Causes of Injury and Litigation in Cutaneous Laser Surgery: An Update From 2012 to 2020

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OBJECTIVE To identify common causes of injury and liability claims related to cutaneous laser surgery from 2012 to 2020.

MATERIALS AND METHODS Search of online national legal database of public legal documents regarding cutaneous laser surgery litigation.

RESULTS From 2012 to 2020, 69 cases of liability claims due to a cutaneous laser surgery device were identified. Of these, 49 (71%) involved a nonphysician operator (NPO); 12 incidents (17%) involved non–core physician operators performing the procedure; 6 cases (9%) involved a plastic surgeon operator; and 2 cases (3%) involved a dermatologist operator. Laser hair removal was most litigated (44 cases, 64%), followed by laser skin rejuvenation (20 cases, 30%). Thirty-six of 69 cases had a discernible outcome, 53% ($n = 19$) rendered judgements in favor of the plaintiff, with a mean indemnity payment of $320,975 (range, $1,665–$1.5 million).

CONCLUSION Previous work evaluating trends in laser surgery litigation from 1985 to 2012 identified increasing injury and legal action when performed by NPOs. Data from this study are consistent with these previous findings. Both studies demonstrate that NPOs account for most cases of legal action with an increasing proportion of cases being performed by NPOs. In this study, unsupervised NPOs comprise nearly three-quarters of laser surgery lawsuits, but the data may underestimate the frequency of injury and litigation caused by unsupervised NPOs.

The number of laser, light, and energy-based cutaneous surgeries continue to rise in the United States, and these treatments continue to be among the most utilized elective cosmetic procedures. Among dermatologists alone, it is estimated that approximately 3.2 million laser, light, and energy-based treatments were rendered in 2017, which comprises a 17% increase from the previous year and a 2-fold increase from 2011.[1] Countless more of these procedures were performed by physicians specializing outside of dermatology, as well as nonphysician operators (NPO) of these devices. Plastic surgeons accounted for an additional 2.5 million cutaneous laser surgeries in 2017.[2] The increased utilization of these energy-based modalities has demonstrated a concomitant proliferation in the incidence of patient injury and adverse outcome–related litigation.

Previous work from the author group evaluating trends in malpractice litigation pertaining to cutaneous laser surgery from 1985 to 2012 identified increasing patient injury and legal action when the procedure was performed by nonphysicians, and particularly when performed outside of traditional medical settings, such as medical spas. Nonmedical facilities providing cosmetic and aesthetic procedures and services, termed medical spas or "med spas," continue to increase in number and post record revenues, and are more likely to have NPOs with varying degrees of training and certification performing these procedures.[3] In the context of medical spas, unsupervised NPOs frequently deliver these treatments without any physician oversight or involvement.[4,5] Meanwhile, physicians in traditional medical practices also often delegate these procedures to NPOs in an effort to increase revenue. The increased utilization of NPOs to deliver these treatments has led to a steady increase in the number of legal claims naming both the supervising physician and NPO as defendants since 2008.[6]

There are currently no federal regulations that address who may operate a laser or whether physician supervision is required. Different state regulatory bodies have various requirements dictating specific instances where physician supervision is lawfully required; however, in many states, a physician is not even required to be available on site at the time treatment is rendered by the NPO.[7,8] Despite the fact that physicians may act as supervisors and delegate the laser procedure, they are still legally liable for any services

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provided by any physician extender, including laser surgery, within the scope of their employment.

The objective of this study was to update previously published data exploring laser procedures that resulted in legal action and to further examine the incidence of litigation when laser- and light-based cutaneous surgeries are delegated to NPOs or performed outside of traditional medical settings versus when performed by physicians.

Materials and Methods

The online legal research resource Thomson Reuters Westlaw (http://www.westlaw.com), which is a national database used as a primary source in law to collate legal documents in the public record, was queried. Various keywords were used as previously reported to maintain continuity between studies.[4] The study was exempt from review, as determined by the Institutional Review Board at the Massachusetts General Hospital.

Using the search terms, 1,147 documents consisting of cases, trial court orders, and jury verdicts and settlements were identified. Each of these documents were thoroughly reviewed for relevance. Pertinent information included year and cause of action, provider education or certification, type of procedure, alleged injuries, verdict, and indemnity payments. Of these 1,147 documents, 69 cases involving cutaneous laser surgery injury were identified. Of these 69 cases, only 36 had discernible outcomes. A nonphysician operator (NPO) is defined as a non-MD or non-DO provider/operator. A variety of allied health professionals were noted to comprise this category, including medical assistants, registered nurses, nurse practitioners, physician assistants, aestheticians, and laser technicians.

