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Complications associated with needle-based medical aesthetic procedures: clinical and medico-legal aspects from the Polish perspective

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ABSTRACT

Aesthetic medicine is a rapidly developing branch of modern medicine. Its main procedures include needle-based procedures such as mesotherapy, botulinum toxin injections and filler injections. Each of them may result in unwanted complications. In the case of mesotherapy, the complications are usually local, while in the case of the usage of botulinum toxin, there have been reports of deaths, whereas filler injections have been reported to cause stroke and loss of vision. It is of the highest importance for the professional to properly prepare for the procedure. In Poland, there is no such thing as a specialization in aesthetic medicine. The lack of precise regulations contributes to an increased number of complications caused by people without appropriate qualifications and offences defined in law as damage to health. It is especially important in cases when the procedure is carried out by people, who are underqualified and do not have appropriate permissions.

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Keywords: needle-based procedures, aesthetic medicine, botulinum toxin, hyaluronic acid, complications

INTRODUCTION

Aesthetic medicine is a relatively young, yet dynamically developing field that was initiated in Paris, in 1973. This is when the first aesthetic medicine association was established. Since then, it has spread all over the world. Its main goal is to improve patient's appearance and their general well-being by reducing the visible effects of ageing and perfecting their bodies [1]. Nowadays, more and more different treatments are performed in aesthetic medicine. This is due to the emergence of newer, more sophisticated products and devices on the market. In 2023, the global aesthetic medicine market grew to 62.8 billion USD compared to 56.93 billion USD in 2022 at a compound annual growth rate (CAGR) of 10.3% [2]. Aesthetic medicine procedures are minimally invasive, performed on an ambulatory basis and usually do not require any anaesthesia or only local anaesthesia, which distinguishes aesthetic medicine from plastic surgery [3]. These include needle-based procedures such as mesotherapy, botulinum toxin and fillers. The patients of aesthetic medicine doctors are healthy adults. The goal of aesthetic medicine is not to treat patients but to improve their appearance. Among the main reasons with which patients come forward are the desire to reduce wrinkles, improve the quality of their skin, reduce stretch marks or improve hair growth [2, 4, 5]. In aesthetic medicine, it is of great importance for the doctor to be adequately prepared for the procedure since each procedure is associated with possible complications. In Poland, aesthetic medicine does not exist as a separate medical specialization, and its procedures can be performed by any doctor or dentist. Due to the lack of strict legal regulations, some treatments are also performed by beauticians and representatives of other professions bordering on medicine [5]. In order to properly prepare before the procedure, a thorough interview should be conducted with the patient, paying particular attention to diseases including allergies. The plan of the treatment should be developed based on the patient's expectations [6]. It is important that all products used during aesthetic medicine procedures come from known sources, and are properly tested and approved for use in humans [7]. Appropriate preparation by both the doctor and the patient reduces the risk of complications and unwanted side

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effects. The study aims to present complications related to needle-based aesthetic medicine procedures and to discuss their effects in the context of forensic medical opinions.

EPIDEMIOLOGY

In 2022, non-surgical procedures such as soft tissue fillers and botulinum toxin injections dominated over invasive plastic surgery procedures with a 54.6% market share [8]. Botulinum toxin (BoNT) injections have become one of the most popular treatments in aesthetic medicine. In North America, between 2000 and 2018, the number of BoNT injections performed increased by as much as 845% [8]. Approximately, 3 million injections are made annually around the world [9]. The American Society for Dermatologic Surgery found a 50% increase in the use of botulinum toxin in patients 30 years of age and younger from 2012 to 2016. The society predicts that by 2025, young adults will be the largest users of preparations containing botulinum toxin [10]. In turn, according to the report of the American Society for Aesthetic Plastic Surgery, in 2015, over 2 million procedures were performed using soft tissue fillers [11]. According to a report published by the British College of Aesthetic Medicine (BCAM) in 2023, the highest risk of complications occurred during treatments using fillers and botulinum toxin. It was also shown that as many as 69% of these complications were caused by people without appropriate qualifications, such as beauticians, representatives of various medical-related professions and people without the required training [12].

