, cosmetology institutes, and hair and tattoo studios*, PEs are employed solely, without any supervision by a trained dermatologist. The underlying legal premise supporting this situation is that these practitioners are not treating disease. Thus, there is no need for a diagnosis by a physician, and procedures may be performed by trained laypersons.

While The American Society for Lasers in Medicine and Surgery, American Academy of Dermatology, and the American Society for Dermatologic Surgery have all developed guidelines for PE using lasers in the dermatologic and cosmetic laser setting, though corresponding Indian societies have failed to formulate similar guidelines. In the US, according to most guidelines a PE, where allowed by state law to do laser treatments is required to have a supervising physician on site and immediately available while the laser procedure is being performed.

Since lasers may have untoward effects on the body if incorrectly used, only those persons are legally allowed to use lasers who are qualified in medicine and surgery, i.e. who hold a proper MBBS degree from an MCI recognized medical college. Section 27 of The Delhi Medical Council Act, 1997 deals with “False assumption of Medical Practitioner or Practitioner under this Act to be an offence” and states, “Any person who falsely assumes that he is a medical practitioner and practices the modern scientific system of medicine, shall be punishable with rigorous imprisonment which may extend up to three years or with fine which may extend up to Rs. 20,000 or with both.”

A study by Hammes S, et al. found that the following complications occurred, with laser procedures performed by medical laypersons: 81.4% pigmentation changes, 25.6% scars, 14% textural changes, and 4.6% incorrect information. The sources of error were the following: 62.8% excessively high energy, 39.5% wrong device for the indication, 20.9% treatment of patients with darker skin or marked tanning, 7% no cooling, and 4.6% incorrect information.

VICARIOUS LIABILITY

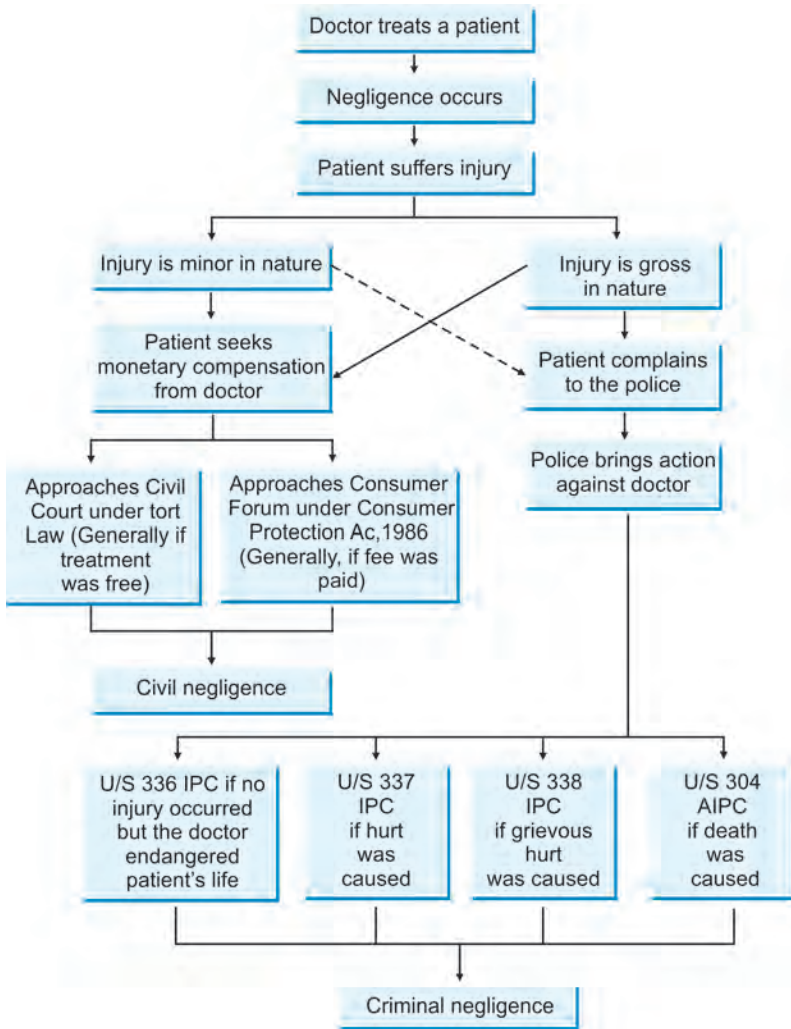
A qualified medical practitioner, however, may ask a PE to assist him in laser surgery. In such cases, the medical practitioner would be liable for all damages (even if actually committed by PE) under the doctrine of vicarious liability (syn., vicarious responsibility). It simply means that a person “A” is liable for the wrongful acts or omissions of “B”, if “B” was under A’s control. It arises under the principle of ‘*respondeat superior*’, which holds that the employer is responsible not only for his own negligence but also for the negligence of his employees, if such acts occur in the course of the employment and within its scope. It is also sometimes known as “captain of the ship” doctrine. As

