REVIEW

# Complications in aesthetic medicine resulting from procedures that use fractional lasers in skin regeneration treatments

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Abstract. Fractional lasers are used in aesthetic medicine for skin resurfacing, the number of treatments that employ them is constantly increasing. They represent a safer alternative to the previously dominant full ablative and non-ablative lasers, due to the smaller area of skin exposed to the laser. Despite improved technology and increased safety of laser treatments, as well as their shortened recovery time, complications still occur. The most common ones include erythema or swelling, however serious and long-term complications also occur. Considering the risk of complications and their severity, the person performing the procedure should be well trained, use appropriate equipment with correctly selected parameters and follow the principles of antisepsis. The number of lawsuits against people performing laser treatments is growing significantly, as patients are suing for compensation. Due to the fact that the continuity of the skin is not broken during the procedure, in many countries there are no precise legal regulations regarding the principles of laser treatments, which significantly complicates the pursuit of such claims.

Key words: fractional ablative lasers, fractional non-ablative lasers, complications, malpractice, litigation

## Introduction

Laser technology has been used in aesthetic medicine for a long time. Fractional lasers are used in treatments focusing on skin resurfacing, which involve the removal of scars, wrinkles and discolorations<sup>1,2</sup>. The origins of lasers date back to the 1980s. That is when a continuous wave CO2 laser was first introduced. It had many unwanted side effects such as scarring. Subsequently, a CO2 laser with a focused beam and a laser with a yttrium-aluminum garnet with the addition of erbium were introduced, allowing for a much more precise operation<sup>3</sup>. To overcome the limitations of classic lasers, fractional photothermolysis laser technology was created<sup>4</sup>. Its operation is based on the formation of microscopic treatment zones (MTZs), which inflict thermal damage with a specific depth, width and density as a result of the laser, leaving the rest of the skin areas completely intact<sup>2,5,6</sup>. The skin damaged in this process is stimulated to rebuild through the synthesis of elastin and collagen<sup>7,8</sup>. The first fractional laser was the non-ablative 1550 nm Er:Glass laser<sup>6,9</sup>. The advantage of fractional lasers is that they can be safely used in patients with any skin phototype according to the Fitzpatrick scale. Fractional lasers have become the most frequently used lasers in aesthetic medicine<sup>10</sup>.

Fractional lasers are also divided into ablative and non-ablative lasers<sup>1,11</sup>. Non-ablative lasers rely on mid-wavelength infrared light to coagulate the dermis while preserving the epidermis. Examples include with wavelengths of 1550 nm and 1927 nm<sup>8,12</sup>. The first approved non-ablative laser was Fraxel<sup>®</sup> SR750<sup>5</sup>. Ablative lasers act thermally on the epidermis and dermis, causing the epidermis to be removed under the influence of high temperature. Such lasers include the 10,600-nm CO2 laser and the 2940-nm Er:YAG laser<sup>8</sup>. Procedures using non-ablative lasers have fewer complications than those using ablative lasers<sup>8</sup>. Although fractional lasers are safer than full ablative and non-ablative lasers and have a shorter recovery time, their operation is still associated with complications. The most common ones include erythema, superficial erosions, swelling, acne and contact dermatitis<sup>10</sup>. Risk factors for complications after laser procedures can be grouped according to their etiology. These include inappropriate patient selection, improper treatment selection, failure to follow procedure protocols, poor equipment selection, inadequate post-procedure care, and individual patient response to the procedure<sup>13</sup>. The aim of this paper is to present cases of clinical complications in patients after procedures using fractional lasers in the office of aesthetic medicine practitioners. Although the risk of complications following fractional laser procedures is low, the number of procedures performed is steadily rising<sup>10</sup>. Patients are increasingly willing to undergo laser procedures, and their general knowledge of fractional lasers is expanding. For this reason, treatment providers should be generally aware of complications that may occur and be prepared to address any concerns addressed by the patients.