MESOTHERAPY

Mesotherapy is an intradermal drug delivery technique that uses needles to stimulate the production of collagen and elastin by fibroblasts in the field of aesthetic medicine [13, 14]. The low cost and minimal qualification requirements of mesotherapy have contributed to its rise in popularity in recent years [14]. Indications for this type of treatment in aesthetic medicine include skin bio revitalization, baldness treatment, cellulite and fat reduction. The substances administered by the mesotherapy technique include a variety of meso-cocktails, plasma, fibrin or stimulators [13, 15]. In this case, the aim is to focus on complications after meso-cocktail administration. The substances most commonly used in the creation of them include, among others, hyaluronic acid, dimethylaminoethanol (DMAE), vitamin C, phosphatidylcholine and caffeine [16]. The choice of the appropriate meso-cocktail depends on the patient's indications and expectations. Mesotherapy is believed to be a safe treatment. There are a few complications it can result in, most of which can be prevented [17]. After mesotherapy procedures, most patients experience pain, swelling, bleeding and redness associated with disruption of the skin. Allergic reactions to the ingredients of the mixtures or infections at the injection sites may also occur [18]. Several moderate and severe complications following needle-based mesotherapy procedures have been described in the literature.

Phosphatidylcholine is a glycerophospholipid that participates in the metabolism of many different lipid compounds. It is an ingredient of cocktails administered using mesotherapy in a cellulite reduction procedure [16]. The most frequently described complication following the administration of phosphatidylcholine is the formation of granulomas at the injection sites and inflammation of the subcutaneous tissue. It may also turn into fat tissue necrosis [14, 19]. Another substance used in lipolysis cocktails is deoxycholate. Following a mesotherapy with its use, the observed complication was non-infectious inflammation of adipose tissue [19, 20]. Acetyl-L-carnitine (ALC) is also utilized for lipolysis. Additionally, it has a modulating effect on the human immune system. Hence, a complication was observed after its use during mesotherapy, which was the induction of a severe form of lupus in the patient's abdominal area [21]. Triiodothyroacetic acid is a derivative of thyroid hormone used in mesotherapy to reduce cellulite. In this case, the literature reports iatrogenic thyrotoxicosis as a complication after mesotherapy of the patient's buttocks and thighs. This example shows how incredibly important it is to collect an appropriate interview with the patient before the procedure, with an emphasis on autoimmune diseases [22]. Dutasteride is a substance used for scalp mesotherapy. Its usage was reported to cause painful changes related to hair loss, bald spots on the head and facial swelling were observed [23]. Another ingredient used in scalp mesotherapy cocktails is mesoglycan, which is a heparinoid derivative. A case has been described, in which a few days after a procedure with its use to rebuild hair, the formation of bald spots on the scalp could be observed [24, 25]. Table 1 presents a comparison of the number of complications resulting from the treatment itself versus those caused by the active substances administered [14, 18, 19, 21–25].

Table 1. Comparison of the number of complications caused by the treatment itself and those caused by the active substances administered

Mesotherapy with meso-cocktail complications	
Procedure-related	**Substance-related**
Pain	Allergic reactions
Swelling	Granulomas
Bleeding	Hair loss
Redness	Inflammation of the subcutaneous tissue
Infections	Tissue necrosis
	Severe and rare complications (*e.g.* induction of lupus, thyrotoxicosis)

BOTULINUM TOXIN INJECTIONS

Botulinum toxin is an exotoxin produced by the anaerobic bacteria *Clostridium botulinum* [26]. In aesthetic medicine, it is used mainly to correct wrinkles. It is currently the most popular cosmetic procedure performed on adults worldwide. It works by blocking the release of acetylcholine from the presynaptic terminals of the neuromuscular junction, causing flaccid paralysis of the muscle. Botulinum toxin is administered through an intramuscular injection [27]. Intradermal administration of botulinum toxin is used to treat hyperhidrosis [28]. The original motor function of the muscle, from before the procedure, returns within 3 to 6 months [29]. The most commonly used type of botulinum toxin is the type A. It is given in units, its amount depends on the area and the muscles involved [30]. Three types of botulinum toxin are approved: onabotulinumtoxin (ONA), abobotulinumtoxin (ABO) and incobotulinumtoxin (INCO). They differ primarily in molecular weight and additives. Depending on the type of botulinum toxin, attention should be paid to its dosage. In aesthetic medicine, ONA and INCO doses are used in a 1:1 ratio. The ABO dose relative to ONA in aesthetic indications is taken as 2.5:1 [31]. Depending on the medical preparations, botulinum toxin is registered for administration in different areas. Before administering a substance as part of an aesthetic medicine procedure, registration information and product characteristics should be known. The comparison of botulinum toxin doses in registered indications in the face according to the types of preparations is presented in Table 2 [32–34].

