Skin Treatment Clinic
Beauty Therapist, Ms B

A Report by the
Deputy Health and Disability Commissioner

(Case 19HDC00698)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report considers the care provided to a woman by a beauty therapist and the manager of a skin treatment clinic (the clinic) in June and July 2018.

2. The woman attended the clinic for the management of broken capillaries and redness on her cheeks. The beauty therapist treated the woman's broken capillaries with laser treatment over three treatment sessions. During the third treatment session, the beauty therapist increased the laser settings, which caused burns to the woman's cheeks.

3. The report discusses the adequacy and appropriateness of the treatment provided by the beauty therapist, the post-treatment advice provided by both the beauty therapist and the manager, as well as the services provided by the clinic.

Findings

4. The Deputy Commissioner found that the clinic failed to support and educate its staff adequately to provide services of an appropriate standard and, accordingly, breached Right 4(1) of the Code. The Deputy Commissioner also found that the clinic failed to ensure that staff met the requirements of the Auckland Council Health and Hygiene Code of Practice 2013, and therefore breached Right 4(2) of the Code.

5. The Deputy Commissioner made adverse comment about both the beauty therapist and the manager for the post-treatment advice provided to the woman, but considered that primarily the responsibility for their failings sat with the clinic.

Recommendations

6. In response to the recommendations in the provisional opinion, the clinic agreed to develop a comprehensive protocol for training its staff in the use of all types of laser, develop a policy and protocol for informed consent for all clients who are to undergo laser treatment, develop a client record sheet template to be used for all clients who undergo laser treatment, provide evidence of training for staff on the requirements of the Auckland Council Code of Practice, and develop a process for recording incidents and near misses.

7. The Deputy Commissioner recommended that the beauty therapist undertake formal training in the use of laser for skin rejuvenation, and familiarise herself with the Auckland Council Code of Practice.

8. The Deputy Commissioner also recommended that the clinic, the beauty therapist, and the manager apologise to the woman for the care criticised in this report.

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Complaint and investigation

9. The Health and Disability Commissioner (HDC) received a complaint from Ms A about the services provided by the clinic and Ms B. The following issues were identified for investigation:

- *Whether the clinic provided Ms A with an appropriate standard of care in June and July 2018.*
- *Whether Ms B provided Ms A with an appropriate standard of care in June and July 2018.*

10. This report is the opinion of Kevin Allan, Deputy Health and Disability Commissioner, and is made in accordance with the power delegated to him by the Commissioner.

11. The parties directly involved in the investigation were:

Ms A	Consumer/complainant
The clinic	Provider/skin treatment clinic
Ms B	Provider/laser therapist
Ms C	Clinic manager

12. Independent expert advice was obtained from a laser therapist, Ms Ruth Nicholson (Appendix A).

Information gathered during investigation

13. This report relates to laser treatment provided to Ms A, then aged in her thirties, by beauty therapist Ms B at the clinic between June and July 2018.

Laser skin treatment

14. Laser skin treatment is a non-invasive treatment that uses concentrated light to heat the target area. The thermal effect produced by the light can be used for hair removal, and to treat pigmentation, rosacea,[1] and redness caused by broken capillaries.

The clinic

15. According to the clinic's website, it offers laser and enzyme skin treatments for hair removal and skin rejuvenation.

16. Ms C, the clinic manager, told HDC that the clinic uses the highest medical-grade lasers for hair removal and for treatment of broken capillaries.

17. Ms C told HDC that its staff are trained in all laser treatments. She stated:

[1] A skin condition that causes redness and visible blood vessels on the face.

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> "We not only get trained by our laser companies but they also give us safety manuals. We are always getting our knowledge updated to keep up with the new treatment techniques."

18. Ms C provided a statement from the clinical nurse laser educator for the manufacturer of the hair removal laser machine. The clinical educator stated: "[U]pon purchasing a device from the manufacturer and meeting the needs of our service and warranty agreement, we provide clinical training to the clinic and any users within it." She told HDC:

> "It is common practice that a Clinical Educator will spend up to 2 full days in a clinic thoroughly explaining Laser Physics & Safety and the associated use of the laser for various treatment indications."

19. Ms C said that initially staff are trained in laser hair removal. She stated that staff are trained in laser skin rejuvenation only when they have a "minimum of 1 year of experience". Ms C provided a copy of her training certificate in the use of the laser machine used in this case, but no further evidence of Ms B's training in the use of this device. In response to the provisional opinion, the clinic acknowledged that it did not provide a formal training certificate for Ms B. However, it stated:

> "[Ms C] who is formally certified and qualified to train staff by [the manufacturer of the laser machine for skin rejuvenation], trained [Ms B] on the [machine] for 3 months. This training period was solely dedicated to vein treatments. [Ms B] has therefore attended and successfully completed her extensive, in-depth training teaching her to correctly identify, diagnose and treat skin conditions such as rosacea and veins. Further, [Ms B] was trained on the [machine] only after having amassed a year's worth of successful work experience on all the satisfied and happy laser clients [Ms B] had serviced up until that point."

20. Ms C said that Ms B was trained solely for laser hair removal for the first year before they began training on vein treatments. Ms C explained: "This is because vein treatments require additional skill and expertise, beyond those of laser …"

21. In response to a request for any relevant written policies on client consent and documentation, Ms C said that when new staff members start working at the clinic, they are provided with the relevant training manuals for the laser devices. She stated that they are given in-house training in the use of the laser machines, and are trained to document "the settings, client feedback and clinical appearance on paper and [on the] computer". Further, Ms C said that staff are "asked to fill in the Consultation form" as part of this training. In response to the provisional opinion, the clinic also stated: "[A]ll our therapists are trained in delivering standardised post-treatment management advice."

Ms B — training and experience

22. Ms B qualified as a beauty therapist in 2016 and began working as a beauty therapist at the clinic in 2017. She told HDC that her training in the use of laser therapy began at that time and included "four weeks of training and observing laser treatments carried out by

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the manager and senior laser therapist at the clinic". Ms B said that in addition, she had "further training at the clinic in laser therapy and skin rejuvenation treatments" from her manager and senior therapist, which included "practising the treatments using laser machines, either on each other, or on model client[s]. For the skin rejuvenation treatments such as for broken capillaries or vein we also practi[s]ed on each other and on models using the laser machines."

23. Ms B also said that she attended a two-day training course run by technicians from the manufacturer of the hair removal laser machine, which focused on "the theory and practical training of laser safety, laser hair removal treatments". Ms B stated: "At the end of the course I was presented with my laser certificate."

24. Ms B provided a copy of her training certificate from the manufacturer of the hair removal laser machine for "Laser Physics & Safety, Laser Hair Reduction". However, the clinic has provided no evidence of training specifically in relation to laser treatment for skin rejuvenation/capillary/vein treatment, including the use of the laser machine used in this case. Nor has the clinic provided any documented record of Ms B's in-house training.

Initial consultation and consent

25. On 14 June 2018, Ms A attended the clinic for a consultation with Ms B regarding management of broken capillaries and redness on her cheeks.

26. Ms A had attended the clinic previously for laser hair removal in 2017.

27. Ms B told HDC that during the initial consultation, she assessed Ms A's skin "by examining it and asking the client questions". Ms B did not provide details about what her assessment entailed or what questions she asked Ms A.

