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Conflict of interest

The authors Christian Raulin and Hans-Robert Metelmann have practices/clinics where laser treatments are performed.

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Treatment errors resulting from use of lasers and IPL by medical laypersons: results of a nationwide survey

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Summary

Background: The demand for hair and tattoo removal with laser and IPL technology (intense pulsed light technology) is continually increasing. Nowadays these treatments are often carried out by medical laypersons without medical supervision in franchise companies, wellness facilities, cosmetic institutes and hair or tattoo studios. This is the first survey to document and discuss this issue and its effects on public health.

Patients and methods: Fifty patients affected by treatment errors caused by medical laypersons with laser and IPL applications were evaluated in this retrospective study. We used a standardized questionnaire with accompanying photographic documentation. Among the reports there were some missing or no longer traceable parameters, which is why 7 cases could not be evaluated.

Results: The following complications occurred, with possible multiple answers: 81.4 % pigmentation changes, 25.6 % scars, 14 % textural changes and 4.6 % incorrect information. The sources of error (multiple answers possible) 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.

Conclusions: The causes of malpractice suggest insufficient training, inadequate diagnostic abilities, and promising unrealistic results. Direct supervision by a medical specialist, comprehensive experience in laser therapy, and compliance with quality guidelines are prerequisites for safe laser and IPL treatments. Legal measures to make such changes mandatory are urgently needed.

Introduction

The demand for hair and tattoo removal using laser or intense pulsed light (IPL) technology has been rising for years. Although such procedures used to be performed almost exclusively by physicians, due to their commercial potential and apparent simplicity, a multitude of wellness facilities, cosmetology institutes, and hair and tattoo studios are also now offering them. Most treatments are performed by trained laypersons without any medical supervision. In addition, the expectations of patients are often raised unrealistically (for instance: “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”) [1, 2]. The underlying legal premise supporting this situation is that the practitioners are not treating disease. Thus there is no need for a diagnosis by a physician, and procedures may be performed by trained laypersons [3].

Yet dermatologists are seeing growing numbers of patients with complications following such treatment. Typical side effects include loss of pigmentation/hyperpigmentation (depending on laser/IPL setting, skin type, and pre-interventional or post-interventional sun exposure), crusts, blistering, burning, hypertrophic scarring/keloids, pruritus, localized herpes virus infections, folliculitis, color changes (with removal of permanent make-up), allergic reactions

(due to unknown tattoo inks) and even contact dermatitis after hematogenous dissemination of the allergens, as well as paradoxical hair growth (especially with IPL technology). 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 post-operative recurrent nevus or pseudomelanoma. Conversely, amelanotic melanomas may be allowed to progress without detection and may even metastasize [3–10]. This is the first study of its kind to document and discuss the extent and importance of this problem, as well as its effect on public health.

Patients and methods

This retrospective analysis from October 2009 to January 2010 evaluated 50 patients who reported treatment errors arising from laser and IPL treatments by laypersons. A standardized survey and accompanying photo-documentation were used. The survey contained the following characteristics:

- ▶ Age, sex, skin type
- ▶ Name/type of institute that performed the treatment, professional qualifications of the person who administered treatment (cosmetologist, tattoo artist, etc.)
- ▶ Type of complication: scar, textural change, pigmentation change, other
- ▶ Localization
- ▶ Presumed cause of treatment error
- ▶ Time between lacking treatment to photo-documentation
- ▶ Laser type/pulse light laser, wavelength, energy density, pulse duration, beam diameter, cooling
- ▶ How, when and who caused the complication
- ▶ Legal recourse procedures (initiated or completed)

Seven patients could not be included in the analysis due to missing, uncertain, or unspecific data. The data from the 43 patients included in the study were collected from 30 reports from German dermatologists in response to a request for co-operation by institutions such as the German Dermatological Laser Society (DDL), Diploma in Aesthetic Laser Medicine (DALM), as well as a previous announcement in the German journals “Der Hautarzt” and “Derm” and 13 of our own reports.