Most side effects associated with botulinum toxin are temporary and mild [35, 36]. Most often, after botulinum toxin injection; pain, swelling, bleeding or bruising might occur at the injection site, even despite the correct technique [37]. In order to avoid bruising and similar side effects, patients are advised not to take medications that inhibit clotting, such as aspirin or non-steroidal anti-inflammatory drugs, for up to 2 weeks before the procedure, unless there are significant medical indications for taking such medications [38, 39]. More serious complications are usually related to poor toxin injection technique and arise from the diffusion of botulinum toxin into adjacent muscles, also causing their paralysis [35].

Correction of wrinkles in the upper part of the face is the most common use of botulinum toxin in aesthetic medicine [27]. One of the complications of the procedure in this area is the dropping of eyebrows. It is a common complication. It occurs during treatments in the area of the frontalis muscle. The causes are too high a dose and incorrect injection site. Ptosis may appear up to 7–10 days after the procedure and last even longer than 4 weeks. The complication can be prevented by administering the toxin approximately 2–3 cm above the supraorbital rim [27].

Another complication is the development of a "spock" eyebrow or the so-called Mephisto sign, *i.e.* lifting the lateral part of the eyebrow upwards caused by relaxation of the central part of the frontalis muscle while maintaining the activity of the lateral part of this muscle. To correct the complication, the lateral part of the muscle should also be relaxed [27, 40]. Iatrogenic asymmetry occurs when doses of botulinum toxin are unevenly injected, anatomical differences between muscle fibres or when the toxin diffuses improperly. In order to mitigate the undesirable effect, an additional dose should be administered in the right place [27].

Complications in the mid-face area occur mainly when correcting crow-feet wrinkles [26]. One of the complications is drooping of the upper eyelid as a result of paralysis of the levator palpebrae superioris muscle. It may appear for up to 14 days of the procedure and lasts approximately 6 weeks [35]. It is caused by injecting too much botulinum toxin or administering it too close to the superior rim of the orbit, which promotes diffusion [41]. Apraclonidine 0.5% eye drops can be used to alleviate eyelid ptosis, which cause contraction of the superior papilledema muscle, which is also responsible to a lesser extent for lifting the upper eyelid. A possible complication is also the development of iatrogenic strabismus. It is caused by administering too much botulinum toxin or injecting it too close to the edge of the eye socket. The inferior oblique muscle of the eye becomes paralyzed most often. This is a relatively rare complication [27, 41, 42]. This may result in the patient developing

Table 2. Comparison of botulinum toxin doses in registered indications in the face according to the types of preparations

Types of botulinum toxin and units			
Indication	**ONA**	**ABO**	**INCO**
Glabellar lines	20 units	50 Speywood	20 units
Lateral canthal lines	12 units per side	30 Speywood per side	12 per side
Forehead lines	20 units	No registration	20 units
Hyperhidrosis of the axillae	50 units per axillae (Botox®)	No registration	No registration

ABO — abobotulinumtoxin; INCO — incobotulinumtoxin; ONA — onabotulinumtoxin

diplopia, or double vision. It is also a rare complication caused by the administration of botulinum toxin beyond the safe margin of the bony orbit, which is an incorrect injection technique [26]. The lateral rectus muscle of the eye and other extraocular muscles then become paralyzed [27].

