# ORIGINAL ARTICLE: BIOETHICS

# The cancer patient and medical dermo-pigmentation: psychological aspects.

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**Abstract.** This work aims to assess breast cancer treatment's physical and psychological impact on patients undergoing it, particularly regarding emotional and social issues. The focus is on the extent to which reconstructive procedures can alleviate problems the operated patients are facing and on whether the completion of the reconstructive procedure, through the reconstruction, or restructuring of the nipple-areola complex through minimally invasive methods, such as tattooing, i.e. micropigmentation, is an important requirement in order for the patient to forget about the disease, or reduce the impact its memory brings.

**Keywords:** humanisation, medical tattooing, reconstructive surgery, to care, lived experiences, psychology, evaluation, patient satisfaction

### Introduction

Breast cancer is the most common cancer pathology among women and the second most frequent cause of death from malignant disease in Europe (1). Italy has an estimated 55,000 new cases per year, with an increase of 0.3 %. Furthermore, according to the frequencies with which it is diagnosed in the various age groups, breast cancer is the most frequently diagnosed cancer among women in the 0-49 age group (41%), the 50-69 age group (35%), and the older +70 age group (22%) (2). In Italy, over 834,000 women have been diagnosed with breast cancer, accounting for 43% of all women living with a previous cancer diagnosis and 23% of all prevalent cases (accounting for both men and women).

The visible decrease in breast cancer mortality (minus 6% from 2015 to 2020) can be attributed to more widespread early detection programmes and therapeutic advances. Today, considering all stages of the disease, the 5-year survival rate for women with breast cancer is 87% in Italy.

In order to achieve these results, the Breast Units were set up since it has been proven that a multidisciplinary approach increases the probability of survival and improves the quality of life prospects of breast cancer patients. These units comprise a team of highly qualified specialists dedicated to diagnosing, supporting, and treating breast pathology (3). The aim is to accompany the patient through the entire diagnostic, therapeutic, and follow-up process from the earliest possible stage of the disease. Any woman who receives a diagnosis of breast cancer, in fact, suddenly sinks into a psychological condition of extreme distress, not only because of the meaning and implications of the pathology itself but also because the breasts are a part of the body that, together with the genital apparatus, concretely and symbolically represent femininity (4).

Female identity is mainly structured around concepts such as motherhood, femininity, attractiveness, and desirability. Because of such a paradigm, many women consider having intact and healthy breasts indispensable.

We must consider how, over time, the female image has played an important role and changed the canons of aesthetics with the historical moment. We can follow the evolution of this feminine ideal through the artistic representations handed down to us, from Willendorf's Venus to Milo's Aphrodite, to Rubens' paintings, to the fashions of the 1970s, with Twiggy's provocative thinness. The search for body harmony can be seen in the ancient Egyptian world as well, with the discovery, thanks to scanning, of Queen Nefertiti's 'retouched' face on her death mask (5, 6).

So, if the diagnosis and the course of chemotherapy (and often radiotherapy) create a deep furrow in a woman's life, surgery, even with increasingly fewer mutilating operations, leaves an indelible furrow visible daily. Moreover, the contact with one's maimed, 'cut', and incomplete breast entails a psychic wound that involves the whole spheres of one's life, such as the physical, the relational and the professional (7). It is a reality that demands much of the woman, disrupting her life in all areas, which makes the presence of psychological support necessary to help her deal with the psychic experience and emotional burdens, that this new reality entails.

The possibility of reconstruction, or remodelling, of the operated breast using reconstructive plastic surgery is of great importance. This procedure can begin during oncological surgery or subsequent thereof (8). It aims to attempt to restore that body image altered by the therapeutic, surgical procedures as best as possible,

Numerous reconstructive techniques can be used for this purpose, depending on the type of surgery performed and the woman's wishes, physical condition, and work and family situation (9). The final stage of this process involves the reconstruction, or revision, of the nipple-areola complex.

Many different techniques can be used to this end as well. Some require the reconstruction with local flaps or the removal of a portion of the areola from the contralateral breast; others need the removal of a superficial layer of skin to be grafted in the area to be reconstructed (10). The choice of reconstructive method for the areola-nipple complex depends on several other variables as well.

An important recent option for non-surgical reconstruction, or revision, of the nipple-areola complex is tattooing. This is a minimally traumatic procedure, with good aesthetic results, that, since 2019, has been included in the LEAs and is, therefore, recognised by the NHS.

This treatment originates from procedures handed down through the ages and used for various reasons and purposes, even medicinal ones often with oils and ointments (11). The historical reasons for tattoos are incredibly varied too. For example, a tattoo could signify religious affiliation, caste, or honour. In other circumstances, tattoos have been used to mark outcasts, political (and war) prisoners, and certain criminals. This to such an extent that tattoos became highly stigmatised, together with other physical or behavioural manifestations, being looked upon as the prerogative of people with a violent and criminal character (12, 13).

