

# Complications of permanent makeup procedures for the eyebrow and eyeline

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## Abstract

Japan is one of the few countries that consider the application of permanent makeup a medical procedure, and only doctors and nurses are allowed to perform this procedure. Studies on the safety and esthetic outcomes of permanent makeup procedures are not available, although there are studies that report allergies and other complications associated with permanent makeup. Thus, we aimed to study the complications and esthetic outcomes of permanent makeup.

We surveyed clients who underwent permanent eyebrow or eyeliner makeup procedures at the Shibuya Mori Clinic between November 2016 and March 2020 using a paper-based questionnaire. The permanent makeup procedures involved inorganic pigments, such as iron oxide and titanium dioxide. The questionnaire consisted of 2 parts: the first part asked whether the clients had experienced persistent redness, itching, swelling, infection, or any other complications (multiple answers possible). The second part used a 5-point Likert scale to rate the clients' satisfaction with the color, shape, and overall appearance of their permanent makeup. We retrospectively studied the clients' responses to survey items.

A total of 1352 clients participated in the survey. The median period between the procedure and survey response was 15 days. Overall, complications were reported in 12.1% of cases. The most common complication for each type of procedure was itching for eyebrow procedures (8.2%) and swelling for eyeliner procedures (13.2%). Infections were reported in 3 cases (0.2%). None of the post-procedure symptoms persisted until the time of this study. The Likert scale measurements revealed that 89.6% of subjects were satisfied with the aesthetic outcome of their permanent makeup procedure(s).

We believe that all symptoms observed in this study were due to needle insertion. No allergies were observed, and the infection rate was quite low (0.2%). Thus, our results suggest that permanent makeup procedures are safe and are associated with high client satisfaction. We must note that the appropriate environment, equipment, and techniques are important prerequisites.

**Abbreviation:** MHLW = Ministry of Health, Labour and Welfare.

**Keywords:** claim substantiation, color cosmetics, complication, permanent makeup, safety testing, tattoo

## 1. Introduction

Permanent makeup refers to the act of coloring the skin by applying pigments to the tip of a needle and inserting the needle

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under the skin. Permanent makeup is often performed in an effort to simulate eyebrows, eyeliner, lipstick, or parts of the body using makeup products. Essentially, permanent makeup is a form of tattooing because it involves the use of a needle to insert pigments directly into the dermis of the skin. However, its aims, social background, and history differ considerably from those of tattooing, which has existed in society since ancient times.

Approximately 40 years ago, the concept of permanent makeup was introduced to Japan from America. However, permanent makeup was initially performed at nonmedical institutions, such as beauty salons, resulting in a various health-damaging complications, such as corneal damage and infection of the tattooed area.<sup>[1]</sup> Consequently, in 2000, a notice from the chief of the Medical Professions Division of the Health Policy Bureau at the Ministry of Health, Labour, and Welfare (MHLW) stated that alongside hair removal using laser (including photoepilation) and chemical peeling, permanent makeup would be considered a procedure whose "professional practice by an individual without a medical license constitutes a violation of the Medical Practitioner's Act." In other words, permanent makeup was classified as a medical procedure.<sup>[2]</sup> Japan is one of the few countries that considers the application of permanent makeup a medical procedure, with only doctors and nurses being allowed to perform this procedure. However, despite studies that have reported allergies and other complications associated with permanent makeup,<sup>[3]</sup> medical studies on the safety and aesthetic outcomes of permanent makeup

procedures are rare, and sufficient medical evidence does not exist.

In this study, we focused on the two most commonly performed permanent makeup procedures—eyebrow and eyeline makeup—and retrospectively analyzed survey polls on the incidence of complications and the satisfaction of clients. Our results show the complications associated with permanent makeup procedures and subjective evaluations of the esthetic outcome of the procedures.

## 2. Methods

### 2.1. Participants

Individuals who underwent eyebrow or eyeline procedures at the Shibuya Mori Clinic between November 2016 and March 2020, and later provided responses to a questionnaire surveying complications associated with the procedure and client satisfaction with the permanent makeup during the first outpatient visit constituted the study participants.

Based on information from available literature regarding complications of tattoos,<sup>[4]</sup> we designed our written questionnaire to ask participants whether they experienced persistent redness, itching, swelling, infection, or any other complication (multiple answers possible). For the second part of the survey, we used a 5-point Likert scale to evaluate esthetic outcomes, with 1 being very dissatisfied and 5 being very satisfied, to assess the satisfaction of the clients with the color, shape, and overall appearance of their eyebrow, eyeline, or the eyebrow and eyeline procedures. The demographic information of the survey respondents, including their age, sex, and the length of time between the procedure and the outpatient visit, was also collected. The survey was completed in a few minutes. When the questionnaire was handed out to the clients, the doctor asked the clients about their clinical symptoms after the permanent makeup procedure. Clients who reported infection or allergic symptoms were examined in detail. Written informed consent was obtained from the clients for the inclusion of their clinical details in the manuscript for the purpose of publication. The results of the survey were tabulated. Finally, descriptive statistics were used to summarize the clients' responses to the survey questions.

