Dental Service

Dentist, Dr B

A Report by the
Deputy Health and Disability Commissioner

(Case 19HDC01697)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary 1
Complaint and investigation 2
Information gathered during investigation 3
Opinion: Dr B — breach..10
Opinion: Dr C — adverse comment...17
Opinion: Dental service — no breach 18
Changes made by Dr B..19
Recommendations...20
Follow-up actions 21
Appendix A: Independent clinical advice to Commissioner 22

Executive summary

1. This report concerns the care provided to an 8-year-old girl by a general dentist in 2018 and 2019, when the girl underwent frenectomy procedures.

2. The report highlights the importance of providing information on the risks of treatment and the available options to allow a consumer to make an informed decision about their care and give informed consent. It also highlights the importance of robust and clear clinical record-keeping.

3. The girl attended the dental service with her mother on 6 August 2018 and saw a general dentist, who diagnosed her with a tongue and lip tie and referred her to his colleague to perform the recommended frenectomy procedures. The colleague performed the procedures on 29 January 2019. On 12 February 2019, the girl experienced an episode of uncontrolled bleeding from the surgical site and was diagnosed with a bubble haematoma. On 15 February 2019, the girl experienced a further episode of uncontrolled bleeding and had to undergo emergency surgery to control the haemorrhage.

Findings

4. The Deputy Commissioner considered that the operating dentist did not provide the girl and her mother with adequate information prior to the frenectomy procedures, including information on the lack of clear evidence supporting the procedures; clinical justifications for recommending the procedures despite the lack of clear evidence; and information on the risks specific to the procedure. Accordingly, the Deputy Commissioner found that the operating dentist breached Right 6(1) of the Code. The Deputy Commissioner also found the dentist in breach of Right 7(1) for failing to obtain informed consent for the frenectomy procedure.

5. In addition, the Deputy Commissioner found the operating dentist in breach of Right 4(2) of the Code, for deficiencies in his clinical documentation. The Deputy Commissioner was also critical that the dentist was operating at the boundaries of his scope of practice and undertaking a procedure for which there is little evidence of support. In light of this, the Deputy Commissioner was critical that the dentist did not maintain records to provide evidence of his training in this area.

6. The Deputy Commissioner was critical that the first dentist did not provide adequate information about the procedures when he recommended them to the girl's mother.

7. The Deputy Commissioner considered that the dental service did not breach the Code.

Recommendations

8. The Deputy Commissioner recommended that each dentist provide a written apology to the girl's family for the issues in the care they provided, as identified in this report.

9. The Deputy Commissioner also recommended that the operating dentist arrange for an external audit to ensure that adequate informed consent was obtained for treatment, and

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that the clinical documentation was of an appropriate standard; undertake further education and training on informed consent and clinical documentation in conjunction with DCNZ; and develop a written information sheet containing information specific to frenectomy procedures, particularly the risks, benefits, and lack of evidence to support frenectomies for orthodontic purposes.

10. The Deputy Commissioner recommended that DCNZ consider whether a review of the operating dentist's competence is warranted.

11. The Deputy Commissioner recommended that the first dentist provide a written report to HDC on the changes he has made to his practice as a result of these events, and that the dental service develop a written information sheet containing information specific to frenectomy procedures.

Complaint and investigation

12. The Health and Disability Commissioner (HDC) received a complaint from Mrs A about the services provided to her daughter, Miss A, by Dr B at the dental service. The following issues were identified for investigation:

- *Whether the dental service provided Miss A with an appropriate standard of care between 2018 and 2019 (inclusive).*
- *Whether Dr B provided Miss A with an appropriate standard of care between 2018 and 2019 (inclusive).*

13. This report is the opinion of Deputy Commissioner Deborah James, and is made in accordance with the power delegated to her by the Commissioner.

14. The parties directly involved in the investigation were:

Miss A	Consumer
Mrs A	Consumer's mother
Dental service	Provider
Dr B	Provider, general dentist
Dr C	Provider, general dentist

15. Further information was received from a medical centre and a district health board.

16. Independent expert advice was obtained from a prosthodontist, Dr Donald Schwass (Appendix A).

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Information gathered during investigation

Introduction

17. This report primarily relates to frenectomies performed on Miss A (aged eight years at the time of events) in 2019. A frenectomy is the removal of a frenulum, a small fold of tissue that prevents an organ in the body from moving too far. In this case, it relates to the fold of tissue connecting the tongue to the base of the mouth, and the fold of tissue connecting the lip to the top of the gum. When these folds are very short or dense, the patient can be diagnosed as having a "tongue tie" or a "lip tie" respectively.

Tongue tie and lip tie procedures

18. As this Office has stated previously,[1] there is no consensus on national standards for the assessment, diagnosis, or classification of a tongue tie. Similarly, there is no consensus on the techniques that should be employed to perform a frenectomy. There is a further lack of literature and research on frenectomy procedures for orthodontic purposes, especially in the case of young children (as opposed to infants).

Dental Council of New Zealand

19. The Dental Council of New Zealand (DCNZ) has stated previously in respect of frenectomy:[2]

> "Although within the scope of an oral health practitioner — as the correction of the condition is within the oro-facial complex — dentists need to be certain that they are clear [about] the indications for the surgery … Although this surgery is within the oro-facial complex, those undertaking these procedures need to be able to demonstrate they have the necessary training, qualifications and experience."

New Zealand Dental Association

20. A position statement from the New Zealand Dental Association (NZDA) (April 2018) states:

> "The significance of [tongue tie], including its diagnosis, its relationship with … speech disorders and other oral conditions, and the management of [tongue tie] for these issues is controversial. This controversy results from a lack of robust research data and is exacerbated by the strongly held parochial opinions of some advocacy groups."[3]

21. NZDA states that research suggests that tongue tie may be present in 1.7–10.7% of neonates and in 0.1–2.08% of children, adolescents, and adults, which suggests that tongue tie resolves with growth in most cases, and that "[t]here is no robust evidence supporting an association between [tongue tie] and malocclusion[4]".

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[1] 16HDC00988 — in this case, the comments were made about the performance of frenectomies on newborn infants.

[2] Newsletter: July 2017 dcnz.org.nz/resources-and-publications/publications/newsletters/view/25?article=6.

[3] NZDA Position Statement Ankyloglossia and Frenal Attachments: April 2018 nzda.org.nz/assets/files/Standards__Guidelines/Position_Statements/Position_Statement_Ankyloglossia.pdf

[4] An abnormal occlusion in which teeth are not in a normal position in relation to adjacent teeth in the same jaw and/or the opposing teeth when the jaws are closed.

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Best Practice Advocacy Centre (bpac^{nz}) guidelines 2010

22. The bpac^{nz} 2010 guidelines also acknowledge that there is a lack of consensus on the clinical significance of tongue tie and whether or not it requires correction.

6 August 2018 — initial consultation

23. Miss A (aged eight years at the time of these events) had been a patient at the dental service since 13 February 2017. On 6 August 2018, Miss A attended the dental service with her mother, Mrs A, for an orthodontic consultation with a general dentist, Dr C.[5] Dr C documented in the clinical notes that Miss A had limited movement of the upper lip owing to an abnormally short frenulum attaching the upper lip to the gums (lip tie), limited mobility of the tongue owing to an abnormally short frenulum attaching the tongue to the floor of the mouth (tongue tie), and a retained baby tooth.[6]

24. The proposed treatment plan for Miss A included two phases — the active treatment phase and the retention phase. The active treatment phase included upper and lower removable devices[7] to "develop the arches and make room for teeth", the use of braces on the front teeth, and myofunctional therapy "to correct the mouth muscle posture". The retention phase included the use of retainers,[8] "to be worn all the time for 3 to 6 months then at night — PROBABLY FOR MANY YEARS — to hold the teeth in their new positions during settling and final growth of the jaws".

25. Mrs A told HDC that she was advised by Dr C that in order to help with the planned orthodontic treatment, the lip and tongue ties should be released (frenectomy).

26. The dental service told HDC that Miss A was diagnosed with a tongue and lip tie as she was "unable to poke her tongue out past her teeth without the tip of her tongue becoming notched or 'heart shaped', and that she was unable to put the tip of her tongue on the roof

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[5] Dr C was registered to practise in the general dental scope of practice. According to the Dental Council of New Zealand: "General dental practice encompasses the practice of dentistry in the maintenance of health through the assessment, diagnosis, management, treatment and prevention of any disease, disorder or condition of the orofacial complex and associated structures in accordance with this scope of practice and a dentist's approved education, training, experience and competence." Orthodontics is defined by DCNZ as: "Orthodontic specialists practise in the branch of dentistry that is concerned with the supervision, guidance and correction of the growing and mature dentofacial structures and includes the diagnoses, prevention, interception and treatment of all forms of malocclusion of the teeth and associated alterations in their surrounding structures. Specialist orthodontics is undertaken by a dental practitioner who possesses additional postgraduate qualifications, training and experience recognised by the Dental Council as appropriate for registration."