Thanks to the support of "Italian League for the Fight Against Cancer "(LILT), we conducted a study to ascertain both how much the patients wished to complete their physical and psychological rehabilitation process with the reconstruction of the nipple-are-ola complex and how satisfied they were with this procedure.

### The cancer patient's emotional experience

It is difficult for any woman, such a sensitive, multifaceted, and profound person, to understand and describe a breast cancer diagnosis's impact on her life. This impact can, metaphorically and reasonably, be compared to the shockwave of a bomb exploding a few metres away. Generally, the prevailing emotions related to the diagnosis are shock, uncertainty, fear, bewilderment, and existential threat (14).

The woman remains stunned and does not immediately understand what is happening to her. She suddenly feels anxiety and nervousness, as if everything has lost meaning, or she feels nothing at all, each emotion so powerful that it must be suppressed not to overwhelm her psyche completely.

The swiftness with which the medical and care staff take charge of her and the activation of the therapeutic protocol, on the one hand, help the patient understand how vital her current clinical condition is, in some way bringing her back to reality and, on the other help her perceive an initial sort of protection concerning what is happening to her.

A breast cancer diagnosis profoundly changes a woman's perception of personal identity, her body's identity, her femininity, the meaning of motherhood, and how attractive and pleasant she believes she is perceived to be. The woman who experiences a breast tumour and the invasiveness of therapies and surgeries has to deal with deep feelings of loss, impairment, and despair. Generally, she experiences cancer as a monster, an unwelcome guest, and a threat to her existence and her plans for life and family relationships.

Everything fades into the background, and other elements, no less significant than the 'trauma shock' and fear of death, enter the woman's emotional experience, such as

- psychosocial consequences: such as the interruption (or loss) of a career, changes in one's role in the family, significant changes in one's social life.
- consequences of treatment: nausea, loss of fertility, alopecia, pain, and others.
- the evolution of the illness causes the patient to live in a state of continuous alertness, with fear being rekindled at every check-up, even when things are going well (15).

Intrafamilial and extrafamilial relationships are transformed since this pathology requires the person affected by cancer and the whole family to adapt to significant changes. Most often, one member of the patient's family assumes responsibility for her care and assists her in caring for her health, emotions, finances and logistics. This family member becomes the rock that must not crumble, risking, in turn, needing psychological support for him or herself (16).

The cancer patient goes through various phases during her personal experience with the illness, which may alternate between each other or settle with a prevailing one dominating the others: the Denial or Rejection Phase, the Anger Phase, the Coping Phase, the Depression Phase and the Acceptance Phase (17).

The Denial or Rejection Phase, which usually follows diagnosis, represents a period of shock, denial and rejection of the current state of affairs. Catastrophic experiences arise, and reality is too painful to be faced (18). Only during the Anger Phase does the first im-

pact on reality occur. The woman often becomes angry with herself, the illness, the doctors, or her loved ones. She also feels anguish, despair, and bitterness. She finds it difficult to control her emotions, experiences a childlike feeling of bewilderment, and may engage in regressive defensive behaviour. The Coping Phase generally follows the active period of treatment. The patient has experienced her vulnerability and senses the limits of her life and body. It is the time to reflect on her past choices, future intentions and desires. The Depression Phase represents when the woman begins to become aware of the losses she is suffering or is about to suffer, and, therefore, experiences a depressive state, in the first case of the reactive type, in the second the anticipatory type. In this phase of the illness, the patient can no longer deny her condition and becomes aware that rebellion is no longer possible, so a strong sense of defeat replaces her previous denial and anger. Finally, during the Acceptance Phase, the woman resumes living by including the experience of her illness, the changes in identity or lifestyle that have become necessary, and the learning about herself that she has achieved in it (19).

The woman with breast cancer copes with these phases by implementing particular attitudes and behaviours that characterise her as an individual, which she uses to face difficulties.

These attitudes and behaviours are grouped into what was initially defined by Lazarus and Folkman as Coping Styles. The main ones are Combative, Fatalist, Anxious, Avoidant, and Desperate (20). For example, to cope with the emotional burden of her diagnosis, the patient may, once she has discovered that she is ill, implement (more or less consciously) strategies to try and cope with the event and what follows it. She may, for example, seek better information (rationalisation), underestimate the seriousness of the diagnosis (minimisation), lash out at someone (projection), accept the diagnosis, and find favourable aspects (redefinition), and try not to think about it (repression). At other times she may fall into substance abuse (tension reduction) or isolate herself socially (stimulus reduction).

Other factors that generally influence the patient's reaction to a cancer diagnosis, and her adaptation to the illness, are: medical, spiritual, social, and psychological (21).

Coping styles, in addition to personal attitude, are also determined by the patient's meaning of her illness and the clarity and accuracy of the information she receives about her condition. That is why the work of the Breast Unit is vitally crucial in addressing the psychological aspects, which are no less important than any other since having a positive personal attitude may improve health status. Conversely, a negative attitude may not be conducive to better health (22).

