

Dermopigmentation of the nipple-areola complex in a dedicated breast cancer centre, following the Treviso Hospital (Italy) LILT model

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Abstract

Background. Dermopigmentation, also known as medical tattooing, is a complementary technique in the reconstruction of the nipple-areola and an adjuvant procedure to improve colour mismatch. In 2009, tattooing of the nipple-areola complex (NAC) was introduced by Treviso Hospital through a project conducted in cooperation with the local section of the Italian Anti-Cancer League (LILT).

Methods. From 2010 to 2016, 169 patients treated for breast cancer underwent dermopigmentation treatments. Patients were selected by the hospital plastic and breast surgeons. Dermopigmentation was performed at the LILT (*Lega Italiana per la Lotta contro i Tumori*, Italian Cancer League) facility following a specific procedure to ensure safety. A sterile disposable surgical set was used.

Results. Of 169 patients treated in 309 treatment sessions, no serious complications were reported after tattooing, with only three cases seen of minor complications. Patients expressed a high level of satisfaction (90%) with the aesthetic results.

Conclusion. The study found that dermopigmentation of the NAC is a safe approach, providing benefits both to the patients and the hospital itself. Medical tattooing of the NAC is a simple and safe nonsurgical technique that reduces missed workdays and increases the time available for other commitments. This ultimately translates into savings for society and the healthcare system.

Key words

- tattooing
- nipple areola complex
- restore
- scar

INTRODUCTION

Breast cancer is the most common tumour found among women in Italy. In 2018, 52,800 new cases were estimated, accounting for 29% of affected women [1]. Surgery is usually the initial treatment and, in the early stages of the disease, conservative surgery associated with radiotherapy has replaced radical mastectomy, which is still the standard approach in more advanced stages of the disease. When the mammary neoplasm affects the tissue below the areola and/or invades the

surrounding skin, excision of the whole nipple-areola complex (NAC) may be necessary [2], which seriously compromises the aesthetic results of any subsequent reconstruction. This may lead to a more severe psychological impact on the patient.

Considerable attention is now given to the likely psychological reaction to the reconstruction of affected areas. In order to improve outcomes, breast cancer in Italy today is tackled by a multidisciplinary group under the organizational structure of a dedicated breast

centre. In this multidisciplinary specialist centre (called the “Breast Unit” locally), experts from different backgrounds work together to provide patients with customized treatment to successfully treat the disease and to guarantee a satisfactory quality of life.

Reconstruction of the NAC after mastectomy is a straightforward procedure from a technical point of view, but its importance from an aesthetic perspective [3] should not be underestimated. NAC reconstruction can be performed with all types of reconstructive procedures, and at any time following surgery. Studies have shown that recreation of the NAC has a high correlation with overall patient satisfaction and acceptance of body image [4].

The evolution of NAC reconstruction started with the initial description of the nipple-areola graft and labial graft [5, 6]. Following this, Millard proposed the nipple sharing concept, where the contralateral nipple tissue was used as a composite graft for the reconstructed nipple [7].

These techniques were, to some degree, successful in providing passable aesthetic results, but at the expense of significant donor site morbidity [8, 9].

Dermopigmentation (medical tattooing) can be used as a complement to reconstructive surgery [10, 11], and is generally used to cover skin conditions and restore the appearance of healthy skin.

Tattooing of the areola in post-mastectomy reconstruction, initially introduced by Rees in 1975 and Spear *et al.*, is an important nonsurgical technique that serves as an adjunct to areola reconstruction [12-14].

Recently, 3D dermopigmentation has become a technique of choice in the NAC reconstruction process; it mimics the nipple-areola complex by means of defining the areolar contour and Montgomery’s tubercles [15, 16].

As part of this approach, dermopigmentation is often used in NAC reconstruction as it is the easiest and safest way to restore much of the appearance of the original anatomy in women who have undergone mastectomy [17, 18].

This tattooing technique is a simple, quick and safe procedure which has achieved a high level of patient satisfaction and can provide an excellent areolar colour match with limited morbidity [19, 20]. As a result, the aesthetic improvements obtained can reduce the psychological impact of physical changes following surgery [21].