[6] Deciduous tooth.

[7] Removable devices (also known as retainers) are explained by the dental service: "We use removable orthodontic plates for the majority of our patients, both children and adults. They are used to change the shape of the palate and jaws and to alleviate the crowded teeth, they are also used to correct bad bites. Removable plates are usually worn full-time, including when eating, and are removed only when brushing the teeth."

[8] Removable retainers are explained by the dental service in the Orthodontic Treatment Letter: "Removable retainers are usually worn full time (removed only for meals and cleaning) for 6 months, followed by night time wear for 6 months, then less frequent night time wear (1–2 nights a week) for several years. Sometimes it is necessary to continue the occasional night time wear permanently to ensure that the teeth stay in position."

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of her mouth and open her teeth, and she was unable to move her tongue comfortably from side to side". The dental service also told HDC that because of Miss A's narrow dental arches, and the severity of the tongue tie, a lower removable device could not have been used, and for these reasons combined, the frenectomy procedures were recommended.

27. Mrs A stated that when expressing doubt about the procedures, "[the family] were assured that the dental service was very experienced in frenectomies as the practitioners do a lot of these operations".

28. Mrs A told HDC:

> "We made an appointment for that procedure so we could start orthodontist treatment afterwards. At no time did we realise that [Dr C] was only a dentist and not an orthodontist. In doing so, we trusted [the dental service] to have the knowledge and expertise to not only make a sound judgement on the necessity of such a procedure, but also to have the knowledge and skills to execute a frenectomy with no prolonged health risks to our healthy and normal eight-year old child."

29. Mrs A stated that at that time, she did not believe that the tongue and lip tie were causing problems for Miss A, and she thought that it was only a problem for babies who could not breast feed. Mrs A stated that Miss A's speech and the movement of the tongue appeared normal to her. Mrs A said that they were not informed of the potential risks involved with the procedure, and believed that "it was supposedly like every other routine dental procedure". Mrs A also told HDC that Dr B[9] had pointed out Miss A's tongue and lip tie to her previously during regular check-ups, but that she didn't consider it an issue until Dr C told her that it was causing Miss A's teeth to get "crooked". Mrs A said:

> "Since he was the expert on this in my eyes and the practice had already pointed the 'issue' out to me, I was convinced … I do not recall [Dr C] informing me of the risks involved, as I might have grilled him a bit more if I knew I was risking her tongue movement and her speech abilities versus accepting bottom crooked teeth."

30. Mrs A told HDC that when the frenectomy procedures were mentioned by Dr C, "the emphasis was on how easy and quick the procedure was". Mrs A said that even had she been aware of the possible complications, she never would have agreed to the procedures had she not been under the impression that the frenectomies were needed to avoid crooked teeth. Mrs A stated: "[M]y decision was based on misinformation given by [Dr C]."

Consent to frenectomy

Information supplied

31. The dental service stated that as part of its informed consent process, Mrs A was provided with a "Consent for oral surgery" form prior to Miss A undergoing the procedure. The form outlines possible complications of oral surgery generally, such as pain and swelling, stiffness

[9] Another general dentist at the dental service.

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of jaw, and discoloration, and includes a range of other possible outcomes.[10] The "permission for oral surgery" section states:

> "I understand the practice of oral surgery can involve variables, which cannot be predicted, such as complications involving the surgery, drugs, and medications administered. These have been explained to me, no assurance has been given as to the results that may be obtained."

32. The form has not been signed by either party, and Mrs A cannot recall whether she was provided with the form, or whether or not she signed it.

33. An "Orthodontic Treatment Letter" provided to Mrs A on 6 August 2018 and signed by Dr C contains a section titled, "Information and Informed Consent Document", which details the possible risks associated with orthodontic treatment,[11] but does not discuss the risk of bleeding or haemorrhage. There is also no mention of the frenectomy procedures in this section. Treatment alternatives are noted as: no treatment at all, referral to a specialist orthodontist for assessment and treatment, adult tooth extraction treatment, and jaw surgery to align the jaws.

34. Under the "Qualifications" section of the letter, it states:

> "[Dr C] is not a specialist orthodontist, but rather a general dentist who has many years of orthodontic experience and has taken many post graduate courses in orthodontics. [Dr C] stays abreast with all the newer techniques in all aspects of dentistry including orthodontics, orthotropics, orthopaedics and TMJ[12] therapies in an effort to provide the very best treatment for our patients."

35. On 22 August 2018, an email was sent to Mrs A from Dr B. Dr B provided Mrs A with costs for the frenectomies and the removal of the retained baby tooth. He wrote:

> "It is sometimes beneficial for a meet and greet appointment with [Miss A] to show her some of what may occur in the surgical appointment, and we can use this to answer any further questions you may have. Feel free to book this 15 minute appointment via reception. As a parent if you think that [Miss A] does not need [the appointment] as she has had an examination with me before; we can directly proceed to the longer appointment and explain things on the day."

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[10] "Include (but are not limited to) complications resulting from the use of dental instruments, drugs, medicines, analgesics (pain killers) and local anaesthetics could lead to temporary or permanent nerve damage causing numbness/tingling in the lip, tongue, chin, gums, cheeks and teeth, thrombophlebitis (inflammation of a vein), reaction to injections, change in occlusion (biting), muscle cramps and spasms, TMJ (temporomandibular joint) difficulty, loosening of teeth or restoration in teeth, injury to other tissues, referred pain to the ear, neck and head, nausea, vomiting, allergic reactions, itching, bruises, delayed healing, sinus complications and reaction to metals causing gum discolouration."

[11] Including cavities, swollen gums, white spots, root resorption, unfavourable growth, jaw joint problems (TMJ), enamel reduction, and tooth size discrepancy.

[12] Temporomandibular joint, being the joint just in front of the ears where the jaw meets the skull.

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36. In the email, Dr B also recommended that the procedure be performed using nitrous oxide gas and oral sedation. There is no record in the clinical notes of Miss A attending a further consultation until the day of the procedure.

37. Dr B told HDC that on the day of the procedure, he provided Mrs A with information regarding the steps of the procedure and postoperative expectations, and gave her the opportunity to ask questions. He said: "This process was the attempt to obtain informed consent. On this occasion, the consenting process had shortcomings …" Dr B told HDC that Mrs A was also a patient of his. He stated:

> "[This] was a factor in casualising the consent process for her daughter. This meant on the day, I focused more on the expectation I had of the process of healing, rather than emphasizing all necessary information in a more balanced delivery for the procedure."

38. When asked whether he provided all relevant and necessary information to Mrs A, or whether it was his usual practice to do so, Dr B responded:

> "Disclosure of other opinions including differing views and factions of orthodontic needs of the procedure is part of the information provided. A conjunctive appointment was used in [Miss A's] case. This does not allow time to consider risks and explore options."

39. Mrs A told HDC:

> "I do not recall any specific conversation with [Dr B] about the risks, or let's say I do not recall him telling me clearly the biggest risks involved … I do not recall him giving me written information, except for the after care … I would never have agreed to anything if the real and big risks had clearly been laid out to me."

Frenectomy procedure

40. The clinical notes show that Miss A attended the dental service (with Mrs A) on 29 January 2019 for the frenectomy procedures. The clinical notes state that Dr B administered 15mg oral midazolam and nitrous oxide gas (sedative medications) for the procedure, and that Miss A "coped well and was compliant" and that there was "little/no bleeding". The notes show that a diode laser[13] was used for both the tongue and lip tie releases. Dr B did not document any further details about the surgery.

41. Dr B recorded that he had given both verbal and written postoperative care instructions to Mrs A, and had stressed the importance of tongue exercises to "enhance [the] result". A follow-up appointment was booked for 1 February 2019.

42. Mrs A told HDC:

> "[R]ight after the procedures, [Miss A] already bled profusely while in the practice, we had to go back to [Dr B] as I was paying at reception because of it. [Dr B] [assured] me

[13] A device that generates light of high intensity.

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this was normal and it would settle down. In hindsight that was an early indication something wasn't right, but [Dr B] didn't act upon it."