As previously mentioned, the Breast Unit, or Multidisciplinary Senology Centre, specialises in diagnosing, treating, and psychophysical rehabilitation of breast cancer women. The staff of the various teams spread throughout Italy, in collaboration with that of the local LILT offices, plays a fundamental role in taking care of patients in every aspect. From a psychological point of view, factors such as a welcoming environment, the presence of help nearby, empathy, emotional support, and professionalism on the part of the staff of both the aforementioned bodies are essential to guarantee an acceptable level of emotional wellbeing in a traumatic life situation, such as that of neoplastic pathology. As mentioned above, the Coping Styles are also determined by comprehensive information about the disease and its secondary aspects and by the ability of medical (and care) staff to put the breast cancer patient at ease so that she feels completely confident to place herself in their hands.

A further step forward in the psychological and physical care of women is represented by breast micropigmentation (23).

The procedure was made possible in Liguria (north Italy), thanks to the funding of a research project of the national LILT at the local section of Sanremo which involved the Breast Units of ASL1 Imperiese, San Martino Polyclinic Hospital and ASL4 Chiavarese.

The University of Genoa has also set up courses to qualify health workers to practise medical tattooing and providing regulatory and deontological support (24).

## Materials, Methods, and Results

Concerning the psychological aspects of the use of dermo-pigmentation in healthcare, an anonymous

questionnaire was prepared by the working group to ascertain the satisfaction of patients who received this treatment.

The questionnaires were proposed to 81 patients at the Breast Unit, Asl 1 during a follow-up visit. Participation in the compilation was entirely voluntary and was aimed at verifying:

- How much patients desired a complete breast reconstruction, including the areola-nipple complex.
- The opinion of patients who have undergone such a procedure.
- The patient's opinion of the reception, and helpfulness, of the medical and nursing staff.

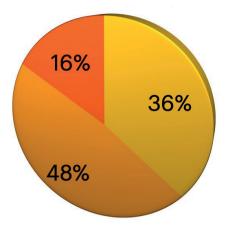
All but one of the patients underwent a total mastectomy and received an anatomical prosthesis. In addition, approximately half had undergone chemotherapy, while 18% also received radiotherapy.

The patients were asked how important they considered reconstruction of the areola-nipple complex to be: 36% considered it extremely important, Value 3, 48% considered it somewhat necessary, Value 2, and only 16% considered it unimportant, Value 1 (Figure 1).

Similarly, the patients were asked how useful they considered completing the reconstructive process, with the areola-nipple complex resurfacing, to be for themselves and their relationship life. Seven out of 81 (9%) patients considered it exclusively valuable for their relationship with others, 25 (31%) deemed it valid for themselves 49 (60%) thought the reconstruction of the areola-nipple complex was necessary from both points of view (Figure 2).

As far as being tattooed was concerned, given that medical micropigmentation consists of the three-dimensional tattooing of a nipple and an areola, we wanted to investigate the patient's familiarity with the subject. Approximately 75% of the sample group had no tattoos, of which 48% felt that the dermo-pigmentation procedure was invasive. Interestingly, only 25% of the patients in the sample who had already experienced tattooing felt the same way.

Eighty-nine per cent agreed that they had received comprehensive information about the procedure, while about the patient's satisfaction following the administration of the dermopigmentation treatment of the areola-nipple complex, the work group wanted to explore some parameters such as shape, ap-



**Figure 1.** How important they considered reconstruction of the areaola-nipple complex

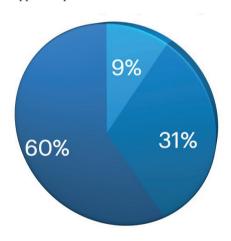


Figure 2. How useful they considered completing the reconstructive process, with the areola-nipple complex resurfacing

pearance, naturalness, colour and height of the result in toto.

Concerning shape, only 6% of the patients in the sample were dissatisfied, while 52% were fairly satisfied and 42% were highly content (Figure 3).

Similar results were obtained about colour 7% (somewhat dissatisfied patients), 53% (rather satisfied) and 40% (very satisfied) and height 4% (somewhat dissatisfied patients), 55% (rather satisfied) and 41%, (very satisfied).

Appearance and naturalness represent less tangible criteria, if one can say so, but are decisive for the whole procedure's success. For these parameters, the percentages of satisfaction were: 56% for the first cri-

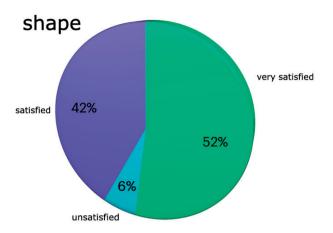


Figure 3.

terion and 52% for the second, while those who reported great satisfaction represented 38% and 42% of the sample.

As for the relationship with the medical, nursing, and care staff: it was considered essential. Therefore, patients were asked to report their opinions on professionalism, preparation, kindness, and welcome shown by the staff.