Results

From January 2012 to January 2020, 69 cases of injury and liability claims resulting from operation of a cutaneous laser surgery device were identified. Of these, the greatest number of cases arose from New York (21), California (12), Texas (7), Nevada (7), and Massachusetts (4), followed by several states with 1 or 2 reported cases (See **Supplemental Digital Content 1**, Figure S1, http://links.lww.com/DSS/A994). Consistent with previously published data, the most common procedure involved laser hair removal, in 44 of the 69 cases (64%). This was followed by laser skin rejuvenation related suits in 20 of the 69 cases (30%). For the purpose of this study, laser rejuvenation encompassed several procedures, including intense pulsed light (IPL), pulsed dye laser (PDL), fractionated and nonfractionated ablative resurfacing, and fractional nonablative resurfacing. Two additional cases involved ablative laser resurfacing, in combination with surgical face lifts. There were several single isolated cases involving laser tattoo removal, laser treatment for cutaneous warts, and IPL treatment to "melt away" improperly placed dermal fillers.

Similar to previous studies, injuries sustained in legal cases from January 2012 to January 2020 were led by burns (77%), scarring (39%), pigmentary disturbances (23%), and blistering (12%), with infection/cellulitis (4%), pain and suffering (3%), ocular injury (3%), and dyspareunia (1%) being other reported injuries (Table 1). The most frequently documented legal cause of action was negligence (89%) and lack of informed consent (22%), followed by a variety of others, including fraud and battery (Figure 1). Note that the sum exceeds 100% as multiple injuries were sustained and multiple causes of action were reported in some cases.

Of the 36 cases with a discernible outcome, 53% of them had judgments in favor of the plaintiff with damage or indemnity payments ranging from $1,665 to $1.5 million. The mean and median was $320,975 and $132,108, respectively (See **Supplemental Digital Content 2**, Figure S2, http://links.lww.com/DSS/A995). However, cases that were brought in more recent years have not yet reached a final outcome because these cases are either pending or ongoing.

Laser surgical cases performed by nonphysicians comprised the largest number of legal actions, regardless of supervising physician subspecialty, with 71% ($n = 49$) of legal claims occurring when NPOs performed the procedure. When laser treatments were administered directly by a physician, plastic surgeons were alleged to have caused patient injury with 6 identified claims (9%), followed by dermatologists with 2 identified claims (3%). The lower incidence among dermatologists, who perform more laser surgeries than any other specialty, may be attributable to the greater emphasis on laser education in dermatology residency programs with a higher minimum laser case requirement in dermatology training programs as highlighted by the Accreditation Council for Graduate Medical Education.[9] Most other medical specialties do not have any specific laser training curriculum or minimum case number prior to graduation. Physician operators outside of dermatology and plastic surgery specialties, when taken as a group, were alleged to directly cause patient injury leading to legal action in 12 cases (17%) (Figure 2). These specialties included family medicine, general surgery, obstetrics/gynecology, ophthalmology, emergency medicine, pediatrics, and radiation oncology.

The data were further stratified by categorizing the physician subspecialty supervising the NPO laser operator implicated in the legal suit. Nine cases were initiated against internal medicine/family practice, followed by 5 cases against dermatology, 4 cases against obstetrics/gynecology, 3 cases against plastic surgery, 2 cases against pulmonology, and 1 case each against emergency medicine, gastroenterology, general surgery, and neurology (See **Supplemental Digital Content 3**, Figure S3, http://links.lww.com/DSS/A996).

Discussion

The current work evaluating legal data from January 2012 to January 2020 further demonstrates that NPOs account for the majority of cases of legal action pertaining to the use of cutaneous laser surgical devices. In fact, there is an increasing national trend in the past decade for a higher proportion of cases being performed by NPOs. As physician

TABLE 1. Cutaneous Injuries Sustained in Legal Cases From January 2012 to January 2020	
Injury	**Number (%)**
Burn	53 (77%)
Scarring	27 (39%)
Pigmentary disturbance	16 (23%)
Blistering	8 (12%)
Cellulitis/infection	3 (4%)
Pain & suffering	2 (3%)
Ocular injury	2 (3%)
Dyspareunia	1 (1%)

delegation of laser procedures increase, health care providers must remain vigilant to the fact that the supervising physician may be legally liable for any patient injury, misconduct, or negligence that occurs when the laser is used by anyone under the physicians' purview, despite their lack of physical involvement in the case. This scenario falls under the legal doctrine of respondeat superior, as this principle is frequently invoked within legal proceedings to hold an employer responsible for the conduct of the employee when he or she is operating within the scope of employment.