Results

The average age of the patients was 31.8 years (33 women, 9 men, and 1 transsexual). The breakdown by skin type (based on Fitzpatrick) was as follows: I (0 %), II (27.9 %), III (44.2 %), IV (23.3 %), V (2.3 %), and VI (2.3 %). Of the laypersons administering treatment, 51.2 % were cosmetologists, 2.3 % tattoo artists, 13.9 % trained assistants, and 32.6 % had unknown qualifications (Figure 1).

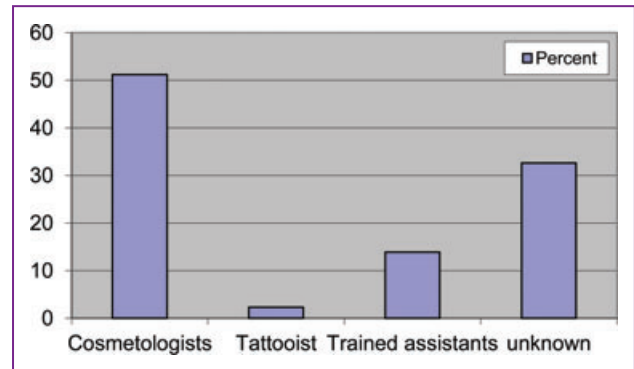


Figure 1 Qualification of the medical laypersons in percent.

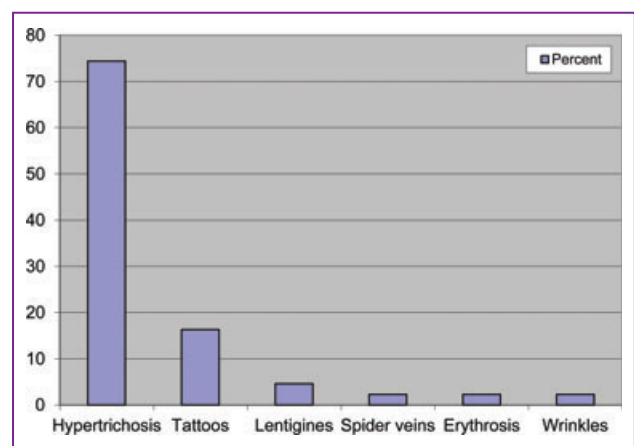


Figure 2 Indications for treatment in percent (multiple answers were possible).

The patients were treated for the following indications (multiple answers are possible): hypertrichosis (74.4 %), tattoos (16.3 %), “age spots” (4.6 %), spider veins (2.3 %), erythrosis interfollicularis colli (2.3 %), and lines/skin rejuvenation (2.3 %) (Figure 2).

In the 43 patients included in our study, the following equipment was used for treatment: 62.8 % were treated with IPL, 18.6 % with laser, and in 18.6 % the modality was uncertain (laser or IPL).

The following complications occurred (multiple answers were possible) (Figure 3): pigmentation changes (81.4 %), scarring (25.6 %), textural changes (14 %), inadequate information without physical injury, e.g., non-clearance after laser epilation in 4.6 % (e.g., hair was too thin or light and would not have been treatable by the methods used).

The following treatment errors occurred (multiple answers were possible): excessive energy application in 62.8 % of patients; wrong technology for the indication, e.g., selection of unsuitable treatment device and thus non-selective treatment in 39.5 %; 20.9 % of patients had a deep tan or a skin tone

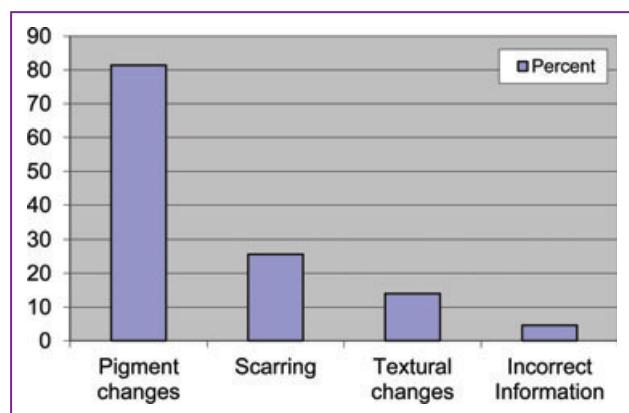


Figure 3 Complications in percent (multiple answers were possible).

