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Research Article

Clinical experience of a tattoo application device

Elizabeth Brown [a,*], Tamara Barry [a], Tao Mai [a,b], Jennifer Harvey [a,b]

[a] Radiation Oncology Princess Alexandra Hospital – Ipswich Road, Brisbane, Australia
[b] School of Medicine, University of Queensland, Brisbane, Queensland, Australia

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ABSTRACT

Introduction: The use of tattoos for radiation therapy (RT) treatment is common practice. The Comfort Marker 2.0 (CQ Medical, Iowa, USA) has been designed to apply tattoos with a controlled depth injection, potentially resulting in tattoos that fade over time. The aim of this study was to investigate the clinical implementation of the Comfort Marker 2.0 tattoo device including the patient experience and clinical workflow.

Methods: Patients undergoing RT treatment for breast cancer were invited to participate in this prospective pilot study. Patients completed a questionnaire after the planning session rating the level of pain experienced during tattoo application. Staff rated ease of use after each patient recording any feedback regarding the device. To evaluate tattoo fading, patients were followed up at 6 and 12 months after treatment to assess if tattoos could be visualised.

Results: Between August and December 2021, 50 breast cancer patients were recruited to the study. All patients received at least 3 tattoos. The majority of patients (80%) rated their pain between not hurting or hurting a little. More than 85% of staff indicated the device was easy or very easy to use. The three most common areas staff identified for improvement were: cordless device (39.1%), pen size (20.3%) and consumable rubbish (13.0%). All tattoos remained visible at the final follow up appointment.

Conclusion: Clinical implementation of the Comfort Marker tattoo device has been successful. Overall, patients found the process reasonably painless and staff found the device easy to use, providing a consistent result.

Introduction

The application of skin tattoos for radiation therapy (RT) has been a long-standing practice across the international RT community. These permanent skin marks, often created using dark coloured ink, are used as external references to assist in setting up the patient in an accurate and reproducible manner [1,2]. Many published studies have reported on the negative impact tattoos can have on patients both cosmetically and psychologically [3–6]. The pain related to tattoo application has been identified as one contributing factor to the negative feelings experienced by patients [1]. Tattoos can also be a permanent reminder of the patient's diagnosis and their RT treatment causing psychological distress [3–6]. This has been shown to be a significant issue amongst breast cancer patients due to the location of the tattoos required for treatment set up. A recent study showed that approximately 70% of women receiving breast RT treatment had negative feelings about having permanent tattoos [5]. This negative impact on body image can continue well after the completion of treatment with reports of 15–30% of patients experiencing body image issues in the survivorship phase [7]. This information has prompted clinicians to seek alternatives to alleviate the concern and distress the application of permanent tattoos causes patients.

Tattoos using ultraviolet ink have been investigated to reduce the psychological and cosmetic burden of dark tattoos on patients [3,8]. These have yielded promising results however the cost of acquiring specialised ink and lighting for tattoo visualisation has been a barrier to its widespread uptake [3]. The advent of surface guided radiation therapy (SGRT) has offered the potential to remove tattoos entirely, using the patient's surface as the primary set up point with encouraging results [9,10]. However, these systems can be cost prohibitive, and it may not be feasible for institutions to implement [11]. A recent UK study made recommendations regarding tattoo practice that included the use of specialised equipment needles and tattoo ink and semi-permanent inks that have the potential to fade after the completion of treatment [12]. The Comfort Marker (CQ Medical Radiotherapy, Iowa, USA) tattoo device is one such product that seeks to address these recommendations.

* Corresponding author at: Radiation Oncology Princess Alexandra Hospital Ipswich Road, 199 Ipswich Road, Woolloongabba, QLD 4102, Australia.
E-mail address: Elizabeth.Brown3@health.qld.gov.au (E. Brown).

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The Comfort Marker 2.0 tattoo device is specifically designed to apply tattoos with a controlled depth injection, resulting in less pain for the patient and tattoos that potentially fade over time or are easily removable using laser therapy [13]. The aim of this study was to investigate the patient and clinician experience of the Comfort Marker tattoo device, the level of pain experienced by patients during tattoo application and evaluate if any tattoo fading occurred over time.