Notably, most lasers used in cutaneous surgery have been developed by dermatologists, and it is the medical specialty performing the largest number of laser cases each year in the United States.[1,2,10] Yet, the current data demonstrate that physicians from other specialties who perform laser surgery, when evaluated as a group, make up a far larger proportion of the legal cases seen from 2012 to 2020. Among the legal claims pursued pertaining to a physician-operated laser malpractice case, 18 cases (90%) were brought against nondermatologist physicians, while 2 of the 20 cases (10%) were initiated against dermatologists. This may reflect the level of training received while in residency and fellowships, and merits further study.

The current data show that litigated injuries occurred more commonly when the laser procedure was performed by an NPO in either medical spa or traditional medical setting, despite a deterrent for attorneys to pursue cases against practitioners who are not covered by medical malpractice insurance. In exploring the legal structure of a medical spa, it is notable that many of these establishments, which are owned and operated by nonphysicians, do not have medical liability insurance to satisfy a potential malpractice claim. To satisfy a claim against a medical spa, an attorney must address an alternative set of legal elements to those necessary to satisfy a claim against a defendant with medical malpractice insurance in a medical malpractice case. The set of elements that must be proved against a defendant who is not a health care professional are likely more opaque. The imprecision of the set of claims that would sufficiently satisfy a case against a non–health care professional could act as a deterrent for an attorney to bring a case against a medical spa. Alternatively, the legal elements necessary to satisfy a claim against a medical practitioner are less impervious to frivolous claims because professional liability insurance inherently addresses the financials of frivolous lawsuits more efficiently and fully.[11]

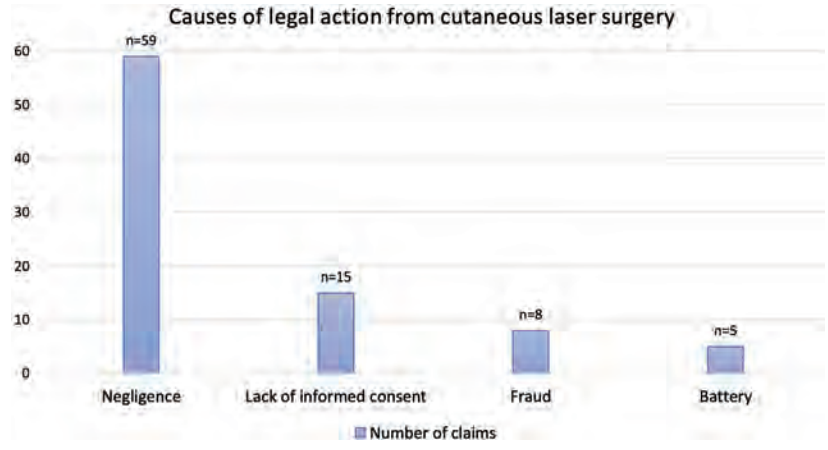

Figure 1. Causes of legal action from January 2012 to January 2020 resulting from operation of a cutaneous laser surgery device.

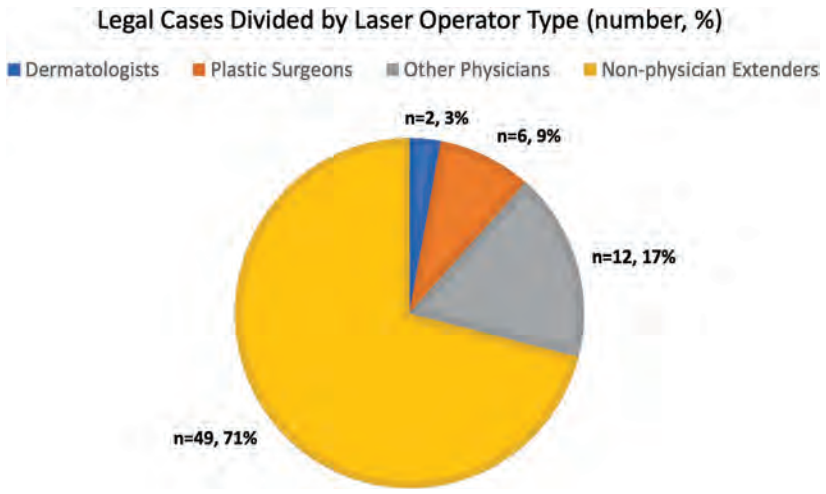

Figure 2. Legal cases divided by laser operator type. "Other physicians" refers to physicians representing the following specialties: Family medicine, general surgery, obstetrics/gynecology, ophthalmology, emergency medicine, pediatrics, and radiation oncology.