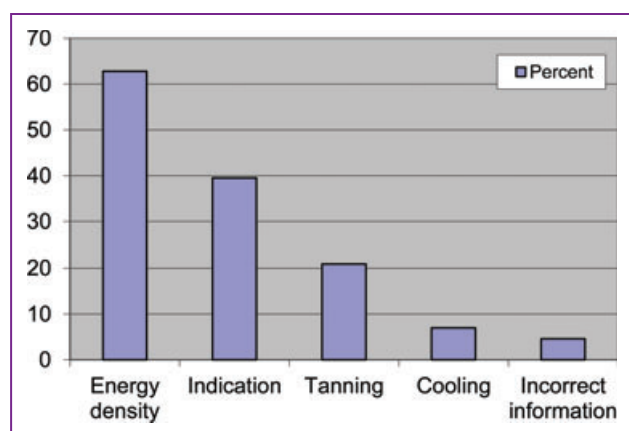


Figure 4 Type of treatment error in percent (multiple answers were possible).

that was too dark for the selected intervention; 7 % had inadequate cooling, and 4.6 % of patients received inadequate information (Figure 4).

The damage due to the intervention was treated by a dermatologist in 25.6 % of patients and by another type of specialist in 20.9 % of patients (antibiotics and/or topical steroids). 34.9 % of patients were not treated by a physician; 2.3 % returned to the tattoo artist for help. Typically, medical consultation was avoided out of embarrassment or because the patient was unaware of whom to consult. Nor did patients always know that prompt treatment of complications could help reduce any long-term damage. This became clear during our conversations with various patients, and presumably an even greater number of patients experienced the same problem. 16.3 % of follow-up treatments could not be specified in detail.



Figure 5 Hair removal with a ruby laser by a tattooist on a patient with skin type IV with subsequent burns and hyperpigmentation. Photographic documentation in this picture 3 months after laser treatment.



Figure 6 Hair removal in the face and on the neck with IPL at skin type VI with subsequent burns, pigmentation changes and scars after the first and only treatment. Photographic documentation 3 days after IPL treatment.



Figure 7 Hair removal in the genital area with IPL at skin type VI with subsequent burns, pigmentation changes and scars after the first and only treatment. Photographic documentation 3 days after IPL treatment.



Figure 8 Tattoo removal by a cosmetician with a q-switched Nd:YAG laser (1064 nm) with subsequent development of keloids after the first treatment. Photographic documentation 4 weeks after laser treatment (Photo: Dr. Rezai, Münster).

27.9 % of patients who experienced complications took legal measures; 53.5 % did not; and in 18.6 % it is uncertain. Only one of the lawsuits was successful (compensation

for pain and suffering); two cases were settled out of court (compensation for pain and suffering or redress). The result of the remainder of lawsuits is unknown or still pending. Figures 5–8 show patients who experienced treatment errors due to interventions performed by laypersons.

Discussion

Treatment with laser and light systems is viewed by the general public - and to some extent by official bodies - as harmless or “merely cosmetic” in nature. Treatment applications by medical laypersons (cosmetologists, tattooists, trained laypersons, etc.) are widely accepted, not least due to the effectiveness of intense marketing strategies. Yet the safe use of laser and light systems requires experience as well as sound medical knowledge beyond what a layperson possesses [2, 11].