Methods

Patients

Patients scheduled to receive RT treatment for breast cancer between August and December 2021 were invited to participate in this prospective clinical cohort pilot study in the order they presented to the department. The target sample size was 50 patients. Eligible patients were females aged 18 years or older that were undergoing RT treatment for breast cancer that required the application of tattoos. Patients also needed to be able to attend follow up appointments up to 12 months after completing treatment for tattoo visibility assessment. All patients provided written informed consent and the study was approved on 12th May 2021 by the Metro South Human Research Ethics Committee (HREC/2021/QMS/74266).

Tattoo device description and implementation

The Comfort Marker tattoo device comprises of a docking station and tattoo pen. The tattoo ink (comprised of organic pigments dispersed in glycerol) and safety needle (0.01 mm width) are supplied separately and are for individual patient use. After inserting the safety needle in the tattoo pen, applying ink to the patient's skin and switching the device on, the pen starts to vibrate. The vibration provides a haptic sensation for the user with the intensity of the vibration changing with different depth settings. The user can choose one of three insertion depth settings: 0.2 mm, 0.4 mm and 0.7 mm. To apply the tattoo, the pen is placed vertically on the patient's skin and rotated 180 degrees in the user's fingers whilst applying light pressure on the patient's skin. The safety needle (comprised of three needles oscillating at 70 times per second) continuously punctures the skin to produce the tattoo.

Prior to the commencement of the study, Radiation Therapists rostered to the simulation area were trained in the use of the device by the local distributor. Due to hospital restrictions related to the COVID-19 pandemic, this training was conducted virtually. A 'train the trainer' model was then adopted to equip a wider group of Radiation Therapists to use the tattoo device. Tattoos were applied as per the department protocol (anterior reference, lateral levels). A superior tattoo was used on the anterior surface if a patient was receiving treatment to the supraclavicular region. Inferior lateral level tattoos were given if the lateral breast tissue was deemed unreliable for levelling purposes.

Patient and clinician rated experience

At the completion of their computed tomography (CT) planning session, patients were asked to complete a questionnaire rating the level of pain they experienced during tattoo application. The questionnaire asked the patients to rate the pain experienced on a 10-point Likert scale utilising the Wong-Baker FACES pain rating scale [14] with 0 being no pain and 10 being the worst possible pain. Patients were also asked if there were any tattoo sites that were more painful than others and a section was provided for additional feedback (Supplementary material 1).

Radiation Therapists completed a separate questionnaire after each patient's CT planning session where the Comfort Marker tattoo device was used. The Radiation Therapist applying the tattoos was the person to complete the questionnaire. They were asked to rate the ease of use of the device on a 5-point Likert scale (Supplementary material 2). They were also asked to record any observations they had regarding patient pain levels and any additional feedback they had about the device. Radiation Therapists also recorded the patient's age, number and location of tattoos applied and the depth setting used for tattoo application. As per standard departmental practice, Radiation Therapists took photos of the tattoos applied at the CT planning session and these were saved in the patient's chart in the Radiation Oncology Information System.

Tattoo visualisation assessment

At the final treatment session, Radiation Therapists were requested to take a photo of the tattoos applied as a record of visualisation at this timepoint. They were also requested to record any comments regarding tattoo visualisation in the Radiation Oncology Information System, including if tattoos needed to be reapplied during treatment due to fading. To evaluate any tattoo visualisation after treatment, patients were asked to attend follow up visits at the department 6 and 12 months after treatment completion. Where possible, these visits were scheduled to coincide with standard clinical follow up appointments. As such, some variation in the timing of follow up visits occurred depending on when the patient could attend the hospital. Photographs and assessment of tattoo visibility was performed by the study team Radiation Therapists at these follow up visits. Photographs were saved in the patient's chart. Tattoos were deemed still visible if any part of the tattoo mark could be seen in the photographs.

Statistical analysis

Likert scale responses for patient pain rating and clinician ease of use were assessed using percentage frequency of responses. Additional patient and clinician comments on tattoo application were analysed using content thematic analysis. Content analysis was also performed to reveal any common feedback themes in clinician feedback on the ease of use of the device. The long term visibility of tattoos was assessed using percentages of what proportion of tattoos faded and mean and standard deviation of length of time to fade for participants where this occurred.