43. Mrs A was provided with a "Post Frenectomy Instructions" sheet, which stated that the wound site would take seven to ten days to heal and that during this time it would become a whitish-yellow colour.[14] The sheet advises the patient to ice the area if it swells or is tender, and in the case of bleeding to "apply soft damp gauze to the area with light pressure for 10 mins". At the end of the document it states: "If you have any concerns after hours, in the 48 hours following the procedure, please phone [Dr B] …"

Subsequent events

44. On 1 February 2019, Miss A attended the dental service for a follow-up appointment with a dental assistant. The dental assistant recorded that the area was still healing, and that Miss A had fallen on her face on the trampoline the day before, causing the wound to bleed. However, in response to the provisional opinion, Mrs A told HDC that the area did not bleed as a result of the fall, and emphasised that it was a "very minor incident". Mrs A and Miss A were advised to continue with the exercises that Dr B had provided, and keep the tongue moving in all different directions, and that Miss A was to be seen again by the dental assistant in two weeks' time.

First episode of bleeding

45. Mrs A was woken on the night of 12 February to find Miss A bleeding from the mouth and vomiting up blood that she had swallowed. Mrs A telephoned a telehealth service as she was struggling to control the bleeding. The nurse advised to present to the emergency department if the bleeding did not stop after one hour, or if it started again. The nurse also advised not to allow Miss A to sleep on her back, and to visit the general practitioner (GP) or the dentist who performed the procedure the following morning for follow-up.

46. The following morning (13 February), Mrs A took Miss A to see her GP, who advised that Miss A had a haematoma.[15]

47. On 13 February 2019, Miss A and Mrs A visited the dental service for a follow-up appointment with Dr B. The clinical notes from the consultation state: "Had bleeding episode last night. Reports of 'significant' amount; had seen med GP and referred back to us; [on examination] has bubble hematoma present at floor of mouth." Mrs A was advised that it was unusual to have bleeding issues beyond one week post-operation, and was told to be careful of the area and to review in three weeks' time. In its response to HDC, the dental service stated that at this time, Dr C consulted with an ENT surgeon, who advised that any trauma to a healing surgical site that has a high density of capillaries has the potential to cause a postoperative bleed that is not seen immediately. Mrs A told HDC that she was told on this visit that it would not happen again, and that there was no need for her to see an ENT specialist.

[14] This formation of healing tissue is called "slough" and is a normal healing stage.

[15] A collection of clotted blood, usually caused by trauma to the area.

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Second episode of bleeding and hospital visit

48. On the night of 15 February 2019, Miss A experienced a further severe bout of bleeding. Miss A presented to hospital, where she underwent an emergency operation to stop the bleeding. Mrs A told HDC that she sent Dr B a message advising of the situation, but did not receive a response. The district health board (DHB) told HDC:

> "Intraoperatively, [an otolaryngologist surgeon] found a granulation tissue at the operative site. This is a sign of infection and healing happening at the same time. This explained the on-going and recurrent bleeding. Her haemoglobin was below normal from recurrent bleeding and potentially an earlier referral to [hospital] would have been appropriate."

Further information

Dr B

<u>Scope of practice</u>

49. At the time of these events, Dr B had a Bachelor of Dental Surgery and had been practising as a general dental practitioner for many years. Dr B told HDC that he has high surgical competence from an accumulation of training and experience. He stated: "I routinely perform surgical removal of teeth, place dental implants with bone augmentation, have performed sinus lift surgeries, and periodontal surgeries." Dr B said that prior to 2015, he had performed between five and ten tongue tie releases, and between 2015 and 2019, he performed 70.

50. Dr B stated that he was first trained in the use of lasers "in or around 2008", and he underwent a "comprehensive multi-day training associated with the Biolase[16] equipment that was purchased". Dr B said that Biolase is considered in high regard within the dental industry, and the certification process included theoretical and practical training as well as mentorship. Dr B told HDC that he furthered his experience and training over the subsequent years, and that between 2009 and 2011, his practice was targeted at laser dentistry and involved about 40% of his routine dental procedures.

51. DCNZ states:

> "General dental practice encompasses the practice of dentistry in the maintenance of health through the assessment, diagnosis, management, treatment and prevention of any disease, disorder or condition of the orofacial complex and associated structures in accordance with this scope of practice and a dentist's approved education, training, experience and competence … Areas of general dental practice which were not included in a practitioner's training should not be undertaken unless the practitioner has completed appropriate training and practices to the standards required by the Standards Framework for Oral Health Practitioners."

[16] Dental laser company.

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Mrs A

52. Mrs A told HDC that she considers that the frenectomy procedures were performed unnecessarily, "[for] which the risks [were] (on purpose or not) completely downplayed or not mentioned".

Responses to provisional opinion

53. Mrs A, the dental service, Dr B, and Dr C were given an opportunity to comment on relevant sections of the provisional opinion. Where appropriate, their comments have been incorporated into this report.

Mrs A

54. Mrs A reiterated her concerns that the frenectomies were performed without reason, and queried whether they should have been referred to other specialists. She told HDC:

> "[I believe] the care [Miss A] needed was adults knowing where their expertise ends and having her interest[s] at heart, instead of pushing through a risky procedure on a healthy child because it fits in with their usual [practice] and enables them to proceed with orthodontics."

Dr B

55. It is with some criticism that I note that Dr B did not provide a response to the provisional report.

Dr C

56. Dr C had no additional comments to make, and agreed to action the recommendations.

Opinion: Dr B — breach

Introduction

57. Miss A attended the dental service for an orthodontic consultation on 6 August 2018. Dr C told Mrs A that in order to help with orthodontic treatment, the lip and tongue ties should be released. Subsequently, Miss A underwent the frenectomy procedures, performed by general dentist Dr B at the dental service on 29 January 2019.

58. Dr B told HDC that Miss A's tongue tie was released as a precursor to orthodontic treatment, in particular the use of upper and lower removable devices. However, this was not documented in the clinical notes.

59. As part of my investigation into whether Dr B provided Miss A with an appropriate standard of care, I obtained expert advice from prosthodontist Dr Donald Schwass. Dr Schwass told HDC:

> "Based on the lack of evidence in the literature regarding frenectomy procedures for orthodontic purposes, it is highly questionable whether the frenectomy procedure

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conducted for [Miss A] was clinically necessary at all. Neither the [NZDA] or [DCNZ] have identified evidence to support this procedure under such circumstances."

60. Dr Schwass further advised HDC:

"[H]ad an obvious clinical indication presented, it is reasonable to expect that this should have been documented clearly in the patient record, and that this would have been explained when informed consent was obtained regarding the pros and cons of the procedure specific to this case. This would then have provided justification for a subsequent reviewer to form a different view about the clinical necessity of the procedure for [Miss A]."

61. The NZDA has stated:

"[T]here is no robust evidence supporting an association between [tongue tie] and [imperfect positioning of teeth] … There is insufficient evidence regarding the benefits or harm of surgical treatment of [tongue tie] for speech difficulties."

62. Based on the lack of evidence in the literature, it appears that performing frenectomy for orthodontic purposes on a child is considered to be a "grey area" of practice, and this will form the basis of my opinion.

63. I agree with Dr Schwass that had there been a valid clinical reason for frenectomy, much more detailed justification was required to explain why the lack of evidence to support the procedures should be disregarded. In my view, in order for a practitioner to perform a frenectomy safely for orthodontic purposes, the indications and clinical justification for the procedure must be robust and well documented, the consumer must be fully informed, and the practitioner must be able to demonstrate that they have the necessary training, qualifications, and experience to carry out the procedure safely.

Informed consent

64. The dental service told HDC that as part of the informed consent process, Mrs A was provided with a "Consent for oral surgery" form prior to the procedure. The form outlines the possible risks associated with oral surgery in general, including pain and swelling, stiffness of the jaw, and discoloration, and other risks, but no information or risks specific to frenectomies.

65. The consent form was unsigned by both parties. Mrs A told HDC that she does not recall receiving or signing the form, but recalls agreeing to the procedure. On the balance of the evidence before me, I consider it more likely than not that the dental service did not provide Mrs A with a copy of the consent form.

66. Mrs A agrees that she was provided with an "Orthodontic Treatment Letter". The letter outlined Miss A's treatment plan, but did not specifically mention the frenectomy procedures or the risks of bleeding or haemorrhage. There is no mention in the letter of the lack of evidence supporting frenectomy procedures, or documentation of the reasons why the procedures were clinically indicated and advised for Miss A.

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67. In addition to any written information provided to Mrs A, there is no record of a discussion between Dr B and Mrs A regarding the risks, benefits, lack of evidence supporting the procedure, consent, or the clinical indications for the treatments.