This is evidenced by the type of treatment errors which we discovered in the course of our study. Typical errors consisted of using energy settings that were too high or using unsuitable equipment; moreover, the degree of tanning or skin type were also often incorrectly identified. Such errors are far less common with proper training and medical knowledge. Another indication of lacking knowledge among laypersons was that only a fraction of their customers returned to them afterward for treatment of problem. Rather, the majority of patients who experienced a problem went to a specialist instead for treatment.

The most commonly treated indication was hypertrichosis. Often larger surfaces are treated and thus almost invariably include areas of skin that should not be treated (nevus cell nevi, melanomas, etc.). In our patients these were not identified by the laypersons due to lacking knowledge. The next most common indication was tattoo removal. The problem is similar, but the use of q-switched laser is even more serious [11]. Another major problem is the treatment of “age spots” by non-medically certified personnel. These pose the greatest potential for confusion with premalignant or malignant skin changes.

The most common form of damage resulting from treatment was pigmentation changes, followed by scarring and textural changes. In the best case, disorders of pigmentation may be transient, but scarring and textural changes are usually permanent. Thus it is surprising that less than one-third of patients who experienced complications took legal steps, only one lawsuit ended favorably, and two cases led to out-of-court settlements.

Tanned patients and those with skin types III–VI (based on Fitzpatrick) should only be treated with laser and light systems designed for such skin types and extra caution must be exercised [12]. The majority of treatment-related mistakes were: use of the wrong laser/IPL system and/or incorrect setting [13], incorrect use or application of excessively high

energy densities, overlapping pulses, and no or inadequate cooling [12]. Yet the biggest hazard is in treatment with the wrong indication (e.g., confusing lentigo maligna and lentigo benigna). The treatment of pre-cancerous lesions or even melanomas which are mistaken for “moles” and treated with laser/IPL, can delay or prevent proper diagnosis and treatment; or worse, it could even possibly contribute to malignancy [14]. Performing histological analysis following treatment is often no longer useful, and curative treatment, given potential progression may no longer be possible. The diagnosis of a malignant skin change that is covered by a tattoo can be difficult even for an experienced dermatologist, and is unquestionably outside the realm of a layperson’s expertise [2, 3, 15]. According to the AWMF guideline on “melanocytic nevi”, the use of laser and IPL equipment is contraindicated for melanocytic nevi [16].

In the event that a serious side effect does arise, the trained layperson is generally unable to adequately help the situation [17–19]. At best, he or she can provide the honest advice to consult a physician. A similar problem occurs in wrinkle treatment with radiofrequency devices used by laypersons. Reports have been published on severe scarring due to facial treatments [20].

The documentation and provision of information to the patient should cover the following points: all facts discussed in the interview, preoperative diagnosis and prior histological findings, the indication for laser therapy, a test treatment, the type of anesthesia/topical anesthesia to be used, laser type and parameters, results of treatment including possible side effects, complications (intraoperative and postoperative problems, infections, delayed complications, etc.). It is essential to confirm the diagnosis and rule out potentially malignant skin changes before administering laser therapy [10, 12, 19]. Especially for cosmetic treatments, additional photo-documentation is advisable. This may be relevant later due to forensic reasons or if the patient questions the success of treatment [12].

Legal situation in other countries

In the majority of European countries, only physicians have the right to make a diagnosis, inform the patient of his condition, and perform treatment. In a decision from 11 July 2002, the European Court ruled that this was consistent with the current European legal situation [21].

In 2005 the Swiss Federal Office of Public Health published an article by the Swiss Society for Dermatology and Venereology in a bulletin which explicitly warned against treatments performed by laypersons [21].

In Denmark, the law states that laser treatments may only be performed by medical doctors [22]. This law was passed as a result of scientific research on the risks of laser treatments performed by laypersons which reflects the present situation in Germany [3, 19, 22, 23].