The lower part of the face is much more complex anatomically than the upper part, therefore the administration of botulinum toxin in this area requires far greater precision from the doctor [43]. Lip asymmetry occurs either when botulinum toxin enters the levator muscle of the upper lip or the muscle of the levator of the upper lip and wing of the nose. If too large doses of botulinum toxin are directly administered to the upper lip, it may lead to articulation disorders and the inability to close the mouth. This side effect may last up to a month [27]. Also, when correcting the droopy corner of the mouth and injecting the depressor angularis oris muscle, there is a risk of botulinum toxin diffusing towards the orbicularis oris muscle, causing an asymmetric smile [26]. What is more, if chin wrinkles are treated with too high doses, the lower lip may droop and the mouth cannot be closed [27]. Injecting too much botulinum toxin into the masseter muscles causes expression disorders of the lower part of the face, such as a change in facial appearance, an unnatural smile or sunken cheeks. Most often there is a blockage of the musculus risorius. These complications disappear approximately 1–2 months after the procedure. To prevent this, injections should be made at least 1 cm from the anterior edge of the masseter muscle [27]. Additionally, in the area of the face, a swelling might occur. Treatments using botulinum toxin are also performed in the neck area to reduce wrinkles. The most common complications after injection in the area of the broad neck muscle are dysphagia and weakness of neck flexion [26, 44]. These side effects are more common in older patients because they require higher doses of botulinum toxin and because there is less fatty tissue in this area, the toxin penetrates more quickly into the deeper layers of the neck [27]. Botulinum toxin injections are also used to treat hyperhidrosis. In case of the hand treatment, after the procedure, weakness is often felt in the hand area, which may last a few months [26]. Common side effects of BoNT injections include headaches and dizziness, chronic fatigue and inflammation in the injection area (*e.g.* sinusitis or nasopharyngitis) accompanied by fever [45–47]. Importantly, adverse effects may also appear only during subsequent treatments, despite their absence in the prior ones [48]. Cases of systemic complications related to botulinum toxin injections in aesthetic medicine treatments have also been described, such as prolonged general fatigue and fever, allergic reaction or a set of symptoms resembling botulism [39, 49–52]. In addition, deaths have also been reported following BoNT injection procedures, even for cosmetic purposes [47, 53]. It is suggested that deaths may occur due to anaphylactic shock [53, 54]. Moreover, during botulinum toxin poisoning, no specific symptoms may occur during autopsy diagnosis, therefore additional tests, including toxicological and histopathological ones, will play a key role [53, 55]. It is also suggested that the severity of side effects depends on the dose [46]. When performing botulinum toxin treatments, one should keep in mind its registered indications, also depending on the preparation, as well as those off-label, and always inform the patient. A comparison of registered and off-label procedures using botulinum toxin is presented in Table 3 [56].

Table 3. Comparison of registered and off-label procedures using botulinum toxin

Botulinum toxin procedures	
Registered	**Off-label**
• Glabellar lines • Forehead lines • Lateral canthal lines • Axillary hyperhidrosis	• Eyebrow lift • Midface (*e.g.* bunny lines, lowered nasal tip) • Lower face (*e.g.*, gummy smile, platysmal bands) • Scar minimization • Rosacea • Face contouring • Oily skin • Hyperhidrosis (apart from axilla)

SOFT TISSUE FILLERS

Fillers are used in aesthetic medicine to rejuvenate the face and correction of abnormalities. They can be divided into temporary, semi-permanent or permanent, taking into account the period for which they remain in the tissues. The most commonly used fillers include cross-linked hyaluronic acid and calcium hydroxyapatite [57]. Autologous fillers are also used, including autologous fat [58]. The most frequently used one is hyaluronic acid due to its quick effect and the ability to reverse side effects by using hyaluronidase [41, 59]. It is very important to select the appropriate filler and its quantity for the patient. The doctor injecting fillers should possess detailed knowledge of the facial anatomy, with emphasis on its vascularization. A way to check whether the needle is in a blood vessel or not is aspiration before injecting [60]. Most fillers are injected into the dermis or subcutaneous tissue. Complications that appear immediately after the procedure include swelling, redness and bruising. Too shallow injection of the filler may result in the appearance of palpable and visible lumps [57]. Too superficial administration of hyaluronic acid can also cause the Tyndall effect. A blue shadow is then visible on the skin. Most often arises in areas where the skin is thin, such as under