68. Mrs A told HDC that she does not recall any specific conversation with Dr B about the risks involved with the procedures, nor does she recall being given any other written information about the frenectomy procedures aside from the after-care information sheet. Mrs A stated: "I would never have agreed to anything if the real and big risks had clearly been laid out to me."

69. Dr B told HDC that he provided Mrs A with information regarding the steps of the procedure and postoperative expectations, and gave Mrs A the opportunity to ask questions. He said that information about the "differing views and factions of orthodontic needs of the procedure" is part of the information provided, but that there was insufficient time in [Miss A's] case to "consider risks and explore options".

70. Dr Schwass advised that the risk of haemorrhage or haematoma following frenectomy procedures should be discussed with patients, "particularly where the frenectomy site is [the] floor of mouth involving beneath the tongue as this is a richly vascularised area with significant density of vessels". Dr Schwass told HDC:

> "In this case, where the floor of [the] mouth was involved I would consider that failure to mention this complication would represent a moderate departure from accepted practice."

71. I accept Dr Schwass's advice and consider that these are potentially serious complications that should have been disclosed to Mrs A as part of the informed consent process.

72. Dr Schwass also advised: "Informed consent should have admitted the lack of clear evidence supporting this procedure, with justification why in this case it should proceed. This did not occur." He added that Dr B should have provided detail to Mrs A about the possible risks and complications, the evidential basis for the procedure, "or importantly to note in particular if evidence for the procedure is lacking but where the practitioner has strong reason to believe it should be conducted despite this".

73. Right 6(1) of the Code of Health and Disability Services Consumers' Rights (the Code) stipulates:

> "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including — (a) an explanation of his or her condition; and (b) an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and … (e) any other information required by legal, professional, ethical, and other relevant standards …"

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74. Right 7(1) of the Code states:

> "Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent."

75. In my view, and having regard to Dr Schwass's advice, a reasonable consumer in Mrs A's circumstances (as the mother of the child for whom the procedure was to be performed) would expect to be informed that there was a lack of clear evidence supporting the frenectomy procedures, of the clinical justifications for recommending the procedures despite that lack of clear evidence, and of the risks specific to the procedures, including the risks of haemorrhage and haematoma.

76. Dr Schwass told HDC:

> "Practitioners are individually responsible for ensuring that patients are appropriately informed about procedures they provide. Consequently, in this case responsibility would sit with [Dr B] regarding the frenectomy he performed."

77. I accept Dr Schwass's advice. While I acknowledge that previously Mrs A had seen Dr C, who had discussed the procedure with her, as the dentist performing the procedure, it was Dr B's responsibility to ensure that appropriate information had been given and informed consent obtained for the procedures. For the avoidance of doubt, I note that there was no basis either in the clinical record or otherwise to reassure Dr B that the options, risks, and justifications for frenectomy had been outlined to Mrs A previously.

78. The written information provided to Mrs A did not canvas risks or justifications for the procedure adequately. Mrs A's evidence is that there was no discussion of risks, and Dr B stated that he did not have sufficient time to consider risks or explore options with Mrs A, and the consenting process was "casualised" and therefore had shortcomings. It is unclear why Dr B had not ensured that he had sufficient time to canvass these topics with Mrs A adequately. In the circumstances, I do not consider that Dr B provided sufficient information to Mrs A to enable her to give her informed consent for the procedure.

79. Accordingly, I find that Dr B breached Right 6(1) of the Code for failing to provide Mrs A with information that a reasonable consumer in Mrs A's circumstances would expect to receive, as outlined above. It follows that by not providing such information, Dr B also breached Right 7(1) for failing to obtain Mrs A's informed consent for the frenectomy procedure.

Standard of documentation

80. Adequate documentation is an integral part of clinical practice, and the requirement for practitioners to keep clear and accurate clinical records is a fundamental obligation.[17] It is important that when undertaking treatment — in this case surgical treatment — the practitioner thoroughly document in the clinical notes all assessments, medication, details

[17] https://www.hdc.org.nz/media/5302/do-the-basics-right.pdf.

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of the procedure, reasoning, recommendations, and discussions. The DCNZ Practice Standards (Standard 1) states:

> "You must create and maintain patient records that are comprehensive, time-bound and up to date; and that represent an accurate and complete record of the care you have provided."

81. Miss A's patient records do not contain any of the following information:

- Explicit clinical reasoning for the diagnosis of lip-tie
- Clinical indications for the lip-tie release
- Anaesthetic record
- Details of the surgical procedures

82. Dr Schwass stated: "[F]or the actual procedure undertaken, clearly [Dr B] would be responsible for recording what happened during and after the procedures ha[d] been conducted."

83. I note that the DCNZ Professional Standards (10) also states: "You must maintain accurate, time-bound and up-to-date patient records."[18]

84. Miss A's patient records are scant and lacking in detail. There is no documented justification of why the procedures were clinically necessary, no documentation of the anaesthetic procedure, and no details about the surgery. Dr B had a responsibility to ensure that the clinical notes were robust and detailed to support his clinical view, and to ensure that the details of the frenectomy procedures were documented clearly. I am critical that he did not do so.

85. In addition, DCNZ's Informed Consent Practice Standard (Standard 7) required "written informed consent of the patient when a patient will be sedated". Dr B administered 15mg of oral midazolam and nitrous oxide gas for the procedures, both of which are sedative medications, yet no written consent to that sedation was recorded.

86. In my view, Dr B's deficient clinical documentation represents a failure to meet the standards set out by his profession's regulatory body, DCNZ. Accordingly, I find that Dr B breached Right 4(2) of the Code.[19]

Scope of practice — adverse comment

87. At the time of these events, Dr B was a general dentist practitioner. Dr Schwass told HDC that surgical training in the management of frenectomy procedures is not part of the core qualification delivered for dental practitioners. Dr Schwass advised: "The treatment offered for [Miss A] fell outside the core scope of dentistry and involved techniques for which there

[18] The Dental Council of New Zealand. Standards Framework for Oral Health Practitioners. 1 August 2021.

[19] Right 4(2) states: "Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards."

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is little or no evidence to support." However, Dr Schwass told HDC that it is considered acceptable for dentists who have received appropriate training to offer such services to their patients.

88. Dr Schwass advised:

> "General dental practitioners who elect to provide such specialist services could be expected to comply to similar standards of care as would be expected within the scope of a specialist orthodontist or oral surgeon where relevant, providing similar services."

89. The DCNZ Standards Framework for Oral Health Practitioners states:

> "8. You must practise within your professional knowledge, skills and competence, or refer to another health practitioner. Practise safely and competently to ensure you do not cause harm to your patients. Only carry out a task or a type of treatment you have the knowledge and skills to do so competently within your scope of practice."

90. Dr B told HDC that he had received industry training on the use of a laser from its manufacturer. The training included theoretical, practical, and mentoring components over several days. He said that at the time of events, he had performed 139 frenectomy procedures over the previous five years. Dr B was unable to provide HDC with documentation of the training.

91. Dr Schwass told HDC that it is unclear whether courses such as the one undertaken by Dr B would constitute appropriate training that would be recognised by his specialist peers. Dr Schwass considers that it is the responsibility of all practitioners to ensure that they are working within the scope of their skills and competencies, and if they are to offer services that fall outside the core scope of their registered qualification, they have a responsibility to ensure that they are trained appropriately to meet the standards of their peers.

92. I am prepared to accept that Dr B had undertaken some training and had some experience in performing frenectomies. However, having regard to Dr Schwass's advice and owing to the lack of documentation, I am unable to determine whether such training and experience was sufficient.

93. However, I note Dr Schwass's comment:

> "Where a practitioner knowingly practises towards the boundaries of their core scope of practice, it should be considered inadvisable to provide treatment for patients where there is little or no evidence to support it, particularly where the risk and consequences of adverse outcomes can be significant, and better to explore evidence-based practices that have high predictability."

94. Despite my above finding that Dr B had undertaken appropriate training in the performance of frenectomies, I agree with Dr Schwass's advice in this regard. I consider that Dr B was operating at the boundaries of his scope of practice and undertaking a procedure for which there is little evidence of support. Given the controversial nature of frenectomies on

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children for orthodontic purposes, I am of the view that Dr B should maintain records to provide evidence of his training in this area, particularly considering that both the use of a laser and the frenectomy procedures appear to have comprised a significant part of his practice at the time of these events.

Referral to ENT specialist — other comment

95. I note the DHB's comments that the otolaryngologist surgeon found granulation tissue at the operative site, which is a sign of infection and healing occurring at the same time. The otolaryngologist surgeon said that this explained the recurrent bleeding, and that potentially an earlier referral to hospital could have been appropriate.

