Ophthalmologist, Dr B
District Health Board

A Report by the
Health and Disability Commissioner

(Case 18HDC01420)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Contents

Executive summary

1. This report concerns the care provided to a woman by an ophthalmologist at a district health board (DHB). The report highlights the universal issues with detecting LASIK-treated cornea prior to use in corneal transplant procedures, and the importance of open disclosure.

2. The woman has a progressive eye disease that affects the cornea and causes distorted vision. Prior to 2018 she had undergone two corneal transplants to restore her vision, but subsequently both had failed.

3. On 19 February 2018, the ophthalmologist performed a third corneal transplant on the woman. Initially the surgery was uneventful, but prior to suturing the corneal tissue to the eye, the ophthalmologist discovered that the donor tissue had been treated with LASIK[1] surgery. Prior refractive surgery (such as LASIK) on a donor cornea is listed as an exclusion for the type of surgery performed on the woman, owing to the potential for adverse outcomes.

4. The ophthalmologist told HDC that when he discovered the issue, it was neither practical nor safe to wake the woman to explain what had happened, as had he done so, almost certainly she would have lost the eye altogether. The ophthalmologist decided to continue with the surgery, as the existing cornea had already been removed, and he believed that there was a chance that the new cornea could work successfully.

5. The remainder of the surgery proceeded uneventfully, and the woman was kept in hospital overnight for observation. The ophthalmologist reviewed her at 7.15am the following day, but did not disclose the issue with the donor cornea at this time. He told HDC that he decided to inform the woman at a time when he could explain fully what had occurred, and when she had a support person present. He considered that telling her on the day after surgery would cause unnecessary additional stress. The ophthalmologist did not see the woman again until 5 March 2018 — two weeks after the surgery — when he disclosed the issue with the cornea.

6. Unfortunately, the third corneal graft became opaque and vascularised, and subsequently failed.

Findings

7. The Commissioner considered that the decision to continue with the surgery was reasonable, owing to the risks of waking the woman up, and with the chance that the new donor tissue could work successfully and provide improved vision.

8. However, the Commissioner found the ophthalmologist in breach of Right 6(1) of the Code for failing to disclose the issue of the compromised donor cornea until two weeks after the woman's surgery. The Commissioner considered that the woman should have been told in

[1] Corrective eye surgery in which a flap of the corneal surface is raised and a thin layer of underlying tissue is removed using a laser.

a more timely manner, and that it was unreasonable for the ophthalmologist to decide that the disclosure would cause unnecessary stress for the patient.

9. The Commissioner was satisfied that the DHB's policy for open disclosure in place at the time of these events was adequate, and that the ophthalmologist was aware of the guidelines. The Commissioner considered that the ophthalmologist's omission was an individual decision, and did not indicate broader systems or organisational issues at the DHB. As such, the DHB was not found in breach of the Code.

Recommendations

10. It was recommended that the ophthalmologist provide an apology to the woman for the delay in open disclosure, review HDC's "Guidance on Open Disclosure Policies" and identify areas for improvement in his practice, and provide HDC with an update on his communication with the Eye Bank regarding his newly discovered method of checking corneal tissue prior to commencing surgery.

11. It was recommended that the DHB consider updating its "Open communication (open disclosure)" policy to include guidance on what to do when a lead clinician is not available.

12. It was recommended that the Ministry of Health consider asking all clinics that perform corneal transplants to include this issue as a potential risk in the consent process.

13. It was recommended that the Eye Bank consider the issues identified in this report that relate to the checking of corneal donor tissue, and consider trialling the use of optical coherence tomography machines to screen donor corneal tissue for previous laser surgery.