Patients who ultimately agreed (value 3) on the fact that the healthcare personnel were prepared stood at 60%; 51% found them to be very thorough (51%) and professional (52%), while those who reported that they were only instead in agreement with the statement about the staff's preparedness (value 2) averaged 42% for the three parameters considered here (Figure 4).

With regards to the characteristics of humanity and empathy of the healthcare personnel, the patients ultimately agreed that personnel had been respectful

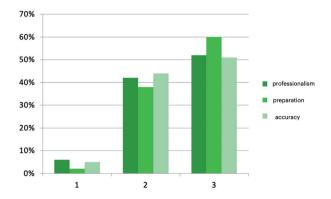


Figure 4.

(54%), friendly and kind (55%), had put them at their ease (47%), and had devoted the right amount of time to their concerns (55%). On the other hand, the dissatisfaction rates were between 4% and 7%.

#### Conclusions

A total reconstruction of the breast complex is crucial in perfecting physical and psychological healing following surgery and chemo- and/or radiotherapy treatments during a breast cancer diagnosis. The work group study outlined above showed that breast cancer patients consider reconstructing the areola-nipple complex significantly important. They regard it as a beneficial procedure, not only for themselves, to restore the integrity of their sense of identity, but also for their aspiration to live a satisfying relational life after the illness. Moreover, about 40% of the sample believes that micropigmentation is invasive. However, this percentage is halved if only patients who have already experienced tattooing are considered. Having experienced a similar procedure before (in addition to being given accurate information) allows for a more objective assessment. In this regard, it would be interesting to verify whether the subjective evaluation of patients who have never received a tattoo is negatively affected by the invasiveness of the treatments and surgeries they have already undergone so that, at a certain point, any further 'touch' in such a sensitive, and intimate, area as the breast is experienced as an intrusion, even when it would not have been otherwise...

The humanity of people is one of the main drives for women with breast cancer to go on despite their illness. Sharing and talking about the experience of the disease, the emotional experience, the problems at home, feeling understood and supported in one's difficulties and needs, and at the same time being able to rely on health personnel at such a difficult time in one's life, is, in our opinion, fundamental for a correct, and complete, patient care, and favours a better psychophysical response to the cancer event on her part.

Above all, this happens at the end of the reconstructive pathway, when tiredness and suffering have become her regular companions. Nevertheless, the pa-

tient begins to glimpse a future for herself beyond the suffering caused by the illness, so it is vital for her to encounter the humanity, professionalism, and welcome of the health personnel and to face the final steps of the reconstructive phase through medical dermopigmentation of the areola and nipple, with hope and serenity.

The patients of the practice who have undergone this procedure are remarkably pleased, not only with the overall result but also with individual features such as the shape and height of the nipple, the colour of the reconstructed areola-nipple complex, and the appearance and naturalness of the result, which are less tangible qualities, more subjective to personal biases.

As professionals dedicated to the care of the whole person, we believe it is necessary to inform clinicians, and patients, of the value and safety of breast-areola tattooing as an intervention downstream of the diagnosis and course of treatment, to restore balance, provide the patient with an excellent final aesthetic outcome, and recover the patient's wellbeing (psychological as well as physical), according to the concept of health defined by the WHO as the ability to adapt and self-manage in the face of physical, psychic, and emotional challenges (25).

When we speak of breast cancer, we often mainly focus on prevention and treatment without fully considering the 'after' and the psychological repercussions of the disease that require taking care of the person to be overcome.

Post-surgery psychological rehabilitation, and related recovery opportunities, also involve treatments with aesthetic purposes. To this end, we aim to make health dermopigmentation the treatment of choice.

The emotion and light in the eyes of our patients, when they see themselves for the first time after the reconstructive process has been completed is the ultimate proof of this, and that is all we need.

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None of the authors of this manuscript has a financial or per-

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# ORIGINAL ARTICLE: BIOETHICS

# To heal and take care: medical micropigmentation and its role in improving body image

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**Abstract.** The practice of tattooing dates back to a remote past and is characterised by its many different purposes. However, in the last decades, such practice has become a cultural phenomenon, extending its reach to a broader population, including adolescents. More recently, in the perspective of enhancing a broader therapeutic approach, heedful of the many different needs of the individual, the practice of micropigmentation has become widespread in the medical field in order to offer the possibility of reconstructing the body image where skin, pathological manifestations, and congenital or acquired imperfections, have altered its physiological appearance with a non-invasive methodology. Its application indicates a commitment to a more humane form of treatment based on a multidimensional approach to the person and on integrating different skills and expertise, not only from the medical area but also from the technological one. However, the practice of dermal pigmentation presents risks that require adequate professional training and broad communication between practitioner and patient to assess the existence of ideal conditions for its implementation carefully.

**Keywords:** micropigmentation, tattoo, dermal pigmentation, humanisation, medical micropigmentation, reconstructive surgery, camouflage, to care, holistic medicine

## Introduction: historical background

In its most widespread form, the tattooing technique consisted of scarifying or incising the skin, delaying its healing through particular substances, making punctures, and introducing dyes into the wound (1). This procedure, seemingly easy to perform, has been made possible over time by the succession and evolution of several methods, some very different from each other, used since ancient times.