Results

Patient demographics

Between August and December 2021, 50 breast cancer patients were recruited to the study. Coincidentally, there was an even split between left and right sided breast cancer patients. All patients were female and received at least 3 tattoos at a depth of 0.4 mm with black ink. No tattoos needed to be reapplied during treatment. All patient demographic information can be seen in Table 1.

Patient rated pain levels

Fig. 1 demonstrates patient pain ratings for tattoo application at CT

Table 1
Patient demographics.

Parameter	Number (n = 50)
Age (years), median (range)	61 (34–79)
Treatment side	
Left	25
Right	25
Number of tattoos	
3	37
4	11
5	2

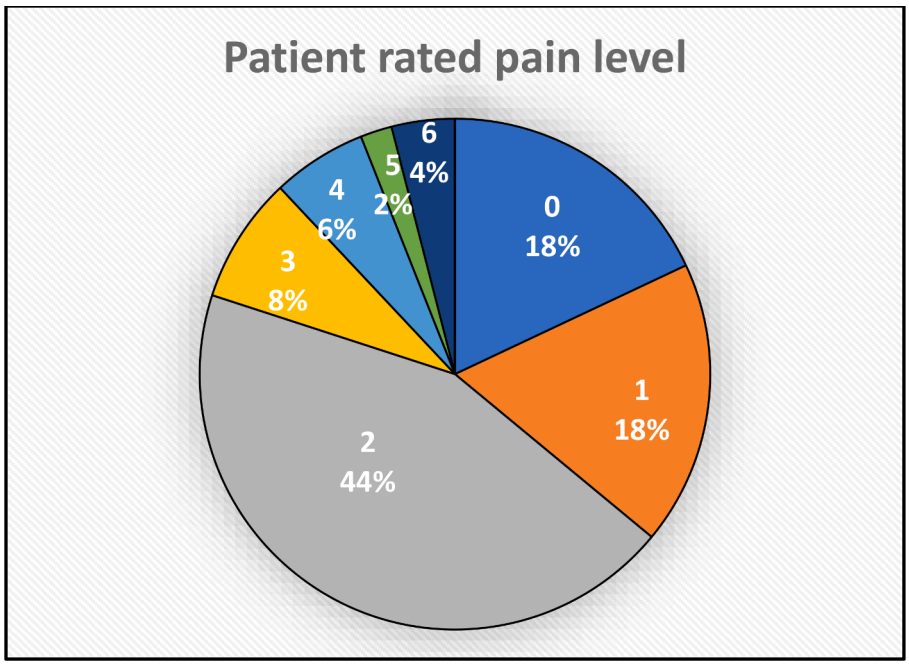

Fig. 1. Patient rated pain levels. 0 = no pain at all, 5 = moderate pain, 10 = worst possible pain.

simulation using the 10-point Likert-style Wong-Baker FACES pain rating scale. The majority of patients (80%) rated their pain between not hurting or hurting a little bit (0 to 2). Of the patients that rated their pain level greater than 2, all stated that the anterior tattoo (over the sternum) caused them the most pain and one patient indicated a phobia of needles.

Table 2 summarises patient comments regarding their feedback on whether one or more tattoos hurt more than others. Of the 50 patients, 36 made comments (72%). Almost three-quarters of these patients stated that the anterior tattoo over the sternum was the one that caused them the most pain. Staff were also asked to indicate whether they observed any pain experienced by the patient when applying the tattoos. Staff made comments for 47 of 50 patients (94%), the results of which are displayed in Table 3. Comments in the 'Other' section related to the patient's reaction when the tattoos were applied (E.g. 'Patient slightly jumped before tattoo applied but said it was ok').

Clinician rated ease of use

Staff ratings of how easy they found the Comfort Marker tattoo device can be found in Fig. 2, with a scale of 1–5 used where 1 was very difficult and 5 being very easy. More than 85% of staff ratings after each induvial patient CT simulation session indicated that the device was easy or very easy to use. The one respondent who rated the device very difficult to use indicated this was due to the needle slipping when the patient flinched, resulting in the application of 2 separate tattoos, located close to each other.