Complaint and investigation

14. The Commissioner received a complaint from Ms A about the services provided to her by Dr B at the DHB. The following issues were identified for investigation:

- *Whether the DHB provided Ms A with an appropriate standard of care in February and March 2018.*
- *Whether Dr B provided Ms A with an appropriate standard of care in February and March 2018.*

15. The parties directly involved in the investigation were:

Ms A	Consumer
Dr B	Ophthalmologist/provider
DHB	Provider

16. Further information was received from the Eye Bank.

17. Independent expert advice was obtained from an ophthalmologist, Dr Brian Kent-Smith, and is included as Appendix A.

Information gathered during investigation

Background

18. Ms A (41 years old at the time of events) suffered from keratoconus, a progressive eye disease that affects the cornea and causes distorted vision. She had noticed a rapid deterioration of the vision in her left eye over the last 10 years, and was referred to Dr B,[2] an ophthalmologist, for ongoing specialist ophthalmology care.

19. In an attempt to regain the vision in her left eye, Ms A had undergone two previous corneal transplants with Dr B as her surgeon; however, subsequently both transplants had failed. Dr B told HDC that in this situation, further attempts at corneal transplantation have a significantly reduced chance of success.

20. Ms A told HDC that her appointments with Dr B were generally 5–10 minutes long at most, and that this was insufficient time for a comprehensive discussion about the pros and cons of having the surgery a third time. She said that had the surgery been discussed with her at length, she may have been deterred from going ahead with the third procedure.

21. Ms A stated that her job is very important to her, and that her vision is crucial to her role and for her to remain independent, and so a decision was made to proceed with a left repeat penetrating keratoplasty.[3] In her complaint to HDC, Ms A said that this third transplant was to be her last attempt, as she had used all her leave entitlement for her previous transplants, and her post-operation recovery had placed excessive pressure on her work and finances.

Corneal transplant surgery

22. Ms A's third corneal transplant was booked for 19 February 2018 with Dr B as the surgeon. The surgery was to include removal of the existing opacified corneal graft and replacement with a fresh graft using donor tissue obtained from the Eye Bank.

23. Initially, the surgery proceeded uneventfully. The donor tissue was cut to size, the existing corneal graft was removed from Ms A's eye, and the new tissue was inserted into the eye.

[2] Dr B is a Fellow of the Royal Australasian College of Surgeons and 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.

[3] Corneal transplantation where the entire cornea is replaced.

However, prior to suturing the tissue to Ms A's eye, Dr B discovered that the donor cornea had been treated with LASIK[4] surgery.

24. Prior refractive surgery (such as LASIK) on a cornea is listed as an exclusion for use in penetrating keratoplasty for the following reasons:

1. Flaps created by the laser can lead to variable amounts of keratocyte[5] necrosis, creating fibrotic scarring (manifesting as haze) at the flap interface;
2. The structural integrity of the cornea can be compromised, as the cornea may separate at the lasered plane during donor tissue preparation, or during the surgery; and
3. Long-term epithelial hyperplasia[6] is a possibility.

25. Dr B told HDC that the issue with the corneal tissue was not known by the Eye Bank prior to distribution of the tissue, nor was it detectable by him prior to commencing the surgery. He said that when he discovered the issue, it was neither practical nor safe to wake Ms A to explain what had happened. Dr B stated: "Had I done so she would almost certainly have lost the eye altogether."

26. Dr B further explained to HDC:

> "Because the existing graft had been removed, it was not possible to use this again, and I made the decision to use the fresh donor tissue even though it had had previous Lasik surgery performed on it. I believe that this was the correct decision to make because using the old graft tissue would have had no chance of success as this tissue was opaque and incapable of giving useful vision. I believed there was at least a chance that the new 'Lasik affected' donor tissue could work successfully and provide improved vision."

27. Dr B noted that although another donor cornea was available that day for the second patient on the surgery list, the cornea had been sourced from the same donor, and had also been treated with LASIK.

Post-surgery

28. The remainder of Ms A's surgery proceeded uneventfully, and she was kept in hospital overnight for observation. Dr B reviewed her at 7.15am the following day, and documented:

> "Can go home today,
>
> Script for Maxitrol drops,

[4] Corrective eye surgery in which a flap of the corneal surface is raised and a thin layer of underlying tissue is removed using a laser.
[5] Cells of the corneal stroma (structural tissue).
[6] The growth of too many epithelial cells in the eye.