28. Ms B said that she assessed Ms A as having broken capillaries and facial redness, and discussed the treatment options available for the management of each of these issues, which included laser and enzyme therapy facials.[2] Ms B stated:

> "During my initial consultation with [Ms A], we talked about two different treatments for two different concerns. [Ms A's] first concern was her broken capillaries and we discussed treating these with the laser. Her second concern was facial redness so we discussed treating the redness with the … Enzyme therapy facial which helps the rosacea/redness. These are the only treatment options offered by the clinic for broken capillaries and facial redness."

29. Ms B said that during this consultation they also discussed how the laser treatment worked and the expected outcomes, including the risks of treatment. Ms B told HDC that all clients who attend the clinic have to sign a consent form when they first attend, and that because Ms A had attended the clinic previously for laser hair removal, Ms B did not ask her to complete the form again. Ms B said that the consultation form contains "all of

[2] According to the clinic, "These are effective & safe para medical treatments for Acne, scaring, rosacea, capillaries, rejuvenation and age management."

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the standard treatment information for hair removal, pigmentation, veins", and "sets out potential risks such as blistering". Ms B said that she also "mentioned this" during the consultation.

30. Ms C told HDC:

> "We always get the clients to fill a 4-page consultation form which includes Medical history and skin type details along with any special notes that might be of relevance for the treatment and save it as paper & digital file. [Ms A] was initially our Laser hair removal client and at that time [the] same form was used for Vein consultation and treatments were also recorded in the same form. … In [Ms A's] case the therapist made a decision to use the same laser hair removal file for consultation and to record treatments."

31. There is no documentation relating to what Ms B discussed with Ms A during this consultation.

32. The medical history and consent form completed by Ms A at her previous consultation for hair removal treatment is dated 23 February 2017. The form documents that treatment was for hair removal in various areas. Ms A recorded her personal details, including her past medical history and current medications. She completed the skin type questionnaire, and signed a "consent for laser treatment" form for "Laser Treatment", which states:

> "I understand the side effects associated with the treatment and I freely assume these risks.
>
> These may include but are not limited to, include:
>
> - Serious complications are rare, but possible.
> - Common side effects include temporary redness and mild 'sunburn' like effects that may last a few hours to 3–4 days or longer.
> - Other potential risks include crusting, itching, pain, bruising, burns, infection, scabbing, scarring, swelling and failure to achieve the desired result. …"

33. Ms B and Ms C told HDC that Ms A opted for only laser treatments, instead of the enzyme therapy facials, which were also recommended.

34. Ms A told HDC that when she attended the clinic for management of the redness on her cheeks, Ms B recommended three sessions of laser treatment. Ms A said that no other treatment options were discussed with her, and she does not recall any discussion regarding the risks of the treatment. She said that because she had had laser hair removal at the clinic previously, she assumed that the machine being used was the same, and that the instructions would be the same.

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Treatments

35. Ms A underwent three laser treatments[3] for her "broken capillaries". Ms B said that she undertook a test patch prior to the first treatment, and waited 10 minutes to check Ms A's response to the laser treatment prior to commencing treatment.

36. The treatment notes from the first two sessions record that the laser settings used were 150 joules/20 milliseconds (ms) and a 3 millimetre (mm) spot size in accordance with the manufacturer settings for the treatment of broken capillaries.[4] The records from the third session are less clear, and appear to depict either 150 or 180 joules/20ms and a 3mm spot size. This is all that is recorded of the three treatment sessions, and Ms B did not document her treatment observations, or what advice she provided to Ms A post-treatment.

37. Ms B said that after each laser shot she watched for the "end point" (changes observed following treatment), which during the first two treatments were as expected — "vessel blanched turning a slight grey colour". Ms B told HDC:

> "After the first two treatments there were positive but minimal results and it was clear that [Ms A] was hoping to see more of a result. After talking to her and re-assessing the skin, we decided to turn the laser setting up by 1 for the third treatment."

38. Ms B explained that the laser machine goes up in increments of only 10 joules, and that by turning it up by "1", she turned the settings up to 160 joules/20ms using a 3mm spot size. Ms B stated that this was still "well within the suggested parameters" set by the manufacturer. This increase is not documented in the treatment notes.

39. Ms B told HDC that after starting the treatment, Ms A told her that it was too hot, so she turned the parameters back down immediately and also turned up the cooling. In response to the provisional opinion, Ms B said that she did not stop the treatment, and continued until the treatment had been completed. Ms B's adjustment of the settings part way through the session is not recorded in the treatment notes.

40. In contrast, Ms A told HDC that the first two treatments had no effect. She stated that during the third treatment, she experienced acute pain after the treatment started. Ms A said that when she told Ms B that it hurt, Ms B turned up the cooling air but continued with the treatment at the higher setting on both cheeks. Ms A said that she stopped the treatment before it was finished because of the pain.

Management following third treatment

41. Ms B said that after the completion of the third treatment, "there did not appear to be any adverse reaction", but she noted that generally any reaction would not show immediately.

[3] Ms A had treatments on 14 June 2018, 30 June 2018, and 14 July 2018.

[4] The treatment parameters set by the manufacturer for skin type I–IV (type I refers to skin that is very pale with freckles and burns easily, type IV refers to moderately brown skin that burns minimally) for treating "Facial Telangiectasia" (broken capillaries) are 3mm spot size, 120–180 joules, 10–30ms pulse width.

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42. In relation to what advice she had given Ms A, Ms B said that she "had explained in the consultation how treatment would work and what to do post care", including applying a post-laser gel or Aloe vera gel for 2–3 days, applying ice packs, avoiding hot baths or showers, not wearing make-up, avoiding sun exposure, and applying an SPF 30–50 sunblock daily. Further, Ms B said that Ms A had been given a post-treatment advice sheet the previous year, when she had received her hair removal treatment, "which has all information about post care on laser hair removal and veins".

43. In response to the provisional opinion, the clinic accepted that it was an oversight for Ms B not to have provided Ms A with another post-treatment advice sheet.

44. In relation to post-treatment advice, Ms A told HDC that the only advice she recalls being given was not to exercise after treatment, not to sweat or wear make-up, and to keep her face cool.

45. Ms A said that by the time she had returned home, both of her cheeks had started to swell and blister. She stated: "It was very painful, there was a large amount of swelling and there were multiple large weeping blisters over my cheeks." Ms A said that she took photographs[5] and emailed the clinic the same day to ask whether this type of reaction was normal. She stated that she "did not know that could happen".

46. At 6.49pm that evening, Ms C responded to Ms A by text message, stating:

> "As you have had previous successful treatments you must be aware that it's very rare to get blisters after vein treatment. However it should subside on its own please do not puncture or scratch them. Just apply cool compress and sleep with your head a little elevated. You can have [an] anti inflammatory if that suits you."

47. Ms C also recommended that Ms A attend the clinic to see Ms B in the next week, so that Ms B could assess Ms A's face.

48. Ms A responded to the message, noting that there were about 15 blisters and that her cheeks were "quite swollen", but she thanked Ms C for her response and stated: "Glad [it's] in the [realms] of normal."