In the United States, tattoo removal may also be done by certified medical personnel, but only under the supervision of an experienced physician. In addition as decreed by the Board of Directors of the American Academy of Dermatology (AAD), patients must be thoroughly informed of potential side effects (including rare complications) [24, 25]. Yet a publication from 2003 reported that medical “supervision” often meant that a wellness facility merely had a doctor on its staff, but that he or she was often not on site and usually even had an office elsewhere [26].

In England all private and public clinics offering laser treatments are registered and monitored by the Care Quality Commission. The use of lasers is not limited to doctors, but certain requirements (e.g. documentation of treatment progress) must be adhered to. In addition, users of laser systems are required to participate in certified continuing education courses [27].

Legal situation in Germany

In Germany, basically any therapy that causes a bodily change (including laser therapy) is a physical injury in a legal sense. The consent of the patient must be obtained after properly informing him or her of all associated risks and side effects. If the patient is inadequately informed, the person delivering the treatment is already guilty of bodily injury, regardless of whether the intervention caused a complication or not [2, 3]. It is the sole responsibility of the physician to inform the patient about the intervention. This responsibility may not be delegated to a non-physician. If written consent is obtained from the patient before he or she has been properly informed, it may be considered invalid. In addition, the treatment should not take place on the same day to ensure patients have sufficient time to consider their decision [14, 28].

In Germany the use of laser and IPL devices as emitters of non-ionizing radiation is governed by a law on protection against non-ionizing radiation (NiSG) [29]. § 2 of the law states that only certified doctors or dentists, or those otherwise permitted to practice dentistry or medicine, may deliver treatment. Yet § 3 states that devices that emit non-ionizing radiation may only be used for cosmetic purposes, or other uses on humans outside of medicine or dentistry, when their use is in accordance with the requirements set forth in the decree based on § 5. The related decree has not yet been passed by the federal government. Thus the only regulation based on the NiSG which has been passed by the cabinet, but which is not yet in force, is the UV protection regulation against the effects of artificial ultraviolet radiation (UVSV) based on § 4 of the NiSG. Those who offer “cosmetic treatments” have already responded [30].

Hence there is no current legal basis for stating that the application of laser and IPL treatments is reserved for physicians. Clarification of the regulations based on § 5 in relation to § 3 is needed.

In addition, it is still being discussed whether hair and tattoo removal, the most commonly performed procedures by medical laypersons, should be considered medical treatment (based on § 2 NiSG) or cosmetic treatment (based on § 3 NiSG). Supporting their classification based on § 2 is the need for a correct diagnosis, including differential diagnosis, and the potential for medically relevant sequelae such as permanent side effects or the exacerbation or triggering of potential malignant skin changes. Yet tattoos and piercings are a form of “bodily-harm-on-demand”, and are certainly not medical treatments, despite their potentially enormous health hazards.

At the present time, in Germany operators of laser systems need only complete a course in laser protection and do not need any other qualifications [2]. In 2000 the Commission on Radiological Protection (SSK) of the German Ministry for the Environment already warned against unregulated use of laser devices, stating that laser therapy should only be performed by specially trained physicians and that legal regulations are needed [2]. Statements such as these from the Federal Ministry of Health - “If non-medical personnel perform these services, they must know what they are doing and should be well insured” (cited in [28]) – are to be viewed extremely critically and in a legal sense certainly do not set a precedent.

According to § 1 of the German law on non-medical practitioners (HPG), laypersons are prohibited from professional and/or commercial diagnosis and treatment of disease. This law states that in the interest of the “common good” and “public health” the practice of alternative medicine includes any activity requiring medical knowledge [15]. Any laser treatment, even if performed for purely cosmetic reasons and not due to a medical indication, is thus considered an alternative therapy. Yet there are often issues with regard to this law, because cosmetic interventions are not intended to heal a disease. For some legal experts, laser treatment clearly does not belong to the realm of alternative medicine. In addition the prevailing court decisions on this law have become more critical. Even cosmetic interventions may be considered a healing intervention if the procedure requires medical knowledge of potential consequences, or the assessment of differential diagnoses, and/or if the treatment itself could damage one’s health [15].