QID [four times a day],

Has been given tape for eye shield, cleaning material."

29. Dr B did not disclose the issue with the donor cornea to Ms A when he reviewed her. He noted that she would need a follow-up appointment with a registrar the subsequent Thursday and Monday, and documented that he would be away over this time but would see Ms A when he returned on 5 March 2018.

30. Ms A was seen by the registrar at follow-up appointments on 22 February, 26 February, and 1 March 2018. A postoperative leak was managed successfully at these appointments. On 5 March 2018 — two weeks after her surgery — Ms A had her follow-up appointment with Dr B. He reviewed her left eye and noted that her sutures looked satisfactory and the epithelium was intact, and that although there were no leaks, there was a mild corneal haze. At this appointment, Dr B first mentioned the LASIK issue with Ms A's new corneal graft. He documented: "[Impression]: doing ok … told about LASIK/donor issue, see Friday."

31. Ms A told HDC that when Dr B reviewed her the day after her surgery, he advised her that the surgery had gone well. She stated that she was shocked when she was told about the LASIK issue two weeks later.

32. Dr B agreed that he did not tell Ms A about what had happened immediately after the surgery, and stated:

> "I made the decision — which might be considered wrong — that telling her immediately after surgery when she was still getting over the actual operation would not change the situation and would cause unnecessary additional stress at that point. I did so as soon as I could after this."

33. Dr B told HDC that had there been a necessity to inform Ms A at that time, for example if there had been a need to return her to theatre acutely for whatever reason, he would absolutely have done so. However, as there was not, he decided that he should inform Ms A at a time when he could explain fully what had occurred, and when she had a support person present. He explained that when he reviewed Ms A at 7.15am on 20 February 2018, he had to start work elsewhere at 8am, and he considered there to be insufficient time for such a discussion. Dr B noted that when he did tell Ms A about the corneal graft issue, he spent a significant amount of time talking to her about it, and did so again on a separate occasion when she came in with a support person.

34. Ms A told HDC that Dr B's comment about causing unnecessary stress was an assumption on his part, and that she would have preferred to have been told at the earliest opportunity possible, such as before she was discharged. She stated that waiting two weeks to be told only made things worse.

35. At the time of these events, the DHB had a policy for "Open communication (open disclosure)", of which Dr B was aware. The policy stipulated:

> "[The DHB] requires open communication with patients and their families as part of normal care and services. This includes when a patient suffers an adverse event under the care of [the DHB]. The process (including who leads the communication) relates to the level of harm. Initial communication should be as soon as practicable after the event is identified and information is to be provided in a planned way and a timely, open and honest manner."

36. The policy also notes that patients prefer to hear from the lead clinician responsible for their care, with whom they have rapport or previous contact. While it is less preferable to hear from managers, patients appreciate direct communication, and do not appreciate, and may be antagonised by, a perception that information is being withheld.

37. Unfortunately, Ms A's third corneal graft became opaque and vascularised, and subsequently failed.

Further information

Dr B

38. Dr B told HDC that subsequent to Ms A's surgery, he discovered a simple and reliable way to check corneal tissue prior to commencing surgery, which he believes will eliminate the problem. He stated that he used this method in a recent corneal graft to identify that the donor of the corneas had had LASIK, and he will be advising the Eye Bank of this detection method. He told HDC that he will also publish this method in a refereed medical journal to make it widely known.

The DHB

39. The DHB told HDC that no changes have been made to the service it provides in relation to corneal grafts, as currently there is no reliable method of identifying which patients have had LASIK refractive surgery.

The Eye Bank

40. The Eye Bank is the main facilitator for cornea donors in New Zealand, and was the supplier of the donor cornea used in Ms A's surgery of 19 February 2018. The current Eye Bank standards relating to exclusionary eye history for donor tissue state that tissue with previous corneal surgery involving incision is not suitable for donation. Further, the standards state that corneas that have undergone refractive surgery should not be used for penetrating or anterior keratoplasty owing to concerns about structural integrity of the cornea.