Further treatment

GP consultation

49. On 16 July 2018, two days after her third laser treatment, Ms A saw her GP because she was concerned that the blisters were serious and would need medical intervention to prevent scarring. The patient notes from this GP consultation record:

[5] Ms A provided HDC with a selection of photographs she said she sent to the clinic, which show numerous blisters on both cheeks.

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> "Had laser for facial telangiectasia[6] last [Saturday]. … 2 h[ours] later had blisters, that night eyelids swollen causing eyes to be shut.
>
> Few clusters of vesicles[7] on L[eft] > R[ight] cheek (6 on R[ight], 10 on L[eft]), upper half > lower half of cheeks [o]edematous,[8] eyelids appear normal. [Slight] golden yellow crusting at L[eft] cheek lesions cluster."

50. The GP's impression was "burns [from] laser treatment, infected on left". Ms A was prescribed antibiotics and a steroid cream, and an ACC claim was made.[9]

Further consultation at the clinic

51. On 17 July 2018, Ms A returned to the clinic and was assessed by Ms C. Ms A told HDC that Ms C was unable to tell her why the burns had occurred, but assured her that no scarring would occur.

52. Ms C offered Ms A a credit for the cost of the laser treatment, which Ms A chose to use for further hair removal treatment. Ms A was also offered two facials to help with the scarring, which Ms A accepted.

Subsequent events

53. Owing to persistent scarring, Ms A sought advice from another skin treatment clinic. On 16 April 2019, almost a year after her treatment at the clinic, Ms A saw an appearance medicine nurse at the second clinic. The nurse recorded that Ms A was attending because of "[s]carring/hypopigmentation[10] on cheeks post laser burn, and surrounding redness and vessels".

54. On 18 April 2019, Ms A saw a facial plastics and reconstruction surgeon at the second clinic, who noted that Ms A had "punctate partial thickness burns [11] with hypopigmentation".

55. Subsequently, Ms A underwent Intense Pulsed Light (IPL)[12] therapy at the second clinic to try to improve the appearance of the scarring.

Further comment from Ms B

56. In relation to the laser settings used during the third treatment, Ms B stated:

> "With respect to vein treatments I had always used the machine Suggested Treatment Parameters as guidance for the treatments. Further I knew I could always ask my manager for help if I don't know what to do.

[6] Small dilated blood vessels just below the skin surface.
[7] Small blisters.
[8] Swelling from fluid accumulation.
[9] ACC accepted the claim and provided cover for the ongoing treatment of Ms A's scars caused by the burns.
[10] Patches of skin that are lighter.
[11] Small, circular burns.
[12] A type of laser treatment.

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> At all times, I was following the instructions as set out in the Suggested Treatment Parameters. At the time of [Ms A's] treatment, I had already completed two treatments and [Ms A] had not reacted badly to these. I followed the instructions in the manual to turn up the laser joules from 150 to 160 and used this on a 3mm spot (this is the only size I would use for this type of laser treatment as set out in the parameters)."

57. Ms B told HDC that following Ms A's reaction, she apologised and sympathised with Ms A when she came in for further treatment.

Further comment from the clinic

58. Ms C told HDC that it is "very rare" for laser therapy to cause blistering, but, like all treatments in medicine, side effects can occur. Further, she stated:

> "We use Medical grade class IV lasers[13] for hair removal and skin treatments including spider veins. These machines cannot be use[d] without adequate training. Our staff [are] trained and experienced for laser hair removal and skin treatments, laser physics and laser safety. Staff attends regular trainings and workshops.
>
> We understand that the treatment of laser hair removal is very different to that of red vein or laser resurfacing and train the staff accordingly."

59. In relation to the treatment settings used, Ms C stated:

> "Both the Initial setting & the later one that were used during the treatment for [Ms A] were in the safe parameters.
>
> We have a chart of settings which are dependent on the size of the area being treated/number of treatment[s]/size of the capillary and thickness which we follow.
>
> The settings are altered depending on the clinical end point (which can be redness/bruising or untolerable heat) and the result of the treatment.
>
> After 2 successful treatments of [Ms A] the energy levels were raised well within the safe parameters and after 2 shots when our client [Ms A] felt the treatment to be hot the settings were brought back to the original setting.
>
> The Vein treatment involves mild to moderate redness, bruising & scabbing which is explained during the consultation. The treatment is carried on only for those clients who understand and are happy to accept the side effects and process of healing."

[13] Lasers are classified according to their output power. Class 4 lasers are the highest classified laser that can produce a thermal effect that can cause injury.

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60. Further to this, Ms C stated:

> "Although the blisters were caused due to increase in energy **the settings were in the recommended range and appropriate cooling and pulse duration was used**. Appropriate cooling was used before and after treatment … It is explained in consultation that blisters can be a side effect of the treatment." (Emphasis in original.)

Response to provisional opinion

Ms A

61. Ms A was provided with a copy of the "Information gathered" section of the provisional report. She noted that she and Ms B have differing accounts about what occurred during the treatment, but otherwise had no further comments in relation to this section of the report.

Ms B

62. Ms B was provided with the sections of the provisional opinion relevant to her. She reiterated that she assessed Ms A as having broken capillaries and rosacea, and that the laser was used for the treatment of the broken capillaries only.

63. Ms B also reiterated that during the third treatment session she did not stop the treatment after Ms A complained of it being too hot, but turned down the settings and continued until the treatment had been completed.

The clinic and Ms C

64. The clinic's response to the provisional opinion has been incorporated into this report where relevant. In addition, the clinic submitted that there is no evidence that Ms B lacked relevant knowledge and experience in the use of laser for skin rejuvenation. The clinic stated:

> "From a clinical perspective, the settings never went outside the safe zone. This is to say that the reaction observed on [Ms A] was therefore not a mistake caused using incorrect settings, but simply a rare and unfortunate reaction [Ms A] developed. It is inaccurate to view this rare occurrence as avoidable, especially when given that [Ms B] made no technical errors in her choice of settings."

65. Further, the clinic submitted that there is no evidence that Ms C displayed a lack of knowledge in relation to the advice provided to Ms A after Ms A contacted the clinic reporting blisters. The clinic stated:

> "[Ms C] responded immediately the very same evening to [Ms A] when [Ms A] messaged with concerns of her blisters. She reassured her that her skin would return to normal based on case studies [Ms C] has seen during her 10+ years of laser industry experience and advised her of the necessary follow-up actions."

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66. Further to this, the clinic stated:

> "We contend this to be a case of a rare adverse reaction which was a known but unlikely risk and one that did not stem from lack of training or expertise from members of the clinic. It was simply a regrettably unavoidable situation as no one could have predicted or foreseen [Ms A's] skin would react so adversely seeing as [Ms A] had already undergone two completely risk free treatments of the same type prior."

67. The clinic said that previously it had never had any issues with its laser treatments. It noted that it has passed its annual inspection by Auckland Council, which looks at the clinic's "qualifications, machinery and equipment, client files and consent forms, safety & hygiene standards of treatments and post-treatment practice".

Opinion — introduction

68. Ms A suffered scarring as a result of burns caused by laser treatment to her face, which was intended to improve the appearance of redness on her cheeks. This report considers the adequacy and appropriateness of the services provided to Ms A by beauty therapist Ms B and the clinic. It also considers the post-treatment advice provided by Ms C, the clinic manager.