stated above, this doctrine becomes applicable when the superior had the “right, ability or duty to control” the activities of a violator.

CIVIL AND CRIMINAL NEGLIGENCE

Though cases in consumer forums are common against laser clinics to the best of our knowledge criminal cases are not usually filed. But we will dwell on this aspect as the difference between the two depends largely on how the police interprets the same (Flow chart 16.1).

Flow chart 16.1: Civil and criminal negligence. Action along the dotted line generally does not occur, but is possible



There is no absolute or watertight differentiation between cases of *civil negligence* and *criminal negligence*. If a patient decides to go to a *civil court* or *consumer forum* to ask for compensation, it is called civil negligence. However, if the harm caused to the patient is so great (e.g. death) that he decides to report the matter to police instead, it becomes a case of criminal negligence. A patient can simultaneously sue the doctor in a civil court and can lodge a complaint with the police also. Thus, the same case would be fought in both civil and criminal courts. In such a case, the same negligent action of the doctor would be civil as well as criminal in nature. The differentiation between the two, thus, depends on patient's action (Flow chart 16.1 and Table 16.3). Also, it is important to understand the difference between negligence and misconduct (Table 16.3).

Components of Medical Negligence

For a case of medical negligence to be established, the following components must be present (4Ds). These are the components required for *civil compensation*. For *criminal charges* they do not apply (e.g. Section 336 07 IPC is applicable, even if no damage occurs).

Duty

The doctor begins to owe a duty towards a patient (i) as soon as he agrees to treat him (ii) when he is in emergency (S12(2) Clinical Establishments Act 2010). A doctor-patient relationship between the doctor and the patient is established at that point in time. Doctor-patient relationship is not formed

Table 16.3 Differences between professional negligence and professional misconduct		
<i>Trait</i>	<i>Professional negligence</i>	<i>Professional misconduct (syn. Infamous conduct, ethical negligence, ethical malpraxis)</i>
Offence	Absence of reasonable care and skill in the treatment of patient	No absence of care and skill, but the doctor did not adhere to the ethical standards befitting a doctor
Duty of care towards the patient	The doctor must have a duty towards his patient, which he neglected	No such duty is necessary. Doctor may be accused of professional misconduct even in the absence of such duty, e.g. dichotomy, or when he puts up an unusually large sign board
Damage to the patient	Must be present	Need not be present
Trial by	Civil or Criminal Court	Medical Council of India or State Medical Councils
Punishment	Imprisonment or fine	Warning or erasure of name from the medical register
Appeal	In higher court	To State or Central Governments

when patient is not in emergency, and the doctor did not agree to treat the patient.

Remember in all laser cases, if the doctor initiates treatment, the duty is automatically assigned.

Dereliction of Duty

Once the presence of duty has been established, there has to be a dereliction of duty on the part of the doctor, i.e. the doctor should have been negligent in performing his duties towards the patient.

The interpretation is open to debate but if due consent is taken, checklist followed and patient instructions given in the Appendix of the book this is difficult to prove !

