Ophthalmology Clinic
Ophthalmologist, Dr B

A Report by the
Health and Disability Commissioner

(Case 17HDC02370)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided by an ophthalmologist at an ophthalmology clinic (the clinic). The report highlights the importance of having a checking procedure in place during surgery, and keeping comprehensive and clear clinical documentation.

2. On 12 October 2017, the ophthalmologist performed LASIK surgery to treat a woman's long-sightedness. During the surgery, the laser failed to cut through the cornea completely, and this part of the surgery was completed manually by the ophthalmologist. Initially, the ophthalmologist thought that the side cut had not come through to the surface fully, and that completion of the side cut would be relatively straightforward with the combination of a blade and fine ophthalmic scissors. However, this "proved more difficult than anticipated".

3. The ophthalmologist told HDC that he considered abandoning the procedure, and that had he known at the time that the side cut was completely absent, this would have been his obvious choice.

4. At the end of the procedure, it was discovered that a small-sized treatment pack had been used erroneously, as opposed to the medium size that was required for flap formation in the surgery. As a result, the flap size was smaller than expected, and the laser could not complete the side cut of the flap.

5. The woman told HDC that since this event, she has been experiencing severe headaches, double and blurry vision, and migraines. The woman transferred her care to another ophthalmologist, and subsequently ACC cover was approved to provide her with re-treatment surgery.

6. The clinical notes do not contain any record of a conversation detailing the risks of the surgery, or what to expect throughout the course of, or after, the procedure. The woman signed a consent form prior to the surgery, but the risks and complications of the procedure were not stated on the form.

Findings

7. The Commissioner found the ophthalmologist in breach of Right 4(1) of the Code for failing to ensure that the correct treatment pack was given to him before commencing the surgery, and for using the pack when it was the wrong size.

8. The Commissioner made adverse comment about the ophthalmologist for failing to document in the clinical notes any discussion that occurred with the woman regarding the risks of the surgery.

9. Adverse comment was also made about the ophthalmologist for failing to abandon the procedure when the incomplete flap was identified, and for using Westcott scissors and a scalpel to complete the corneal cut manually.

10. The Commissioner was critical that there were no policies in place at the clinic to guide the preoperative checks, and that the consent form was not comprehensive and specific in terms of risks and complications. As such, he found the clinic in breach of Right 4(1) of the Code.

Recommendations

11. It was recommended that the ophthalmologist provide a written apology for his breach of the Code, undertake further training on documentation, and undertake an audit of his informed consent process over the last six months.

12. The clinic is no longer in operation, and accordingly no recommendations were made for the clinic.

Complaint and investigation

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

- *The appropriateness of the care provided to Ms A by Dr B between August 2017 and December 2017.*
- *The appropriateness of the care provided to Ms A by the clinic between August 2017 and December 2017.*

14. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	Ophthalmologist/provider
Ophthalmology clinic	Provider

15. Further information was received from:

Dr C	Ophthalmologist
RN D	Perioperative nurse

16. Independent expert advice was obtained from Professor Charles McGhee (Appendix A).

Information gathered during investigation

Background

17. Ms A, aged in her fifties at the time of events, had a history of low hypermetropia[1] in both eyes, with a degree of astigmatism[2] in her right cornea. Even with the use of spectacles, Ms A's eyesight and reading vision were poorer than normal.

18. On 10 October 2017, Ms A consulted with ophthalmologist Dr B[3] for a free assessment regarding the option of laser eye surgery to correct her vision. It was documented that Ms A wore progressive glasses, and was found to have Duanes 1[4] syndrome in her left eye. A plan was made for Ms A to undergo bilateral LASIK,[5] with left eye Presbyond,[6] and surgery was booked in with Dr B for 12 October 2017.

19. LASIK surgery consists of a flap at the front of the eye first being formed with the use of a Zeiss Visumax Laser. The laser uses a sized, single-use "treatment pack" to fit the size of the patient's cornea, ensuring that the laser cuts are placed in the correct position. This flap is then removed, and a second laser is used to perform the LASIK treatment on the inner layer of the corneal tissue.

20. Dr B stated that at the free assessment, the clinical coordinator nurse will usually take measurements of the eye, and spend time explaining the laser treatment process and expectations, along with the risks. The patients are then seen by Dr B to discuss any questions they may have.

21. Ms A told HDC that because of the time that has elapsed since the surgery, she cannot remember the conversation regarding to the risks of the procedure; however, she stated: "I vaguely remember [Dr B's receptionist] saying there is a 1 in 100 or 1 in 1000 chance of a complication." There is no documentation in Ms A's clinical notes regarding a conversation detailing the risks of the surgery, or what to expect throughout the course of, or after, the procedure.

Surgery of 12 October 2017

Consent process

22. On 12 October 2017, Ms A presented to the clinic for her booked LASIK surgery. She told HDC:

[1] Long-sightedness.
[2] Blurred vision caused by irregularities in the shape of a person's cornea.
[3] Dr B is a Fellow of the Royal Australian and New Zealand College of Ophthalmologists and has an annual practising certificate from the Medical Council of New Zealand. He was the sole director and shareholder of the clinic.
[4] An eye movement disorder that is present at birth. People with Duane syndrome have restricted ability to move the affected eye(s) outward toward the ear and/or inward toward the nose.
[5] Commonly referred to as laser eye surgery or laser vision correction, LASIK is a type of refractive surgery for the correction of nearsightedness, farsightedness, and blurry vision.
[6] A treatment that extends the range of vision in each eye for patients who have presbyopia (the inability to focus up close).