In the province of Treviso, about 800 new cases of breast cancer are reported each year. Since 2009, they have been managed following the advice of a multidisciplinary team based at the dedicated unit (“Breast Unit” of Treviso Hospital). In 2009, a project was launched to introduce tattooing in the reconstruction of the nipple-areola complex. This project resulted from the synergy created between the multidisciplinary team of the Operational Plastic Surgery Unit of the former Local Health and Social Care Services Unit number 9 and the Treviso section of the Italian Cancer League (LILT).

This dedicated breast unit was the first centre in Italy to apply this technique, in 2010, and was the first to officially recognize the role of “dermopigmentators” in its

Diagnostic and Therapeutic Pathway for breast cancer. A dermopigmentator is defined as a professional who has been suitably trained to take part in a multidisciplinary team treating patients; he/she works by complying fully with a strict health and hygiene protocol specifying the use of appropriate materials and equipment in a suitable work environment.

Dermopigmentation is indicated for:

- tattooing of the nipple-areola complex, specifically for correcting dyschromia due to surgery and correction of the newly reconstructed areola;
- eyebrow and infraciliary eyeliner, known as Permanent Make Up (PMU), which restores the effect of eyebrows and eyelashes in patients with alopecia due to chemotherapy;
- correction of scars due to demolitive surgery or the camouflaging of scars due to surgery.

Since 2013, the Treviso team has been collaborating with the *Istituto Superiore di Sanità* (National Institute of Health, ISS). The latter contributed to the evaluation and improvement of the medical tattooing procedure used, under an agreement with the Italian Ministry of Health that aimed to evaluate risks and benefits of this type of treatment compared with the traditional treatments. This cooperation started with the National Centre ONDICO and is currently continuing with the National Centre for Innovative Technologies in Public Health (TISP Centre), which has carried out various studies regarding the safety and the advantages of medical tattooing.

This paper reports on the dermopigmentation of the nipple-areola complex performed from 2010 to 2016 on cancer patients treated in the specialist unit of Treviso Hospital.

The aims of the project were to:

- improve breast aesthetics by creating, as far as possible, an areola and a nipple matching the contralateral breast or its original appearance before surgery, thus improving patients’ self-confidence;
- design a specific procedure to ensure the complete safety of the patient;
- measure the levels of patient satisfaction with the results of the treatment received;
- assess the usefulness of dermopigmentation for patients;
- provide benefits both to the patients and the health care unit.

MATERIALS AND METHODS

According to the diagnostic and therapeutic pathway set down by Treviso Hospital’s Breast Centre, tattooing is used after the completion of reconstructive surgery; the Breast Centre laid down a detailed procedure that establishes when and how to intervene. Patients selected for dermopigmentation are chosen by the plastic and breast surgeons. After careful assessment of the patient’s medical history, they complete a form authorizing tattooing. The following factors are taken into consideration and assessed: original disease, type of surgery and adjuvant therapies undergone by the patient (chemotherapy, radiotherapy), general state of health, administration of medication, allergies, and

time lapse before tattooing can take place. In the case of Treviso Hospital, dermopigmentation is performed at least 6-12 months after the completion of breast reconstruction, which is enough time for the healing to complete and for the breast to stabilize.

If no contraindication is found, consent for treatment is given and a briefing with the professional in charge of performing the tattoo is held. The plastic surgeon presents the patient's case and precautions to be taken during the treatment. Before tattooing, the patient receives information about the treatment and the associated risks. The patient signs the informed consent form to declare that she has fully understood the information and suggestions received and commits to carefully and strictly following the aftercare guidance. The patient also reports any local or general diseases, anomalies in the wound healing process, allergies and intolerances, medical treatments in progress, and abnormal reactions following previous tattooing or PMU treatments. She also declares that she is not pregnant or breastfeeding. Photographs are taken before and after the treatments.

Dermopigmentation is performed at the LILT facility, in close cooperation with the Treviso multidisciplinary team.

The training and professional experience of the operator dealing with the medical tattoo are crucial. The tattooing needs to be performed swiftly and with full mastery of the dermograph, avoiding excessively stimulating or inflaming the tissue as this may jeopardise the patient's general health. In addition, the pigment should be injected at the right depth in the skin to avoid excessive loss of colour.

For patients affected by dermatological problems (e.g. a nickel allergy), a specific procedure is agreed with the dermatologist. According to the procedure laid down, the most suitable ink colours are selected and the patient is referred to the dermatological unit where the pigments' safety data sheets and composition are

assessed to exclude the risk of specific reactions. If in doubt, an allergological test is carried out. Upon completion of the investigations, the treatment can start, if the medical opinion is favourable.