Damage

1. The damage must occur as a result of dereliction, and it must be foreseeable.
2. Even if doctor is negligent, patient cannot sue him for compensation, if no damage has occurred. He can however be sued criminally u/s 336 IPC (Flow chart. 16.1).
3. Some examples of possible damages are as follows:
 - i. Aggravation—of a preexisting condition (Paradoxical hypertrichosis with hair removal lasers).
 - ii. Diminishing patient's chances of recovery.
 - iii. Expenses incurred—e.g. hospital and medicine expenses, special diet and of course lasers !
 - iv. Pain and suffering—causing either physical or mental [embarrassment, fright, humiliation] pain or increasing it.
 - v. Loss of earning—due to absence from work (may be the case if a resurfacing is done, which is not commonly done nowadays).
 - vi. Loss of potency.
 - vii. Prolonging the illness.
 - viii. Reduced enjoyment of life, e.g. loss of a limb or sense.
 - ix. Reduction in expectation of life.
 - x. Death.

Direct Causation

1. Damage must result directly from dereliction (**proximate cause**), and not from any other cause.
2. **Proximate cause** refers to a cause, which in natural and continuous sequence, unbroken by any efficient intervening cause, produces the injury, and without which the injury would not have occurred. It may also be conceived of as a series of “falling dominoes”. If the **final domino**

[damage] can logically fall by “pushing” the first domino [dereliction], the “push” is the proximate cause [direct causation] of fall of final domino.

There is a defense of *Novus actus interveniens*, which is based upon lack of this component. It refers to a situation, where the doctor has been negligent, but a completely unexpected and unforeseen act happened, which further worsened the patient’s condition. The new act intervening should be completely unexpected and unforeseen. Sometimes, referred to as an “Act of God”. It must break the natural chain of causation between the act of negligence and the resulting damage (Fig. 16.1A and B). Thus, injury **no more** remains a proximate cause of doctor’s negligence. This defence is *not available in criminal negligence or criminal activity*.

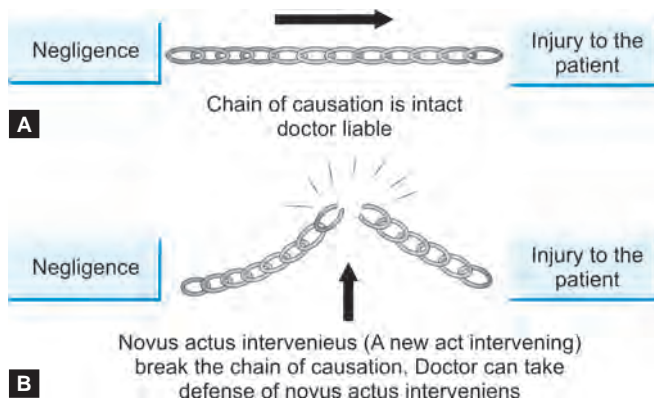
Some examples below would help understand each component above:

Example 1 (Duty): Patient comes to a doctor for treatment of keloid by laser. Doctor demands his professional fee. Patient is not able to give. Doctor refuses treatment. Patient does not take treatment from elsewhere. After some time keloid becomes infected. Patient suffers injury. Patient **cannot sue doctor**, because no duty was established.

Example 2 (Dereliction): Patient comes to a doctor for treatment of hypertrophic scars by laser. Doctor treats him with correct laser, but hypertrophic scars remains. End result is that the patient is not treated. Patient cannot sue, as there was no dereliction on the part of doctor.

Example 3 (Damage): Patient comes to doctor for facial laser resurfacing. Doctor agrees to treat (duty established). Doctor uses lasers carelessly so patient develops blistering and burning (damage). Patient **can sue doctor**. If though despite doctor using lasers carelessly, patient does not suffer any damage, patient cannot sue doctor.

Example 4 (Direct causation): Patient comes to doctor for laser removal of tattoo. Doctor agrees to treat him (duty is established). Doctor fails to use



Figs 16.1A and B: Concept of (A) proximate cause and (B) novus actus interveniens

the right laser (dereliction occurs) * Tattoo is not removed. After ten years, the tattoo becomes cancerous due to nature of dye within (damage occurs). Patient sues first doctor for not using the right laser. He **cannot succeed** because although, there was **duty, dereliction** and even **damage**, but **damage was not a direct result of doctor's dereliction**.