Table 2
Patient indication of which tattoo hurt the most.

Location	Number (%) (n = 36)
Anterior chest (sternum area)	26 (72.2%)
Left lateral chest	4 (11.1%)
Right lateral chest	4 (11.1%)
Superior chest	1 (2.8%)
Surgery side of chest	1 (2.8%)

Table 3
Pain observed by staff during tattoo application.

Response	Number (%) (n = 47)
No pain observed	23 (48.9%)
Confirmation of patient comment on patient survey	20 (42.6%)
Other	4 (8.5%)

Clinician feedback on device

Staff were also invited to provide feedback on the device itself and any suggestions they had for improvement. Eight staff members were involved in applying the tattoos, providing 69 individual items of feedback. Content thematic analysis was performed and comments were grouped into common categories with example representative staff comments, displayed in Table 4. The three most frequently occurring items of feedback were around the device being cordless (39.1%), the size of the pen (20.3%) and the rubbish associated with the consumables (13.0%).

Tattoo fading over time

All tattoos for all patients remained visible at the completion of RT treatment. Staff commented on tattoo visualisation for 12 patients. The vast majority of comments (83%) stated that the tattoos were clearly visible. Two patients were noted to have considerable skin reactions in the area of the tattoos located on the anterior surface rendering these tattoos harder to visualise in the final fractions of treatment. However, these patient's tattoos were clearly visible at all follow up appointments.

One patient requested to withdraw from the study when contacted regarding the six month follow up appointment. Of the remaining 49 patients, three did not attend the six month follow up appointment and one did not attend the 12 month follow up appointment. Although 6 and 12 month follow up was aimed for, variation did occur. The median time from simulation to the six month follow up appointment was 231 days (168–289 days) or 33 weeks. The median time from simulation to 12 month follow up appointment was 464 days (384–581 days) or 66 weeks. All tattoos were still able to be visualised at the 12 month follow

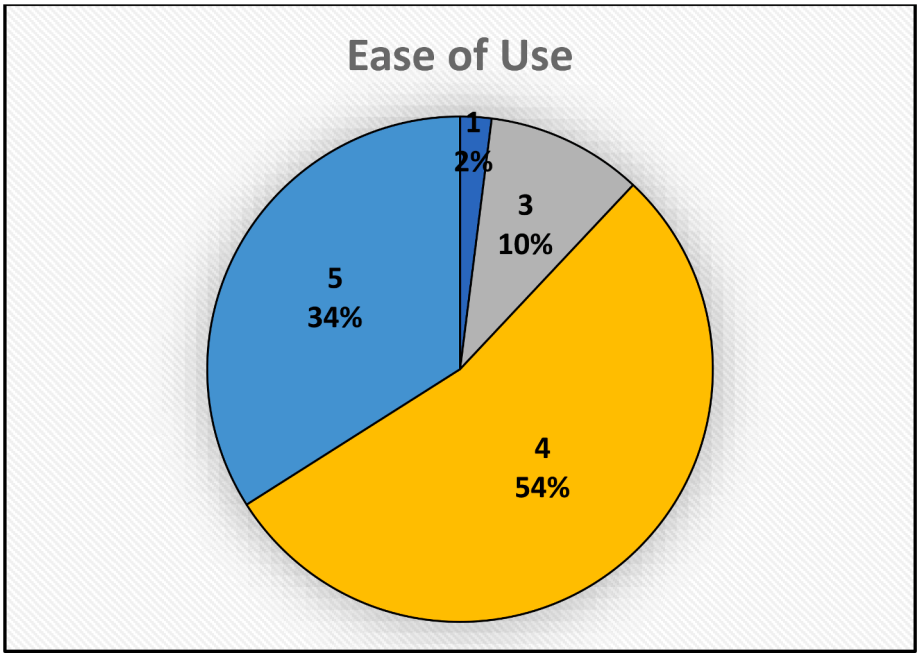

Fig. 2. Staff rated ease of use. 1 = Very difficult, 2 = Difficult, 3 = Neutral, 4 = Easy, 5 = Very easy.