The first official record of tattooing is reported in a written by Commander J. Cook in 1769, who noticed marks on the locals' skin while observing the population of Tahiti. These marks were made with the help of a sharpened shell or incisions made in the skin with sharpened wooden sticks that, while being used, produced a peculiar tapping sound, hence the name "tattow," later to become tattoo (2).

The origin of this procedure is much more ancient, though, as evidenced by the famous discovery of the Similaun mummy "Ötzi" preserved in the mountain ice (3). The analyses to which this specimen has been subjected over the last two decades have revealed it to be a male, between 40 and 50 years old, who died during the Copper Age between 3100 and 3300 B.C.E., probably as a result of an arrow wound. This find has tattoos on its skin surface consisting of vertical incisions coloured with a black powder. The tattoos of the Similaun man consist of simple dots, lines, and crosses, located at the lower spine, behind the left knee and on the right ankle. Radiological examinations of the mummy have revealed forms of arthrosis at those points (4). For this reason,

it is assumed that such tattoos had a religious-healing function to relieve pain. According to other interpretations, the tattoos would constitute points consequent to the practice of acupuncture (5).

Therapeutic tattoos have also been found on the mummy of the Pazyryk man in Central Asia, which has intricate animal tattoos, and on that of the Ukok princess - Altai Mummy - dated around 500 B.C.E. (6). Inside the coffin of Princess Ukok, archaeologists found cosmetics in a kind of makeup "trousse" that had been placed on the princess's left side and contained a horsehair face brush and a fragment of an eyeliner pencil made from iron rings coiled around a shard of vivianite, capable of colouring the skin dark blue green. There was also vivianite powder, apparently to be used for facial applications. According to Professor Vladislav Malakhov of the Boreskov Institute of Catalysis Siberian Branch of the Russian Academy of Science, the analysis showed that the Pazyryk women knew and used the blue mineral dye called vivianite and made face masks from fats and oils, even quite complex ones, for cosmetic and pharmacological purposes and, in particular, to protect the skin from the extreme climates of the high mountains" (7, 8).

Other forms of skin pigmentation are found on ancient Egyptian mummies and on funerary carvings showing pigmentation patterns on the bodies of female figures, which remained 'invisible' for centuries, and were only revealed when the use of infrared photography allowed researchers to observe them on the skin of seven 3,000-year-old Egyptian mummies (9).

In subsequent times, tattoos were intended as a sign of religious affiliation, caste, and honour (10). However, tattoos have also been used in different circumstances to mark outcasts, political and war prisoners, and certain categories of criminals (11).

Well-known scientists, such as Lombroso, considered tattoos, especially when present in particular locations on the body, as a stigmatising mark of a violent and criminal character, along with other physical and behavioural characteristics (12, 13), (fig.1).

More elaborate tattoos found their origins in Japan and were used, again, for different purposes: aesthetic, magical, ritual, or to brand criminals (14).

In 1891 Samuel O'Reilly, the inventor born in Connecticut, patented the first tattooing device in the

U.S., which used an electric motor, a system of tubes to convey pigment into a needle, and a foot pedal to activate or interrupt the movement of said needle (15).

Subsequently, tattoos have been used by ethnic minorities, sailors, war veterans, military organizations, gangsters, prisoners and, generally, considered the prerogative of people marginalized by society, such as "punks" and biker groups in the 1970s like, such as the American "Hell's Angels" (16).

For a few years now, tattooing has become a widespread fashion in many countries, predominantly among young people and adolescents, despite this practice being widespread among all age groups.

More recently, tattooing, alongside a purely ornamental or symbolic purpose, has also been employed in the health care context. In such a context, tattooing or, more precisely, corrective dermal pigmentation has taken on a medical connotation in the scope of a broader and holistic vision of personal care. The possibility of offering, through such a method, the opportunity of regaining the identity of one's own body constitutes an essential aspect of the care of the person itself, which characterises a medicine increasingly aimed not only at "curing" but also at "caring."

For years, indeed, medicine has increasingly turned its attention not only to the elimination of disease or abnormalities but also to the promotion of the person's well-being, according to the broad concept of health as defined by the World Health Organization, as a condition of adaptation and self-management in the face of physical, psychological, and social challenges.

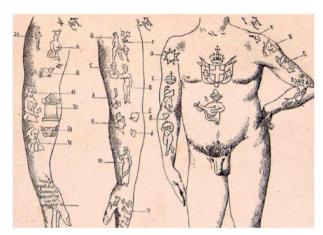


Figure 1. Tattoos like stigmata

# Dermal pigmentation in the medical field: an integral approach of the person

Purposes and areas of application of dermal pigmentation

Dermal pigmentation is a technique akin to tattooing that allows skin colouring through the introduction of specific inks into the superficial layer of the papillary dermis, with the help of an electric device - a tattoo machine or oscillating pen - and disposable needles.