This of course is open to debate, as it is theorized that Azo dyes used in tattoo can potentially cause psudolymphomas, though whether laser can aggravate this is unknown. Again removal of moles (common acquired melanocytic nevi) by lasers, have been linked though controversially to malignancies. This is almost unheard in India, but is reported in world literature.

HOW TO PREVENT MALPRACTICE CLAIMS

A interesting insight into the types of complaints entertained in litigations in USA is given in Table 16.4. A few of them that can be of concern in India include deceptive trade practices, failure to properly hire, train, or supervise staff, failure to select appropriate laser and/or setting, not trained and/or certified to operate laser and failure to properly calibrate and maintain lasers.

We are adding one more to this list, which can be a valid cause of a civil suit, using non US FDA /CE approved lasers. With no certification in India, these are the certifications essential, which I daresay do not exist for most lasers sold.

Thus prevention is better than facing malpractice claims. Following simple rules will help prevent malpractice claims to a great extent.

<i>Cause of action</i>	<i>Specific allegations</i>
Lack of informed consent	Failure to properly hire, train, or supervise staff
Fraud	Failure to properly perform treatment and/or operate laser
Loss of consortium	Failure to select appropriate laser and/or setting
Assault/battery	Failure to warn and/or inform of risk
Strict products liability	Failure to conduct test spot
Breach of contract	Not trained and/or certified to operate laser
Infliction of emotional distress	Failure to recognize and/or treat injury
Negligent misrepresentation	Failure to properly calibrate laser
Gross negligence	Failure to maintain laser
Recklessness	Failure to biopsy
Deceptive trade practices	Failure to supply goggles

Patient Information and Documentation

Many malpractice claims arise due to lack of patient information, or sometimes inflated claims. Physicians should ensure that they themselves inform the patients and do not delegate the responsibility to nurses or paramedical staff. Informed consent must also be taken by dermatologists themselves, and it must be written. A patient's signature on a preprinted consent form, which has not been preceded by a discussion with the physician does not grant doctors free rein, and in the event of a legal dispute, such a form can be declared invalid. The optimal procedure consists of a thorough discussion, after which the patient is given a consent form to which handwritten additions are made as necessary. Detailed information should be provided about the diagnosis; the nature, extent, and process involved in the planned treatment; potential short- and long-term adverse effects; possible alternative treatments; and the costs to be expected. Rare concomitant effects, adverse effects, and risks should also be discussed if they are typical for the procedure in question.

Treatment should not be performed on the same day the discussion is held; patients should have the chance to make a decision without being pressured for time and without being affected by the psychological burden of the procedure awaiting them. Patient documentation should include information about discussions between the physician and patient, the preoperative diagnosis and histologic findings (to whatever degree present or necessary), the indication for laser treatment, test treatments, the kind of anesthesiology, the kind of laser and parameters of application, the results of treatment, and any concomitant reactions, adverse effects, and complications (intra- or postoperative, infections, late complications, etc.). Especially in the case of cosmetic procedures, additional photographic documentation is recommended. This is relevant from a forensic perspective, as well as being useful if the patient should question the success of the treatment.

Some clinicians prefer to write a risk, benefit and alternatives (RBA) note together with a written informed consent.

It is wise to seek informed consent for each type of laser that is operated by the physician. Each laser system functions in a unique fashion. The same laser created by various competitors may differ in terms of treatment settings and potential side effects. For this reason, establishing a relationship with the laser company for support is advantageous for the physician. Furthermore, ensuring that the medical device is FDA approved for patient therapy could minimize liability.

Though a detailed consent form is given in the Appendix of the book, we are detailing the essentials in a consent form, which can be remembered by the mnemonic LASER (Abel Torres, et al.) (Table 16.5).