41. A spokesperson for the Eye Bank provided HDC with a response to this complaint on behalf of the Eye Bank. She stated that there are inherent risks and difficulties involved when transplanting donated human tissue such as corneas, and that the main objective is to ensure as much as possible that a cornea will function in an acceptable optical and physiological manner, and not be the source of any potentially transmissible disease.

42. The spokesperson told HDC that the Eye Bank faces many difficulties when screening for suitable corneal tissue. She stated:

> "Eye donors are always deceased persons. Therefore, post-mortem medical history screening relies on both obtaining documented medical history, and interview of a donor's close relative (and possibly [general practitioner]) to fully ascertain presence of exclusionary criteria, or high risk factors due to lifestyle practices. It is inherently second-hand and not able to be obtained from the donor themselves. In both of these areas, it can be difficult for [the] Eye Bank or staff performing such screening, to ascertain with any certainty whether the donor had previous refractive surgery. Donor history screening is only as effective as the knowledge able to be determined."

43. As well as using post-mortem medical history and interviews with the donor's family, the Eye Bank's screening of donor corneas includes the use of ophthalmic slit-lamp examination of the donated eye, and light microscopy of the corneal endothelium. However, both of these microscopic evaluations are rarely able to detect the presence of previous refractive laser surgery. The spokesperson explained that newer evaluation modalities potentially include corneal topography[7] and optical coherence tomography (OCT).[8] However, she stated that owing to the prohibitive cost of the equipment, it is seldom used in eye banks, and there is still no guarantee that previous refractive surgery will be identified.

44. The spokesperson concluded that post-mortem medical history, interviews of family, slit-lamp examination, and microscopic examination are all error-prone and imprecise mechanisms of identifying donors with a history of refractive surgery, and even modern modalities are not likely to demonstrate effectiveness in identifying these corneas in all cases.

45. The spokesperson told HDC that because of the high rate of patients treated with refractive surgery worldwide, and the inability to detect such procedures every time, it is without doubt that eye banks have inadvertently issued such corneas for penetrating keratoplasty, although there are only a small number of published papers addressing known cases, and poor outcome does not necessarily eventuate. She stated:

> "Significant focus remains on the ability to identify corneas that have undergone refractive surgery to prevent potential complications or poor visual outcomes in penetrating keratoplasty recipients."

Responses to provisional opinion

Dr B

46. Dr B was provided with the opportunity to comment on the provisional opinion, and his comments have been included in the report where relevant.

[7] A computerised test that maps the curve of the cornea and can show problems with the eye's surface, such as swelling or scarring, or conditions such as astigmatism.

[8] A non-invasive technique that uses light waves to take three-dimensional images of structures inside tissues and organs.

The DHB

47. The DHB was provided with the opportunity to comment on the provisional opinion, and advised that it had no comments to make.

Ms A

48. Ms A was provided with the opportunity to comment on the "information gathered" section of the provisional opinion, and her comments have been included in the report where relevant.

Opinion: Dr B

Continuation of surgery — no breach

49. On 19 February 2018, Dr B performed a third left eye corneal transplant on Ms A in a further attempt to restore vision in her affected eye. The corneal tissue for the surgery — sourced from the Eye Bank — had been treated with LASIK, therefore making it unsuitable for Ms A's penetrating keratoplasty surgery.

50. Dr B told HDC that the issue was not detectable by him prior to commencing the surgery. My expert advisor, ophthalmologist Dr Brian Kent-Smith, advised that it was reasonable that Dr B was unable to detect the issue with the donor cornea. Dr Kent-Smith stated:

> "The amount of tissue removed during LASIK is of the order of microns (a micron is a thousandth of a millimetre). It is not possible to see this with the naked eye and even under an operating microscope it can be very difficult to detect. This is evidenced by the fact that the previous LASIK went undetected by the eye bank too and is a recognised problem worldwide."