In the case of patients affected by psoriasis or conditions likely to induce reactive isomorphism, treatment modes are assessed on a case-by-case basis by the dermatologist.

NAC tattooing is performed on cancer patients who may present different degrees of immunodepression. Thus, strict sterility applies both to instruments and devices, and to the execution of the tattoo according to a detailed procedure.

For that purpose, a sterile disposable surgical set has been created to be used at the workstation. It is classified as a Medical Device and commonly referred to as a "sterile field" (Figure 1), and includes:

- covering coupled sterile sheets (100x150 cm);
- cotton yarn 70 cm;
- camera protection cover 14x254 cm to cover the dermograph;
- 10 TNT bandages 10x10 cm with 4 layers;
- 2 chlorhexidine soaked wipes;
- 1 100 ml bowl;
- 1 coupled sterile sheet with adhesive holes (15 cm diameter) 150x100 cm;
- 1 dermographic marker;
- 2 needles 21gx10;
- Sterile transparent cover 50x60 cm for the dermograph console and transformer;
- 1 tray 24x14x2,5 cm;
- 1 gown and towel for the operator;
- double sided adhesive tape 5x15 cm.

The sterile field is essential to avoid complications.

Pigments comply with specific product and process requirements. In particular, pigments are:

- atoxic, hypoallergenic and compliant with the requirements of ResAP 2008/1;



Figure 1
Example of a workstation and practice (sterile field set and disposable equipment).

- disposable;
- manufactured in a sterile chamber with medical grade water;
- sterilised at the end of the manufacturing process using Gamma rays;
- free from metallic impurities likely to cause complications during certain diagnostic tests.

Following research and study, pigments were carefully chosen according to their specific characteristics to enable a selection of inks that could be well tolerated by patients, while simultaneously serving their purpose. The PMU colours commonly marketed are not specific to NAC tattoos as they last for too short a time, thus requiring retouching after a very short period (once a year or every two years). This would cause excessive stress to the skin that would in turn react with the formation of scar tissue. Similarly, colours used for artistic tattoos should not be used as their result is definitive and final. Often, after 5 or 6 years (the average time between retouches) the natural contralateral areola may change in size and colour due to weight or hormonal changes or other reasons. In such cases, retouching is needed to adjust the result. The ideal pigments should be sufficiently stable to enable intervention when deemed appropriate to adjust colour and shape without creating scar tissue.

Thus, inks have been selected keeping in mind that their composition and molecular weight must not interfere with diagnostic tests, as this could lead to false positives or produce vibrations likely to interfere with MRIs [22, 23]. Moreover, the inks used are made with pigments having the same light fastness code to avoid colour alterations following light exposure. Each batch undergoes chemical and microbiological checks.

Stocks of inks and devices must be managed and stored in sterile conditions during their shelf-life.

Special care is taken regarding the choice of the diluent used to create new shades. This diluent also needs to be sterile, disposable and compatible with the formulation of the pigment to be diluted.

Pigments are mixed in special sterile disposable ink cups immediately prior to use.

Before starting, the expert consultant in medical tattooing and the patient choose the colour that best matches the contralateral NAC or her complexion and carry out a test in front of the mirror to obtain a more precise idea of the final result.

To create the same light and shade effects, the expert in dermopigmentation takes pictures before treatment (one in macro mode) of the natural nipple-areola complex to be used as a reference during the execution of the tattoo. The work carried out is photographed and documented; a sterile silicon gauze soaked in vitamin E is applied; and the tattooed area is covered with sterile gauze and a cotton pad, both allowing transpiration.

The photograph, the adhesive labels for the inks, and anything else needed to trace the materials used are attached to the informed consent form which is put in the patient's records and filed for future use.

At the end of the treatment, the patient is taught the correct aftercare procedure and given written self-care instructions. The patient is instructed to ensure the tat-

too is kept well hydrated. For daily hygiene, the patient is instructed to carefully wash the tattooed area with lukewarm water and mild detergent and to delicately dab dry. The patient is discouraged from visiting saunas or Turkish baths or coming into contact with sea or swimming pool water during the first 10 days, and is advised to avoid intense physical activity likely to cause excessive transpiration during the first week. Furthermore, during the first 15 days, the tattoo should not be exposed to direct sunlight or sun lamps without using full screen protection cream/lotion. Applying sunscreen is also advisable after the said period to prevent photosensitization and ensure the colour lasts longer.