69. Ms B and the clinic provided Ms A with laser treatment and advice for broken capillaries and facial redness. Ms C and the clinic provided Ms A with post-treatment advice. I am thus satisfied that the laser treatment, and advice pertaining to that treatment, were both "treatment services" and services to promote and/or protect Ms A's health, within the definition of "health services" under section 2 of the Health and Disability Commissioner Act 1994 (the Act). I therefore consider Ms B, Ms C, and the clinic to be healthcare providers under section 3(k) of the Act. As such, they are required to comply with the Code of Health and Disability Services Consumers' Rights (the Code).

Use of laser in New Zealand

70. The use of laser for hair removal and skin rejuvenation is largely unregulated in New Zealand. However, the Auckland Council[14] Health and Hygiene Bylaw 2013 and associated Code of Practice provides the minimum standards required of operators of laser machines in its area, and is aimed at reducing risks to public health. It does not specify or restrict who can use the type of laser utilised in this case.

[14] Auckland Council is the only Council in New Zealand that provides any legislative requirements for the use of laser in its area.

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71. Beauty therapy expert Ms Ruth Nicholson advised:

> "Lasers are high powered devices that should only ever be used by trained and experienced technicians who have access to correct settings and are educated in the following procedures and protocols including how to manage the potential complications that are associated with laser."

72. The Medical Council's "Statement on cosmetic procedures" stipulates that laser skin treatment must be carried out by a doctor with relevant vocational scope and training.

73. Clearly, the clinic and its staff cannot be held to the same standard as a doctor working in the field of cosmetic medicine. However, it is relevant to note the high standard of training required of a doctor working in this area, compared to the relative absence of regulation for operators outside the medical profession, such as the beauty industry. In my view, many of the issues in this case, as outlined below, are the result of the lack of knowledge, understanding, and training in the use of laser by Ms B, Ms C, and the clinic.

Opinion: Ms B — adverse comment

Assessment

74. Ms A attended the clinic for the management of redness of her cheeks. Ms B assessed Ms A as having broken capillaries and facial redness or rosacea. Ms B said that she recommended laser treatment for the treatment of the broken capillaries and facials for treatment of the rosacea, although I note that Ms A recalls that laser treatment was the only option discussed.

75. Ms Nicholson advised that, in her opinion, Ms A's primary issue may have been rosacea rather than broken capillaries, and that continuous laser may not have been the most suitable treatment. Ms Nicholson considered that if the issue was rosacea, alternatives such as Intense Pulsed Light (IPL) laser or referral to a medical professional should have been considered and discussed with Ms A. In response to the provisional opinion, the clinic disagreed with Ms Nicholson's opinion that Ms A's primary concern was rosacea. However, Ms Nicholson reiterated her opinion that Ms A's primary concern was rosacea. Ms Nicholson advised that there is no evidence in the photos she has seen of Ms A's face that Ms A had broken capillaries, and in light of this, the decision to treat Ms A with continuous laser was inappropriate.

76. While I appreciate the difference of opinion in relation to Ms A's initial presentation, owing to the passage of time and the difficulty in undertaking a retrospective assessment from post-treatment images, I am not prepared to make a finding on the appropriateness of Ms B's assessment that Ms A had broken capillaries.

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Treatment

77. Ms A underwent three laser treatment sessions at the clinic. The first two treatments were uneventful. Ms B said that although there were positive results from the first two treatments, "it was clear that [Ms A] was hoping to see more of a result", and so it was decided to increase the settings from 150 to 160 joules for the third session.

78. Both Ms B and Ms C said that the change made to the settings during the final treatment was still "well within the safe parameters".

79. Ms Nicholson advised that when the desired results were not achieved after the first two treatments, "this should have indicated that perhaps the treatment modality was incorrect for the skin condition, not that there wasn't enough power being delivered". Further, Ms Nicholson advised:

> "The risk of face vein treatment at high settings with [continuous] laser are very different to those posed for laser hair reduction (eg: The spot size is much more concentrated when treating veins and the energy density is therefore greatly increased)."

80. In further advice received following the responses to my provisional opinion, Ms Nicholson said that in deciding to increase the settings, it would have been good practice to undertake a further test patch.

81. After Ms B started the third treatment at the higher setting, Ms A complained of pain. Ms B said that when Ms A expressed discomfort, she turned down the setting immediately and increased the cooling. In contrast, Ms A said that when she complained of pain, Ms B turned up the cooling but continued the treatment to both cheeks at the higher setting. Ms A said that she stopped the treatment before it was finished because of the pain. The records from the third consultation are unclear,[15] and Ms B did not document a change of setting used part way through the session.

82. According to Ms B, at the completion of treatment Ms A was advised of standard post-treatment management, which included applying a post-laser gel or Aloe vera gel for 2–3 days, applying ice packs, avoiding hot baths or showers, not wearing make-up, avoiding sun exposure, and applying an SPF 30–50 sunblock. Ms B said that Ms A had been provided with written advice the previous year when she attended for hair removal treatment.

83. By contrast, Ms A said that the only advice she was given was to keep cool, and not to sweat or wear make-up.

84. Although the general advice provided to Ms A appears to have been relevant and appropriate, as noted by Ms Nicholson, a written advice sheet should have been provided to Ms A, particularly since her previous treatment was one year earlier and, in addition,

[15] The handwritten treatment records for the final session can be read as either 150 or 180 joules, both of which are still within the recommended manufacturer settings.

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was for laser hair removal, not laser skin rejuvenation treatment. Further to this, I note Ms Nicholson's advice:

> "It is my belief that the end point would have been quite extreme, (blanching white, excessive erythema) and that the skin was in fact being damaged during each shot of the laser beam delivered to [Ms A's] skin."

85. I am concerned that no specific written advice or follow-up was provided, particularly in light of the fact that Ms B was aware that Ms A had experienced pain during the treatment and was aware of the risks of burns.

Conclusion

I have some concerns about the care provided to Ms A by Ms B. I note Ms Nicholson's advice that continuous laser may not have been the most appropriate treatment choice for Ms A's presentation, and therefore when treatment did not produce the expected results, turning up the settings may not have been the most appropriate decision. However, my main concern is Ms B's failure to provide written post-care advice to Ms A, including any advice regarding the risk and management of burns. As noted by Ms Nicholson:

> "[T]his case appears to be evidence of a staff member working outside her scope of expertise; this is due to the training provided, and experience being only relevant to laser hair removal, and not in recognising, diagnosing or treating advanced skin conditions such as rosacea or treatment of this condition with [continuous] Laser."

86. I agree. In my opinion, Ms B's actions demonstrate a lack of knowledge and experience in the scope and use of laser treatment for skin rejuvenation, and a failure to appreciate the parameters of, or work within, her level of knowledge and experience. While it is a basic requirement of healthcare providers to work within their scope of practice, given a lack of evidence of adequate support or training provided to Ms B and the fact that she had limited work experience and had not been fully trained on the equipment involved, I consider that the responsibility for the failures sit primarily with the clinic, as discussed below.

Opinion: Ms C — adverse comment

87. Ms C is the clinic manager, and provided advice to Ms A when she contacted the clinic in the evening after the third laser treatment, complaining of swelling and blistering on her face. I have concerns about the adequacy and appropriateness of the health advice Ms C provided to Ms A.

