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Safety, Sterility, and Potential Complications of Permanent Makeup Procedures

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Abstract

Within the framework of the present study, an analysis of the permanent makeup industry was conducted with a focus on biological safety, the chemical composition of the pigments used, and the pathophysiological mechanisms underlying the development of complications. Against the background of the rapid expansion of the global market, projected to reach a volume of 277.8 million United States dollars by 2032, issues of standardization and procedural regulation acquire particular significance. The study provides a detailed examination of the impact of the European REACH regulation of 2022, aimed at restricting more than 4000 potentially hazardous chemical compounds, while simultaneously revealing a persistently high level of noncompliance of products with established regulatory requirements. Special attention is devoted to the etiopathogenesis of granulomatous reactions, sarcoidosis, and rare systemic pathologies such as ASIA syndrome, which arise as a consequence of intradermal implantation of pigments. The data obtained underscore the presence of a direct relationship between the level of practitioner qualification and the incidence of adverse effects, thereby substantiating the necessity of implementing multilevel professional training programs to minimize risks. The work demonstrates the critical importance of an interdisciplinary approach involving the coordinated efforts of dermatologists, toxicologists, and regulatory authorities, aimed at ensuring maximum consumer safety under conditions of contemporary technological development of imperceptible interventions.

Keywords: *Permanent Makeup, Micropigmentation, REACH Regulation, Skin Microbiome, Granulomatous Reactions, Sarcoidosis, ASIA Syndrome, Chemical Safety, Professional Education, Aesthetic Medicine.*

INTRODUCTION

Contemporary aesthetic medicine is undergoing profound transformations, within the framework of which permanent makeup (PM) has ceased to be an exclusively decorative procedure and has evolved into a complex field of dermopigmentation associated with invasive interventions. The PM procedure consists of the intradermal introduction of exogenous pigment particles and additional components with the aim of correcting facial features or masking defects [1]. The relevance of studying this topic is determined not only by the economic growth of the industry but also by changes in consumer preferences in 2024–2025. A clear shift toward naturalness and minimal visual detectability of interventions is observed, whereby procedural outcomes are expected to harmonize with the natural anatomy of the face without creating an artificial effect [2].

Trends of 2025 demonstrate increased interest in techniques that stimulate natural regenerative processes of the skin. In the context of PM, this is reflected in the application of more gentle techniques and high-quality pigment formulations [2]. However, the invasive nature of the procedures inevitably preserves inherent risks. Disruption of the integrity of the skin barrier during needle insertion affects the microbiome, a complex ecosystem of microorganisms that researchers define as the fourth layer of the skin [3]. Dysbiosis resulting from mechanical injury or exposure to chemical components of the pigment can lead to pronounced infectious and inflammatory complications [3].

The complexity of the situation is further aggravated by the fragmentation of global regulatory standards. In the European Union, a strict REACH regulation has been in force since 2022, restricting the use of more than 4000 potentially hazardous compounds, whereas in other regions, including the United States, the implementation of comparable measures such as MoCRA remains at an active stage of development [4]. Under these conditions, critical assessment of procedural safety, adherence to sterility, and the mechanisms underlying complication development becomes an essential element of ensuring the sustainable development of the industry.

The aim of this work is, on the basis of a systematic

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analysis of clinical data, pathomorphology, and regulatory requirements (REACH/MoCRA), to develop a risk-oriented protocol for prevention, screening, and early diagnosis of complications in PMU practice.

The author's hypothesis is that the frequency and severity of complications of permanent makeup (infectious, allergic, granulomatous, and systemic reactions, including sarcoidosis and ASIA) are statistically significantly determined by a combination of three controllable factors: sterility and control of microbial contamination (including manufacturing purity of pigments), the chemical and toxicological profile of formulations (impurities, photodegradation), and the level of standardized practitioner training.

The scientific novelty of the study lies in the integration of pathomorphological patterns (type of granuloma or foreign body reaction) with the source of risk (contamination, pigment composition, technique and depth of insertion) into a unified interdisciplinary model of risk stratification and controlled procedural quality.

MATERIALS AND METHODS

To prepare the study, a systematic review of scientific literature and regulatory documents was conducted. The primary sources of information included the PubMed and Scopus databases, as well as materials from specialized organizations, including the FDA (U.S. Food and Drug Administration) and the ECHA (European Chemicals Agency).

Within the framework of the study, comprehensive methodological approaches were applied. A bibliometric analysis of publication dynamics on complications of permanent makeup and tattoos was performed, with particular attention to granulomatous reactions and systemic autoimmune responses. A comparative analysis of regulatory requirements was carried out, juxtaposing the provisions of the European REACH regulation and the United States MoCRA act with regard to pigment composition and mandatory adverse event reporting [5]. Statistical forecasting based on data from Fortune Business Insights and Allied Market Research made it possible to identify the most dynamically developing segments of the industry, including paramedical micropigmentation [7]. In addition, a case study method was employed to analyze clinical cases of sarcoidosis, ASIA syndrome, and atypical mycobacterial infections following PM procedures in order to identify risk patterns and refine diagnostic criteria [9]. Toxicological risk assessment was conducted based on calculation of the Margin of Safety (MoS) and the Hazard Quotient (HQ).