# Epidemiology

According to the American Society of Aesthetic Plastic Surgery, the number of laser skin resurfacing procedures increased by 270% between 2000 and 2010<sup>14</sup>. The fractional laser market is expected to grow from USD 1.50 billion in 2022 to USD 3.0 billion by 2030 at a CAGR of 9.00% during the forecast period from 2023 to 2030. Due to the increase in the implementation of new technologies, North America dominates the fractional laser market<sup>15</sup>. According to data from the American Society for Aesthetic Plastic Surgery, 38,550 resurfacing procedures were performed using fractional lasers in 2018<sup>2</sup>. The complication rate is relatively low. In the mentioned study it amounted to 4.2%<sup>10</sup>.

# Examples of CE marked and FDA approved fractional lasers

- 1. Fractional ablative lasers
  - Co2 (10600 nm): Fraxel<sup>®</sup> Repair CO2, Lumenis UltraPulse, Life Tech Experts CO2 Fractional Laser, Lutronic eCO2 Plus<sup>™</sup> Laser
  - 2. Er:Yag (2940 nm): Alma Harmony XL PRO iPixel Er:YAG laser
- 2. Fractional non-ablative lasers
  - 1. Er: Glass (1550 nm): Alvi Prague MED-X Er Glass 1550, Fraxel Restore
  - 2. Nd:Yag (1064 nm): Cutera Nd:Yag laser

#### Fractional non-ablative laser

Fractional non-ablative lasers are less invasive than ablative fractional lasers. Most complications resulting from such procedures are self-limiting and easy to treat<sup>16</sup>.

#### Complications

Chronic skin redness has been documented following facial treatments using fractional non-ablative lasers. However, it only affected 1% of the patients<sup>17</sup>. In the case of non-ablative lasers, chronic redness lasts longer than 4 days<sup>18,19</sup>. Infections are another complication. The most common cause of infections after procedures is the HSV infection. Some patients may develop a bacterial infection in the treated area. Intense redness, pain and erosions occur, most often 1-3 days

after the procedure<sup>17</sup>. An example is a case in which, after a treatment on the neckline using a laser with a wavelength of 1927 nm, a staphylococcal infection developed<sup>10</sup>. Another complication is the development of acne lesions in the area of the procedure, which should also be treated with antibiotics<sup>10</sup>. However, acne lesions after fractional laser procedures appear much less frequently than as a result of traditional laser treatments<sup>17</sup>. There are known cases of keratoacanthoma after the use of 1540 nm and 1550 nm lasers<sup>17,20</sup>. Impetigo contagiosum may also occur. However, this is a rare complication affecting only 0.1% of patients<sup>17</sup>. Post-inflammatory hyperpigmentation is also a complication, more common in patients with darker skin types. It lasts relatively longer than other described complications<sup>4,21</sup>.

#### Treatment

Chronic skin redness can be reduced by being treated with moisturizing procedures<sup>10,21</sup>. In a patient with HSV infection, appropriate antiviral drugs such as acyclovir, valacyclovir or famciclovir should be implemented at an appropriately high dose. depending on whether there was prior prophylaxis. In some cases, intravenous administration of acyclovir may be necessary<sup>22</sup>. Bacterial infections are treated with antibiotics<sup>10</sup>. The same method of treatment applies to acne lesions. The use of tetracycline causes the lesions to reverse<sup>4</sup>.

# Prevention

Chronic skin redness is usually caused by an infection, incorrect laser settings or contact dermatitis. To prevent its formation, care should be taken to ensure proper antisepsis during the procedure, the right selection of laser equipment and settings of appropriate parameters<sup>16</sup>. Patients at risk of an HSV infection should be advised to take pre-operative antiviral prophylaxis, starting 1 day before the procedure and continuing for 5-7 days after the procedure<sup>16–18,21</sup>. In order to avoid hyperpigmentation, the patient's skin type should be properly assessed before treatment and the laser parameters adjusted<sup>21</sup>.

#### Fractional ablative laser

Fractional ablative lasers are much safer than non-fractional ablative lasers, because they only ablate specific areas of the skin. Nevertheless, after procedures with their usage complications still occur<sup>23</sup>. In the case of the Er:YAG laser, immediately after the treatment symptoms are greater compared to the CO2 laser. However, the more time passes after the treatment, the more side effects of the CO2 laser become visible<sup>24</sup>. The recovery time after fractional laser treatments is usually 5-7 days<sup>16,19</sup>.