Advice provided

88. After Ms A returned home, she emailed the clinic with photographs and advised that her face had started to blister and swell following treatment. Ms C responded to Ms A the

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same evening, advising that this kind of reaction is rare but that she should be fine, and to apply ice packs. Ms A thanked Ms C for her advice, noting that she was relieved that her reaction was within the realms of normal.

89. When Ms C saw Ms A the following week, Ms C continued to assure Ms A that the blistering was normal and would not cause scarring. Ms C also offered Ms A a store credit for the cost of the laser treatment, and offered her a free facial.

90. In her responses to HDC, Ms C has maintained that the treatment settings were within the safe parameters set by the manufacturer, and that blistering is a known side effect and is part of the healing process. This view was reiterated by the clinic in its response to the provisional opinion, and it noted that the advice Ms C provided to Ms A was based on her previous experience.

91. In relation to the advice provided by Ms C, Ms Nicholson advised:

> "[A]t this point in time, it should have become obvious that this was a serious adverse response, and actions should be swift and professional. It may be acceptable to see one or two small blisters — however the amount experienced by [Ms A] was not acceptable, or normal."

92. Further to this, Ms Nicholson stated:

> "Although referred to as a 'rare side effect' by [Ms C], [Ms A] is given the impression that blisters are in the realm of normal, which would be rejected by myself and industry peers. Blisters are in fact caused by excessive heat, inappropriate or insufficient cooling and excessive energy density for the pulse duration selected (eg: Too hot, too fast) — this is a scientific principle taught at various levels as the technician continues their education."

93. In relation to Ms C offering Ms A a facial, Ms Nicholson advised:

> "My opinion is that these may not be suitable to apply to post laser burns, or broken skin. As there are no client treatment records to establish end points, or times applied to the skin, or reactions, I am unable to consider the reasoning behind the choice to apply such facial treatments."

94. I am concerned at Ms C's apparent lack of understanding and knowledge of the risks and side effects of laser treatment. I do not accept the clinic's submission (made in response to my provisional opinion) that Ms C's advice to Ms A that her skin would return to normal was appropriate and that no one could have predicted that Ms A's skin would react so adversely. As noted by Ms Nicholson, Ms A's response to the laser treatment was not normal, and it should have been obvious to Ms C that the burns that occurred were potentially serious, and Ms A should have been advised to seek medical advice.

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95. As a result of Ms C's failure to provide Ms A with appropriate and timely advice, there was a delay in Ms A seeking appropriate advice from a medical professional for the management of her burns.

Conclusion

96. In my view, Ms C failed to provide adequate and appropriate advice when Ms A advised that her skin had blistered and become swollen. As a result, there was a delay in Ms A seeking appropriate medical advice for the management of her burns. I am concerned about Ms C's failure to provide appropriate advice to Ms A, but, as noted above, I consider that this was compounded by a lack of knowledge of the risks and side effects of laser treatment. While I consider that Ms C must take some responsibility for her lack of knowledge, particularly as a senior member of the clinic, I consider that primarily the responsibility for the failures sits with the clinic, and also reflects the general lack of regulation in the industry, as commented on further below.

Opinion: The clinic — breach

Training and experience

97. Ms B and Ms C both told HDC that Ms B had received in-house training in "all laser treatments". Ms B also attended a two-day training session run by the manufacturer of the hair removal laser machine focused on "the theory and practical training of laser safety, laser hair removal treatments". A training certificate provided by Ms B certifies that she had been trained by the manufacturer of the hair removal laser machine for "Laser Physics & Safety, Laser Hair Reduction".

98. Ms B has provided no evidence of training in laser treatment for skin rejuvenation/ capillary treatment, including the use of the laser machine that was used in this case.

99. In response to the provisional opinion, the clinic submitted that Ms B had completed her training in the use of the laser machine specifically for vein treatments, which it said involved three months of in-house training, provided after Ms B had been working at the clinic for one year, during which time she was trained solely on laser hair removal. However, it acknowledged that it has provided no evidence of any formal training. In addition, Ms C told HDC that training in the use of laser for skin rejuvenation is provided once a staff member has had a minimum of one year of experience.

100. Having started work at the clinic in June 2017, Ms B would have had only approximately one year of experience at the time of these events in June and July 2018. As such, in my view it is more likely than not that Ms B had not completed the three months of training in the use of the laser machine for skin rejuvenation when she provided treatment to Ms A, as Ms B would have been working at the clinic for only approximately a year. It is regrettable that there is no documentation of Ms B's training in this regard. However, even in the absence of any records, I accept that Ms B had at least commenced such training.

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101. I note Ms Nicholson's advice:

> "Although a laser technician may be trained in hair removal, this doesn't imply they can move across to skin rejuvenation without formal training and then supervision. It is a common misconception that skin rejuvenation is an extension of hair removal, they treat very different targets in the skin and pose very different risks to the client, and as such additional and specific education should be sought."

102. As noted by Ms C herself:

> "We use Medical grade class IV lasers for hair removal and skin treatments including spider veins. These machines cannot be use[d] without adequate training."

103. Even accepting that at the time of events Ms B had commenced in-house training in the use of laser for skin rejuvenation, and regardless of whether Ms A was presenting with broken capillaries, rosacea, or both, as noted by Ms Nicholson, the treatment "still caused a completely preventable adverse skin reaction".

104. Ms Nicholson also commented:

> "[T]his case appears to be evidence of a staff member working outside her scope of expertise; this is due to the training provided, and experience being only relevant to laser hair removal, and not in recognising, diagnosing or treating advanced skin conditions such as rosacea or treatment of this condition with [continuous] Laser."

105. I acknowledge Ms Nicholson's views. I am concerned that the clinic, as Ms B's employer, permitted Ms B to provide laser treatment for skin rejuvenation at its clinic when she had yet to complete her training on the use of laser for skin rejuvenation, or in the use of the laser machine.

Information and consent

106. The clinic, as Ms B's employer, had a responsibility to ensure that its staff were aware of, and complied with, the requirements of the Auckland Council Code of Practice and, in particular, the requirements that the customer sign a consent form and receive written advice regarding the precautions and post-service procedures appropriate to the procedure, and that providers identify the customer's suitability for the service.

107. While the clinic's consent form clearly states that potential risks of laser treatment include burns and scarring, and Ms C said that it is normal practice for clients to complete a full consent form and medical history prior to any new treatment, Ms A was not required to sign a new form for her current episode of treatment. Instead, the clinic relied on the consent form signed by Ms A over a year earlier relating to her previous laser hair removal treatment.

108. Ms C told HDC that all new staff are trained to document "the settings, client feedback and clinical experience", and are told to complete the Consultation form. However, it appears that no written policies were in place at the clinic relating to client consent or

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documentation requirements. There is also no evidence that Ms B was made aware of the requirements of the Auckland Council Code of Practice.

109. Ms B said that prior to commencing this episode of laser treatment, Ms A was fully advised of the risks of laser treatment. However, this is not documented, and Ms A does not recall such a discussion. Ms A said that she assumed that the risks would be the same as for laser hair removal.