### 2.2. Permanent makeup procedures

Eyeline procedures were conducted using a permanent makeup machine. The eyebrow procedure consisted of either a 3D brow procedure, in which the eyebrow hairline was pigmented by hand, or a 2D brow procedure, where a gradient was applied either via a permanent makeup machine or by hand, from the head to the tip of the eyebrow. Some clients requested both an eyebrow hairline procedure and the application of a gradient (sometimes called 4D brows). The sterilized needles and pigments (made from inorganic colorants) used for the procedures are research-grade materials manufactured by BioTouch Inc. (City of Industry, CA) and approved by the Ethics Review Committee of the Japanese Organization for Safety Assessment of Clinical Research (AMED IRF No. 18000005). The inorganic colorants included black, red, and yellow iron oxides, and carbon black. This study was conducted with the approval of the Ethics Review Committee of Japan Community Health Care Organization, Tokyo Shinjuku Medical Center (No. H30-14).

**Table 1**

#### Patients' clinical characteristics.

Parameter	
Patients, N	1352
Age, y, mean (SD)	38.8 (12.0)
Sex, n (%)	
Male	83 (6.1)
Female	1269 (93.9)
Tattoo location, n (%)	
Eyebrows	1109 (82.0)
Eyelines	164 (12.2)
Eyebrow and eyeline	79 (5.8)
Post-procedure period, median (range), days	15 (3–1089)

Of all respondents, 93.9% were women. All 83 male patients underwent the procedure for the eyebrows.

### 2.3. Statistical analysis

All *P* values were 2-sided and *P* values of .05 or less were considered statistically significant. The Kolmogorov-Smirnov normality test was performed to test for normality. All statistical analyses were performed using EZR software (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).<sup>[5]</sup> More precisely, the software is a modified version of R commander that is designed to add statistical functions that are frequently used in biostatistics.

## 3. Results

A total of 1352 clients (83 men, 1269 women; mean age, 38.8 ± 12.0 years) responded to the questionnaire. Since the questionnaire was administered for each treatment option, the number of duplicates is unknown because the survey was unmarked, although some participants completed the questionnaire more than once. No client refused to participate in the survey, but 87 clients did not fully respond to the questionnaire. In total, 1109 cases involved permanent makeup for only the eyebrows, 164 involved permanent makeup for only the eyeline, and 79 involved both. The median post-procedure duration (between the procedure and the administration of the questionnaire) was 15 days (Table 1), and 110 of 1352 patients had a follow-up period of at least 6 months. The Kolmogorov-Smirnov normality test revealed that the post-procedure duration of the clients was not normally distributed (*P* < .001).

Of the 1188 individuals who underwent eyebrow procedures, 126 (10.6%) reported post-procedural complications. Itching was the most commonly reported complication (98 cases, 8.2%), followed by redness (20 cases, 1.7%), swelling (13 cases, 1.1%), other/unspecified complications (7 cases, 0.6%), and infection (3 cases, 0.3%) (Table 2). Some clients had multiple complications—11 clients had 2 complications and 3 clients had 3 complications.

Of the 243 individuals who underwent eyeline procedures, 38 (15.6%) reported post-procedural complications. Swelling was the most commonly reported complication (32 cases, 13.2%), followed by itching (7 cases, 2.9%), redness (2 cases, 0.8%), and other/unspecified complications (3 cases, 1.2%) (Table 3). There was no case of infection, and 6 clients had 2 complications.

Overall, complications were observed in 164 (12.1%) of the 1352 participants. All complications improved rapidly, and there

**Table 2**  
**Complications after eyebrow tattoo.**

Eyebrows, N	1188
Any complications after tattoo, n (%)	
Yes	126 (10.6)
No	1062 (89.4)
Complications after tattoo, n (%)*	
Itching	98 (8.2)
Redness	20 (1.7)
Swelling	12 (1.1)
Infection	3 (0.3)
Other and unspecified	7 (0.6)

After the procedure on the eyebrows, 10.6% of patients had some complications. The most common complication was itching (8.2%).

\* Multiple answers allowed.

**Table 3**  
**Complications after eyeliner tattoo.**

Eyelines, N	243
Any complications after tattoo, n (%)	
Yes	38 (15.6)
No	205 (84.4)
Complications after tattoo, n (%)*	
Swelling	32 (13.2)
Itching	7 (2.9)
Redness	2 (0.8)
Infection	0 (0)
Others and unspecified	3 (1.2)

After the procedure on the eyeliner, 15.6% of the patients had some complications. Among them, swelling was the most common (13.2%).