Dermal pigmentation aims to improve a person's appearance and aesthetic image by modifying, correcting, eliminating, or alleviating blemishes on the body and face.

This technique differs from artistic tattooing and even permanent makeup in the type of instrument used, the materials employed, the recipients of the treatment, and, again, the personnel involved in its use. Instead, micro-pigmentation is carried out under medical supervision or indication in people who, after undertaking invasive procedures such as chemotherapy, demolition surgery, reconstructive treatments, or even congenital conditions, need to cover pathological skin conditions to restore the appearance of healthy skin.

In some cases, this technique can also be used for the administration of pharmacological substances with specific therapeutic indications (17).

In the medical literature, lemmas dermal pigmentation, micro-pigmentation and dermatography are often used synonymously.

Tattooing for medical purposes has wide application in numerous areas, such as the reconstruction of the areola and nipple of the operated breast, radiation oncology - repair points-, treatment of alopecia areata and vitiligo, camouflage of atrophic, hypertrophic, and keloid scars, treatment of scarring outcomes of cleft lip and palate, pigmentation of the cornea, treatment of nevus flammeus, treatment of areas of alopecia on the scalp, reconstruction following gum implantation.

From an ethical point of view, such a procedure harmonises not merely with a broad view of the person requiring care, heedful to his or her physical, psychological, cultural, and ethical condition, but also with a multidimensional approach to care. In fact, dermo-pigmentation takes place in close collaboration with a plurality of professional skills and pieces of knowledge: the dermatologist, oncologist and/or plastic surgeon.

The juridical and technical framework of micropigmenta-

In Italy, medical tattooing has been the subject of recent institutional debate following the Note issued by the Ministry of Health (M.S.), "Circular Note on tattoos with medical purpose; clarifications regarding areola-nipple pigmentation" (2019) (18).

This Note specifies that tattooing of the areola-nipple complex for medical purposes is included in the Essential Levels of Care (L.E.A. Annex 4, code 86.02.3 "tattooing for pigmentation of the areola-nipple complex").

The Note also specifies that the "areola-nipple pigmentation" service must be performed exclusively by those practising a health profession in an accredited or licensed outpatient clinic, depending on whether or not the procedure is performed at the expense of the National Health Service. Therefore, this service is not allowed to be performed in non-health facilities and by non-health personnel.

In order to ensure the protection of people undergoing this practice, the M.S. Note urged universities to organise courses to train qualified personnel to administer this procedure.

The Italian Association of Aestheticians "Confestetica" filed, against this Ministerial Note, an appeal, which was upheld by the Italian Council of State and thus annulled the M.S. Circular (19).

According to the decision of the Italian court: specialised beauticians, subject to the authorisation of medical specialists, are now granted to practice medical tattoos. However, the obligation for medical personnel to obtain a qualification through participation in specific courses organised by universities as accredited bodies remains in place. To this end, the University of Genoa - northern Italy - has activated specific training courses on medical micropigmentation aimed at health personnel. In these courses, ample attention has been paid to the technical and behavioural norms posed to protect the person, particularly regarding the basics of

oncology and post-mastectomy reconstruction techniques, the issue of communication and informed consent, and the risks underlying this procedure.

# The micro-pigmentation procedure: safety

According to the ethical principle of non-maleficence, the performance of the micro-pigmentation procedure requires adherence to strict deontological rules and specific precautions in order not to cause harm to the person. Its implementation is, therefore, ruled out whenever changes in colour and texture, everted lesions, or inflammatory states are found on the skin. Furthermore, special rules of caution exclude its application in the presence of nevi within the area to be tattooed, as other lesions of suspected neoplastic nature, whether benign or malignant.

Special care should also be taken for individuals with sensitisation problems, e.g.in patients sensitive to nickel, latex, or other products commonly used in inks and, thus, in the pigments that are injected or in patients who have a history of delayed healing or pathological scarring. It is, therefore, of considerable importance to carefully inspect the area to be treated and carefully screen the person's medical history concerning the possible presence of acute or chronic infectious pathologies in other sites, whether of a bacterial, fungal, or viral nature. For example, in patients with psoriasis or lichen, two chronic inflammatory skin diseases, following a minimal traumatic stimulus, the body tends to reproduce the same lesion, even in areas distant from the major lesion - Koebner's phenomenon (20). On the other hand, in disorders of the dysreactive type, such as pyoderma gangrenosum characterised by peculiar ulcerative lesions, the introduction of a stimulus, even far from the primary lesion, can lead to the patient developing a new area of pyoderma gangrenosum. Likewise, even in the case of, for example, blood sampling, an inflammatory and pustular lesion can form at the point of needle insertion, which may, in turn, develop into a new lesion of pyoderma gangrenosum, a phenomenon of pathergy, which is quite similar to Koebner's phenomenon (fig. 2) (21).