51. The Eye Bank told HDC that it faces many difficulties when screening for suitable corneal tissue, and that post-mortem medical history, interviews of family, slit-lamp examination, and microscopic examination are all error-prone and imprecise mechanisms of identifying donors with a history of refractive surgery. The Eye Bank stated that although new technologies are becoming available, there is still no guarantee that previous refractive surgery such as LASIK will be identified.

52. It is evident that this complaint highlights a global issue with the screening of corneal tissue. Once Ms A's surgery had begun and the donor tissue was ready to be sutured to Ms A's eye, the issue with the graft tissue was discovered. Dr B proceeded with the affected cornea and did not wake Ms A to explain the issue. Dr B told HDC that it would have been impractical and unsafe to wake Ms A to explain what had happened once the issue had been discovered. He stated that if he had done so, Ms A would almost certainly have lost the eye altogether.

53. My expert advisor agrees with Dr B's statement, and believes Dr B had little choice but to proceed as he did. Dr Kent-Smith advised:

> "Once the original, damaged cornea had been removed the eye was open, exposing the intra-ocular contents. To have woken [Ms A] from general anaesthesia with an open eye would have created significant risk of the intra-ocular contents being expelled from the eye. This would have resulted in a permanently blind eye."

54. Dr B considered that continuing with the surgery was the correct decision to make, because using the old graft tissue would have had no chance of success, as the tissue was opaque and incapable of giving useful vision. He stated: "I believed there was at least a chance that the new 'Lasik affected' donor tissue could work successfully and provide improved vision."

55. Dr Kent-Smith advised that under the circumstances, the standard of care that Dr B provided to Ms A was appropriate, and that another corneal surgeon would quite likely have made the same decision.

56. I am guided by this advice and the facts of this case. I consider that Dr B's choice to continue with the surgery was reasonable, owing to the risks of waking up Ms A, and with the chance that the new donor tissue could work successfully and provide improved vision. Accordingly, I do not find Dr B in breach of the Code of Health and Disability Services Consumers' Rights (the Code) for failing to identify the issue with the cornea and for continuing the surgery once the issue had been identified.

Open disclosure — breach

57. The remainder of the surgery proceeded uneventfully, and Ms A was kept in hospital overnight for observation. The following day, Dr B reviewed Ms A and told her that the surgery had gone well. He noted that she could go home with a script for eye drops, and tape and cleaning material for her eye shield. He also noted that he was going on leave and would see Ms A when he returned on 5 March 2018. Dr B did not disclose the issue of the LASIK-treated cornea when he reviewed Ms A on the day after the surgery, and did not tell her what had happened until two weeks later, when he had returned from leave.

58. My expert advisor, Dr Kent-Smith, stated:

> "I can speculate as to the reason [Dr B] didn't discuss the donor tissue on the day-1 review. Typically on a day-1 check the primary concerns are to check that the graft is intact, the wound is sealed and the patient is comfortable. The fact that the donor tissue was from a person who had previous LASIK would not have affected any management decisions at that stage. That said, [Ms A's] desire to understand the details of her procedure and any potential complications is understandable and is her right."

59. Dr Kent-Smith advised that if a departure from the standard of care occurred, he would consider it to be relatively minor in the circumstances.

60. At the time of these events, the DHB had a policy in place regarding open disclosure, which Dr B was to follow. It detailed that "[i]nitial communication should be as soon as

practicable after the event is identified and information is to be provided in a planned way and a timely, open and honest manner".

61. Dr B told HDC that he was aware of the policy, but he considered that telling Ms A of the issue immediately after surgery when she was still getting over the actual operation would not change the situation, and would cause unnecessary additional stress. He said that he decided to inform Ms A of the LASIK issue at a time when he could fully explain what had occurred and when she had a support person present.

62. HDC's "Guidance on Open Disclosure Policies"[9] states that disclosure should be made in a timely manner, usually within 24 hours of the event occurring, or of the harm or error being recognised. Consumers have a right to know what has happened to them, and open disclosure should occur where a consumer has been exposed to possible harm, irrespective of whether harm has occurred or is immediately apparent. While it was not immediately apparent that the LASIK-treated cornea had caused Ms A any harm, the fact was that using such tissue had a greater chance of complications, exposing Ms A to a greater risk of harm.