\* Multiple answers allowed.

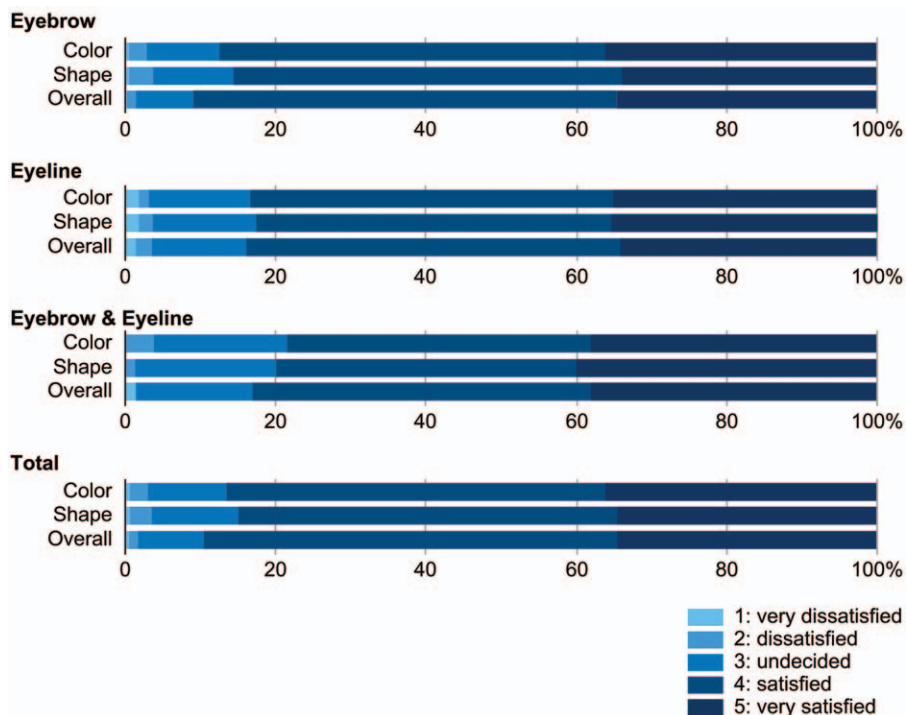
was no case of post-procedural complication persisting until the time of outpatient visit.

All 3 cases (0.2%) of post-procedure infections were reported by clients who underwent eyebrow procedures. When these clients were asked about their symptoms during follow-up visits 11, 14, and 84 days after their procedure, the chief complaint was exudate from the makeup area. The infection did not persist in any case. Furthermore, allergic symptoms were not reported by any of the clients during the post-procedure period.

The mean satisfaction scores for all procedures exceeded 4.1 (Fig. 1), and 89.6% of all clients—a high proportion—indicated that they were satisfied (4 points) or very satisfied (5 points) with the overall appearance of their permanent makeup.

**4. Discussion**

Here, we report that the overall complication rate across 1352 patients was 12.1%, and 0.2% were due to infections. The infection rate seems very low, and none of the infections were severe. The main complications after eyebrow procedures were itching (8.2%), redness (1.7%) and swelling (1.1%), and those after eyeliner procedures were swelling (13.2%) and itching (2.9%). Since there was no control group in which no pigments were tattooed and only the needles were inserted, it is difficult to determine the cause of these symptoms. However, since these symptoms had disappeared at the time of examination and did not persist for long, they are unlikely to be allergic reactions to the tattooed pigments. We believe that they may be associated with needle penetration, but this requires further study.



**Figure 1.** Evaluation of the color, shape, and overall appearance of permanent makeup. A 5-point Likert scale, with 1 being very dissatisfied and 5 being very satisfied, was used to survey the color, shape, and overall satisfaction of the clients with the eyebrow, eyeliner, or both procedures.

We were unable to find any report on complication rates (infections, allergies, among others) associated with permanent makeup procedures in the literature. However, there were several reports on the complication rates of tattoo procedures, which involve the same techniques as permanent makeup procedures. Liszewski et al<sup>[6]</sup> conducted a cross-sectional survey involving 501 individuals with tattoos in America and reported that 3.2% of the individuals experienced infections. Kluger et al<sup>[7]</sup> surveyed 401 tattoo artists belonging to the French Tattoo Union regarding the complications they experienced with their own tattoos and the authors reported an infection rate of 6.2%. A systematic review of 27 studies that assessed tattoo infections and their causative agents indicated that 81% of infections that occurred in tattooed areas were caused by *Staphylococcus aureus*, a bacterium that occurs naturally on the skin.<sup>[8]</sup> In comparison to these tattoo infection rates, our permanent makeup infection rate of 0.2% is quite low. The low infection rates may be associated with the surgically sterile environment in which we performed the procedures, the use of sterilized equipment and pigments, the narrow scope of our procedures, and the guidance we offer our clients on post-procedure wound care, including the application of antibiotic ointments.