96. I acknowledge that Dr Schwass considered that Dr B's management following the first episode of bleeding was adequate. However, I suggest that Dr B reflect on these comments.

Communication following second episode of bleeding — other comment

97. Dr Schwass told HDC that granuloma formation and bleeding are "known but relatively uncommon post-operative complications", and that it is not possible to confirm the cause of the bleeding that [Miss A] experienced. Therefore, I am unable to make a finding as to the exact cause of the unfortunate events that followed the procedure.

98. However, following the second episode of bleeding, Mrs A sent a message to Dr B to advise him that Miss A had gone to hospital as she had experienced a second episode of uncontrolled bleeding. Mrs A told HDC that she did not receive a response from Dr B. Dr B told HDC that he assumed that the situation was being managed appropriately, and knew that he would see Miss A at her next orthodontic appointment (which subsequently did not take place), and therefore he did not consider a response necessary. Dr Schwass advised:

> "Although not essential to ensure the well-being of the patient, on reflection it is perhaps disappointing that the opportunity was not taken by [Dr B] to communicate compassion and empathy for what was no doubt a most distressing situation for [Miss A] and her parents at this time."

99. I agree with Dr Schwass's advice, and consider that in hindsight it would have been appropriate for Dr B to have communicated empathy and compassion to Miss A and her family, given the severity of the situation. I suggest that Dr B reflect on Dr Schwass's comments in this regard.

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Opinion: Dr C — adverse comment

Provision of information and informed consent

100. Dr C saw Miss A and Mrs A for Miss A's first appointment at the dental service on 6 August 2018. Dr C documented that Miss A had an upper lip tie, a tongue tie, and a retained baby tooth. The dental service told HDC that the release of the tongue and lip tie was to help with orthodontic treatment, as Miss A had narrow dental arches, and the treatment plan developed by Dr C included the use of upper and lower removable devices. The dental service stated that because of the severity of the tongue tie, a lower device could not have been used unless the tongue tie had been released. There was no documentation in the clinical notes, or in the dental service's response to HDC, that explained the clinical indication for the lip tie release. Dr C referred Miss A to Dr B to undergo the procedures.

101. Mrs A told HDC that since Dr C was the expert in this area, and Dr B had already pointed out the tongue and lip tie to her during previous appointments, she was convinced that the procedures were necessary. Mrs A stated:

> "I do not recall [Dr C] informing me of the risks involved, as I might have grilled him a bit more if I knew I was risking her tongue movement and her speech abilities versus accepting bottom crooked teeth."

102. Mrs A told HDC that when the frenectomy procedures were mentioned by Dr C, "the emphasis was on how easy and quick the procedure was". Mrs A stated that even had she been aware of the possible complications, she never would have agreed to the procedures had she not been under the impression that the frenectomies were needed to avoid crooked teeth, "so [her] decision was based on misinformation given by [Dr C]".

103. Dr Schwass advised HDC that in his view, both practitioners were individually responsible for the provision of information to Miss A and Mrs A, as they were both advocating for the procedure. He stated:

> "In advocating the surgery, [Dr C] presented this as being a credible treatment approach to [Mrs A]. Given the lack of evidence for benefit from such procedures in the literature generally, ideally it could have helped if [Dr C] had been able to identify specific indicators for performing the procedure. In terms of [Miss A's] parents accepting this approach, clearly they had faith in [Dr C] that he was advocating something considered necessary. So I do see, at least in part, some responsibility for informed consent sat with [Dr C] who was advocating the orthodontic plan."

104. I agree with Dr Schwass's advice. Although Dr C did not perform the procedures in question, and therefore ultimately was not responsible for obtaining consent, he undertook the initial examination of Miss A and developed the treatment plan for her. Dr C wrote and signed the "Orthodontic Treatment Letter" on 6 August 2018, which did not mention the frenectomy procedures, nor did it outline any information about the procedures.

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105. In my view, on that visit Dr C had a responsibility to provide Mrs A with accurate information about the procedures, including the risks, benefits, and clinical rationale behind the proposed treatment. I recommend that Dr C reflect on my comments and those of my clinical advisor in respect of his involvement in Miss A's care.

Scope of practice — other comment

106. As part of her complaint to this Office, Mrs A told HDC:

> "We made an appointment for that procedure so we could start orthodontist treatment afterwards. At no time did we realise that [Dr C] was only a dentist and not an orthodontist. In doing so, we trusted the dental service to have the knowledge and expertise to not only make a sound judgement on the necessity of such a procedure, but also to have the knowledge and skills to execute a frenectomy with no prolonged health risks to our healthy and normal eight-year old child."

107. The "Orthodontic Treatment Letter" provided to Mrs A stated (under the "qualifications" section) that Dr C was not a specialist orthodontist, but rather a general dentist. It also stated that he had "many years of orthodontic experience and ha[d] taken many post graduate courses in orthodontics".

108. I note Dr Schwass's comment:

> "It is plausible that with the vast amount of detailed information provided by the dental service, and with the strong practice emphasis on Orthodontics, that this section could be overlooked by patients or patient advocates when trying to digest all of the information, and that the overall impression about the practice that patients or patient advocates gain could lead to assumptions of specialist knowledge."

109. Although I acknowledge that Dr C has specified in the "Orthodontic Treatment Letter" that he is not an orthodontist, I note Mrs A's comment that they did not realise that Dr C was not an orthodontist. This suggests that Mrs A may not have seen or appreciated the information in the letter. I consider that Dr C should reflect on my comments and those of my advisor, and ensure that he is representing himself and his qualifications clearly and appropriately.

Opinion: Dental service — no breach

110. As a healthcare provider, the dental service is responsible for providing services in accordance with the Code.

111. In addition to any direct liability for a breach of the Code, under section 72(2) of the Health and Disability Commissioner Act 1994 (the Act), an employing authority is vicariously liable for any acts or omissions of its employees. A defence is available to the employing authority of an employee under section 72(5) if it can prove that it had taken such steps as were reasonably practicable to prevent the acts or omissions.

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112. At the time of these events, Dr B was an employee of the dental service. Accordingly, the dental service is an employing authority for the purposes of the Act. As set out above, I have found that Dr B breached Rights 6(1), 7(1), and Right 4(2) of the Code by failing to provide adequate information and obtain informed consent, and for significant deficiencies in the clinical documentation.

113. I acknowledge Dr Schwass's comment: "Practitioners are individually responsible for ensuring that patients are appropriately informed about the procedures they provide."

114. In this case, I consider that the failings identified in this report were matters of individual practice, and am satisfied that they do not indicate broader systems or organisational issues at the dental service. The dental service provided HDC with its policies relating to informed consent, and I am guided by my expert's opinion that generally they are clear and well written. I consider that responsibility for obtaining informed consent sits with the individual practitioners as a cornerstone of their clinical practice.

115. In my view, the dental service had sufficient policies in place to support practitioners to obtain informed consent appropriately, and the dental service was entitled to rely on Dr B to obtain informed consent and provide an appropriate standard of care. Accordingly, I find that the dental service did not breach the Code directly or vicariously.

116. However, I have noted that the dental service's standard written information for patients included only general information about dental surgery, and there was no written information about frenectomy procedures, the lack of evidence to support frenectomies on children for orthodontic purposes, and the specific risks.

117. I am of the view that it would be valuable for the dental service to consider developing a tailored written document outlining information on frenectomy procedures, including the lack of evidence to support them for orthodontic purposes, in order to provide patients with balanced information. Such forms should also outline the risks and benefits specific to frenectomies.

Changes made by Dr B

118. Dr B told HDC that following the events outlined in this report, he made the following changes to his practice:

- He limits his practice of frenectomies to referred cases only for orthodontic purposes.
- When a referral for a frenectomy is received, a separate consultation is made to ensure that informed consent is obtained, and the associated communicative process takes place during this consultation.

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- Written information specific to frenectomy procedures is provided,[20] with verbal confirmation of the information.
- Disclosure of other opinions, including differing views and factions of orthodontics, is part of the information provided during the consenting process.
- An option of referral to an ENT specialist is given to prospective frenectomy patients.
- Institution of a new workflow process that does not allow familiarity with patients to influence the informed consent process. This includes separating the child and guardian at a certain point to ensure a comprehensive consent process, including a discussion of the negatives, risks, and the use of appropriate language.

119. Dr B also told HDC that following this incident he conducted a review of his informed consent process, and can confirm that the cases that he reviewed "both written and verbal meet standards".