63. When Dr B did tell Ms A about the corneal graft issue, he spent a significant amount of time talking to her about it, and did so again on a subsequent occasion when she attended with a support person. However, in my view, Dr B had an opportunity to inform Ms A about the issue at her follow-up review on 20 February 2018, and I am critical that this did not occur at this time. It was not for Dr B to decide that the news of the compromised cornea would cause unnecessary stress for the patient. The patient had the right to be told in a timely manner. Accordingly, I find Dr B in breach of Right 6(1) of the Code.[10]

Opinion: DHB — no breach

64. As a healthcare provider, the DHB is responsible for providing services in accordance with the Code. Ms A attended the DHB on 19 February 2018 to undergo her third corneal transplant with Dr B.

65. The donor cornea provided by the Eye Bank had had LASIK surgery performed on it; however, this was not discovered by Dr B prior to commencing the surgery. Only once the surgery had begun and the tissue had been inserted into Ms A's eye, did Dr B notice the issue.

66. As stated above, there are global limitations to screening donor corneal tissue for refractive surgery such as LASIK. The DHB told HDC that currently there is no reliable

[9] Available at: https://www.hdc.org.nz/media/5372/guidance-on-open-disclosure-policies.pdf
[10] Right 6(1) states: "Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive …"

method of identifying which patients have had LASIK refractive surgery. My expert advisor agreed, and stated:

> "[T]he amount of tissue removed during LASIK is of the order of microns (a micron is a thousandth of a millimetre). It is not possible to see this with the naked eye and even under an operating microscope it can be very difficult to detect. This is evidenced by the fact that the previous LASIK went undetected by the eye bank too and is a recognised problem worldwide."

67. I do not consider that there was anything the DHB could have done to identify the LASIK-treated cornea and prevent it from being used in Ms A's surgery.

68. After the surgery, Dr B reviewed Ms A on 20 February 2018 and advised her that the surgery had gone well. He then went on leave, and next saw Ms A on 5 March 2018 — two weeks after the surgery — and disclosed the issue with the corneal graft.

69. As the surgeon who performed Ms A's surgery, it was Dr B's responsibility to disclose any adverse or unexpected outcomes that occurred in a timely matter. At the time of these events, the DHB also had a policy in place for Dr B to follow, which stated:

> "Initial communication should be as soon as practicable after the event is identified and information is to be provided in a planned way and a timely, open and honest manner."

70. My expert advisor believes that the policy in place was satisfactory. He advised that overall the policy document reads very well and conveys a sense of full and honest disclosure following an adverse event. However, he noted that the policy could be improved by providing guidance on what to do in the event that the lead clinician is not available.

71. I am satisfied that the DHB's policy for open disclosure in place at the time of these events was adequate, and that Dr B was aware of the guidelines. Despite the policy not being clear on the process to follow if the lead clinician is unavailable, I consider that if Dr B had followed the policy after his discovery of the LASIK-affected cornea, he would have disclosed the issue to Ms A before he went on leave. In this case, I consider that Dr B's omission was an individual decision, and does not indicate broader systems or organisational issues at the DHB. In light of the above, I do not find the DHB in breach of the Code.

72. Whilst I do not find the DHB in breach of the Code, I agree with my expert's comment above. I recommend that the DHB update its "Open Communication (Open Disclosure)" policy to provide further clarification on situations where the lead clinician is unavailable, and when it is acceptable for other staff members to disclose such information on the lead clinician's behalf.

Recommendations

73. I recommend that within three months of the date of this report, Dr B:

a) Review HDC's "Guidance on Open Disclosure Policies" and identify areas for improvement in his practice, and provide confirmation to HDC that this has been done.

b) Provide HDC with an update on his communication with the Eye Bank regarding his newly discovered method of checking corneal tissue prior to commencing surgery.

c) Provide an apology to Ms A for delay in open disclosure, as outlined in this report. This apology is to be sent to HDC within three weeks of the date of this report, for forwarding.