110. Ms Nicholson advised:

> "Although it appears [Ms A] was adequately educated about the potential risks of treatment with laser for hair removal (she had also experienced previous hair removal treatments with a laser), she was not properly consented for the specific treatment she then undertook for her facial laser treatment. It is my opinion that handling of [Ms A's] consultation, and consent process was a moderate deviation from standard care, and this would be deemed very significant due to the fact [Ms A] was under the impression risks for laser face veins were like those posed for hair removal, which she had previously experienced."

111. I am concerned that Ms A was not taken through a full consent process relevant to the current treatment session, despite the treatment and risks being significantly different to those for laser hair removal, which Ms A had undergone over a year ago. This is inconsistent with the requirements set out in the Code of Practice, and indicative of a failure by the clinic to educate its staff in the necessary steps for giving information and obtaining consent.

Conclusions

112. It is my view that the failures identified on the part of the clinic are demonstrative of a service provider that did not support and educate its staff adequately to provide services of an appropriate standard. As a result, Ms B provided a treatment for which she had not completed full training, and Ms C failed to recognise the seriousness of Ms A's injuries caused by the treatment provided by the clinic, and failed to give appropriate advice. Accordingly, for the reasons set out above, I conclude that the clinic failed to provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

113. The clinic also failed to ensure that its staff met the requirements of the Auckland Council Code of Practice. Accordingly, I conclude that the clinic also breached Right 4(2) of the Code of Health and Disability Services Consumers' Rights by failing to ensure that services were provided to Ms A in accordance with relevant legal standards.

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Other comment

114. As discussed in the introduction, the use of laser is largely unregulated in New Zealand despite the significant risk of injury when used incorrectly, as demonstrated in this case.

115. The issues identified in this case relate primarily to a lack of understanding and knowledge of staff in the use and risks of therapeutic laser treatment. As a result of treatment, Ms A suffered burns, and staff failed to recognise the severity and provide appropriate advice on how to manage the burns. These are not new issues to the industry, and, in my view, will continue to occur unless there are changes to how the use of laser is regulated. I will bring my views to the attention of the Ministry of Health.

Changes made by the clinic

116. Ms C told HDC that since this incident staff now ask clients to sign an "Exclusionary Criteria" form, which lists exclusionary criteria for light therapy, as well as a "Post-Treatment instructions" form, which sets out recommended aftercare following laser treatment. Ms C said that this is "to make sure that they have read and understood the treatment procedure and side effects if any and agree with the post treatment care".

Recommendations

The clinic

117. I recommend that within three weeks of the date of this report, the clinic apologise to Ms A in writing for its breach of the Code. The apology is to be sent to HDC, and will be forwarded to Ms A.

118. In response to the recommendations of the provisional opinion, the clinic agreed to undertake the following, with reference to advice and comments from my expert advisor, and report back to HDC on the actions taken within three months of the date of this report:

a) Develop a comprehensive protocol for training its staff in the use of all types of laser treatment. This is to cover assessment and consent, basic safety principles, treatment parameters, documentation, and after care, and include regular training refreshers. Records of the training are to be kept by the clinic.

b) Develop a policy and protocol for informed consent for all clients who are to undergo laser treatment. This is to include the requirements for obtaining a client's updated medical information and consent prior to commencing treatment for a new issue, and

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provision of sufficient information about treatment options and alternatives to enable informed choice.

c) Develop a client record sheet template to be used for all clients who undergo laser treatment. The template is to include prompts for recording the treatment administered, observations, and post-treatment advice.

d) Provide evidence of training for staff on the requirements of the Auckland Council Health and Hygiene Code of Practice 2013.

e) Develop a process for recording and responding to incidents and near misses.

Ms B

119. I recommend that within three weeks of the date of this report, Ms B apologise to Ms A in writing for the care criticised in the report. The apology is to be sent to HDC, and will be forwarded to Ms A.

120. I recommend that within three months of the date of this report, Ms B undertake the following and report back to HDC on the actions taken:

a) Undertake formal training in the use of laser for skin rejuvenation. Ms B should provide HDC with evidence of either her attendance or enrolment in a relevant course.

b) Familiarise herself with the Auckland Council Health and Hygiene Bylaw (2013) and Code of Practice.

Ms C

121. I recommend that within three weeks of the date of this report, Ms C apologise to Ms A in writing for the care criticised in the report. The apology is to be sent to HDC, and will be forwarded to Ms A.

Follow-up actions

122. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Ministry of Health and the New Zealand Association of Registered Beauty Professionals, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for educational purposes.

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Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from Ms Ruth Nicholson:

"Report author: Ruth Nicholson

Director of NZ Laser Training Ltd (9 years), Qualified adult tertiary educator, Certified Laser Safety Officer, industry experience of 16 years, Advisor to Ministry of Health, Auckland Council and HDC.

Reference to Auckland Councils Health & Hygiene Bylaw 2013 and associated Code of practice guidelines are stated … for comparison to expected and required standard of care.

My report starts with acknowledging that [Ms A] has suffered moderate–severe blistering and as a result, scarring due to treatment with a high powered … laser device emitting 1064nm of invisible, infrared light. Lasers are high powered devices that should only ever be used by trained and experienced technicians who have access to correct settings and are educated in the following procedures and protocols including how to manage the potential complications that are associated with laser.

Training:

Evidence reviewed established that the technician [Ms B] was a trained and certified laser technician who has completed training in laser science, laser safety and hair removal, however there is no evidence she has been trained in skin rejuvenation, which requires additional, and important education regarding treatment of skin conditions, and the application of suitable laser modalities for each situation. [Ms C] does not appear to play a major role in the treatment of [Ms A's] face; however does play an important role in the delivery of post care management to [Ms A] and it is noted that there are gaps in knowledge on how to deal with an adverse response, or reaction following laser (eg: laser safety officer training). These points may be considered a mild to moderate component in this case.

Skill and care:

Reference C.O.P 7(9) — All operators must ensure that a patch test, or a trial exposure of a small area of representative skin and hair, is carried out to determine the parameters and to judge how the skin might react to full service. Test patch protocol should include which areas to test, the pulsed light or laser settings, how long to wait to judge skin response, and how to spot adverse reactions.

It has been noted that [Ms B] altered the settings based on [Ms A's] pain threshold on the day of her facial laser treatment, she had jumped from 150 joules to 160 joules but noted in her report she 'went up by one' — however going up by one would have indicated 150 joules moves to 151 joules, not to 160 joules. With the use of super chilled air ('[the] cooling machine') the client often experiences an altered pain perception as the skin is chilled to almost numb. This can lead to a false sense of pain

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feedback by the client. The laser technician should also be trained and be watching for end point observations. I am unable to locate any information about this as there is no client record sheet.

Reference C.O.P 7(10) — All operators must keep records of: (a) a customer consent form with medical history and skin type; (b) a record of service.

It is my belief that the end point would have been quite extreme, (blanching white, excessive erythema) and that the skin was in fact being damaged during each shot of the laser beam delivered to [Ms A's] skin. This coupled with my opinion that … continuous laser is not a suitable treatment modality for rosacea; I do not believe the best of skill and care was used on this occasion to diagnose and recommend suitable laser based treatments and that alternatives (such as IPL), or referral to a medical practitioner should have been carried out. These may have been done, but not noted in the case file, and no client record sheet or additional consult notes created.