Recommendations

120. I recommend that Dr B:

a) Provide a written apology to Miss A's family for the failings identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Miss A's family.

b) Arrange for an external audit of a random sample of 20 patients to ensure that:

i) Adequate informed consent was obtained for treatment.

ii) Clinical documentation is of an appropriate standard, as stipulated in the DCNZ guidelines.

The results of the audit are to be provided to HDC within three months of the date of this report. If the audit does not identify 100% compliance, then Dr B is also to report back to HDC on what actions have been taken to address these issues.

c) Undertake further education and training on informed consent and clinical documentation, in conjunction with the DCNZ. Dr B is to report back to HDC with evidence of this training, and any further changes he has made to his practice as a result, within six months of the date of this report.

d) Develop a written information sheet containing information specific to frenectomy procedures, particularly the risks, benefits, and lack of evidence to support frenectomies for orthodontic purposes. Dr B is to provide HDC with a copy of this document within three months of the date of this report.

[20] Dr B did not specify what specific information is provided.

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121. I recommend that the Dental Council of New Zealand consider whether a review of Dr B's competence is warranted.

122. I recommend that Dr C:

a) Provide a written apology to Miss A's family for the issues about the care he provided identified in this report. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Miss A's family.

b) Provide a report to HDC on the changes he has made to his practice as a result of these events. Dr C's report is to be provided to HDC within three months of the date of this report.

123. I recommend that the dental service develop a written information sheet containing information specific to frenectomy procedures, particularly the risks, benefits, and lack of evidence to support frenectomies for orthodontic purposes. The dental service is to provide HDC with a copy of this document within three months of the date of this report.

Follow-up actions

124. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Dental Council of New Zealand, and it will be advised of Dr B's name.

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

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Appendix A: Independent clinical advice to Commissioner

The following expert advice was obtained from prosthodontist Dr Donald Schwass on 20 November 2020:

"**Independent advice to the Health and Disability Commissioner**

I have been asked to advise the commissioner whether [Miss A] received an appropriate standard of care from [Dr B] at [the dental service].

I have read and agree to follow the Commissioner's guidelines for Independent Advisors.

I am the Clinical Director for the Faculty of Dentistry, University of Otago. I hold specialist registration with the Dental Council of New Zealand as a Prosthodontist. My qualifications are BSc, BDS (with distinction) DClinDent (Prosthodontics).

I have had 17 years of general dental practice experience (for 14 years I owned and operated a group practice employing other dentists and hygienists) and 1 year of hospital dental practice. Following completion of a clinical doctorate in 2009, for the last eleven years I have been employed as a specialist Prosthodontist at the Faculty of Dentistry, University of Otago.

I am a consultant for the Dental Council of New Zealand, past Faculty coordinator for Dental Council competence assessment and retraining for practitioners, and an examiner for the NZDREX examinations since 2002. Historically I was a complaints assessor for the Dental Council prior to establishment of the current competence framework. I am also a consultant for the Accident Compensation Corporation (ACC) and the Faculty ACC liaison officer.

Information reviewed

1. Complaint from [Miss A's] mother, [Mrs A], dated 8 September 2019.
2. [Dental service] responses dated 20 September 2019, 20 May 2020 and 24 July 2020.
3. [Dr B's] response
4. Clinical records from [the dental service] covering the period February 2017 to February 2019.
5. Clinical records from [the medical centre] covering the period February/March 2019.

Findings

On 6th August 2018, [Miss A] who was 8 years old at the time, attended [the dental service] for an orthodontic consultation with [Dr C] (General Dental Practitioner). At this visit, it was noted that [Miss A] had an upper lip tie and tongue tie, as well as a retained deciduous tooth ('baby tooth'). [Miss A's] parents were advised that in order to help with orthodontic treatment, the lip and tongue ties should be released. Prior to visiting

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[the dental service] [Miss A's] mother, [Mrs A], was not aware of any significant problems associated with [Miss A's] lip or tongue ties, noting that [Miss A's] speech and tongue movements seemed normal to her. However, [Mrs A] and [Miss A] were told that [Miss A's] tongue and lip muscles were causing problems by pushing the teeth outwards. When expressing doubt about undergoing the frenectomy procedure [Mrs A] and [Miss A] were told that [the dental service] was very experienced at doing the procedure and that they do a lot of them.

Correspondence from [Dr B] following the clinical incident indicates that in 2008 [Dr B] had undergone training on using lasers for surgical procedures involving industry supported theoretical, practical and mentoring components over several days, and that he has subsequently performed 139 frenectomy procedures within the past 5 years.

[Mrs A] alleges that they were not informed of potential risks associated with the procedure, and so assumed it to be routine. [The dental service] [has] subsequently acknowledged that there was need for better written documentation of the consent discussion held.

Subsequently [Miss A] was referred by [Dr C] to [Dr B] (General Dental Practitioner) for laser frenectomy, which was performed by [Dr B] on 29th January 2019. Post-surgical documentation was provided, and [Miss A] was booked in to see a Myofunctional therapist in the same practice for instruction on post-operative exercises.

At a follow up on 1st February 2019 it was noted by a [dental service] assistant who looks after follow-up care for the practice, that [Miss A] had had an accident; having 'fallen and face planted into the trampoline' two days after the surgery. In subsequent correspondence from [the dental service] dated 24 July 2020, it was noted that [Dr C] had contacted an ENT specialist who advised that any trauma to a healing surgical site that has a high density of capillary blood vessels has the potential to cause a delayed post-operative bleed.

[Miss A's] postoperative experience was initially free from problems, until the night of the 13th of February, when [Miss A's] family were woken to find [Miss A] bleeding profusely from her mouth and vomiting up blood that had been swallowed. The family contacted a nurse on duty as they were struggling to stop the bleeding, and her advice was to go to the Emergency Department if bleeding failed to stop after an hour, or if it started again. They were also advised not to allow [Miss A] to sleep on her back due to the risk of suffocating, and to see their GP or dentist who performed the frenectomy procedure the following morning for follow-up.

The next day the family initially took [Miss A] to their GP who told them that she had a haematoma. Following this they visited [Dr B] at [the dental service] who noted that [Miss A] had a bubble haematoma on the floor of her mouth and suggested further review in three weeks, reassuring them not to worry as he didn't think the bleeding would start again. However, on the night of the 15th February 2019 [Miss A] suffered a further severe bout of bleeding which her parents were unable to stop and [Miss A] had

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vomited a lot of blood. This time her parents chose to take their daughter to the Hospital Emergency Department where an ENT Registrar examined her and determined that she needed urgent surgery under general anaesthetic to arrest bleeding associated with a large inflammatory granuloma on the ventral surface of the tongue. Surgical haemostasis under general anaesthetic was performed by [an otolaryngologist surgeon] using bipolar diathermy and suturing. [Miss A's] haemoglobin count of 100 supported that there was significant blood loss prior to surgical haemostasis achieved.

[Miss A's] parents informed the dentist who performed the original frenectomy, [Dr B], that they had taken their daughter to the Emergency Department due to further bleeding but claim that they did not get a reply.

The ENT Registrar who saw [Miss A] advised [Miss A's] parents that laser frenectomy can cause heat damage to blood vessels when performed which can lead to post-operative bleeding complications, so in preference, surgical steel instruments are used to cut which causes less collateral damage[1]. The ENT Registrar also expressed his opinion that dentists or midwives should refrain from conducting frenectomies. [Miss A's] parents were advised by the ENT resident that tongue ties seldom cause tooth displacement in 8-year-old children. It was noted that [Miss A's] tongue has developed a sideways curl and limited movement as a result of scarring due to the surgical procedure. Another specialist, [an ENT specialist at the DHB] who specializes in managing tongue ties also shares the same views and findings. At a subsequent consultation on 6th March, [the ENT specialist] advised that it was highly unlikely that in [Miss A's] case the frenulum was associated with causing tooth crowding.

This view was also shared by [the orthodontist] who saw [Miss A] after her parents elected to change treatment provider for the remaining orthodontic treatment.

[Miss A's] [GP] filed an ACC treatment injury claim.

[Miss A's] parents feel that they were led to believe that [Dr C] was an orthodontist when first presenting at [the dental service], trusting in his specialist expertise, and were subsequently surprised to find that he was actually only a general dental practitioner. However, the letter written addressed to [Miss A's] parents on 6th August 2018 does clearly state in the appended 'Information and informed consent document' under section 'Qualifications' that [Dr C] is not a specialist orthodontist, but that he is a general dentist with many years of orthodontic experience and that he has taken many post-graduate courses in orthodontics, although it does not state what the courses were. It is plausible that with the vast amount of detailed information provided by [the dental service], and with the strong practice emphasis on Orthodontics, that this section could be overlooked by patients or patient advocates when trying to digest all of the information, and that the overall impression about the practice that patients or patient advocates gain could lead to assumptions of specialist knowledge. Services that the practice offers marketed on their website include orthodontic services, cosmetic

[1] These comments (relating to the use of lasers for frenectomies) were later redacted by Dr Schwass.