Liability waiver	A patient needs to be told that Laser procedures are not reimbursable and no other procedure will be shown in lieu of it!
Anesthesia type	There are risks associated with all types of anesthesia, including topical (see Chapter on Drugs)
Surveillance	Observations, outcomes and side effects on the postoperative record documents treatment course in the best interest of the patient
Expectations	A no guarantee clause should be emphasized as no indications has definite cures
Revocation of consent	Offer the option of letting the patient refuse treatment at any time especially if it alters outcome
Snapshot	Photographs are to be taken specifically for documenting results and are confidential unless specified

Training

Malpractice claims are mostly due to professional errors, which in turn, are due to lack of training and experience. Thus, training must be strengthened. The ideal method of ensuring thorough training, is to establish teaching centers for laser treatment in qualified, certified offices or clinics. In such institutions, guidelines should be taught on topics including didactic, hands-on, and laser-specific clinical techniques. Standards of practice are sometimes handled as if they are top secret information. This should not be done; instead, they should be officially instructed and published. In the US and some other developed nations an oral and written examination is a must for every dermatologist in practice. It serves as a rational and fair strategy to assess theoretical and practical proficiency objectively after a defined period of continuing education is completed. Sadly, in India, there is no such program. If such programs are started and widely followed, these may serve to reduce professional errors, and in turn, malpractice claims.

In case a physician is using lasers in dermatology, he must have dermatologic training in addition to laser-specific training.

Do not Make Unrealistic Claims

It has been seen that many malpractice claims originate as a result of failed patient expectations, which in the first place are raised very high almost to unrealistic levels. Some examples are “removal of 80–90 % of the hair in 2–3 sessions” or “1064 nm Nd:YAG laser is superbly suited for removing moles and dark hyperpigmentation spots”. Experience has shown that whenever the patient has been given realistic assurances, the incidence of malpractice claims remains low.

Handling the Press

Proliferation of print and electronic media in India, has caused journalists to look around for cases to feed their 24 × 7 news channels. Medical malpractice cases, being inherently potential TRP enhancers are among the most hotly pursued stories by print and TV journalists. If for example, a patient has been injured by laser treatment, the journalist would approach some top laser practitioners and would like to know their views on it. It would be wise for laser practitioners not to criticize their colleagues for 2 reasons—it is unethical to pass derogatory remarks against a colleague, and secondly, the case may be in court and any comments may cause an unduly adverse outcome in the case. The results of some surveys indicate that doctors need to be trained to handle the press.

HOW TO HANDLE A MALPRACTICE CLAIM IF IT DOES OCCUR?

Involvement in a lawsuit as a defendant may be in a civil or criminal case. Experience has shown that a vast majority of medical malpractice cases in India are civil cases, which is good news for doctors, because at most they would entail payment of damages and not imprisonment. A minority of cases [generally those in which death has occurred], are fought in the criminal court, in which there may be imprisonment to the doctor. However there is no bar for a patient to go to a criminal court even for minor injuries [s 337 IPC] or most surprisingly even if no injury has occurred [s 336 IPC]. The latter case may be unbelievable to some, but there is a distinct theoretical possibility of this occurring. The analogy is fast, reckless driving through a city. Even if no one is injured, the driver is still liable, because he could have caused injury by engaging in such a rash and negligent act. Similarly, if a doctor is rash and negligent in using lasers, and if a patient has ample proof of it, he can approach the court, even if no injury has occurred to him. Thankfully such situations are extremely rare.

It must be noted that a patient can sue for compensation in a consumer court only if he has paid fees to the doctor. If no professional fees has been paid, the patient cannot invoke a consumer court, but he can still approach a civil court under tort law. Generally, such cases drag on for years in India and are a cause of worry for doctors.

The most worrying cases are criminal cases, in which the patient complains to the police, and the police lodges a case against the doctor. In laser applications of dermatology, such cases are likely to be extremely rare, simply because grave laser injuries are virtually unknown, and as already stated, the patient generally would refrain from going to the police until and unless the injury is very grave and debilitating.