Decision to treat:

[Ms B] has concluded that [Ms A] suffered from facial telangiectasia (veins) and then set about discussing this treatment with [Ms A]. From the outset there are some issues noted; these are: based on the discussions and the look of [Ms A's] face, was she suffering from Rosacea and not facial veins? Were all laser and non-laser treatment options explored? — for example a non-continuous beam treatment called genesis that can improve rosacea wasn't discussed? Was it better for [Ms A] to be prescribed a topical Rosacea treatment through her doctor? [Ms A] didn't achieve the desired result after the initial two treatments, and this should have indicated that perhaps the treatment modality was incorrect for the skin condition, not that there wasn't enough power being delivered. As there was no client treatment record sheet, actual settings used could not be verified, only a manufacturer's settings guideline chart (for face veins) was issued in this case. This was a deviation from standard of care and would be considered moderate–severe.

Documentation/Adequate consent process:

Although it appears [Ms A] was adequately educated about the potential risks of treatment with laser for hair removal (she had also experienced previous hair removal treatments with a laser), she was not properly consented for the specific treatment she then undertook for her facial laser treatment. It is my opinion that handling of [Ms A's] consultation, and consent process was a moderate deviation from standard care, and this would be deemed very significant due to the fact [Ms A] was under the impression risks for laser face veins were like those posed for hair removal, which she had previously experienced.

Eg: [Ms A] was misinformed about the potential risks of laser vascular …; it is unclear how long the consultation process was that was conducted by [Ms B]. It is noted that 'outcomes of laser treatment' were discussed, one can only assume that this was for clearance of vessels (face veins).

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What is the standard of care/accepted practice?

A separate consultation form should capture client skin concerns, traits present on the skin, and can include medical questions. This form should also make up the basis to decide if a treatment is suitable for a client or not.

Reference C.O.P. — Precautions, consent and aftercare

7(6) Prior to the commencement of any pulsed light or laser treatment, the operator must: (a) advise the customer who wishes to undergo such service of the risks associated with the service; and (b) give written advice appropriate to the procedure to be undertaken, concerning precautions and post service procedures that should be taken by the customer who wishes to undergo the service;

7(7) Before commencing any pulsed light or laser treatment, a customer must sign a consent form including medical history and skin type;

7(8) Before commencing any pulsed light or laser treatment, all operators must identify if the customer is suitable for the service.

The risk of face vein treatment at high settings with [the] laser are very different to those posed for laser hair reduction (eg: The spot size is much more concentrated when treating veins and the energy density is therefore greatly increased). The documentation provided for [Ms A] was dated 23/2/17 which may indicate there could have been new information about [Ms A's] skin condition that was missed. Eg: what was the steroid cream being used for, was it applied to the face, was there any recent sun exposure, had she been stressed and had an eczema break out. A lot can happen between Feb 2017 and June/July 2018.

The absence of a client record sheet means there is no handwritten record of settings used by the laser technician — [Ms B] has relied on the manufacturer's settings chart (*which could have also been confused for another laser machine — this wasn't ruled out in my investigation*) and not recorded her post treatment observations (such as redness, energy used, client pain score, skincare applied, post care instructions issued etc). Use of a client record sheet is reflective of best practice in the laser industry.

Post care instructions:

Reference C.O.P. 7(6) — Prior to the commencement of any pulsed light or laser treatment, the operator must: (a) advise the customer who wishes to undergo such service of the risks associated with the service; and (b) give written advice appropriate to the procedure to be undertaken, concerning precautions and post service procedures that should be taken by the customer who wishes to undergo the service.

Standard Care/accepted practice would be: Immediately following the treatment and whilst the client is still in [the clinic], a cool post care gel should be applied and SPF 30+ sunblock. A physical copy of post care instructions should be given to the client and include a contact detail in case of need to get in touch about possible

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complications. Post care instructions should include staying out of the sun, wearing SPF, avoiding spa and pools, and hot showers, applying cold compresses (not ice) to the skin if it is hot.

Page 5 'Post treatment instructions' looks adequate and is clear to read.

However the page called 'veins post treatment care' is confusing as it includes instruction for post leg vein treatments. Eg: a face vein client doesn't need to be encouraged to do walking. Or exclude shaving post treatment.

It appears that post care instructions were issued to [Ms A] after her treatment and included (or may have included) applying 'ice' and/or 'ice packs' — one would hope this instruction to [Ms A] was accompanied by 'wrapped in a wet towel', and 'do not apply ice directly to any burns or blisters'?

[Ms A] was contacted by [Ms C] at [the clinic] via [text message] the same evening after receiving [Ms A's] email and pictures (of 15 blisters?) — at this point in time, it should have become obvious that this was a serious adverse response, and actions should be swift and professional. It may be acceptable to see one or two small blisters — however the amount experienced by [Ms A] was not acceptable, or normal.

I am unfamiliar with the … post care facials prescribed to [Ms A] following her report of blisters. Online research suggests the application of the '… facial' designed to 'plump, hydrate & even out skin tone'; this was followed by a … treatment designed for 'fragile capillaries and to defuse redness'. My opinion is that these may not be suitable to apply to post laser burns, or broken skin. As there are no client treatment records to establish end points, or times applied to the skin, or reactions, I am unable to consider the reasoning behind the choice to apply such facial treatments.

Although referred to as a 'rare side effect' by [Ms C], [Ms A] is given the impression that blisters are in the realm of normal, which would be rejected by myself and industry peers. Blisters are in fact caused by excessive heat, inappropriate or insufficient cooling and excessive energy density for the pulse duration selected (eg: Too hot, too fast) — this is a scientific principle taught at various levels as the technician continues their education.

Recommendations for improvements:

During this investigation I have added additional recommendations to improve the clinical practice standards at [the clinic] … In brief these improvements relate to:

- *Further edits to the consent form.*
- *Further edits to the medical history form.*
- *Use of layman's terms and clearer information laid out in the exclusion criteria document and renaming of this document to 'Cautions and contraindications for IPL & laser treatments'*.

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- *Improvements to the post care instruction sheet and process to include [the clinic] contacting the client for follow up via the phone and not via social media.*
- *The instigation of a formal complaints process following a laser incident (which is part of a laser safety officer's responsibilities) — this also provides clients who may be hesitant to contact [the clinic] a way to be informed of their rights and a discreet way to contact management or a third neutral party to review their case.*

Other matters that warrant comment:

- *Operators of Class 4 laser devices should seek regular and updated training including the certification in laser safety officer (LSO).*
- *Education in the identification of skin cancers and signs of melanoma are also essential for those offering skin rejuvenation with IPL and/or Lasers.*
- *Although a laser technician may be trained in hair removal, this doesn't imply they can move across to skin rejuvenation without formal training and then supervision. It is a common misconception that skin rejuvenation is an extension of hair removal; they treat very different targets in the skin and pose very different risks to the client, and as such additional and specific education should be sought.*

In summary I believe [Ms A] has received burns, leading to blisters due to a combination of factors but mostly due to inappropriate use of … laser for a skin condition that didn't appear to be individual face veins known as telangiectasia. The use of facial vein settings at 150 joules–160 joules over a 3mm spot size to treat suspected rosacea has resulted in burns due to excessive energy density — see example illustration below.