> "On arrival at [the clinic], I was asked to pay $7000.00, given sedatives then sat in waiting area. Before entering surgery his receptionist called me over to sign consent form. I was given the sedatives prior to signing the consent form."

23. Dr B told HDC that Ms A was given "the required sedative" after the consent procedure was completed, and the form was signed, as per policy.

24. On 8 June 2020, Dr B provided this Office with new evidence, which showed that Ms A was given Hypnovel[7] and Codalgin[8] at 2.20pm, and that the time of the signature on the consent form was also 2.20pm.

25. The "consent for operation" given to Ms A to sign stated:

> "The information presented here of the major known complications of excimer laser surgery has been provided to improve your understanding of its medical limitations and to initiate a discussion between you and your eye care professional about the relative merits and risks of the procedure … Your decision whether or not to proceed with the surgery should be based on the information you have received in this form, together with the understanding derived from the conversations you have had with your eye care professional."

26. However, the risks and complications of the procedure were not stated on the consent form.

27. Dr B told HDC that on signing the consent form, the patient agrees that he or she has received a full explanation and read the information available, and has had any questions answered. He stated:

> "Extensive detail is not gone into on the form. Written material has been superseded by website information. As one cannot trust a patient to have read or properly understood such information, hence a lot of the explanations are given in the initial 'free assessment' and by myself."

Procedure

28. Registered Nurse (RN) D was the perioperative nurse in theatre on the day of Ms A's surgery, and was responsible for gathering the equipment and preparing the theatre. Prior to commencement of the surgery, RN D selected what she thought was a medium-sized treatment pack for the Zeiss Visumax Laser from the medium treatment pack storage box, as was required for Ms A's cornea size. RN D handed the treatment pack to Dr B, and the first part of the surgery was performed.

29. However, the Zeiss Visumax Laser failed to cut through Ms A's cornea completely, and instead this part of the surgery was completed manually by Dr B.

[7] A medication used for sedation before surgical or diagnostic procedures.
[8] A pain relief medication.

30. Dr B told HDC:

> "When I came to lift the flap on the [right] side, I found the side cut had not been completed to the surface of the cornea. In order to lift the flap, the side cut was completed manually; the flap layer was identified cutting down with a fine scalpel, the flap opened with the flap lifter and the side cut completed using a combination of the scalpel and fine ophthalmic Westcott curved scissors."

31. Dr B explained that initially he was under the impression that the side cut had just not come through to the surface fully, and that once the flap layer was identified and separated, completion of the side cut would be relatively straightforward with the combination of a blade and fine ophthalmic scissors. However, he stated that this "proved more difficult than anticipated", and a bandage contact lens[9] was applied to the right eye to help the cornea to settle.

32. At the end of the procedure, Dr B discovered that he had been handed a small treatment pack by RN D, as opposed to the medium size that was required for flap formation in Ms A's surgery. This caused the flap size to be smaller than expected, and had led to the laser not being able to complete the side cut of the flap. Dr B informed HDC that there are no obvious identification marks for these treatment packs other than a small "S" or "M" on the side of the packaging.

33. RN D told HDC:

> "At the start of an operating session a box of both small and medium treatment packs are put out in theatre. On the day in question, two packs were taken from the 'medium' box for the case in question. The previous week the packs had been audited by the Zeiss company [representatives], and obviously not put back in the appropriate boxes. As a result, a 'small' pack was used inadvertently. I don't consider this an excuse on my behalf as I obviously didn't check the pack carefully enough."

34. Dr B explained that the edge of the LASIK flap formed with the Visumax laser is often difficult to see, appearing complete or absent, and as he had no reason to suspect that the side cut was not partially formed, he chose to use a scalpel to find the edge. He stated:

> "[T]he flap was smaller than expected due to the inadvertent use of a 'Small Ring' creating some difficulty finding the dissection plane."

35. Dr B told HDC that he did consider abandoning the procedure, but a return for retreatment at a later date is not simple, and it was a case of balancing the risks using one's experience. He explained that typically, one would create a thinner flap over the previous treatment, but this could result in two dissection planes and side cuts, potentially creating major problems. He stated that had he known at the time that the side cut was completely absent, abandoning the procedure would have been his obvious choice.

[9] Refers to the use of contact lenses for therapeutic reasons such as facilitating corneal healing or protecting a fragile corneal surface.

Events post surgery

36. Ms A attended four follow-up appointments with Dr B, where her post-procedural progress was monitored. Dr B stated that he advised Ms A that before retreatment or enhancement could be considered, she would need to wait until the refraction and cornea had settled, which would take at least three months.

37. Ms A told HDC that after her last visit with Dr B on 7 November 2017, she telephoned his clinic and the receptionist told her that Dr B was on holiday. Ms A stated that at this time she was still in a lot of pain and her vision had not improved much at all, so she visited her general practitioner (GP). Ms A's GP referred her to another ophthalmologist, Dr C, for follow-up care.

38. Dr B told HDC:

> "I only ever wanted a good outcome for [Ms A], and would have been committed to achieving that had she remained under my care."

39. Dr C first saw Ms A on 14 November 2017. On examination, Dr C found that Ms A's right eye had a poorly made LASIK flap with a small diameter and a very irregular border. He found that the edges of the corneal flap were cut deeper than would be expected, down to more than 400µm (a normal LASIK flap is between 90 and 130µm).