74. I recommend that the DHB consider updating its "Open communication (open disclosure)" policy to include guidance on what to do when a lead clinician is not available, in line with Dr Kent-Smith's advice. The outcome of this consideration is to be communicated to HDC within three months of the date of this report.

75. I recommend that the Ministry of Health consider asking all clinics that perform corneal transplants to include this issue as a potential risk in the consent process. The outcome of the consideration is to be communicated to HDC within three months of the date of this report.

76. I recommend that the Eye Bank consider the issues identified in this report that relate to the checking of corneal donor tissue, and consider trialling the use of optical coherence tomography machines to screen donor corneal tissue for previous laser surgery. The outcome of the consideration is to be communicated to HDC within three months of the date of this report.

Follow-up actions

77. 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.

78. 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.

79. A copy of this report with details identifying the parties removed, except the expert who advised on this case, will be sent to the Director-General of Health (Ministry of Health) and the Eye Bank, and will be published 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 ophthalmologist Dr Brian Kent-Smith:

"18HDC01420

Introduction:

On 19 February 2018 [Ms A] underwent left penetrating keratoplasty (corneal transplantation) at [the DHB]. The surgery was performed by [Dr B]. During surgery, and after removal of the existing cornea, it was discovered that the donor tissue had undergone previous LASIK surgery. [Dr B] made the decision to proceed with surgery using the previously laser-treated cornea. [Dr B] examined [Ms A] on day-1 post-op and then went on leave. He arranged for [Ms A] to be seen by the registrar in his absence. At his follow-up appointment following return from leave on 5 March 2018 he advised [Ms A] about the LASIK-treated donor.

I have been provided with the following information:

1. Letter of complaint dated […].
2. [Dr B's] response dated [2018].
3. [Dr B's] response dated [2019].
4. Clinical records from [the DHB] covering the period from 19 February 2018 to 5 March 2018.
5. [The DHB's] open disclosure policy.
6. Information from The Eye Bank.

Background of complaint:

[Ms A] has keratoconus, a condition that causes thinning and bulging of the cornea with an associated reduction in vision. She had undergone two previous corneal transplants in her left eye and these had both failed. On 19 February 2018 she had a third attempt at corneal transplantation in her left eye. The donor cornea was cut to size and the existing, damaged cornea was removed. Prior to suturing the donor into place it was discovered that it had undergone previous LASIK surgery. Another cornea was available in theatre but it was from the same donor and it too had undergone LASIK surgery. [Dr B] made the decision to proceed with surgery, using the LASIK-affected donor cornea. In the post-operative period there was a leak of fluid from the graft-host interface but this resolved with a bandage contact lens and medications. Unfortunately the corneal transplant has subsequently failed, becoming opaque and vascularised.

Question 1: Was it reasonable to proceed with surgery once the LASIK issue was discovered?

I believe [Dr B] had little choice but to proceed as he did. Once the original, damaged cornea had been removed the eye was open, exposing the intra-ocular contents. To have woken [Ms A] from general anaesthesia with an open eye would have created significant risk of the intra-ocular contents being expelled from the eye. This would have resulted in a permanently blind eye. The second donor cornea was from the same donor and had also undergone LASIK surgery. [Dr B] could have replaced the original, damaged cornea but it was a failed graft ([Ms A's] second transplant) and was the reason for doing the procedure on the 19th February.

Under the circumstances I believe the standard of care was appropriate and another corneal surgeon would quite likely have made the same decision. [Dr B's] assertion that the LASIK-affected donor tissue could give improved vision is reasonable. Given the millions of people around the world who have undergone LASIK surgery, and given the difficulty in identifying those corneas that have undergone the procedure, it is highly likely that many people have been given LASIK-affected corneas unbeknown to themselves or their surgeons.

Question 2: The significance of using a LASIK-affected cornea.