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dentistry, facial rejuvenation and botox as well as general dental services. It does not appear that the practice is deliberately attempting to misrepresent itself.

The relatively uncommon post-operative complications that [Miss A] experienced following frenectomy was no doubt distressing. It is a matter of conjecture as to how much the trampoline injury that [Miss A] suffered two days after surgery played a part in the bleeding complication which followed a little over a week later. Professional opinion from ENT pointed to an association between the use of lasers for performing frenectomies and the risk of collateral damage to capillary vessels from the heat generated, suggesting that the gold standard remains traditional surgical excision using surgical steel blades. On the other hand, advocates of lasers point to the advantages of allowing a clear field of view during surgery due to immediate haemostasis and of the ability to control laser power to minimize heat impacts.

Supporting evidence relating to this treatment

Speaking on behalf of the Dental Council of New Zealand (DCNZ), in an article about management of tongue ties published on the DCNZ website, Dr Dexter Bambery commented the following:

While some dentists may have the training, qualifications and experience necessary to undertake the treatment of tongue ties, the reasons for addressing the issue are not always within their scope of practice.

Anyone practising this type of treatment must be able to demonstrate they have the necessary training, qualifications and experience to be able to do so safely.

The New Zealand Dental Association (NZDA) have also released a position statement on Ankyloglossia (tongue ties) and frenal attachments, dated 14 April 2018 and available on the NZDA website for all oral health practitioners, including general dental practitioners. To quote, they state that: ‘The significance of ankyloglossia, including its diagnosis, its relationship with breastfeeding problems, speech disorders and other oral conditions, and the management of ankyloglossia for these issues is controversial. This controversy results from a lack of robust research data and is exacerbated by the strongly-held parochial opinions of some advocacy groups’.

They state: ‘Ankyloglossia may be present in 1.7% to 10% of neonates, and in 0.1% to 2.8% of children, adolescents and adults suggesting ankyloglossia resolves with growth in most cases’.[1–5]

Further, they go on to say: ‘There is no robust evidence supporting an association between ankyloglossia and malocclusion’.[6]

And:

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There is insufficient evidence to support the surgical release of the labial/buccal frenal in infants to assist with breastfeeding difficulties[7–8], or orthodontic issues, including midline diastema closure[9–10].

'Ankyloglossia, in the absence of breastfeeding difficulties, is functionally normal and requires no active intervention. Available evidence does not support frenectomy for all infants with ankyloglossia. There is insufficient evidence regarding the benefits or harm of surgical treatment of ankyloglossia for speech difficulties. There is insufficient evidence to support the surgical release of the labial/buccal frenum in infants to assist with breastfeeding difficulties, speech outcomes, or orthodontic issues.'

Summary

Based on the lack of evidence in the literature regarding frenectomy procedures for orthodontic purposes, it is highly questionable whether the frenectomy procedure conducted for [Miss A] was clinically necessary at all. Neither the New Zealand Dental Association nor the New Zealand Dental Council have identified evidence to support this procedure under such circumstances.

Copies of the [dental service's] generic 'Consent for oral surgery form', and the 'post-frenecotomy post-operative instructions', are generally clear and well written. However, if there was a valid clinical reason for the procedure to be undertaken, much more detailed justification is required to explain why the lack of evidence should be disregarded. Because of this it is clear that informed consent surrounding this procedure was inadequate. Informed consent should have admitted the lack of clear evidence supporting this procedure, with justification why in this case it should proceed. This did not occur. Informed consent was inadequate with neither [Miss A] nor her mother [Mrs A] fully informed. Following internal review of this case by [the dental service], the practice has implemented a more comprehensive informed consent process to support proposed treatment.

It is evident that frenectomy surgery is a reasonably routine part of orthodontic treatment offered by [the dental service] for instances where it is believed of benefit. This service is supported by a dedicated myotherapy therapy follow-up programme.

Orthodontics is not considered part of the core scope of dentistry as it is not part of the Bachelor of Dental Surgery curriculum, but it is considered acceptable for practitioners who have received appropriate training in Orthodontics to offer Orthodontic services for their patients. Surgical training in the management of frenectomy procedures is also not part of the core qualification delivered for general dental practitioners. [Dr B] did identify to having received industry training on the use of laser from the manufacturer which extended to theoretical, practical and mentoring components over several days, and that he has subsequently performed 139 frenectomy procedures within the past 5 years.

It is unclear whether courses of this nature constitute appropriate training that would be recognised by specialist peers also involved in providing such services, or whether

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more formal training should be expected. It is obvious that the ENT specialist involved in this case has a differing opinion to the general dental practitioners at [the dental service] about the value of using lasers as opposed to the traditional surgical approach of using a scalpel to perform frenectomies. The choice of approach taken is more the issue than whether the practitioner providing the surgery used the laser device competently.

General dental practitioners who elect to provide such specialist services could be expected to comply with similar standards of care as would be expected within the scope of a specialist orthodontist or oral surgeon where relevant, providing similar services.

Granuloma formation and bleeding are known but relatively uncommon post-operative complications. It is difficult to confirm whether use of a laser device to perform the procedure increased the risk of this event occurring or not, or whether the trauma experienced two days following surgery is a mitigating factor or not. Irrespectively, it is reasonable to expect that the clinician performing the procedure should be capable of managing such post-operative complications effectively.

At the initial post-operative presentation with bleeding, [Dr B] made a judgement call that the tissues appeared satisfactory and that haemostasis had been achieved. Management of this visit seems appropriate.

A couple of days later when [Miss A] experienced a further, more serious, bout of bleeding, [Miss A's] parents chose to take their daughter directly to hospital. [Mrs A] phoned [Dr B] to advise him that [Miss A] had been taken to hospital for management. Based on this information, [Dr B] decided not to return the call, assuming that the situation was being managed appropriately. Although not essential to ensure the well-being of the patient, on reflection it is perhaps disappointing that the opportunity was not taken by [Dr B] to communicate compassion and empathy for what was no doubt a most distressing situation for [Miss A] and her parents at this time. The extent of blood loss as confirmed by blood test results, indicated this was a serious situation requiring emergency surgical intervention, with bipolar diathermy and suturing.

The treatment offered for [Miss A] fell outside the core scope of general dentistry and involved techniques for which there is little or no evidence to support. Consequently, the treatment offered fell outside what could be considered accepted practice for general dental practice, as supported by the NZDA position statement provided for its membership (which constitutes a large proportion of registered dental practitioners in New Zealand).

The postoperative complications experienced are a known risk associated with frenectomy procedures, but normally occur relatively infrequently. Specialist opinion suggests that use of a laser device to perform the procedure may have increased the risk of postoperative bleeding complications, while on the other hand it is possible that the trampolining trauma experienced two days after surgery may have also contributed.

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Given the seriousness of the postoperative bleeding involving serious risk of harm, requiring emergency intervention, the departure from accepted practice could be considered to have serious consequence.

It remains the responsibility of all practitioners to ensure that they work within the scope of their skills and competency whether they are general practitioners or specialists. Where a practitioner elects to become involved in providing procedures that fall outside the core scope of their registered qualification, they have a responsibility to ensure that they are appropriately trained to an acceptable standard that would meet the standards of their professional peers whose core scope of practice includes the procedure undertaken. In this case this includes the scope of specialist orthodontists, oral surgeons and ENT surgeons who also manage this condition. Where a practitioner knowingly practises towards the boundaries of their core scope of practice, it should be considered inadvisable to provide treatment for patients where there is little or no evidence to support it, particularly where the risk and consequences of adverse outcomes can be significant, and better to explore evidence-based practices that have high predictability.

To avoid a repeat of the same event occurring again, apart from the aforementioned changes to informed consent procedure which should include advising where there is little evidence to support the proposed procedure, practitioners should preferably refrain from activities which are out on the edge of their scope of competency and focus on activities that are core to their qualification. Failing to do this poses risk for both the practitioner and patient, and any adverse events that occur are likely to be judged at the level of specialist competency core to these procedures.

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Further expert advice was obtained from Dr Schwass on 1 December 2020:

“Practitioners are individually responsible for ensuring that patients are appropriately informed about procedures they provide. Consequently, in this case responsibility would sit with [Dr B] regarding the frenectomy he performed.