The result is assessed after about two months and, on that occasion, a second treatment may be decided upon. A third treatment may be needed, particularly when the original tattoo is more superficial in order to avoid complications (i.e. if the skin is particularly sensitive and thin, or if scars are very thick, or if the patient is taking medication that slows down the ordinary healing process). In this case also, treatment will be performed a minimum of two months after the previous procedure.

Patients tattooed from 2010 to 2016 were asked to rate their level of satisfaction regarding their dermopigmentation treatment in phone interviews conducted in 2017 by LILT volunteers. During the interview, patients were also asked to rate the usefulness of the project that enabled them to have medical tattooing, delivered according to their needs, cost free, under the medical supervision of the specialist.

To rate their satisfaction regarding the results of treatment, the patients were asked to express their views by selecting one of the following options: Very satisfied, Satisfied, Not very satisfied, Dissatisfied.

To assess the usefulness of the project, the patients were also asked to rate it by selecting one of the following options: Very useful, Useful, Neither useful nor useless, and Useless.

RESULTS

From 2010 to 2016, Treviso Hospital operated on an average of 300 breast tumour cases annually, of which 40% were mastectomies (approx. 120 patients). Of the latter, the surgery involved the sacrifice of the NAC in approximately 50 cases per year (a total of 350 cases over the period).

In this period, 169 patients were treated using dermopigmentation. The number of sessions required to achieve a satisfactory result ranged from a minimum of 1 to a maximum of 3 per patient, amounting to 309 treatment sessions in total (*Table 1*).

Treatments of various types were performed:

- tattooing of the NAC, with a surgically reconstructed nipple;
- 3D tattooing with missing NAC;
- restoration of symmetry between NACs and/or reduction in differences in terms of position, shape, dimension, or colour.

Cases and figures are shown in *Table 1*.

In addition to medical tattooing performed as part of breast reconstruction, the following treatments were

Table 1

Number of sessions and treatments performed from 2010 to 2016 compared with the number of patients per type of treatment

Number of treatment sessions required to achieve final result		
n. of patients treated	n. sessions	n. of treatments performed
42	1	42
114	2	228
13	3	39
169	Total	309
Type of treatment		
49	3D tattoo with missing NAC	
110	NAC tattoo following nipple reconstruction surgery	
6	Tattoo to restore NAC symmetry	
4	3D tattoo with missing NAC on one breast, plus tattoo on surgically reconstructed nipple on the other breast	
169	Total	

NAC: nipple-areola complex.

performed: 33 permanent makeup, scar camouflage, and tattooing of the vitiligo of the NAC.

It should be noted that out of 169 treated patients, two were affected by psoriasis, and 38 patients, one of whom was allergic to nickel, had previously undergone radiotherapy.

In one case, a patient who had to undergo tattooing presented erythema and tenderness. She was therefore referred to the dermatologist who diagnosed erysipelas. Tattooing was postponed for three months, accompanied by appropriate prophylaxis. The area tattooed subsequently healed without complications.

Complications

Of 169 treated patients, no serious complications or toxicity were reported after tattooing.

In three cases, there were minor complications:

- One patient reported altered sensitivity and localized soreness, which the dermatologist diagnosed as dysesthesia due to irritation of the scar. These symptoms completely resolved after 3 weeks of physiotherapy.
 - One patient who received a tattoo on a labia majora skin graft displayed small areas of skin abrasion covered by tiny scabs that lasted for about 10 days (on average, small scabs remain for 5/6 days, so in this case the healing process was slower). The clinical picture resolved completely after topical treatment of tetracycline medicated cream;
 - One patient reported an allergic reaction that was resolved with topical cortisone treatment.
- No treated patients showed late sequelae.

Satisfaction level

At a later stage, the 169 patients who underwent dermopigmentation of the nipple-areola complex between

2010 and 2016 were contacted by phone to respond to a satisfaction survey on the treatment received.