Table 4
Staff feedback on the device and suggestions for improvement.

Comment category	Number (n = 69)	Percentage	Explanation	Example comment
Cordless	27	39.1%	Make device cordless for ease of use	"Cordless for ease of use"
Pen size	14	20.3%	Pen too large to promote ease of handling	"Pen is heavy and thick"
Rubbish	9	13.0%	Concerns about excess packaging and large amounts of plastic rubbish produced from consumables	"More reusable parts/equipment as more rubbish is created with the various single use components"
Needle insertion	5	7.2%	Suggestion for light to illuminate when needles inserted into skin to provide indication of when to stop twisting pen	"Would help user if a light went on once the needles have gone in to know when to stop turning the pen"
Twisting motion	4	5.8%	Twisting action awkward and would be good to remove	"Twisting action is awkward"
Tattoo issues	3	4.3%	Tattoo reapplication due to pen slipping on skin	"Pen slipped on rotation, made one normal size tattoo and a tiny tattoo a few mm inferiorly"
Other	7	10.1%		"Provide ergonomic trolley for ease of use of transporting device around" "Label depth buttons" "Unable to clean device well (white with black ink!)"

up appointment. Fig. 3 depicts photos of representative tattoo examples at simulation and at the 12 month follow up appointment. It should be noted that one patient demonstrated evidence of their anterior tattoo starting to fade at the 12 month follow up appointment (Fig. 4) however the tattoo was still able to be visualised at that time (simulation to final follow up = 398 days).

Discussion

Clinical implementation of the Comfort Marker tattoo device has been successful. Overall, patients found the process quite painless and staff found the device easy to use, providing a consistent result. The most common areas staff identified for improvement with the device were: making it cordless (39.1%), pen size (20.3%) and reduction in associated rubbish (13.0%). All tattoos for all patients participating in the study were able to be visualised at the final follow up appointment.

To the author's knowledge, this is only the second study reporting outcomes on the use of the Comfort Marker tattoo device. Pires and colleagues conducted a randomised trial comparing the use of the Comfort Marker tattoo device with tattooing using traditional Lancets [15]. The use of traditional Lancets is also the current method of tattoo application in our department. Similar to the current study, patients found the Comfort Marker tattoo device to be reasonably painless with 44% describing the procedure painless, compared to 36% of patients rating their pain as 0 to 1 in the current study [15]. This is despite the fact that different injection depths were used in the two studies (Pires et al – 0.2 mm, current study – 0.4 mm). The low level of pain associated with the application of tattoos using this device may be associated with the controlled needle insertion depth the device provides. The Comfort Marker tattoo device offers three insertion depths that all penetrate less than 1 mm below the skin surface (0.2 mm, 0.4 mm and 0.7 mm), only impacting the epidermal layer. Comparatively, traditional tattoo application using Lancet needles may penetrate as much as 3–4 mm beneath the skin's surface, impacting both the epidermal and dermal layers [16]. As the dermis contains more pain receptors than the epidermis [17], it is hypothesised that penetration of this layer would result in increased pain for the patient, potentially explaining the low levels of pain associated with the Comfort Marker device. Further investigation would be required to confirm this theory. Observationally, both staff and patients