Possible adverse events of major significance cannot be overlooked either, such as:

- Aseptic inflammation - i.e., inflammation without bacterial or fungal agents -. This complication might

- result from the procedure implemented in individuals with psoriasis, eczema, or all those previously named skin manifestations.
- Viral or bacterial infections in case a sterility defect has led to a pathogen being injected into the micro-traumatised area of the skin.
- Allergic-type reactions in individuals intolerant to any of the various components of the pigmentation ink.
- Appearance of hypertrophic or keloid scars in patients prone to an abnormal scarring response.
- Evidence of benign and malignant neoplastic lesions, even in neighbouring areas.

Before performing the procedure, the performing practitioner shall offer comprehensive and empowering communication about the type of procedure proposed to the patient. The communication of the nature of the procedure, its purpose, possible alternatives, risks, and possible complications indeed represents a central ethical and deontological node that requires special care and attention. Its importance is remarked in the recent provisions of Italian Law 219 of 2017, "Norms on informed consent and advance treatment dispositions" (22, 23) as well.

Although micropigmentation is commonly considered a cursory process, pre-treatment clinical and inspection assessment is a well-established practice to be respected. Therefore, a careful anamnesis should consistently be implemented to ascertain whether the subject presents systemic skin conditions overall, not



Figure 2. Koebner's phenomenon

only in the area to be treated with the tattoo. If so, a specialist evaluation is advised.

## Evolution of micropigmentation and critical issues

The current spread of tattooing has created a significant economic spin-off and a consequent growth of tattoo parlours with staff and equipment that are not always suitable with the primary safety standards and technical skills.

From its origins as a purely aesthetic, decorative, or ritual, the practice of tattooing has gradually turned to the medical field in the scope of medicine that is increasingly attentive to the patient's different psychic and existential dimensions. Through micropigmentation, the possibility of hiding severely disfiguring lesions, covering imperfections, and reconstructing missing pigmented areas, either due to congenital or acquired problems, can constitute a crucial non-invasive factor for the well-being of a person. Especially if said well-being has been made particularly fragile by physical anomalies that have also led to relational problems in particularly delicate moments of one's life or as a consequence of demolishing and disabling therapeutic courses.

The same possibility of confronting issues related to reconstruction, at least to improving self-image, represents an important moment in recovering one's security towards one's relational life.

Plastic surgery, which for years has been engaged in the search for the best damage-benefit ratio in reconstructive treatments, has found a very minimally invasive and, at the same time, an efficacious possibility in the method of micropigmentation to achieve the goal of restoring conditions of psycho-physical well-being.

An important application of micropigmentation is the nonsurgical option of areola-nipple complex reconstruction for postmastectomy completion of the reconstructive pathway (24).

There are several surgical options for reconstructing the areola-nipple complex, some of which involve simultaneous restoration. For example, the nipple can be reconstructed with local flaps or harvested from the contralateral. In contrast, the areola can be reconstructed by harvesting from the contralateral areola, if

it is of congruous size, or from the thigh root (25). The choice of reconstructive method for the areola-nipple complex depends on the physical characteristics of the patient, their general condition, previous and or current treatments performed on the breast - e.g., radiotherapy -, and finally: on the patient's wishes. Therefore, the tattoo methodology becomes a possibility that is easy to perform, generally well tolerated by patients both psychologically and physically, and capable of giving good cosmetic results. Moreover, the possible complications described above are highly reduced if the good rules of conduct described are followed.

However, using this method for health purposes must involve careful control of the premises where it is practised, the equipment, the injectable substances, and adequate training of the personnel in charge of the treatment.

With regard to standards of good conduct, the following points are of paramount importance:

- The necessity to wear personal protective equipment - mask, headgear, sterile gloves after washing hands, sterile gown, goggles, or protective visor
- The preparation of the site and patient: preparation of sterile drapes suitable for delimiting the area of surgery; disinfection of the skin with gauze, preferably soaked in chlorhexidine
- The restriction of access to the area where the treatment is performed
- The assessment of the patient's general condition, any allergies or coagulation problems, and the local conditions of the area to be treated. It is essential to remember that, in the case that the tattoo should be placed in the site overlying a prosthesis, the utmost care must be taken to avoid risks of infection that could compromise the prosthesis, particularly in the case of areas previously treated with radiotherapy where the skin may present with extreme thinness and feeble vascular circulation
- Use of sterile and disposable pigments and materials.
- At the end of the session, the treated area should be covered with a sterile dressing and Vaseline gauze, which should be replaced at least daily until complete healing
- Because this is a procedure involving injury to the skin, medical waste should be disposed of in appropriate "biobox" containers.

# Typologies of tattoo machines, inks and pigments

### Inks

One of the most critical aspects of tattooing concerns the quality of the inks used.