These thermal injuries were not noticed on the day of treatment by [Ms A] whilst still at [the clinic] due to the extreme cooled air delivered by the … cooling device. Subsequent delay in seeking first aid due to [Ms A] thinking her response was in the realms of normal has meant the damaged skin was exasperated and ended up in moderate blistering and subsequent scarring as the skin attempted to heal itself.

Illustration example of why we need to get the settings correct:

150 joules x 3 mm spot x 10 ms (pulse duration) = 1500 w/cm²

150 joules x 3mm spot x 20 ms (pulse duration) = 750 w/cm²

160 joules x 3mm spot x 10 ms (pulse duration) = 1600 w/cm²

160 joules x 3 mm spot x 20 ms (pulse duration) = 800 w/cm²

Remedial recommendations:

In cases such as this, a clinic should have public indemnity insurance which covers the cost of interventional medical care to reinstate the client's former skin condition. This may include a trip to a dermatologist, and subsequent laser treatment for scarring, and/or needling, or other modality deemed appropriate by a third and qualified party.

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First and foremost, [the clinic] might like to acknowledge that this event has been upsetting to [Ms A] and a formal apology should be issued.

Reassurance should be given that processes have now been addressed and updated to reflect improvements so as to prevent a similar occurrence in future.

Regards,

Ruth Nicholson
NZ Laser Training Ltd"

Further advice

"Report author: Ruth Nicholson

Director of NZ Laser Training Ltd (9 years), Qualified adult tertiary educator, Certified Laser Safety Officer, industry experience of 16 years, Advisor to Ministry of Health, Auckland Council and HDC.

Dated: 26th June 2020

I have revisited the original case notes, as well as reviewed both parties' responses that you have provided. They do not cause me to change any of my previous advice or overall opinion of the situation.

- The certificate of training for [Ms B], that has been provided, is for Hair removal only. There is no evidence or proof that she completed any formal training in Skin Rejuvenation, particularly treating vascular lesions, which is considered an advanced treatment, best performed by experienced operators.
- I question if [Ms B] has obtained any supervised hands on training from the trainer on skin rejuvenation. It appears the training focused on theoretical teachings, which may have been mostly relating to hair removal not skin rejuvenation, which is a separate topic and speciality.
- It was noted in [Ms B's] report, that the machine that she was trained on, was different to the one that she uses in [the clinic].
- Observations of client skins (provided in black and white images only) show marked swelling (Odema) which is indicative of the excessive energy being emitted from the ⋯ laser — I believe this swelling was contributed to, by the laser energy not being aligned to a target at the depth it was working to, eg: looking for deeper blood which won't be present in rosacea. The excessive heat is trying to dissipate and in doing so it has caused fluid build-up and swelling as part of an inflammation response.
- In my opinion, and that of my senior clinical educator colleague, we concur that this case appears to be evidence of a staff member working outside her scope of expertise; this is due to the training provided, and experience being only relevant

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to laser hair removal, and not in recognising, diagnosing or treating advanced skin conditions such as rosacea or treatment of this condition with [the] Laser.

- After reviewing the notes and cross-examining the files, pictures, and supporting evidence to the contrary, the decision has been made that this case remains a preventable and avoidable scenario for which [Ms A] did not need to endure.

Regards,

Ruth Nicholson
NZ Laser Training Ltd"

The following further advice was obtained from Ms Nicholson:

"*Question posed was: 'Please advise whether your criticisms would be the same if [Ms A] presented with broken capillaries/vein damage only?'*

Our response is:

[W]e have reviewed all the case notes again. We have located the original evidence notes we made where [Ms B] had referred to [Ms A's] skin condition as 'broken capillaries and rosacea' — This document was comments from first submitted case notes couriered to me by HDC (submitted with or via their solicitors).

I refer to some of my previous comments and will highlight fundamental facts.

- In [Ms C's] initial response report she says the 'consultation was for broken capillaries and rosacea'
- There was no evidence of 'broken capillaries' or even the later suggested 'facial veins' in the images supplied of [Ms A's] blistering. The type of broken capillaries/facial veins that would respond to the treatment type carried out and the treatment parameters used, would be quite large, red in colour and very visible.
- It was noted that [Ms A] didn't achieve the desired result after the initial two treatments, this should have indicated that perhaps the treatment modality (laser type and settings) was incorrect for the skin condition, **not**, that there wasn't enough power being delivered.
- If the treatment modality chosen was correct, then these broken capillaries/facial veins (that had not responded), would still be visible in amongst the pictures of the blisters. However there was no indication that they were there at all.

To answer your question, yes, my criticisms would still be the same, no matter what skin complaint was presented and then treated.

- Blisters are **not** an expected outcome or predicted end point. They are a result of incorrect treatment settings.

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- There is no proof that a consultation for this treatment ever took place. There is also no consent form signed for this treatment and not one for the original hair removal treatment either.
- A client cannot be expected to give 'informed consent' unless she has had a thorough consultation and been allowed time to consider all risk factors involved, including potential side effects.
- The comment made about 'Normal practice is to increase Joules (energy) in the 2" or 3" treatment' is incorrect and shows poor understanding and judgement. There is no protocol that suggests you do this, for each and every client. The decision to adjust treatment settings is based on clinical knowledge, as well as understanding of the treatment, the condition of the client's skin and risk factors involved with making changes, especially without test patching.
- Test patching was supposedly done at the first treatment to check for skin response. However, skin response should be checked every time you want to adjust treatment parameters (eg: energy/joules up and/or pulse duration shorter or longer). This is the only way to know that they are safe to use.
- Best practice would involve test patching the client's skin, each time you want to use a new treatment setting on them. You can never predict the skin's response until you have test patched for it first. Just because the first test patch setting was deemed ok, doesn't mean that an additional test patch shouldn't have been conducted prior to using the new treatment setting. An increase of Joules (energy), no matter how big or small, still comes with risk.
- Treatment parameters provided by the [machine manufacturers] clearly state 'these guidelines are based on current clinical use; however, they do not substitute for the clinical judgment of a physician and the individual patients needs'.

In my opinion, [Ms B] hasn't accurately chosen the correct treatment modality and treatment settings to match the client's skin complaint.

Even if [Ms A] did indeed have 'facial veins', then [Ms B] has still caused a completely preventable adverse skin reaction. One that has more than likely left permanent marks and a constant reminder to [Ms A].

I am in no doubt from looking at the extent of the blisters, that there would have been some visual indication to [Ms B] that something was going wrong during the treatment.

Ruth Nicholson
Director"

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Appendix B: Relevant standards

The Auckland Council Health and Hygiene Code of Practice 2013 (Code of Practice) sets the minimum standards of hygienic and safe practices in the Auckland Council area. Under the Health and Hygiene Bylaw 2013, services providing laser treatment are required to meet these standards. Relevant sections include:

> "Precautions, consent and aftercare
>
> 7(6) Prior to the commencement of any pulsed light or laser treatment, the operator must: (a) advise the customer who wishes to undergo such service of the risks associated with the service; and (b) give written advice appropriate to the procedure to be undertaken, concerning precautions and post service procedures that should be taken by the customer who wishes to undergo the service;
>
> 7(7) Before commencing any pulsed light or laser treatment, a customer must sign a consent form including medical history and skin type;
>
> 7(8) Before commencing any pulsed light or laser treatment, all operators must identify if the customer is suitable for the service.
>
> …"

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