No allergic symptoms were observed in this study. However, Kluger et al<sup>[7]</sup> reported an allergy occurrence rate of 8.5% in their survey of the complications associated with tattoo artists' personal tattoos. An important point to note is that 94.1% of these allergic reactions involved colored tattoos. Further, Serup et al<sup>[9]</sup> reported that among 405 individuals (493 tattoos) who visited their hospital, allergic reactions were observed for 185 tattoos, and 157 tattoos (85%) involved a red pigment. Several other studies have also reported allergic reactions to tattoos in which red pigments were used.<sup>[10,11]</sup> It is believed that red pigments made with azo pigments or quinacridones are the chief causes of allergic reactions.<sup>[12]</sup> A study that used shave biopsies and matrix-assisted laser desorption/ionization-mass spectrometry to analyze the components of the red tattoos of 104 individuals that experienced allergic reactions found that Pigment Red 22, Pigment Red 170, and Pigment Red 210 were the primary causative agents of chronic allergic reactions.<sup>[13]</sup> A second study reported that Pigment Red 181 was the chief allergic agent in 4 cases.<sup>[13]</sup> However, the actual components of colorants and pigments vary widely between manufacturers, and the identification of the causative substances seems difficult. Furthermore, allergic reactions to tattoos should be monitored over weeks, months, or even years, after the completion of the tattooing.<sup>[9]</sup> Late occurrence of allergic symptoms suggests that the allergens are formed over time due to local metabolic breakdown or photodegradation. These breakdown products are regarded as components of haptens, which include tissue proteins.<sup>[9]</sup> Van der Bent et al<sup>[11]</sup> included 101 individuals with tattoo allergies in a cohort study, and reported that 32% of reactions were exacerbated by exposure to sunlight and that sunlight is one of the factors that may cause such allergic reactions. This is one of the reasons why the pigment inks considered to cause tattoo allergies do not register as positive in patch tests.<sup>[14]</sup>

Therefore, it is difficult to measure allergic risks in advance, either through patch tests or other methods. For this reason, as much as possible, it is vital to include only components that are very unlikely to cause allergic reactions in the application of permanent makeup in medical settings. At our facility, we

exclusively use pigments whose main components are inorganic colorants, such as iron oxides. In addition to iron oxides commonly used in makeup products or as food additives, red iron oxide is also used as a magnetic resonance imaging contrast agent (Resovist: Fujifilm Toyama Chemical Co., Ltd., Tokyo, Japan). In light of this evidence, our views align with those of Serup et al<sup>[13]</sup> that metals may not have a major role in chronic tattoo allergies, as observed in red tattoos.

The Food and Drug Administration and MHLW are yet to approve the use of any pigment or colorant used in permanent makeup and tattoo procedures. Despite the fact that permanent makeup application is considered a medical procedure in Japan, no permanent makeup device has been recognized as a medical device and no makeup pigment or colorant has been recognized as a medical product. Therefore, we believe we have a duty to demonstrate and report the medical safety and utility of permanent makeup procedures in Japan.

#### 4.1. Limitations

There were some limitations in this study. First, it was a single-center study. Second, not all clients who received the treatment revisited the outpatient clinic, and thus, participated in this study. Third, the complications mentioned in this study are based on the responses of the clients. When the questionnaire was handed out to the clients, the doctor asked them about their clinical symptoms after the permanent makeup. Clients who reported infection or allergic symptoms were examined in detail. However, the other questionnaire items provide useful data because they indicate the subjective symptoms of the clients.

This study was based on pigment from a single manufacturer. To verify the safety of art makeup, it will be more appropriate to conduct a prospective study using the products of several manufacturers. In addition, a longer follow-up period is required to evaluate the safety of permanent makeup in relation to allergies.

#### 5. Conclusion

We conducted a survey of complications and satisfaction among 1352 clients who received eyebrow and/or eyeliner permanent makeup. The most common complication associated with eyebrow permanent makeup was itching, and the most common complication related to eyeliner permanent makeup was swelling. These symptoms improved quickly without any treatment and did not persist for long. The infection rate was quite low (0.2%), and no allergies were observed. Furthermore, clients were highly satisfied with the eyebrow and eyeliner makeup. Therefore, we conclude that if the proper environment, equipment, and techniques are used, permanent makeup procedures would be safe and well-received.

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#### Author contributions

**Investigation:** Katsuya Mori.

**Validation:** Hitomi Yamazaki, Kaori Mori.

**Writing – original draft:** Shoichi Tomita.

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