40. Ms A told HDC that since this event, she has been experiencing severe headaches, double and blurry vision, and migraines. Further laser correction was discussed with Dr C, and subsequently ACC cover was approved to provide Ms A with retreatment surgery.

Further information

41. Dr B advised that in response to these events, the clinic instituted protocols to make sure that treatment packs were kept in separate boxes, and that on arrival at the clinic they were marked to identify the different sizes. Checks were also performed preoperatively, to ensure that the right pack had been chosen, along with the usual patient checks. Dr B stated: "[T]here [was] not … a single incident of the wrong size pack being used or even presented to the surgeon since this incident."

42. RN D advised that she has worked in all perioperative specialities, and never in her career had she opened the incorrect treatment pack previously. She stated: "[T]his is a regrettable incident, in particular the resultant problems with [Ms A]."

43. Dr B stated that he considers that there are two things to learn from this incident:

> "First, a more robust check of the pack to be used with the Visumax laser and this [was] incorporated into our protocol. Second, is careful observation of all parts of the Visumax laser treatment, in particular the side cut to identify when lifting the flap."

Responses to first provisional opinion

44. The clinic was provided with an opportunity to respond to the provisional opinion. It advised HDC that since 2019, clinic is no longer in operation.

45. Dr B was provided with an opportunity to respond to the relevant sections of the provisional opinion, and his comments have been incorporated into the report where relevant. He stated that he does not agree with Professor McGhee's comment that where a side cut is not achieved, it is inappropriate to proceed with the treatment. He told HDC:

> "Sometimes, for a variety of reasons — such as loss of suction or conjunctive blocking the laser — incomplete flaps do occur and such are a recognised occurrence with the Visumax laser and strategies to complete a side cut are well described in the training process for both SMILE[10] and LASIK."

46. Dr B provided a comment from another New Zealand ophthalmologist with Presbyond experience. The ophthalmologist stated:

> "I have had two occasions that I can recall when the side cut was incomplete … In both cases I completed the side cut with scissors and also a blade in one case. Both patients did absolutely fine and I would do exactly the same thing again if the problem happened again. I would not consider it necessary to abandon the procedure with an incomplete side cut."

47. Ms A was provided with the opportunity to respond to the "information gathered" section of the provisional opinion, and her comments have been incorporated into the report where relevant.

Response to second provisional opinion

48. Dr B was provided with an opportunity to respond to the second provisional opinion, and provided this Office with further evidence and information, which has been incorporated accordingly.

Relevant standards

49. The Medical Council of New Zealand's statement on "Information, choice of treatment and informed consent"[11] (March 2011) states:

> "Trust is a vital element in the patient–doctor relationship and for trust to exist, patients and doctors must believe that the other party is honest and willing to provide all necessary information that may influence the treatment or advice. The doctor needs to inform the patient about the potential risks and benefits of the options available and support the patient to make an informed choice."

[10] SMILE is a minimally invasive type of refractive eye surgery.
[11] Available from https://www.mcnz.org.nz/assets/standards/edc0457381/Information-choice-of-treatment-and-informed-consent.pdf

50. The Medical Council of New Zealand's statement on "Maintaining patient records" states:

> "1 You must maintain clear and accurate patient records that note:
>
> a clinical history including allergies
> b relevant clinical findings
> c results of tests and investigations ordered
> d information given to, and options discussed with, patients (and their family or whānau where appropriate)
> e decisions made and the reasons for them
> f consent given
> …

Opinion: Dr B

51. On 10 October 2017, Ms A presented to the clinic for a free assessment regarding the option of laser eye surgery to correct her vision, as even with the use of spectacles, her eyesight and reading vision were poorer than normal. A surgical plan was made to perform bilateral LASIK with left eye Presbyond in order to correct her poor vision. Surgery was booked for two days later, on 12 October 2017, to be performed by Dr B.

Use of incorrect treatment pack — breach

52. Pursuant to Right 4(1) of the Code of Health and Disability Services Consumers' Rights (the Code),[12] Ms A had the right to have services provided with reasonable care and skill when she presented to Dr B for her laser eye surgery on 12 October 2017.

53. The first part of the LASIK procedure used a Zeiss Visumax Laser, which required a medium-sized treatment pack to ensure that the laser cuts were placed in the correct position of Ms A's cornea. RN D was the perioperative nurse in theatre that day, and when setting up for the surgery, she handed Dr B what she thought was a medium-sized treatment pack from the "medium" box. However, RN D failed to check the treatment pack, and a small size was used erroneously.

54. Dr B explained that the small treatment packs had been misplaced in the box of medium packs, as there are no obvious identification marks other than a small "S" or "M" on the side of the packaging.

55. My expert advisor, Professor McGhee, advised:

> "Although these packs are only identified by 's' and 'm', in all ocular surgical procedures, where diameter and sizing are important, the standard of care would be a 'double check'. This failure to check that the correct pack was used falls below the standard of care expected in refractive surgery."

[12] Right 4(1) states: "Every consumer has the right to have services provided with reasonable care and skill."

56. While I am concerned that RN D did not double check the treatment pack size before using it, I consider that Dr B had overall responsibility, as the supervising ophthalmologist performing the surgical procedure, to ensure that the correct treatment pack size had been selected prior to commencing the surgery. I find that by failing to ensure that the correct treatment pack was given to him before commencing surgery, and then using the wrong sized pack, Dr B failed to provide services to Ms A with reasonable care and skill, and breached Right 4(1) of the Code.