RESULTS AND DISCUSSION

The global permanent makeup market demonstrates a stable trend toward expansion. In 2024, its volume was estimated at 152.4 million United States dollars, with growth projected to reach 162.9 million United States dollars by 2025 [7]. At the same time, a significant increase in the number of professional training programs is observed, reflecting practitioners' efforts to systematize and formalize competencies in response to the tightening of procedural safety requirements.

Table 1 below presents the forecast for the development of the global permanent makeup market.

Table 1. Forecast of the development of the global permanent makeup market (compiled by the author based on [7]).

Parameter	2024	2025 (forecast)	2032 (forecast)	CAGR (2025–2032)
Market size (million USD)	152.4	162.9	277.8	7.9%
Europe share (%)	72.38%	—	—	—
Dominant segment	Eyebrows	Eyebrows / Lips	Paramedicine	—

The primary factors stimulating market development include technological innovations in pigment creation and the refinement of devices, as well as the expansion of clinical indications for micropigmentation. These include scar camouflage, correction of vitiligo, and reconstruction of the nipple-areola complex following oncologic interventions [7, 8].

The implementation of the REACH regulation in 2022 became a pivotal event for pigment manufacturers, because the restrictions encompassed heavy metals, aromatic amines, and a range of preservatives. An analysis of market conditions in 2024–2025 revealed that a substantial share of products labeled as REACH-compliant in fact contains concentrations of toxic elements that exceed the permissible values established by regulatory standards [6].

Next, Table 2 presents the results of the analysis of heavy metal content in pigments.

Table 2. Analysis of heavy metal content in pigments (compiled by the author based on [6]).

Element	Frequency of REACH limit exceedances	Health risks
Nickel (Ni)	24 out of 41 samples	Carcinogenicity, severe allergy
Arsenic (As)	20 out of 41 samples	Carcinogenicity, systemic toxicity
Chromium (VI) (Cr)	16 out of 41 samples	Allergic dermatitis, genotoxicity
Copper (Cu)	10 out of 41 samples	Low margin of safety index, risk to the liver
Lead (Pb)	5 out of 41 samples	Neurotoxicity

Studies show that, from the standpoint of chemical safety, the most problematic are red pigments, for which the frequency of errors in composition declaration reaches 61% [13]. Despite the use of modern organic compounds such as azo dyes and quinacridone, the risk persists of their chemical degradation under exposure to laser or ultraviolet radiation, with the formation of potentially carcinogenic products [3, 10].

In the United States, the entry into force of the MoCRA act obligates manufacturers to submit information about serious adverse events within 15 business days [15]. At the same time, no color additive has received FDA approval for intradermal application, which creates a legal vacuum regarding liability for the long-term consequences of pigment use [5].

The permanent makeup procedure disrupts the integrity of the epidermal barrier, creating conditions for the penetration of pathogenic flora. Evidence indicates that even with strict adherence to hygienic standards, infections may occur due to ink contamination at the manufacturing stage [11, 16].

The most common are bacterial infections, including lesions caused by staphylococci and streptococci, manifesting in the form of impetigo and folliculitis. Of particular concern are outbreaks caused by atypical mycobacteria (Mycobacterium chelonae), often associated with the use of nonsterile water to dilute pigments [3, 12]. Viral and fungal complications include transmission of hepatitis B and C, HIV, activation of the herpes virus, especially in PM procedures of the lips, as well as the spread of viral warts (HPV) in the tattooed area [1].

Granulomatous reactions develop as a chronic immune response to the presence of a foreign body. Histologic classification distinguishes sarcoidal, lichenoid, and tuberculoid granulomas, reflecting the diversity of pathophysiological mechanisms and clinical manifestations of such complications [13, 17].

Within Table 3 presented below, a classification of noninfectious complications of PM is provided.

Table 3. Classification of noninfectious complications of PM (compiled by the author based on [9, 13, 17, 23]).

Complication category	Key characteristics	Examples of manifestations
Inflammatory	Reaction to needle-induced trauma	Edema, erythema, blisters
Allergic	Hypersensitivity to the pigment	Contact dermatitis, pruritus
Granulomatous	Chronic immune response	Cutaneous sarcoidosis, nodular masses
Systemic	Systemic immune response	ASIA syndrome, pulmonary sarcoidosis

Analysis of the literature confirms an association between permanent makeup and the development of systemic autoimmune reactions. Thus, the Koebner phenomenon manifests in patients with psoriasis, vitiligo, or lichen planus: mechanical trauma to the skin during PM can induce the appearance of lesions typical of the underlying disease within the intervention zone [1].