Of these, 141 subjects answered the survey: 137 patients reported they were "Very satisfied" or "Satisfied", and only four were "Not very satisfied" or "Dissatisfied" (Table 2, a). Reasons for dissatisfaction were: in one case, early fading of the colour compared with the average duration time initially communicated to the patient; in another case, dissatisfaction was due to a very light areola against which the tattooed NAC did not look very realistic. The other two cases of dissatisfaction were due to psychological factors implying rejection of their new personal image.

Project usefulness

As for the usefulness of the project, 137 patients rated the opportunity of having dermopigmentation treatment as "Very useful"/"Useful". The project was considered "Neither useful nor useless" or "Useless" by only four interviewees, those that reported low satisfaction with the results of the treatment. (Table 2, b).

DISCUSSION AND CONCLUSION

Medical tattooing of the NAC complements the process of breast reconstruction and seeks to achieve a more natural and pleasing result. It contributes to patient recovery and psychological and physical integrity. Tattooing the NAC is a simple and safe technique that can accompany plastic reconstructive surgery, enhancing the final aesthetic result and, in some cases, replacing the need for reconstructive surgery.

The benefits can be numerous: the procedure does not require anesthesia; in addition, it does not require tissue transfer from other areas and does not leave any scars; quite the opposite, it can cover any existing scar tissue [15, 17, 24, 25].

The patient has an immediate economic advantage as she receives the treatment free of charge. It should also be noted that medical tattooing of the nipple-areola complex was initially considered a mere complement to surgical NAC reconstruction. However, it is increas-

Table 2

Patients' level of satisfaction regarding the treatment received compared with patients' opinion regarding the usefulness of the project

a) Level of satisfaction	n. cases	%
Very satisfied	128	90.8
Satisfied	9	6.4
Not very satisfied	1	0.7
Dissatisfied	3	2.1
Total	141	100%
b) Usefulness of the project		
Very useful	96	68.1
Useful	41	29.1
Neither useful nor useless	2	1.4
Useless	2	1.4
Total	141	100%

ingly becoming an effective alternative to grafts of pigmented skin taken from other areas of the body. And in the case of 3D tattooing, it could replace nipple reconstruction itself [16]. In these cases, the patient can take advantage of the fact that she does not need to undergo another surgical operation and be hospitalized. This reduces missed workdays and increases social interaction opportunities for patients.

Another benefit is the savings for hospitals opting for this service as an alternative to traditional surgery. It should be noted that cost analyses of different NAC reconstruction techniques are not available in Italy as dermopigmentation of the NAC has only recently been introduced. To our knowledge, this technique has been adopted in Treviso and a few hospitals in Friuli Venezia Giulia, Lazio and Liguria. In the literature, it would seem that only one study, carried out in the USA by Koumanis DJ *et al.* [26] has provided a cost analysis of NAC reconstruction under general versus local anesthesia.

As the dermopigmentation of the nipple-areola complex described in this study is an outpatient procedure, there are no variable costs included. If we consider costs such as operating room time (approximately 1 hour), medical and nursing staff, recovery room, pharmacy, medical supplies, and anesthesia fees, we could calculate a minimum cost of about 1,600 euros which could be saved. Koumanis *et al.*, showed that a local anesthesia procedure costs 3,157 US dollars and, therefore, we could assume that dermopigmentation of the NAC, as an alternative to surgery reconstruction, may allow saving a minimum of 1,600 euros to 3,157 US dollars [26], about 2,900 euros.

The nipple-areola complex tattoo is an important treatment for women who want to recover their sense of self and their femininity, after overcoming cancer. As such, it ought to be considered an integral part of the rehabilitation process that starts after total or partial breast removal [27].

As mentioned above, the dedicated breast unit is specialized in supporting women affected by breast cancer. Women treated in these centres show higher survival rates than those treated in non-specialist units. Above all, such women report a better quality of life, as they feel supported through all the various stages of their treatment [28]. These treatments enable them to accept their self-image more easily, along with their role within the family and society. Today, the Italian National Healthcare System (SSN), through its Essential Levels of Assistance (LEA), includes tattoos for pigmentation of the nipple-areola complex among its specialist outpatient assistance services (code 86.02.3), provided that certain conditions are met [29].

Special care is needed when tattooing cancer patients, as they are particularly vulnerable. They have low immune defenses as well as skin alterations, depending on their specific disease, chemotherapy in progress, and any radiotherapy treatment given.