Completion of surgery — adverse comment

57. After the Zeiss Visumax Laser had made the cuts to Ms A's cornea, Dr B attempted to lift the corneal flap on her right eye to continue with the procedure. He stated:

> "When I came to lift the flap on the [right] side, I found the side cut had not been completed to the surface of the cornea. In order to lift the flap, the side cut was completed manually; the flap layer was identified cutting down with a fine scalpel, the flap opened with the flap lifter and the side cut completed using a combination of the scalpel and fine ophthalmic Westcott curved scissors."

58. My expert advisor stated:

> "As a consequence of this failure to complete the corneal flap side cuts, [Dr B] completed these with a scalpel and scissors (in a procedure where accuracy is measured in terms of microns these are relatively crude surgical instruments). I believe the acceptable standard of care would have been to abandon the procedure when the incomplete flap was identified, allow the cornea to heal and perform the treatment a number of weeks later."

59. Dr B explained that the edge of the LASIK flap formed with the Visumax laser is often difficult to see, appearing complete or absent, and that although he considered abandoning the procedure, it was a case of balancing the risks. Dr B stated that at the time, he had no reason to suspect that the side cut was not completed, as he was unaware of the issue with the treatment pack until the end of the surgery, and that had he known at the time that the side cut was completely absent, then abandoning the procedure would have been his obvious choice.

60. Professor McGhee advised:

> "It is possible that a partial side-cut might not have been identified initially, however, it would certainly have been identified on attempting to lift the flap and the flap could have been repositioned immediately at that stage — i.e. he did not need to progress to the use of scissors to complete the incomplete flap. I have posited this as an anonymous hypothetical scenario to five experienced laser refractive surgeons in recent weeks and all stated they would have not lifted the flap, or if they had lifted before discovering the incomplete cut, they would immediately have repositioned the flap and postponed treatment. None would have used Westcott scissors to complete a flap."

61. In response to the provisional opinion, Dr B submitted that incomplete flaps do occur, and are a recognised occurrence with the Visumax laser. He stated that strategies to complete a side cut are well described in the training process for both SMILE[13] and LASIK. He also submitted a comment from an ophthalmologist who stated that he has experienced such a situation, and that he proceeded just as Dr B did.

62. I prefer my expert's analysis on this issue, which is demonstrably comprehensive. I note Professor McGhee's credibility in this field, and also his consultation with experienced colleagues on the matter.

63. I am critical of Dr B's approach for the reasons outlined above.

Informed consent and documentation — adverse comment

64. Informed consent under the Code is a process with three essential elements: effective communication between the parties (Right 5); the provision of all necessary information to the consumer (Right 6); and the consumer's freely given and competent consent (Right 7). As the treating clinician, Dr B was responsible for ensuring that he had obtained Ms A's informed consent to any procedure he carried out on 12 October 2017. Prior to the surgery on 12 October 2017, Ms A was provided with a consent form. The consent form stated:

> "The information presented here of the major known complications of excimer laser surgery has been provided to improve your understanding of its medical limitations and to initiate a discussion between you and your eye care professional about the relative merits and risks of the procedure … Your decision whether or not to proceed with the surgery should be based on the information you have received in this form, together with the understanding derived from the conversations you have had with your eye care professional."

65. However, the risks and complications of the procedure were not stated on the consent form.

66. Dr B told HDC:

> "Extensive detail is not gone into on the form. Written material has been superseded by website information. As one cannot trust a patient to have read or properly understood such information, hence a lot of the explanations are given in the initial 'free assessment' and by myself."

67. Professor McGhee stated:

> "Certainly, nurses or other practice staff e.g. optometrists may often provide preliminary information to the patient in relation to fully informed consent. Additional information may also be provided on pamphlets, websites etc, however, it is a primary

[13] SMILE is a minimally invasive type of refractive eye surgery.

> role of the physician/surgeon to FULLY inform and consent the patient and highlight the risks and benefits of the procedure.
>
> Physicians cannot rely on the participation of other staff, or other materials provided and must confirm details of properly informed consent themselves."

68. Dr B told HDC that at the free assessment, the clinical coordinator nurse informed all patients about the laser treatment process and the risks. The Medical Council of New Zealand's statement on information, choice of treatment, and informed consent stipulates:

> "The doctor needs to inform the patient about the potential risks and benefits of the options available and support the patient to make an informed choice."

69. Because of the time that has elapsed since these events, Ms A cannot remember the conversation she had at Dr B's clinic regarding risk, but vaguely remembers being told that there is a 1 in 100 or 1 in 1,000 chance of a complication. There is no documentation in Ms A's clinical notes that details what she was told regarding the risks of the surgery before she signed the consent form.

70. Balancing the evidence, I cannot make a finding of fact as to whether Ms A was adequately informed of the risks of the LASIK procedure; however, I would be extremely critical if Ms A was not adequately informed of the risks of the LASIK procedure.

71. The absence of a sufficient record in this case is unhelpful. The importance of the medical record is well established. While it was the clinic's usual practice to discuss these risks verbally beforehand, I would have expected such a discussion to have been documented and supplemented with written information. Baragwanath J acknowledged the importance of medical records in *J v Director of Proceedings*,[14] stating that meticulous record-keeping is a fundamental obligation of the practitioner. This Office has often observed that in the absence of written records, providers whose evidence is based solely on their subsequent recollections may find their evidence discounted.[15]

72. The Medical Council of New Zealand's statement on the maintenance of patient records states that clear and accurate patient records must be maintained. These records must note the information given to patients, the options discussed with patients, the decisions made and the reasons for them, and any consent given by the patient.