Manufacturers of tattoo inks are, in fact, not obliged to disclose the components of their products and, in addition, those who practice tattooing mix various inks (26). Most inks, among their components, include: metals, salts, vegetable dyes, and plastics (27). The vehicle has the function of evenly distributing the pigment in a fluid matrix, preventing the occurrence of pathogenic substances, pigment agglomeration, and facilitating the application to the skin. The most commonly used vehicles are ethanol, purified water, witch hazel of plant origin, Listerine, propylene glycol, and glycerol. Sometimes denatured alcohol or other alcohols such as methanol, antifreeze, or formaldehyde are used. However, the use of all of these substances has to be discouraged since they are toxic.

The most severe issues with inks in healthcare, though, are their interference with M.R.I.s, caused by the metals present in their formula, burn hazards caused by the needle's heat in case of large treated areas, infection, and allergy (28).

### **Pigments**

The pigments are used to achieve the desired colour shade for the ink. Some pigments are of natural origin. In the latter case, they are obtained through treating particular minerals, but in most cases, they are synthetic. The synthesis methods are most varied; they use wet and/or dry processes and include intermediate steps such as dissolutions, more or less complex reactions, precipitation, filtrations, washing, drying, calcination or other types of treatment.

Due to the absence of transparency, including about the pigments used by manufacturers, various studies have been conducted to identify the elements most commonly present (29). Aluminium, titanium, oxygen, and carbon were found to be present (Tab.1). Such evidence urges the need for regulation requiring labelling and full disclosure of the various constituents of inks intended to be injected into the skin due to their potential to cause harmful reactions.

Table 1. Inks used in tattoo.	
Color	Chemical Composition
black	acrylic resin, black pigment, glycerin, water, witch hazel, isopropyl alcohol
white	acrylic resin, titanium dioxide, water
red	acrylic resin, pigment red 210, pigment blue15, glycerin, aqua, isopropyl alcohol witch hazel
orange	acrylic resin, pigment orange 13, pigment red 210, glycerin, water, isopropyl alcohol witch hazel
yellow	acrylic resin, yellow pigment65, titanium dioxide
dark green	acrylic resin, pigment green, glycerin, water, witch hazel, isopropyl alcohol
Lightb lue	acrylic resin, titanium dioxide, pigment blue 15, glycerin, water, witch hazcl, isopropvl alcohol
Violet blue	acrylic resin, titanium dioxide, pigment violet1, glycerin, water, witch hazel, isopropyl alcohol

Medical tattoo inks require specific studies concerning their application. For example, they must provide for the total exclusion, or maximum reduction, of metal derivatives in order not to be visible in X-rays and not to create artefacts during M.R.I. (30). Such inks must also be subject to a guarantee of sterility through single-use container usage and the obligation to report on the product label their manufacturing lot, quantity, expiration date, and components in descending order of percentage and weight.

### The Dermograph

Significant innovations have also been achieved in the design of recent dermograph equipment in order to overcome problems related to the excessive vibrations of the handpiece, thermal expansion of the needles - which results in rapid wear and risk of causing skin injury -, and reflux of the inks due to defective dosage adjustment.

Currently, the most innovative equipment involves an injector attached to the handpiece through a simple but highly stable fixation method, a transparent and sterile Plexi structure equipped with a decompression reservoir useful for a gradual pouring of pigment, needles attached to the propulsive structure and equipped with a thermal laser to allow the operator to use the device with extreme stability and precision thanks to the absence of vibrations.

Pigment inoculation protocols, both for areola reconstruction and camouflage of scars and dyschro-

mia, contemplate the use of different types of injectors equipped with needles ranging from 1 to 12 tips, with a variable thickness from 0.18 mm to 0.4 mm and capable of puncturing the skin at a permanent and constant depth, adjustable from 0.1 to 3.3 mm.

Different needle-beating speeds are an integral part of the injector's engineering design. The equipment's display makes it easy to vary the number of beats from 900 to 7000 per minute, achieving excellent three-dimensionality, pigment persistence, and versatility.

The synergy of all these innovative technologies, together with sterility precautions, allows for a highly safe operation on the patient, characterised by the absence of pain, bleeding, and risk of infection.

### **Conclusions**

Tattooing, a method that finds its origins in very distant times, has taken on different meanings with historical moments, social situations, fashions, religions and also, and not just of late aesthetic and medical purposes.

The methods and technologies used have been varied, but all shared the intent of leaving an indelible mark on the skin.

In the medical field, micropigmentation is used in selected cases to improve a congenital or acquired abnormality with the best possible result and minimal traumatic impact.

The problems that micropigmentation can procure are many and significant, and therefore adequate training is paramount.

The application of micropigmentation in health care, and its inclusion in the L.E.A.s, is an expression of a broader approach to care and a commitment to building relationships between different professions, medical and non-medical, that play a pivotal role in a good patient's life.

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### A disclosure / conflict of interest statement

None of the authors of this manuscript has a financial or personal relationship with other people or organizations that could inappropriately influence or bias the content of the paper. It is to precisely state that "No Competing interests are at stake and there is No Conflict of Interest" with other people or organizations that could inappropriately influence the content of the paper.

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