Thus, because most medical spas are more likely to employ nonphysicians to carry out a procedure, it may be logically concluded that the number of cases that could be brought against medical spas are likely underreported. Conversely, attorneys would be more likely to bring a lawsuit against health care professionals covered by medical malpractice insurance. However, despite this deterrent, it was found that NPOs still had the highest rate of alleged patient injury and legal cause of action. In reality, this rate is likely underrepresented based on the lack of malpractice insurance and corresponding lack of indemnity to be pursued in a legal claim.

When the current data are taken together with prior work by the authors, dating back to 1985, a clear trend emerges in the current legal framework and jurisprudence surrounding laser-related litigation. Specifically, the trend shows that even in the absence of state regulations that mandate physician supervision, physicians are more likely to be held legally liable for patient injuries that occur under their purview, regardless of whether they operated the laser- or light-based device. Furthermore, identifying common causes of legal action can highlight areas that should be addressed to improve patient safety and decrease professional liability. Patient injuries and negative outcomes will continue to occur because these are risks inherent to any surgical procedure. However, physicians who wish to perform laser surgery may mitigate these associated risks by ensuring that the laser operator has a deep fund of knowledge regarding laser physics, skin optics, and both therapeutic and warning endpoints.

A coalition called the Patients/Physicians United for Laser Safety and Efficacy (PULSE), started by the American Society of Dermatologic Surgery Association, calls upon state regulatory boards to have more stringent regulation of NPOs in terms of training and supervision.[12] As shown in Jalian and colleagues,[4,5] and echoed in the current work, current trends in legal precedent show that physician and nonphysician laser operators are held to the same standard of care under the legal doctrine of respondeat superior. Thus, in light of this doctrine, it is in the best interest of physicians who delegate laser operations to nonphysician employees to be aware that claims for negligence, battery, or medical fraud arising out of improper technique or a failure to obtain informed consent may still be legally aimed toward the physician; this is regardless of personal involvement in the delivery of the procedure. Furthermore, current data lend support for increased regulations of NPO laser treatments.[13] It is critical that physicians mitigate risk to patients by ensuring robust training for their extenders, by directly supervising procedures or by being immediately available and physically on-site, as is recommended by the official position on this matter by the American Society for Laser Medicine and Surgery, A multispecialty laser- and energy-based devices society.[14]

Notably, core aesthetic physician practitioners understand that patient complications associated with nonphysician operators are not uncommon, especially when performed outside of traditional medical settings, such as medical spas. A survey of members of the American Society for Dermatologic Surgery found that in the preceding 2 years from that study, 61% to 100% of complications seen in their practices were performed in medical spas, with LHR and IPL being among the top 3 most common procedures with complications.[15] Indeed, the rising demand for cosmetic services has seen a significant increase in the number of medical spas performing such procedures by NPOs, particularly with medical directors from non–core physician practioners.[16] As noted in the present study and supported by prior work, such nontraditional contexts are where the preponderance of patient complications occur. Despite this, most cities in the United States have more medical spas than core aesthetic physician practices, and most aesthetic physicians have a medical spa within 5 minutes of their office.[17]

There are limitations to this study. The search included only one legal database, and it does not include cases handled outside of the court/judicial system. Thus, many frivolous claims brought outside of the judicial system may be immediately dropped. Additionally, claims may be settled through third-party arbitration. The study is also limited by the search terms entered into the database—the authors may have not captured cases that did not include the terms that were used. Finally, only incomplete information was available for some cases even when supplemented through other resources and additional research.

Conclusion

The data suggest that most cases of legal action and claims of injury in the setting of cutaneous laser surgery involve nonphysician operators, supporting the past published literature. The data published by the author group suggest that patient safety increases, and legal claims of negligence and injury decreases, when laser surgery is performed by physician operators, in particular those with a medical subspecialization in dermatology. If the physician does delegate laser surgical procedures to an NPO, the physician is ultimately responsible in the court of law for the NPO's performance and actions. It is thus essential that physicians and their agents receive appropriate and robust training in the execution of cutaneous laser surgery in attempt to minimize adverse outcomes for patients and subsequent legal risk.

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