A typical cornea is approximately 550 microns thick in the centre. During LASIK a flap is cut and lifted up. The flap is typically 120–160 microns thick. A predetermined amount of the underlying corneal stroma is removed by the laser, approximately 12–14 microns per dioptre of correction. For example a person whose pre-operative prescription is -3.50 might have 40 microns of corneal stroma removed. The flap is then replaced over the laser-treated cornea.

Cornea that has been treated by LASIK has been slightly thinned and flattened. It is possible that LASIK-affected corneal tissue may be less viable in the longer term. The flap might separate from the underlying cornea, thinning it further. LASIK-affected corneas may still be used for endothelial donation (the innermost lining of the cornea) but not usually for full thickness transplants.

Question 3: Was it reasonable that [Dr B] did not detect the laser treated donor earlier?

Yes it was reasonable. As mentioned above the amount of tissue removed during LASIK is of the order of microns (a micron is a thousandth of a millimetre). It is not possible to see this with the naked eye and even under an operating microscope it can be very difficult to detect. This is evidenced by the fact that the previous LASIK went undetected by the eye bank too and is a recognised problem worldwide.

I don't believe this represents a departure from standard of care.

Question 4: The decision to wait two weeks before advising [Ms A] of the potentially defective tissue.

[Ms A] has asked why she was not woken up from anaesthesia to make the decision when the problem with the donor tissue was identified. Her defective cornea had already been removed and it would not have made any sense to suture it back into position. To have woken her with an open wound in her left eye would have put her at considerable risk of expulsion of the intra-ocular contents and left her with an irretrievably blind eye. I believe [Dr B] had little choice but to make the decision he did at the time.

The notes indicate that [Dr B] examined [Ms A] at 7:15am on the 20th February, day-1 post-op. It appears she was examined in her hospital bed rather than in the clinic. He established that the eye looked good and prescribed post-operative drops. He requested a follow-up appointment with the registrar. [Dr B] went on leave and [Ms A] was seen by the registrar in his absence.

[Ms A] was examined by the registrar on multiple occasions. On 26/02/2018 a wound leak was identified and successfully treated with a bandage contact lens and medications.

The first note by [Dr B] following his return from leave is dated 05/03/2018. At that appointment he has documented the fact that he advised [Ms A] about the LASIK donor issue.

I can speculate as to the reason [Dr B] didn't discuss the donor tissue on the day-1 review. Typically on a day-1 check the primary concerns are to check that the graft is intact, the wound is sealed and the patient is comfortable. The fact that the donor tissue was from a person who had previous LASIK would not have affected any management decisions at that stage. That said, [Ms A's] desire to understand the details of her procedure and any potential complications is understandable and is her right.

One could argue that one of the other clinicians should have told [Ms A] about the donor sooner. It might be that they didn't do so as they were waiting for the operating surgeon ([Dr B]) to return from leave, or it might be that they didn't think it would affect any clinical decisions for the foreseeable future. They successfully dealt with a leaking wound and it is possible the focus was on that.

If a departure from the standard of care occurred I would consider it to be relatively minor in the circumstances.

Question 5: The adequacy of [the DHB's] policy on open disclosure.

I have read [the DHB's] policy entitled 'Open communication (open disclosure).' This states, inter alia that 'Initial communication should be as soon as practicable after the event is identified'. It gives advice on who should inform the patient, typically the lead clinician. In this instance the lead clinician went on leave shortly after the surgery and

the patient was looked after by other members of the team. I was unable to find any guidance on this particular scenario in the policy.

Overall the policy document reads very well and conveys a sense of full and honest disclosure following an adverse event. The policy states 'Patients prefer to hear from the lead clinician responsible for their care, with whom they have rapport or previous contact. While it is less preferred to hear from managers, patients appreciate direct communication and do not appreciate, and may be antagonised, where it is perceived that information is being withheld.'

It might be helpful for the policy to give guidance on what to do in the event that the lead clinician is not available. In [Ms A's] case the adverse event could have been explained to her by the clinicians who took over her care from [Dr B]. I believe this represents a minor deviation from standard of care."