73. Dr B did not document in Ms A's clinical notes any information she was given, or any discussion that occurred regarding the risks of the surgery before she signed the consent form, and I am critical of this omission. I remind Dr B of the importance of the medical record, and of his obligation to adhere to the Medical Council of New Zealand's standards.

[14] *J v Director of Proceedings* HC Auckland CIV-2006-404-2188, 17 October 2006 at [63] per Baragwanath J.
[15] For example, see Opinion 13HDC00749 and 13HDC01557, available at www.hdc.org.nz.

Opinion: Ophthalmology clinic — breach

74. As a healthcare provider, the clinic is responsible for providing services in accordance with the Code. Ms A presented to the clinic on 12 October 2017 for her scheduled appointment with Dr B for LASIK surgery.

75. Prior to the commencement of surgery, RN D obtained what she thought was a medium-sized treatment pack needed for Ms A's surgery, and presented it to Dr B. Neither RN D nor Dr B checked that they had the correct sized treatment pack, and as such a "small" sized pack was used erroneously.

76. At the time of these events, the clinic did not have any policies or procedures in place to ensure that small-sized packs and medium-sized packs were stored in a way that ensured that they would not get mixed up, and there was no checking process in place to ensure that the correct size was used for the procedure.

77. Professor McGhee advised:

> "Although these packs are only identified by 's' and 'm', in all ocular surgical procedures, where diameter and sizing are important, the standard of care would be a 'double check'. This failure to check that the correct pack was used falls below the standard of care expected in refractive surgery."

78. I agree with this statement, and am of the view that checking that the correct equipment is being used is simply good practice for health professionals. It is concerning that both RN D and Dr B failed to check the equipment before beginning the surgery. Whilst it is evident that there are individual failures involved in this case, there were no policies in place at the clinic to guide the preoperative checks, for which I am critical. This lack of an appropriate process adversely affected the care provided to Ms A, and as such I find the clinic in breach of Right 4(1) of the Code.

79. Professor McGhee also advised that the consent form utilised by the clinic was rudimentary and non-specific in terms of complications (e.g., infection, haze, loss of vision, retreatment). Dr B, the sole director, explained:

> "Extensive detail is not gone into on the form. Written material has been superseded by website information. As one cannot trust a patient to have read or properly understood such information, hence a lot of the explanations are given in the initial 'free assessment' and by myself."

80. As stated above, it is a health provider's responsibility to ensure that the information provided is understandable to the patient such that a reasonable patient is informed to the extent sufficient for the patient to make an informed choice. A consent form that was comprehensive and specific in terms of risks and complications would have supported the staff at the clinic with their informed consent process, and ensured that Ms A understood the risks involved in her surgery. I am critical that no such form was in place.

81. Following this event, the clinic instituted protocols to make sure that the correct treatment pack was being used, to reduce the risk of such an incident. Professor McGhee advised that the new procedures were appropriate.

Recommendations

82. I recommend that Dr B:

a) Provide Ms A with a written apology for his breach of the Code. The apology is to be sent to HDC within three weeks of the date of this report, for forwarding to Ms A.

b) Undertake further training on documentation, to be arranged by the Medical Council of New Zealand. Dr B is to provide evidence of attendance at such a course within three months of the date of this report.

c) Undertake an audit of his informed consent process over the last six months, to ensure that all verbal discussions relating to consent are being documented adequately. Dr B is to provide HDC with the results of the audit within six months of the date of this report.

83. Dr B has advised HDC that he no longer performs laser refractive surgery, and as such I make no recommendations regarding training.

84. The clinic is no longer in operation, and accordingly I make no recommendations for the clinic.

Follow-up actions

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

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

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

Appendix A: Independent advice to the Commissioner

The following expert advice was obtained from an ophthalmologist, Professor Charles McGhee:

"**Re: [Dr B] at [the clinic]; HDC Ref: C17HDC02370**

Thank you for asking me to provide this HDC independent opinion. For the record I have met [Dr B] briefly, 2–3 times at conferences. In respect to other material you have sent me I can recall I have met [Dr C] perhaps a dozen or more times at various conferences/professional meetings in the last 20 years. I regard both as professional colleagues but have no regular professional or social interaction with either.

In respect to the specific questions you have asked, based on the materials you have forwarded, and in the context that I have not personally examined the patient [Ms A]:

1. **Whether [Dr B's] treatment of [Ms A's] right eye was reasonable and appropriate.**

I note that [Ms A] had low hypermetropia (long-sightedness) in both eyes with a degree of astigmatism in the right cornea. Right eye achieved 6/9+ visual acuity with +1.75/-2.25x180 and left eye 6/9+ visual acuity with +1.25D. She also obtained N8 near vision with +1.25D reading addition. Therefore it is notable that her spectacle corrected vision pre-operatively was a little poorer than normal (6/9 rather than 6/6) as was her reading vision (N8 rather than N5). She also had Duane's Syndrome (an eye movement disorder).

Allowing for the slightly poorer starting vision, with the appropriate fully informed consent of relative risks and benefits (including reduction in vision), I believe that offering bilateral LASIK 'Presbyond' was reasonable and appropriate and meets the standard of accepted practice.

The consent form utilised is rudimentary and non-specific in terms of complications e.g. infection, haze, loss of vision, retreatment etc. but these risks may be covered in other materials offered to the patient for consideration prior to the surgery (any other patient information was not in the file forwarded to me).