the eye. A firm massage immediately after treatment can be an effective treatment. However, the primary treatment is the administration of hyaluronidase. Before using hyaluronidase, an allergy test should be performed to ensure that the patient is not allergic to it [61]. A very serious complication of filler treatments is central retinal artery occlusion and blindness [41, 62]. This is caused by incorrect administration of the filler into the vessel, most often around the area of the forehead, nose and temples [63]. It is the most common in procedures that use hyaluronic acid or autologous fat [64]. This leads to a decrease in visual acuity, which turns into blindness. Additional symptoms reported by patients include eye pain, headache, nausea and vomiting. Up to 1,500 units of hyaluronidase should administered to the ischaemic area while waiting for an ambulance. Treatment should be started immediately and should additionally include the administration of 600 mg of aspirin, to prevent clot formation, topical timolol and warm compresses. The longer the obstruction lasts, the worse the prognosis for vision recovery. Ophthalmologists with relevant experience can try administering hyaluronidase retrobulbar [65–67]. Improper administration of fillers also causes ophthalmoplegia. It is believed to occur as a result of ischaemia of the extraocular muscles and cranial nerves [66, 68]. Injecting fillers may also result in an ischaemic stroke [69]. Cases of death due to cerebral infarction as a result of hyaluronic acid entering the cerebral circulation have been reported [70]. Through the ophthalmic artery and internal carotid artery, the filler may enter the middle cerebral artery retrogradely, causing its occlusion. Particular care is advisable when treating the glabella, eye and nasolabial folds [66, 71]. As a result of venous filler administration, reticular cyanosis may appear on the face, which should be differentiated from bruises. Treatment in this case is warm compresses, aspirin and, in the case the filler used was hyaluronic acid, hyaluronidase (400 IU) [72]. Due to the vascularity of the nose in this area, complications may often occur [66]. The most common one, by a good margin, is pain [63]. If filler is injected into the lateral nasal artery and the dorsal nasal artery, necrosis may occur. The ala and tip of the nose are particularly sensitive to ischaemia [66]. The place, where infections occur most often after filler treatments are the cheeks. Scarring has also been reported during procedures with calcium hydroxyapatite [63]. The glabella is most predisposed to ischaemia due to vascular occlusion. It is supplied with blood by the supratrochlear artery, which is unable to generate sufficient collateral circulation in the event of occlusion [73], therefore too deep administration of complement may prevent blood supply and cause necrosis of the glabella [74, 75]. Following the administration of fillers, lumps may appear in the area of the nasolabial folds [75]. Providing the vessels are occluded by the filler, necrosis may also occur in this area [76]. A common problem is the administration of an excess amount of the filler, which disturbs the aesthetic effect of the treatment [77]. In addition, after the filler is injected, a biofilm, a cluster of bacteria, such as *Staphylococcus epidermidis* or *Staphylococcus aureus*, can form on the surface of the filler, embedded in the matrix that they produce. This can trigger a chronic immune response leading to infection. Treatment includes oral broad-spectrum antibiotic therapy and hyaluronidase (150–200 IU), which helps remove the filler if hyaluronic acid is used. If the inflammation is still severe, oral steroids are used, followed by intravenous steroids [78]. A milder complication is the formation of granulomas in response to a foreign body. They form up to several months after surgery. Treatment includes triamcinolone and 5-fluorouracil. Fillers applied to the lip may migrate to its inner surface, creating visible unevenness [77]. When administering filler, it can also be inadvertently administered into the superior or inferior labial artery, causing necrosis. To avoid this, the needle should be inserted no deeper than 3 mm [66]. There are also various types of illegal fillers available around the world, not approved by the competent authorities responsible for pharmaceutical control. However, they are significantly cheaper. The most popular illegal fillers include biopolymer, which is a type of silicone. It is often unsterile and mixed with other non-sterile substances. Such fillers are also able to migrate easily due to their low viscosity. Nodules then form in places distant from the injection sites. They cause facial deformation and are extremely difficult to remove. Some complications appear within 72 hours of the procedure, while others may appear up to several years after. Patients after procedures with illegal fillers may experience cellulitis, ulcerations or non-healing wounds that may lead to sepsis and even death [77]. Deaths resulting from the use of fillers have also been reported as a result of pulmonary embolism, moreover, infections also play an important role [70, 79–81].