#### Complications

A potential complication that can arise from the procedure is infections. The most common is an HSV infection, although there are also bacterial and fungal infections<sup>25</sup>. An example of another complication is drooping of the lower eyelid of the right eye, i.e. ectropion. There is a known case, in which ectropion was caused by scarring after a wrinkle correction procedure using a CO2 fractional laser<sup>17,23</sup>. The skin around the eye is particularly sensitive, so any treatment in this area may cause redness, erosion and swelling, which will be visible 3-5 days later. Vesicles may also appear around the eyes. During a laser treatment damage to the cornea, retina and vitreous body may occur<sup>16</sup>. Cracks in the skin may develop after the procedure, as well as thickened tissue and scarring<sup>23</sup>. After face lifting procedures combined with a CO2 fractional laser, complications were documented such as longlasting redness, the appearance of acne lesions, as well as a case of hematoma<sup>25–27</sup>. Redness resulting from an ablative laser may persist for more than a month<sup>18,19</sup>. In such cases, it can be categorized as prolonged redness, which affects 12.5% of patients<sup>17</sup>. Patients also often experience itching, and crusts may develop on their skin<sup>28</sup> The development of cold-induced urticaria following a CO2 laser treatment as a result of a cooling process during the procedure has also been described<sup>29</sup>. Another complication is bruising<sup>17,30</sup>. People with darker skin phototypes are at risk of hyperpigmentation after the treatment<sup>16,17,25,31</sup>. Cases of hypopigmentation have also been described, however they

are rare. The hypothesis for its formation is damage to melanocytes as a result of the laser<sup>25,28</sup>. Laser treatments may induce skin diseases such as psoriasis or vitiligo<sup>16</sup>. Moreover, any laser treatment may cause the patient to be dissatisfied with the results of the treatment, which can lead to filing charges in court<sup>27</sup>.

## Treatment

Viral, bacterial and fungal infections should be treated with antiviral drugs, antibiotics and antifungal drugs, depending on the infection. In case of ectropion, the administration of 0.1 ml of triamcinolone acetonide solution with a concentration of 5 mg/ml and the use of moisturizing drops results in the resolution of the problem. Treatment lasts about 2 months<sup>17,23</sup>. Thickened tissue and scarring should be treated with steroids<sup>16,23</sup>. Some postoperatively formed hematomas may require evacuation<sup>25</sup>. In case of prolonged redness spontaneous recovery often occurs within 3 months<sup>17</sup>.

#### Prevention

Patients at risk of an HSV infection should be advised to take pre-operative antiviral prophylaxis in the case of treatments with non-ablative fractional lasers. To prevent fungal infections, it is important to avoid unnecessary occlusive dressings after surgery<sup>25</sup>. The skin of the eye area is one of the particularly sensitive areas, so the doctor should pay special attention to it during the laser procedure<sup>16</sup>. Likewise the skin of the neck is particularly susceptible to scarring due to poor vascularity and a small number of seborrheic glands<sup>27,32</sup>. During the laser procedure, the patient should be blindfolded to prevent damage to the eye<sup>16</sup>. Bruising can be prevented by avoiding anticoagulants before the procedure. It is believed that the use of drugs such as non-steroidal anti-inflammatory drugs may cause delayed purpura to occur only a few days after the procedure<sup>17,30</sup>. In people with dark skin types, the intervals between subsequent treatments should be longer, with lower densities and higher frequencies. Such patients should also avoid sun exposure for 2 weeks before and after treatment<sup>16,17,25,31</sup>. The jawline is particularly susceptible to hypopigmentation,

therefore, in order to avoid it, a laser with specific, appropriate parameters should be used  $^{28}$ .