The main issues in the right eye stems from the failure to complete the hinged LASIK flap 'side cuts' with the laser — stated as being due to a 'small' rather than 'medium' treatment pack being accidentally used in the procedure. Although these packs are only identified by 's' and 'm', in all ocular surgical procedures, where diameter and sizing are important, the standard of care would be a 'double check'. This failure to check that the correct pack was used falls below the standard of care expected in refractive surgery. I note [Dr B] and his team appear to have instituted appropriate procedures to prevent this circumstance happening again.

As a consequence of this failure to complete the corneal flap side cuts, [Dr B] completed these with a scalpel and scissors (in a procedure where accuracy is

measured in terms of microns these are relatively crude surgical instruments). I believe the acceptable standard of care would have been to abandon the procedure when the incomplete flap was identified, allow the cornea to heal and perform the treatment a number of weeks later. However, some surgeons might consider reapplying the suction device to complete the laser cuts but that would not be appropriate in this circumstance. Notably use of a scalpel appears to have created a deep incision temporal to the right LASIK flap, the Westcott curved scissors utilised are not generally used in fine corneal flap surgery (due to their relatively large size) and these may have also contributed to the creation of an irregular flap edge as noted by [Dr C].

I believe a) the use of the incorrect treatment pack, b) failure to abandon the procedure when the incomplete LASIK flap was identified, and c) the use of scalpel and scissors to complete the vertical cut all fall below the standard of accepted practice.

2. Whether [Dr B's] explanation regarding [Ms A's] left eye haze and likely recovery time is reasonable and appropriate.

I believe that [Dr B's] explanation and suggested initial management i.e. that the haze and refractive error in the left eye might stabilise over time (3 months or more) and possibly benefit from topical steroid is reasonable and appropriate in this case of excessive haze.

3. The seriousness of the residual refractive error, and how commonly this occurs.

The planned treatment was for monovision or blended vision with the right eye seeing for distance (approximately zero refraction) and the left eye seeing for near (a myopic refraction). The main issue of the residual error is the anisometropia — i.e. the under-correction of the right eye (due to the incomplete LASIK flap and altered healing, and the myopic over-correction of the left eye. On 04/12/2017 refractions were Right +1.25/-1.00x13 (6/7.5) and Left -1.75/-1.50x 7 (6/7.5) this provides a spherical equivalent power of +0.75D right and -2.50D left — a difference (anisometropia) of 3.25D between the eyes which can be difficult to tolerate. There is also under correction of astigmatism right and 1.50D of induced astigmatism left which might also make comfortable spectacle correction more difficult. Such a degree of over and under-correction respectively is relatively uncommon and should typically affect less than 5% of cases — though I have not considered data for this specific laser set-up at this stage. I note that [Dr C] highlights that the patient found distance and near work difficult and was unable to correct readily with spectacles — the refractive error in terms of anisometropia and astigmatism would be in keeping with these symptoms.

4. Was the overall care provided by [Dr B] reasonable and appropriate?

In relation to the points in section (1) I believe the care fell below acceptable standards, however, the patient failed to attend for longer term follow-up and whether [Dr B] would have pursued the management course provided by [Dr C], that enabled recovery of good vision for the subject, remains unknown.

5. **Are there any other matters in this case that you consider warrant comment?** No

Yours sincerely,

Professor Charles NJ McGhee MBChB, BSc(Hons), PhD, DSc, FRCS, FRCOphth,
FRANZCO Maurice Paykel Professor and Chair of Ophthalmology,
Director, New Zealand National Eye Centre"

The following further advice was sought from Professor McGhee:

"In relation to your enquiry for further information in relation to my **earlier HDC report 17/02370,** I have answered each of your supplementary questions below.

1. [Dr B] stated that although the risks are not in extensive detail on the consent form, the risks are explained by the clinical coordinator nurse at the initial free assessment. *Please advise if this is consistent with accepted practice*.

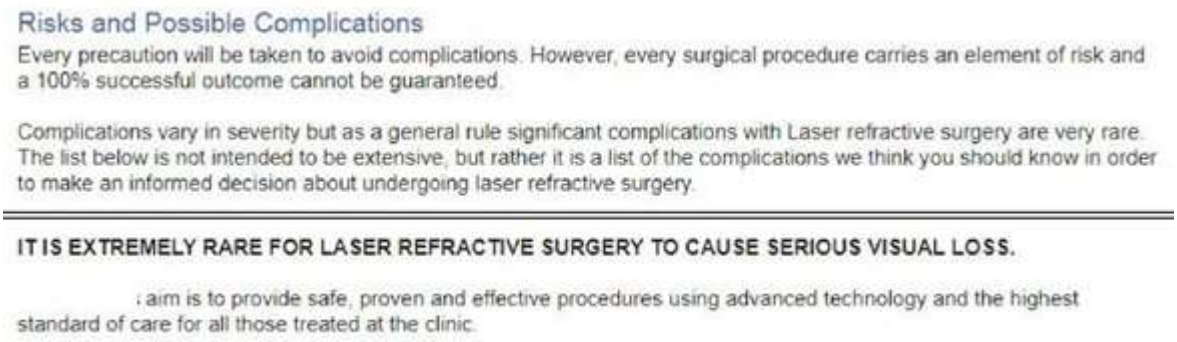
Certainly, nurses or other practice staff e.g. optometrists may often provide preliminary information to the patient in relation to fully informed consent. Additional information may also be provided on pamphlets, websites etc., however, it is a primary role of the physician/surgeon to FULLY inform and consent the patient and highlight the risks and benefits of the procedure.