Such treatments and/or the administration of medicines to treat other diseases can make dermopigmentation more complicated and increase the risks involved. They can, for example increase skin sensitivity, trigger

skin reactions [30, 31], hinder blood coagulation [32, 33] or slow down the scar healing process. Given the above, cooperation between the breast unit's medical team and the operator who carries out the NAC tattoo is crucial to ensure patient safety. In our experience, the dermopigmentator's role fits appropriately into the dedicated breast unit as he or she complements the multidisciplinary team.

The study described in this paper suggests that cooperation and synergy between a public healthcare facility (Treviso Hospital) and a volunteer patients' association (such as LILT) can overcome certain bureaucratic obstacles and, above all, provide patients with a safe and effective service. In fact, no severe complications were reported following this treatment in either the short or the long term - possible complications may include allergies to ink components, risk of infection, scars, or granuloma [34, 35]. Furthermore, only a small number of minor complications were reported by the patients, amounting to 1.78% (3/169).

It should be pointed out that the 169 patients evaluated in this study is a relatively low number compared with the number of cases involving the breasts that were indicated for medical tattooing. This is due to several bureaucratic reasons within the public health service which, with the help of LILT, were partially overcome by employing a part-time dermopigmentator. It was not possible to treat all the cases indicated as only one to two days per month of free treatment were available.

As for the level of satisfaction, it should be noted that one hundred percent satisfaction cannot be guaranteed and the degree of success depends on the patient's expectations, the type of skin (dryness, oiliness, sun damage, acidity), the presence of scars or traumatized tissues from surgery, the tattooing method used and the characteristics of the operator (skill, experience and professional preparation). Furthermore, the habitual use of alcohol, smoking, sun exposure and/or tanning lamps, sweating, frequent swimming in pools and/or Turkish baths, the habitual use of the hot tubs and/or saunas might affect the results [36]. The degree of satisfaction with the final aesthetic result found in our study was high: 97% (137/141) of patients said they were satisfied/very satisfied. The same level of satisfaction was expressed concerning the usefulness of the project.

These results were achieved thanks to a well-designed procedure, to a careful selection of patients, suitable facilities, careful selection of pigments, and the dermopigmentator's advanced training and extensive experience.

One limit of the study should be mentioned; the results obtained for patient satisfaction may be influenced somewhat by a methodological bias. Measurement through only a single evaluation represents a cognitive and interpretative limit. The protocol followed was focused on patient safety and did not include specific evaluation procedures; therefore, a phone survey was conducted after the period of study. Essentially, the parameters considered were based on subjective satisfaction and self-evaluation, taking inspiration from certain papers found in the literature [37, 38].

In any case, despite being an incomplete evaluation, it nevertheless provides clear indications of the high

level of patient satisfaction. Future studies ought to ensure more detailed evaluations, following specific criteria and evaluation parameters. The surgeon, the Breast Centre team, the dermopigmentator, and the patient should all be involved. All these subjects should give an opinion on: size and shape of the NAC, colour, three-dimensional effect, similarity with the contralateral NAC.

As already mentioned at the beginning of the paragraph, hospitals opting for this service as an alternative to traditional surgery make savings by avoiding the use of operating rooms, surgeons and medical staff who can therefore be used to treat new patients, thus reducing waiting lists. This ultimately translates into savings and increased productivity for both the hospital and the healthcare system.

Hypothetically, if this model were to be scaled up to a national level, it would lead to considerable savings for the National Healthcare System.

The NAC dermopigmentation described in our work was carried out over the period 2010-2016, and this was not subject to specific official regulation until 2018. Subsequently, the Ministry of Health issued an order on the 15th May 2019 that regulates tattooing of the NAC [39]. Now, the operator authorized to carry out this

kind of tattooing must be a health professional, which means a specialist recognized by law no. 43 (2006), and such health professionals can only operate within accredited or authorized centres. This order does not define a new specific profession to carry out this kind of treatment, instead, it envisages specialist training within University Faculties of Medicine and Surgery, open to existing health professionals. While these courses are yet to be established and completed, it will be difficult to find certified operators capable of carrying out such treatments.

Therefore, there is concern that patients needing this corrective treatment of the NAC may turn to unsuitable operators in unauthorized centres if they cannot access this service under the National Health Service; clearly there are associated risks.

Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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