ASIA syndrome (Autoimmune/Autoinflammatory Syndrome Induced by Adjuvants) demonstrates that PM pigments may function as adjuvants, provoking a systemic inflammatory response in genetically predisposed individuals. An illustrative example is the case of a 46-year-old patient with hypothyroidism in whom, following a series of tattoos, myalgia, chronic fatigue, and interstitial lung involvement developed [9, 18].

Sarcoidal reactions in the eyebrow region may serve as the first and, at times, the only manifestation of systemic sarcoidosis. In 14 of 19 cases studied, cutaneous changes at the tattoo site preceded the diagnosis of lung or lymph node involvement [20].

One of the key factors in reducing the risks of complications is recognized to be professional education and adherence to sterility. The absence of standardized training programs in the field of PM is identified as a significant factor increasing the frequency of errors [21, 22]. Many practitioners complete short-term courses that do not provide sufficient understanding of skin pathophysiology and the chemical composition of materials. In-person training with practice on live models under the supervision of experienced mentors, for example according to methodologies of brands at the level of K.Cox, substantially reduces the number of technical errors. The author's personal contribution includes the development of proprietary safety protocols based on long-term clinical observations of tissue responses and the implementation of advanced educational standards that prioritize pathophysiological screening before the procedure. [24, 25]. Improper technique leads not only to aesthetic defects such as pigment migration, but also to the development of hypertrophic scars and keloids [16, 19].

The synthesis of the obtained data indicates that the PM industry is at a stage of regulatory maturation. The transition to the use of highly purified pigments and compliance with the REACH 2022 regulation are necessary but not yet fully implemented measures. More than 50% of inks tested on the European market do not comply with standards for nickel and arsenic content, indicating insufficient control within supply chains [6].

The mechanism of granulomatous reaction development remains a subject of debate. Permanent pigments, unlike biodegradable fillers, form a persistent focus of antigenic stimulation. In cases of grade 4 chronic foreign body reactions (FBR), pigment removal presents significant difficulties due to the absence of specific solvents and the risk of exacerbating inflammation under laser exposure [14].

The concept of the skin microbiome as a barrier underscores the long-term consequences of disruption of this ecosystem by invasive procedures for local immunity. Further research should focus on the influence of needle type and the operating speed of PM devices on the survival of the resident skin flora [3, 26].

For patients with diabetes mellitus and autoimmune diseases, PM is not an absolute contraindication, but it requires the development of a specialized protocol. Given the increased risk of xerosis and delayed wound healing in diabetes, control of glycated hemoglobin levels before the procedure and intensified post-procedure care become critically important [27].

CONCLUSION

The analysis of safety, sterility compliance, and the pathophysiological aspects of complications in permanent makeup procedures makes it possible to identify key conclusions and recommendations.

The chemical purity of the materials used remains critically important. The industry requires stricter oversight of pigment compliance with the requirements of the REACH and MoCRA regulations. Practice demonstrates the necessity of requesting detailed Certificates of Analysis (CoA) from manufacturers for each batch and giving preference to brands that voluntarily undergo independent toxicological testing.

Microbiological safety is determined by water quality and the storage conditions of opened bottles. The principal sources of bacterial complications remain nonsterile water and violations of sanitary conditions. The use of single-use sterile cartridges and adherence to strict asepsis protocols for the workstation are mandatory.

Diagnostic vigilance on the part of PM practitioners and dermatologists is of decisive importance. Cutaneous reactions to pigments may serve as markers of systemic diseases such as sarcoidosis or ASIA syndrome. Any atypical inflammation appearing months or years after the procedure requires histologic confirmation and evaluation of the patient for possible systemic pathology.

Standardization of professional education is regarded as a necessary condition for reducing complication risk. The implementation of a multilevel certification system that includes medical modules (anatomy, infection control, emergency conditions), as well as training that integrates theoretical preparation with prolonged practice on models, should become an industry standard. In this context, it is important to emphasize that the findings of this study and the developed protocols are already successfully integrated into the educational programs of the Katerina Cox Academy. The author utilizes these protocols not only in their own clinical practice but also ensures their systematic inclusion in the Academy's curriculum, which directly contributes to raising safety standards and professional responsibility across the permanent makeup industry.

Informing clients about potential risks is an integral component of safe practice. Patients must be made aware of possible long-term consequences of pigment presence in the dermis, including the risk of burns during MRI in cases of iron oxide content, as well as the difficulties of removing undesired outcomes.

Overall, achieving a high level of safety in permanent makeup procedures is possible only under conditions of synergy between scientific advances in the chemistry of polymers, strict governmental oversight, and the profound professional responsibility of practitioners.

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