GENERAL FACTORS AND CIRCUMSTANCES

Correct performance of the procedure plays an important role in preventing complications after needle-based medical aesthetic procedures. Appropriate medical training is required in this matter. Thorough knowledge of anatomy is necessary, with particular emphasis on the areas where the substances are injected [48]. If the substance is administered to the wrong area, the risk of complications during the procedure is greater. In addition, knowledge of pharmacology is also necessary to properly prepare the substance for administration and select the appropriate dose. Performing procedures by untrained people is associated with a higher risk of complications, also due to the lack of the ability to perform the procedure correctly. It is also necessary to conduct an appropriate interview with the patient in order to

qualify for treatments and to exclude potential interactions between the substance administered for cosmetic purposes and the patient's current condition or medications they use [39]. There have already been reports of deaths related to inappropriate medical procedures performed by people who were not trained to perform them [82]. What is more, the appropriate selection and preparation of substances used for treatments is also important. Only substances approved for human use should be used [48, 83, 84]. However, there are known cases of complications related to the administration of unlicensed products, despite the correct performance of the procedure. Moreover, products of unknown origin may contain excipients or impurities that contribute to the development of complications. In such cases, it becomes crucial to secure product packaging for further analysis [83]. In Poland, in accordance with the Pharmaceutical Law, all medicines must be registered by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and are subject to production and quality control by the Chief Pharmaceutical Inspectorate. The main principles of intended use are described in the Summary of Product Characteristics. Moreover, some of them (*e.g.* injection preparations containing botulinum toxin) require a prescription issued by a certified doctor with an active license to practice the profession.

The trade-in of medicines in Poland is strictly regulated by law. Placing a medicinal product on the market without marketing authorization and trading in medicinal products without authorization are considered prohibited. Moreover, medicinal products with a category of availability requiring a prescription issued by an authorized entity (*e.g.* a doctor) may be distributed retail only by establishments specified in the Pharmaceutical Law, such as, for example, pharmacies or pharmacy points. Each time such a medicine is issued, a prescription issued by an authorized body must be presented. Therefore, the possession, distribution and utilization in a beauty salon of a drug that has a prescription category (Rp.) in order to use it during a cosmetic treatment performed by a person who is not authorized to perform these activities should be considered unauthorized [85]. Importantly, each medicinal product has a Summary of Product Characteristics specifying the dosage and rules of use. If the patient obtains a prescription for a given drug from a doctor and purchases the drug himself in a pharmacy, its administration, with the consent of the client, as part of an aesthetic medicine treatment by a non-medical practitioner remains legally unresolved. In this respect, the content of the Supreme Court's judgment in case I KK 23/21 is particularly important, which indicates that the use of preparations in the form of injections, other than natural body orifices, thus interrupting the continuity of tissues, is a condition for qualifying an activity as a health service under the law in force in Poland [86, 87].

In the case of medical devices, which include *e.g.* hyaluronic acid, they are also supervised by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Another important issue is the uncontrolled and unregulated sale, mainly via the Internet, of unregistered preparations containing active substances and products pretending to be medicines (*e.g.* "botox-like" products), very often imported from abroad. In such cases, there is no control over the actual composition of the substance. Moreover, the black market is also an important phenomenon, where similar substances may be sold as chemical reagents or come from illegal sources of production. In the case of autologous preparations and their use, the legal situation is complex. Under the Pharmaceutical Law, they constitute medicinal products, but their use does not require registration with the relevant office. The very act of collecting blood for the purpose of preparing it is a medical procedure, which requires representatives of medical professions to have appropriate qualifications determined by legal provisions with a distinction between purposes, which are not granted to persons who do not practice medical professions [88]. The above regulations also apply to mesotherapy, depending on the products used to perform it. In addition, places where needle-based medical aesthetic procedures are performed must be properly arranged. Preparations used for procedures must often be stored in appropriate special conditions. Appropriate preparation also includes tools for carrying out treatments. They must be properly prepared and sterile to avoid infections that may result in serious consequences, *e.g.* necrosis [89].