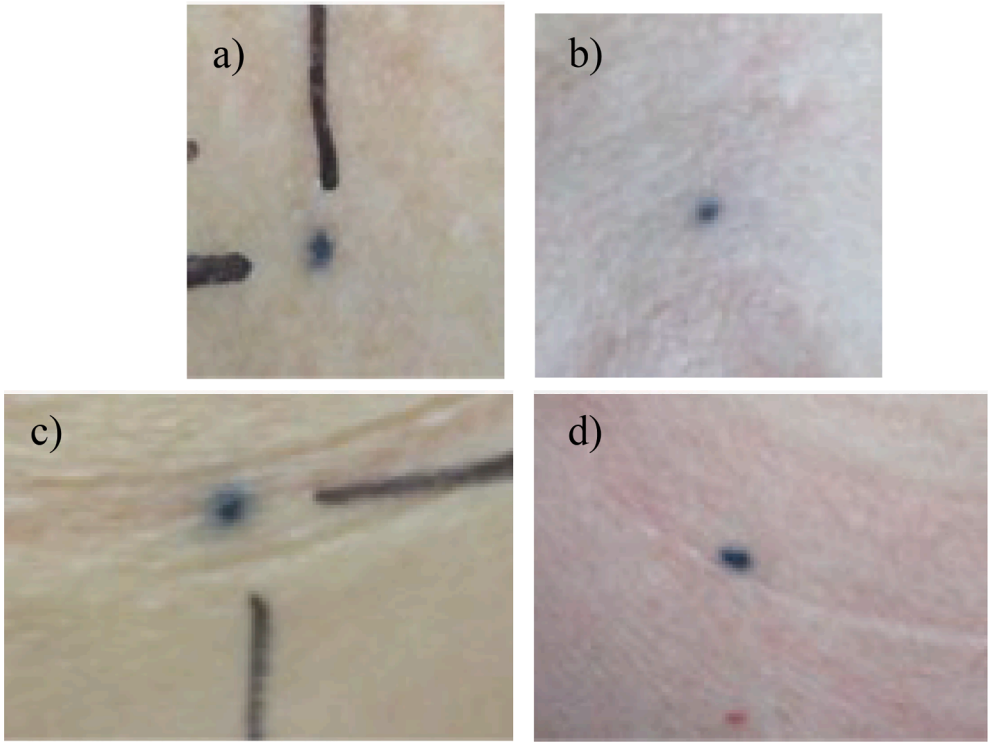

Fig. 3. Tattoo visualisation comparison between simulation and 12 month post treatment. a) anterior tattoo at simulation, b) anterior tattoo at 12 months, c) lateral tattoo at simulation, d) lateral tattoo at 12 months.

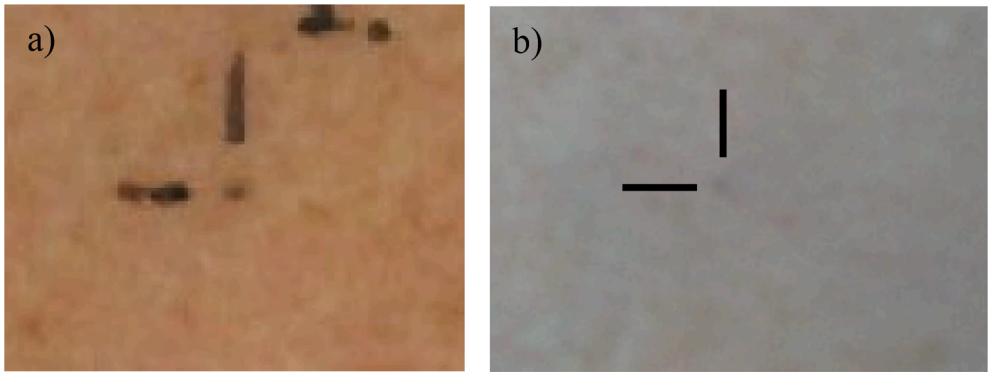

Fig. 4. Anterior tattoo visualisation comparison between a) simulation and b) 12 months post treatment for patient who demonstrated tattoo fading.

commented that the vibration of the Comfort Marker tattoo pen may have also contributed to the lower levels of pain experienced as it served as a minor distraction to the insertion of the needle. As this was not specifically captured as part of the current study and is not the primary purpose of the vibration, this would need to be further explored to gain a better understanding of the role the vibration of the pen may play in the patient's perceived pain levels.

The vast majority of staff found the device easy to use. This was also supported by the consistency, in relation to size and visibility, of the tattoos applied shown through the photographs taken for all patients. This was an inadvertent observational finding from the study which resulted in the additional benefit of treatment staff being able to easily visualise and locate these tattoos throughout a patient's treatment course. This is consistent with the findings from Pires and colleagues [15].

When asked to provide feedback on areas where the device could be improved, four comment categories related to the design of the device itself. The most cited area of improvement was the desire to make the device cordless. As the tattoo pen is attached to the base via a cord, this necessitated the purchase of a small, wheeled trolley to position the base on so the pen could be brought to the area that was being tattooed. This feedback was relayed to the manufacturer for consideration in future iterations of the device.