Physicians cannot rely on the participation of other staff, or other materials provided and must confirm details of properly informed consent themselves.

Notably [Dr B's website] has an FAQ section for patients which is reasonably comprehensive but it is also *overly reassuring of low risk* by stating, without defining magnitude of 'rare' or the nature of 'significant complications' or 'serious visual loss' for the average patient:

> 'As a general rule significant complications with laser refractive surgery are very rare' and
>
> 'It is extremely rare for laser refractive surgery to cause serious visual loss'

Excerpted details from the website accessed 27/08/19 are highlighted below.



Risks and Possible Complications

Every precaution will be taken to avoid complications. However, every surgical procedure carries an element of risk and a 100% successful outcome cannot be guaranteed.

Complications vary in severity but as a general rule significant complications with Laser refractive surgery are very rare. The list below is not intended to be extensive, but rather it is a list of the complications we think you should know in order to make an informed decision about undergoing laser refractive surgery.

IT IS EXTREMELY RARE FOR LASER REFRACTIVE SURGERY TO CAUSE SERIOUS VISUAL LOSS.

; aim is to provide safe, proven and effective procedures using advanced technology and the highest standard of care for all those treated at the clinic.

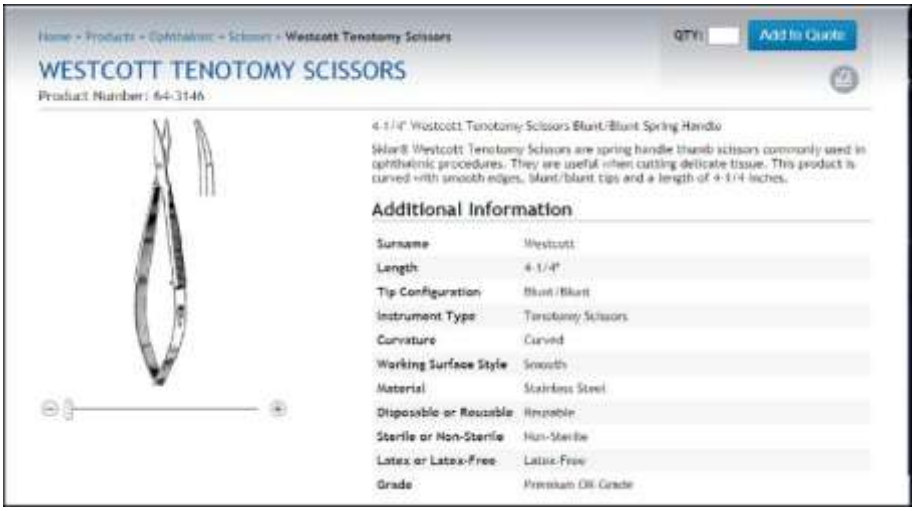
Illustrative guidance from the American Refractive Surgery Council on the importance of informed consent, created by clinicians and experts in the refractive surgery industry, is attached (1a and 1b).

2. [Dr B] stated that the thickness of the flap was 120 microns, and thus the difference between a partial and absent side cut would be undetectable. He stated that as he had no reason to suspect that the side cut was not partially formed, he used the 'Micro Westcott' scissors to open that flap. He said that if he had known that the side cut was complexly absent, abandoning the procedure would have been his obvious choice. *Please advise if [Dr B's] explanation is reasonable in the circumstances.*

It is possible that a partial side-cut might not have been identified initially, however, it would certainly have been identified on attempting to lift the flap and the flap could have been repositioned immediately at that stage — i.e. he did not need to progress to the use of scissors to complete the incomplete flap. I have posited this as an anonymous hypothetical scenario to five experienced laser refractive surgeons in recent weeks and all stated they would have not lifted the flap, or if they had lifted before discovering the incomplete cut, they would immediately have repositioned the flap and postponed treatment. None would have used Westcott scissors to complete a flap.

3. [Dr B] stated that the scissors he used are 'micro' Westcott scissors, that have been scaled down to make them appropriate for such fine work. He stated that he has used them many times before and after this case to successfully complete the side cut at no detriment to the outcome. *Please advise if this changes your initial advice.*

Westcott scissors are typically described as 'Micro' Scissors in ophthalmology use as Westcott make a wide-range of surgical scissors — some in size similar to kitchen scissors! However, in ophthalmic surgery 'Westcotts' are typically spring scissors, present in every standard ophthalmic surgical tray, generally used for dissecting conjunctiva (often termed tenotomy scissors) — and are usually around 11–12cm long with blades much longer than the width of the cornea i.e. not suitable for corneal surgery.



In contrast, proper corneal micro scissors (e.g. Vannas scissors) have much smaller blades with a smaller radius of curvature. A quick check of online surgical catalogues provided several examples of these larger ophthalmic 'Westcott micro scissors' as commented upon in my original report (vide supra). Of course [Dr B] may be using an incomplete or incorrect name for the scissors he actually used, with a number of jointly named micro-scissors available on the market. A catalogue number or a photograph, with a surgical ruler alongside his instrument, would easily clarify this issue. A standard Westcott scissor is shown below. Standard Westcott micro scissors are certainly not suitable for corneal surgery.