MEDICO-LEGAL ASSESSMENT FROM POLISH PERSPECTIVE

In Poland, similar aesthetic medicine treatments are performed mainly in private offices and clinics after obtaining informed consent from the patient. For this reason, there is little data on the scale of complications after needle-based medical aesthetic procedures. Due to the classification of aesthetic medicine treatments in Poland as health services, they should be performed by doctors with appropriate education and technical training. However, there is no separate specialization covering this field of medicine, so the doctor performing the procedure is only required to have a full license to practice the profession, which is regulated by the medical self-government; a medical specialization, however, is not required [3]. Nevertheless, in practice, such treatments are often performed by representatives of other medical professions or even people not related to medicine, such as beauticians. Moreover, the lack of appropriate education and

qualifications translates into the frequency of the occurrence of complications and criminal liability for an incorrectly performed procedure, as professional liability cannot take place in cases, where such procedures are performed by people who do not have a medical profession. In Polish law, health damage and bodily injury are classified into three stages. It includes light, moderate and serious damage, corresponding to the provisions of the Penal Code: Article 157 § 2, Article 157 § 1, and Article 156 § 1 [90, 91]. A minor injury is the impairment of organ function or health disturbance for a period not longer than 7 days, and in the case of a complication after a cosmetic procedure, it may concern, for example, prolonged swelling limiting the interpalpebral fissure, but disappearing without leaving a trace in a time shorter than that specified in the regulation. When the duration of damage to health exceeds 7 days, it is then classified as moderate, and in the case of needle-based aesthetic medical procedures, an example of it may be a temporary paralysis of the branches of the facial nerve that disappears without permanent damage over time. Serious damage to health occurs when, for example, a person is deprived of sight or hearing, or other serious disability is caused [90]. One example of a serious health condition may be loss of vision due to iatrogenic occlusion of the central retinal artery. This provision also covers permanent significant disfigurement or deformation of the body, which becomes crucial in cases of procedures to improve a patient's image. However, the legal-criminal assessment of such an effect falls within the competence of the authority handling the case, while medical opinions should be limited to precisely documenting the changes of disfigurement and deformation of the body. Moderate and severe health damage are considered crimes prosecuted *ex officio*. Moreover, the legislator in Art. 160 of the Penal Code defined the crime of exposing a person to direct danger of loss of life or serious damage to health. Performing a procedure by an unauthorized person, using preparations not approved for human use, or performing procedures using inappropriate or incorrectly prepared tools may be classified as a crime under Art. 160 of the Penal Code. This kind of offence is prosecuted ex officio [91, 92].

Issues related to the performance of aesthetic medicine treatments are also addressed in documents issued by the Supreme Medical Chamber (*Naczelna Izba Lekarska*). The position of the Supreme Medical Council (*Naczelna Rada Lekarska*) defines aesthetic medicine as health services involving interference in tissues aimed at restoring or improving the patient's physical and mental well-being and social functioning. It emphasizes that these procedures should be performed by doctors or dentists, pointing out the key role of having the appropriate knowledge, skills and experience necessary to perform them [93]. Its framework is based on globally accepted definitions [94]. The Supreme Medical Council also clearly indicates in its position the need to legally regulate aspects related to the provision of aesthetic medicine services in the context of the provision of health services and the people and professions performing them [95, 96]. A resolution was also adopted modifying the definition of health care services, taking into account the aspect derived from aesthetic medicine treatments [97]. Issues related to the legal status of products and substances used in aesthetic medicine are also discussed [88]. Moreover, the resolution of the Supreme Medical Council prohibits doctors and dentists from participating as lecturers in practical training on providing health services if the event participants are people who are not authorized to provide medical services [98]. This is motivated, among other things, by causing an unfavourable effect in the form of legitimizing potential unauthorized medical activities [98].

CONCLUSIONS

Needle-based medical aesthetic procedures, such as mesotherapy, injections of botulinum toxin or the use of tissue fillers, despite the low invasiveness of the procedure, may be associated with serious consequences. Therefore, each procedure should be performed by a person with appropriate medical background. Performing the procedure in a technically incorrect manner may result in complications that, in extreme cases, may be life-threatening. The type and quality of products used during procedures also play an important role. In light of the rapidly growing number of aesthetic medicine treatments over recent years, the effects of their performance will become an increasingly important issue from the judicial and medical point of view, both in the case of criminal and civil cases, including for the purpose of obtaining compensation. Further research is necessary on the scale of complications, their types and causes. In addition, it is necessary to clarify and specify the legal issues related to the qualifications of medical professionals who may perform similar aesthetic medicine treatments.

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