Countersuits

One way to deal with a suit is filing a countersuit. A countersuit is an action brought by a physician against the patient (the plaintiff in the original malpractice action), as a retaliation strategy. It is based on the maxim, “attack is the best form of defense”. This strategy works best, if the laser practitioner is sure that the malpractice claim is malafide and unjust. The countersuit movement began in the mid-1970s with enthusiastic support by the medical profession in response to the dramatic rise in medical malpractice suits, many of which were perceived as lacking substantial merit. It must be remembered that courts would not taken this approach very positively if the laser practitioner was actually at fault. They have rejected most countersuits, which were filed merely as an attacking policy. Courts follow a public policy interest in ensuring that injured parties have free and open access to the judicial system

Alternative Dispute Resolution (ADR)

A far simpler and better approach is alternative dispute resolution or ADR. It *refers to dispute resolution techniques that help plaintiffs and defendants resolve conflicts outside of the courtroom.* It is advantageous to both patients and doctors. Patient can save time from litigation and focus efforts on healing. Money saved on lawyers and court goes directly to the patient. Many hospitals in the US have embraced “**early apology**” programs, where physicians and hospital administrators reach out to the injured patient and express sympathy about the adverse event. This protects the natural **doctor-patient relationship** as well as **encourages dialogue**.

Mediation and Arbitration

The most popular **ADR techniques** are **mediation** and **arbitration**. They differ in both their **binding nature** and their **formality**. *Mediation is simple negotiation that is aided by an impartial mediator.* It is **nonbinding**, meaning that if a settlement cannot be reached, the plaintiff may pursue his claim in court. *Arbitration* is more court-like, with an **arbiter** hearing both sides much like a judge would. Similarly, there are **rules for how and when to talk**, and **how to present evidence**. Most importantly, **it is binding**, meaning that the **judgment of the arbiter is final** and litigation is not an option.

Mediation

Mediation has had excellent success where implemented, both in terms of **cost-containment** and **satisfaction** for both parties. From the plaintiff’s perspective, mediation offers **more flexibility** than litigation, which only offers money as a remedy. Experience has shown that patients who come

for laser cosmetic surgery are, by and large from upper echelons of society and often do not engage in litigation for money. Many **sue for nonmonetary reasons**, such as the **desire for disclosure of information** or the **desire to hear an apology or explanation of what went wrong**. In the US, for example, rather than just receiving money, some plaintiffs wish for a **scholarship** to be established in their family's name, or like their **deceased's story told to incoming nurses or medical students** to help prevent similar adverse events in the future. Similar trends are appearing among the rich patients in India. For these reasons mediation often suits plaintiffs' needs better. Non-monetary aspects like the ones mentioned above are withheld in a litigious environment.

Arbitration

Arbitration is different from mediation. It is more acrimonious and expensive, being **more trial-like** than mediation. It is longer and more expensive than mediation, but much shorter and less expensive than court trials. Like court trials, arbitration can only offer money as a form of redress, eliminating the more creative and satisfying solutions offered in mediation.

Pretreatment Arbitration Agreement

Laser practitioners may want to undergo a pretreatment arbitration agreement. Under this arrangement, patients **agree to arbitration** as a condition of being seen in the first place. This has become an increasingly popular form of arbitration in the US. However, it suffers from the great disadvantage that it is awkward to discuss **adversarial postures** during the initial physician-patient visit itself.

Benefits of Mediation and Arbitration

Benefits of mediation and arbitration are almost 100% avoidance of litigation. Thus, these are very appealing to everyone alike—doctor, patient and even the insurer, as even a successful defense can cost a lot. There is a private and informal setting outside of the courtroom. In case of arbitration, the decision of arbiter is binding and there are no appeals process. It occurs as scheduled and without delay, unlike many court cases. Damage awards tend to be more predictable and usually are more in line with settlement values than those afforded by court trials.

CONCLUSION

A detailed patient information sheets, consent form and postprocedure check list has been given in the Appendix of the book which can help to avoid unnecessary medicolegal issues.

Laser cosmetic surgery can legally be done only by a person qualified in modern medicine and surgery. Any other person engaging in laser cosmetic surgery can only do so under supervision of a qualified dermatologist. If dermatologist is sure, the malpractice suit by the patient is malafide, he can respond by filing a countersuit. If on the other hand, he knows he has been negligent, the best approach is mediation and arbitration.

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