In July 1998 the Ministry of Women, Family, and Health of the German state of North Rhine-Westphalia decided that the removal of tattoos using laser is considered an alternative healing method and should only be performed by medical personnel (decision from 30.07.98; file no.: III B 2 [new] – 0401 12 -)“ [1]. The Department of Health and the Environment (Environmental Hygiene/Medicine Unit) (RGU-GS 21), which among other things is responsible for breaches of the German law on non-medical practitioners in and around Munich, makes the following comment: “In the opinion of RGU-GS 21 the use of intense pulsed light (IPL technology)

by non-medical personnel ... should be considered a prohibited practice of medicine in the sense of the law on non-medical practitioners (§ 1 section 1 HeilprG).”

Yet laypersons will point out that side effects can also occur when treatment is performed by a physician, which is to be proved by relevant evaluations. Thus the side effects are not necessarily specific to laypersons, but also occur at medical practices where there is lacking knowledge and expertise. In addition, adverse effects such as transient hyperpigmentation or loss of pigmentation are not uncommon occurrences, even with proper treatment. One should add, however, that should side effects occur, the professional expertise of a physician in their management can often prevent them from becoming worse. This is know-how that laypersons simply do not have, as shown by the fact that almost all patients with treatment-related complications sought the advice of a specialist. In addition, patients who have a potential malpractice claim can get free advice on physician liability from the German Medical Association. Furthermore, every patient is covered by the doctor’s professional liability insurance which is not always true for errors made by laypersons during treatment.

The German Dermatological Laser Society (DDL) and the working group on dermatological laser therapy (ADL), which is part of the German Society of Dermatology (DDG), have established quality assurance guidelines for performing laser and light treatments on the skin. Users can find the theoretical requirements here (professional requirements and certification of knowledge and expertise) [19]. In addition, doctors may obtain a continuing education “diploma in aesthetic laser medicine” (DALM) at an academic level [28].

Further studies are still needed to determine whether laypersons make more mistakes with laser and IPL than medical personnel. We thus plan to expand our registry of errors made by laypersons.

Conclusions for practice

This is the first study of its kind to show that the use of light and laser devices by medical laypersons poses a real threat to public health and that the potential damage should not be underestimated.

Only a doctor with years-long training and education can correctly diagnose skin changes, take into account any contraindications to treatment (e.g., nevus cell nevi), correctly and expertly evaluate the skin prior to therapy, identify any underlying skin disorders or systemic diseases (e.g., hirsutism), promptly detect the potential for side effects and then either avoid treatment or discontinue it to address the side effects in a manner that is appropriate and effective for their level of severity. This is not only important for safe and

effective treatment, but can also limit damage which could eventually require broader compensation.

This requires that the regulations based on § 5 (NiSG [29]) in relation to § 2 (NiSG) which clearly define the use of light and laser systems as medical treatment be clarified. Medical and non-medical treatments need to be distinguished in legal terms.

We would also like to appeal to the German Society of Dermatology to take a clear position on laser/IPL use as an integral part of dermatology training (e.g., including DDL and DALM). This would help create a boundary to treatments performed by laypersons.

According to the present study, the most common complications related to laser and IPL use by trained laypersons are: hyperpigmentation and loss of pigmentation, burns with crusts and blistering or even permanent scarring. The causes of incorrect treatment appear to be inadequate training and education as well as lacking diagnostic abilities. Specialist medical training, extensive experience with laser treatments (as well as proper patient selection), and adherence to established quality guidelines (e.g., DDL and DALM [28]) should be required for safe laser and IPL treatment.

The advice to patients who have experienced a medical error by a layperson is as follows: consult a dermatologist, ensure photo-documentation, obtain prompt treatment of the problem, and see a medical malpractice lawyer to begin civil proceedings. If the damage is serious, the patient should even consider filing charges with the police or state prosecutor for bodily injury due to negligence.

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