#### Protection and law aspects

In recent years, there has been a significant increase in the number of lawsuits filed against performers of minimally invasive aesthetic medicine procedures<sup>33,34</sup>. The reasons include unsatisfactory cosmetic results, increased awareness of patient rights, incorrect information about the procedure and the risks associated with it, as well as complications after the procedure, such as health damage or permanent disfigurement<sup>33,35</sup>. Usually, trials can take place in penal and civil mode, most of them concern procedures performed in private entities<sup>33</sup>. In civil lawsuits, they usually revolve around obtaining compensation. A conversation with the patient and precise presentation of the characteristics of the planned procedure, as well as of the risk of complications is crucial<sup>35</sup>. This form of dialogue should be conducted in a way that is understandable to a patient who is not a medical professional and would be best for the patient to receive this information written on paper<sup>35,36</sup>. Moreover, such a conversation should be confirmed in the documentation by the patient's signature and their informed consent to the procedure<sup>37</sup>. It is also necessary to select the appropriate therapy for the patient. It is crucial to analyze the occurrence of conditions that may constitute a contraindication to carrying out the therapy. The interview and physical examination should include the patient's chronic diseases (with particular emphasis on autoimmune and endocrine diseases that may manifest themselves on the skin) that may influence the effectiveness of the therapy, as well as skin localized diseases (including skin cancers, e.g. melanoma). It is also worth in-depth interviewing about the patient's tanning process and wound healing history<sup>13</sup>. All treatments should be performed by practitioners with appropriate qualifications, with adequate preparation and using functional equipment in the right conditions. The appropriate technical condition of the device is very important in the case of devices that generate an energy beam<sup>38</sup>. A faulty or damaged device may generate a beam with

physical characteristics different than the target one, which would influence not only the effectiveness of the therapy, but also the occurrence of possible complications, e.g. burns<sup>39,40</sup>. The conditions of the procedure should also be strictly controlled. In cases of the lack of sterility, the risk of infection increases significantly. In the case of infections affecting the skin, they may result in the formation of abscesses, necrosis and reduced or nullified effect of the treatment, along with the possibility of permanent disfigurement. In addition, the resulting wounds may heal with unsightly scars, which may affect facial functions, significantly reducing the quality of life and mental condition of patients<sup>39</sup>. The effectiveness of the treatment is also affected by the technique of its implementation. Therefore, it is important that such procedures are performed by qualified and properly trained individuals<sup>39,41</sup>. Among the errors resulting from an incorrectly performed procedure, malpractice includes technical faults as a result of inappropriate performance of the procedure due to improper substantive preparation and wrongdoing resulting from neglecting the patient's symptoms and characteristics both during and after the procedure<sup>36</sup>. It is also a mistake to choose the wrong therapeutic method for the patient. What is especially important, is that most of the complications resulting from such errors are preventable<sup>13</sup>. Moreover, in treatments utilizing lasers, there is usually no disruption of skin continuity in the traditional sense, which in the legal systems of many countries creates ambiguities related to the regulations defining who can provide such medical services, which constitutes a significant difficulty in protecting patients<sup>42</sup>. Additionally, one of the reasons for a patient to apply for compensation may also be an unsatisfactory cosmetic effect. What is more, starting a lawsuit always involves a significant financial, image and emotional burden for both the doctor and the patient. The costs related to legal handling of the dispute, expert opinions and accompanying liabilities may amount to significant financial hefts<sup>43,44</sup>. Moreover, starting a lawsuit against a doctor is associated with a decline in trust among their patients and the associated decline in income, which may lead to the closure of the practice. Another issue is compensation, which in cases of complications ranges from tens

to hundreds of thousands of dollars<sup>39,45</sup>. The role of the expert opinion prepared by an expert is also crucial<sup>46</sup>. It should contain a detailed description of the complications that occurred, with particular emphasis on their location and extent, and explain their impact on the patient's life<sup>47</sup>.

#### Conclusions

The increase in interest in fractional laser procedures performed for aesthetic reasons in recent years is associated with an increase in the incidence of complications. They may include burns and scarring. This also results in an increase in the number of lawsuits against entities providing such medical services. Further research is necessary to determine the frequency of occurrence and types of side effects for specific kinds of laser treatments. Legal regulations regarding minimally invasive aesthetic medicine treatments also require clarification, especially regarding patient rights, and the qualifications required for the performers of such treatments. In addition, it is important to have a proper conversation with the patient in order to explain the principles of the procedure and the risk of complications, as well as to obtain informed consent to the procedure, which may prove crucial, should the patient file a claim.

**Declaration of Conflicting Interests:** The authors declare no conflict of interest.

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Received: 8 May 2024

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