For completeness I have also addressed the remaining issues identified by [Dr B] in relation to my initial report:

4. [Dr B] states incorrectly:

> In Section 3 Prof McGhee's comments are misinformed and erroneous. He himself states: "I have not considered data for this specific laser setup at this stage". Presbyond is significantly different to monovision on which he bases his comments. There are only surgeons in New Zealand with a Zeiss Mel 90 excimer laser and significant experience with Presbyond: myself,

Unfortunately [Dr B] overstates his point here suggesting the unbiased opinion provided is both misinformed and erroneous. What I meant in this statement was I had not gone into detail in relation to the results of this specific laser set-up (indeed there is extremely limited peer-reviewed literature on this matter but I am happy to report on this if required).

I do understand the modifications related to Presbyond® treatment (indeed a simple modification of the laser algorithm) and this is a form of monovision, mini-monovision, or blended vision. Indeed [Dr B] states on his website (accessed 29th August 2019): 'Presbyond® laser blended vision represents the next stage in eye care excellence. *Similar to conventional monovision methods*, one eye is primarily corrected for distance vision and the other eye is corrected for near vision.' [Dr B] also exaggerates

the exclusivity of his knowledge of the Presbyond® procedure and its limited application to a few surgeons in New Zealand, e.g. I believe from past discussions that all refractive surgeons at [a multi-surgeon major centre] have used this approach.

> Question 7: The complete lack of a side cut was not apparent until the end of the list when it was pointed out a "small pack" had been used in error. Once the flap had been identified and dissected the side cut was completed using the "micro Westcotts". The flap thickness was 120 microns (the diameter of a human hair) thus the difference between a partial and absent side cut would be undetectable.

Since these comments by [Dr B] ('misinformed and erroneous' also clearly suggest a lack of expertise on my behalf in this area, for the record: I have been involved in cataract and refractive surgery for 30 years, completed my PhD on PRK and LASIK refractive surgery, headed the Royal College of Ophthalmology (UK) committee on excimer laser surgery guidelines, wrote a major textbook (1997) on laser kerato-refractive surgery with the inventor of the technique (Prof Stephen L Trokel), have trained more than 30 surgical fellows on aspects of corneal, cataract and refractive surgery, am the Life President of the British Society of Refractive Surgery, have published >200 peer-reviewed papers on aspects of cataract and corneal surgery, and in addition to my role as Professor of Ophthalmology in the University of Auckland I work within the largest cataract and refractive surgical centre in New Zealand.

5. In relation to [Dr B's] further comment:

He states that the flap was 120 microns 'the diameter of a human hair' and therefore contends that the difference between a partial cut and absent cut would be undetectable — in fact 120 microns is around 20–25% of the thickness of the normal cornea (range 490 to 620 microns) and therefore a relatively substantial component of the cornea when viewed under a surgical microscope or when elevated with forceps. Although it is entirely possible [Dr B] could not discern whether this cut was made or not for a number a reasons. (For reference the diameter of human hair in Europeans is typically 50–60 microns — although thicker Asian hair can reach 120 microns.)

6. Finally in regard to [Dr B's] comments in relation to deviations from best practice

> In Prof McGhee's further letter 10 Sept 2018:
>
> "Should the incorrect cassette have been used" I agree "definitely no". This was not recognised at the time of surgery, only at the end of the list on completing the daily log. New protocol was immediately instituted to prevent any possibility of another occurrence.
>
> "Should the procedure have been abandoned" I Disagree with "definitely yes". In retrospect is easy to say such. As stated above, had I known of the side cut being completely absent I would have abandoned the procedure. However, I had no reason not to believe the side cut was partially formed and that advancing to completion was appropriate. It is a case of balancing the risk of trying to form a new flap at a later date.
>
> "Should scalpel and scissors been used to complete" I Disagree with "definitely no". The term "micro Westcott" has obviously created confusion. The same scissors had been used to open partially incomplete flap side cuts previously and are continued to be used. Inability to find the side cut with the semi-pointed pick end of the flap lifter in retrospect possibly should have alerted me to something being wrong and looking at abandoning the procedure. At the time use of a sharper instrument to identify the flap seemed appropriate on the basis a partial side cut was expected to be present.

As noted in my email to [HDC] on 10/09/2018 in medicine and biology unlike, say mechanics, there is often not an absolute categorical grading and the points I made are pertinent to [Dr B's] response noted above:

'After due consideration and your advice below, in respect to my report C17HDC02370, I believe all three issues are **severe** departures from best practice (and could have resulted in substantial vision loss). However, once more I would note that these are actually **yes/no choice events** so they don't readily fit comfortably into your preferred rubric of mild/moderate/severe (I note you do not consider the outcomes — which were of moderate, non-permanent, visual disability).

Should the incorrect cassette have been used — definitely no!

Should the procedure have been abandoned — definitely yes!

Should scalpel and scissors been used to complete — definitely no!

I would consider these failures to be **'severe'** though there might be a range of opinions on this and other experts might err on **'moderate'**, however, I do not believe any expert would consider these **'mild'** deviations in practice. Subsequent to this event, it appears that [Dr B] has reflected on these issues and made changes to his practice, judging from the information provided, to avoid re-occurrence of these events. Therefore I am unsure if handing this matter over to the 'Investigations team' will ultimately be of greater benefit to the patient or practitioner (though this is only my opinion).'

With kind regards,

Yours sincerely

Professor Charles NJ McGhee
ONZM, FRSNZ, MBChB, PhD, DSc, FRCS, FRCOphth, FRANZCO,
Maurice Paykel Professor and Chair of Ophthalmology,
Director, New Zealand National Eye Centre"