It has been widely reported in literature that RT tattoos can be a cause of distress and anxiety to patients, particularly women receiving treatment for breast cancer [18,19]. Tattoos for breast cancer patients are generally located centrally on the mid-chest and on each side of the chest. Patients may also have a tattoo located higher up in between the suprasternal notch and shoulder. These tattoos can be quite visible and may influence a patient's choice of clothing and swimwear. With breast cancer patients experiencing ever-improving long-term survivorship, permanent reminders such as tattoos have been found to have a lasting negative impact on body image [7]. This was one of the driving factors behind evaluating the Comfort Marker tattoo device as it was hoped that, due to the controlled, shallower depth of ink penetration beneath the skin, tattoos may fade over time [13]. However, at the final follow

visit, all tattoos were still clearly visible for all patients in the study (median time since simulation = 464 days (384–581 days)). It is important to note that all patients in the current study were tattooed using a depth setting of 0.4 mm. This was a decision made at CT simulation due to the department's unfamiliarity with the device to minimise the potential of any tattoos fading whilst patients were still on treatment. Further investigation would be required to evaluate if a shallower injection depth would result in tattoo fading. Although the study by Pires and colleagues did not assess long term visibility of the Comfort Marker tattoos and used a tattoo depth of 0.2 mm, similar to the current study, they did state that these tattoos did not often fade and tended to remain well-defined [15]. Interestingly to note, one patient did show evidence of potential tattoo fading at the final follow up visit which suggests that tattoo fading may be seen in some patients in the longer term. To gain a better understanding of whether these tattoos would eventually fade over time and at what time point this would happen, a longer follow up period would need to occur. None of the patients included in the study opted to have laser removal of their tattoos so it is unknown how easily they would be able to be removed via this process. If tattoos applied by the Comfort Marker device do prove to fade in the longer term, this provides a financially more viable alternative than more expensive tattooless options like SGRT [9,20].

This study did have its limitations. Due to the challenges of the COVID-19 pandemic, not all patients were able to return for every follow up visit, resulting in information not being captured at all intended time points. A longer follow up period would have enabled a better understanding of if and when the tattoos may fade and future studies should include longer follow up. As this was the first time that staff in the department were using the device, all tattoos were given using the middle depth option (0.4 mm). Future studies should include the use of the shallowest depth option (0.2 mm) to evaluate if this has any bearing on the potential of the tattoos to fade over time. Also, it is unknown if the fact patients knew they were participating in a tattoo study increased their attention to pain, therefore potentially influencing their responses regarding pain levels. Finally, patient's feelings toward the lasting nature of the Comfort Marker tattoos were not officially captured as part of the study. This may have been beneficial to include to garner an understanding of their feelings about these tattoos.

Conclusion

Overall, this study found the Clinical implementation of the Comfort Marker 2.0 tattoo device successful. The vast majority of both patients and staff reported a positive experience with using the device, resulting in little to no pain for patients. No tattoo fading was recorded at the final follow up however future studies should include different depths of ink penetration and a longer follow up to evaluate if tattoo fading is seen longer than 12 months after application. Due to the successful implementation of this device, it is now used standardly in the department across all treatment sites that require the application of tattoos.

Funding declaration

CQ Medical provided the Comfort Marker 2.0 tattoo device and tattoo consumables for 50 patients to enable the conduct of this study.

Informed patient consent

The author(s) confirm that written informed consent has been obtained from the involved patient(s) or if appropriate from the parent, guardian, power of attorney of the involved patient(s); and, they have given approval for this information to be published in this case report (series).

CRediT authorship contribution statement

Elizabeth Brown: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Visualization. **Tamara Barry:** Conceptualization, Methodology, Writing – review & editing. **Tao Mai:** Resources, Writing – review & editing. **Jennifer Harvey:** Resources, Writing – review & editing.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: CIVCO provided the Comfort Marker tattoo device and tattoo consumables for the 50 patients recruited to this study. They were not involved in any part of the study design, data analysis or manuscript preparation.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.tipsro.2024.100254.

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