However, there is also an element where [the dental service] has some responsibility for how they market their services, as it is clear that in this case the parents of the patient were wrongfully led to believe that [dental service] clinician [Dr C] was a specialist orthodontist, when in actual fact he is a general dental practitioner. Services that the practice offers marketed on their website include orthodontic services, cosmetic dentistry, facial rejuvenation and botox as well as general dental services.

As a practice, [the dental service] presumably provides patient information on procedures they offer. If information handouts are offered regarding frenectomies, then it would be important to advise the relative lack of evidence supporting the procedure, and reasons to justify why, despite this, that they recommend the procedure specifically for an individual situation.”

Further expert advice was obtained from Dr Schwass on 12 June 2021:

“Further Independent advice to the Health and Disability Commissioner

Material provided for review:

Letter dated 28 January 2021 from [the dental service] and [Dr B]

I have reviewed the additional material and have come to the following conclusions.

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I remain of the opinion that, generally speaking, there is a lack of literature evidence to support frenectomy procedures; as both the New Zealand Dental Council and the New Zealand Dental Association have attested to.

While a range of literature views and opinions can be found, the quality of evidence needs to be taken into account, for instance considering the hierarchy of evidence from systematic reviews and meta-analyses to be of better value than papers presenting individual clinical trials or case reports. Consensus regarding what is considered best practice by such organizations as the New Zealand Dental Council and the New Zealand Dental Association are based on a balanced assessment of the quality of evidence provided overall. As [Miss A's] specific clinical presentation was not explained in detail, there were no clear or obvious strong lines of evidence that could be drawn.

However, as the [dental service] has commented, I acknowledge that I did not examine [Miss A] prior to her having the procedure, to confirm whether any particular presenting situation warranted the intervention undertaken despite this relative paucity of definitive evidence. However, had an obvious clinical indication presented, it is reasonable to expect that this should have been documented clearly in the patient record, and that this would have been explained when informed consent was obtained regarding the pros and cons of the procedure specific to this case. This would then have provided justification for a subsequent reviewer to form a different view about the clinical necessity of the procedure for [Miss A]. Unfortunately, the original documentation didn't provide sufficient detailed information to take such a stance.

It is commendable that [the dental service] has reviewed their informed consent process to support proposed treatment, implementing a more comprehensive approach now. This shows recognition and understanding that at the time when [Miss A] was treated there was a degree of deficiency in the standard of informed consenting undertaken. By making these changes it is hoped that miscommunication will be avoided in future.

With reference to the comment that 'there are differing opinions on whether the laser or steel blade is better for such procedures, and we believe it comes down to the clinician's personal preference', I have defaulted to the opinion of specialists who regularly perform head and neck surgical procedures which I believe to be the most appropriate approach to take, that is to say, to defer to expert best practice.

As previously stated, the postoperative bleeding complications experienced are a known risk associated with frenectomy procedures, but normally occur relatively infrequently. Specialist opinion suggests that use of a laser device to perform the procedure may have increased the risk of postoperative bleeding complications, while on the other hand it is possible that the trampolining trauma experienced two days after surgery may have also contributed (as suggested by [the dental service]). Given the seriousness of the postoperative bleeding involving serious risk of harm, requiring emergency intervention, even a small departure from accepted practice could be considered to have serious consequence.

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As a general principle, where a practitioner knowingly practises towards the boundaries of their core scope of practice, it should be considered inadvisable to provide treatment for patients where there is little or no evidence to support it, particularly where the risk and consequences of adverse outcomes can be significant, and better to explore evidence-based practices that have high predictability. However, having said that practitioners reserve the right to exercise their best judgement and to decide what degree of uncertainty and risk is acceptable for them. This is fine so long as the patient understands this too.

The well-being of the patient is central to any consideration or decision reached. There is little doubt that the post-operative complications [Miss A] experienced would have been very distressful for her and her parents. I am sure that when faced with these circumstances, all parties involved were concerned for [Miss A's] welfare throughout this time. Unfortunately, such an experience can sometimes have a lasting impact on a patient's confidence and ability to cope when experiencing subsequent dental procedures.

Due to a lack of documented justification recorded before, or at time of treatment, and reflecting on the serious nature of what [Miss A] experienced post-operatively, I remain of the opinion that it is somewhat questionable whether the procedure needed to be performed or not. While possible it may have been justified, insufficient contextual information was recorded to ultimately support it."

Further expert advice was obtained from Dr Schwass on 2 August 2021:

"I have reviewed all of the material.

1. With reference to the first query, my reference to defaulting to ENT specialist opinion was based on comments made by [Miss A's] mother about what ENT specialists had told her (ENT Registrar at Hospital, and [an] ENT Specialist at [the DHB]). As this is second hand opinion, and subject to bias or potential for mis-quoting, I suggest disregarding comments about preference for surgical technique. A brief review of the literature confirmed that either technique can work well when performed by a competently trained individual.

However, in terms of evidence I refer to the following meta-analysis which still finds in favour of scalpel technique.

Laser Techniques or Scalpel Incision for Labial Frenectomy: A Meta-analysis. (2019). Ana Cláudia Rocha Protásio, Endi Lanza Galvão, Saulo Gabriel Moreira Falci Journal of Maxillofacial and Oral Surgery volume 18, pages 490–499.

To quote from the summary of this article: 'This systematic review suggests that labial frenectomies performed with high-intensity surgical lasers are faster and offer better prognosis in terms of pain and discomfort during speech and chewing, than those performed with conventional scalpels. However, these results should be viewed with caution because of the high risk of bias found. Therefore, there is still insufficient

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evidence to conclude that the use of lasers is better than the use of conventional scalpels in frenectomies. Other randomized trials using the two techniques are necessary to allow the dentist to safely choose between either of the techniques.'

Comments made by ENT staff that were quoted by [Miss A's] mother seem to reflect a conservative stance, supporting this position in the literature.

2. This raises an interesting point as to where responsibility for informed consent should lie. In advocating the surgery, [Dr C] presented this as being a credible treatment approach to [Miss A's] parents. Given the lack of evidence for benefit from such procedures in the literature generally, ideally it could have helped if [Dr C] had been able to identify specific indicators for performing the procedure (for example such as an unusually high and/or strongly fibrous and prominent frenal attachment where the fibrous tissue could prevent teeth being moved together orthodontically if the frenum extended between teeth). In terms of [Miss A's] parents accepting this approach clearly they had faith in [Dr C] that he was advocating something considered necessary. So I do see, at least in part, some responsibility for informed consent sat with [Dr C] who was advocating the orthodontic plan.

In addition, the surgeon performing an intervention would normally also seek informed consent, and this is where I would expect perhaps there might be more detail provided about what to expect such as the risks and complications of the procedure, as well as whether or not the procedure is based on solid evidence, or importantly to note in particular if evidence for the procedure is lacking but where the practitioner has strong reason to believe it should be conducted despite this. This is where contextual clinical records that explain the problem such as referencing to an anatomical situation (as per my example) might have helped. I consider that the greatest responsibility for informed consent sits with [Dr B] who conducted the procedure.

Both practitioners, would be, in my view, independently responsible for obtaining informed consent with regards what they proposed. Both were seen as expert authorities by [Miss A's] parents and trusted for providing a balanced opinion. If [Dr B] disagreed with [Dr C's] judgement he could have declined to proceed and explained why, but in this case it appears that both practitioners were of the same opinion regarding necessity for the procedure. For the actual procedure undertaken clearly [Dr B] would be responsible for recording what happened during and after the procedure has been conducted.

3. In my view, both practitioners should be held independently responsible for holding the view of advocating a procedure. Whenever advocating a procedure, informed consent implies explaining about what to expect, known complications, risks and the relative evidence supporting the procedure. Each practitioner was in the position to influence decision making by [Miss A's] parents by appearing to be credible and knowledgeable. Clearly [Miss A's] parents had faith in [Dr C] and [Dr B] to allow their daughter to have surgery performed on her."

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Further expert advice was obtained from Dr Schwass on 27 September 2021:

> "Yes I do consider that the risk of haemorrhage or haematoma following frenectomy procedures should be discussed with patients, particularly where the frenectomy site is floor of mouth involving beneath the tongue as this is a richly vascularised area with significant density of vessels. It would not be such a consideration for a labial frenectomy in the upper arch where the nature of the blood supply is such that it doesn't involve such dense vascularisation. So the site where the frenectomy is performed definitely influences my thinking as the nature of risk of adverse events or post-operative complications is site-specific. In this case, where floor of mouth was involved I would consider that failure to mention this complication would represent a moderate departure from accepted practice."

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