Plastic and Reconstructive Surgeon, Dr D

A Report by the

Health and Disability Commissioner

(Case 99HDC00541)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Complaint

The Commissioner received a complaint from the consumer, Ms A, about the treatment she received from the provider, Dr B. The complaint was that:

- *Ms A consulted Dr B on 13 August 1997 to discuss upper eyelid rejuvenation.*
- *Dr B persuaded Ms A that lower eyelid lipo-infiltration was also needed and on 2 April 1998 Dr B performed corrective surgery to Ms A's upper and lower eyelids.*
- *Dr B did not inform Ms A about possible complications of lipo-infiltration. If he had done so she would not have had the procedure done.*
- *Two months after surgery Ms A complained of persistent asymmetry of the right upper eyelid fold and lumpiness of the left infra-orbital region.*
- *Ms A was reviewed by Dr B on 15 July 1998. Dr B noted persistence of the superficial deposits of the left infra-orbital region and offered to correct this asymmetry and to revise the upper eyelid fold.*
- *The second operation took place on 1 October 1998 at a private hospital, under general anaesthetic.*
- *Ms A was reviewed by Dr C on 30 October 1998. She was unhappy with the result of her left lower eyelid revision. She complained of a residual lump and a small concavity at the junction of the eyelid skin with the orbital margin.*
- *Ms A "wants her old face back". She wants Dr B to take responsibility for the problems she has had with her eyelid surgery. She also wants Dr B to pay the second hospital and anaesthetic bills as well as the cost of any future corrective surgery.*

Investigation process

The Commissioner received the complaint on 13 January 1999 and an investigation was commenced on 30 March 1999. Information was obtained from:

Ms A	Consumer
Dr B	Provider / Plastic and reconstructive surgeon

Relevant clinical records were obtained and viewed. The Commissioner obtained advice from an independent plastic and reconstructive surgeon.

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Information gathered during investigation

Dr B is a plastic and reconstructive surgeon. He attended an advanced aesthetic surgery workshop at an overseas University in February 1997 and has been using the technique of Lipostructure™ or Lipoinfiltration since then. The technique was pioneered by Dr D and involves transplanting small amounts of refined fat from the abdomen or thigh within the body for the purpose of making structural improvements. Dr B advised the Commissioner that he initially applied the technique to cases of traumatic atrophy of fat tissue such as facial and lower limb trauma. Following success with several trauma patients Dr B began applying it to consumers complaining of subcutaneous atrophy in the eyelids, upper cheeks and lip areas. Dr B advised the Commissioner that he has performed lipostructure on approximately 20 consumers since he first began using the technique.

Ms A was acquainted with one of Dr B's relatives, upon whom he had performed eyelid rejuvenation surgery (blepharoplasty). Ms A was impressed with the results and wrote to Dr B on 7 January 1997 requesting information about the cost of a consultation and an "upper eyelid operation". Ms A also queried what laser treatment was available and whether an overnight stay in hospital was required for upper eyelid surgery.

Dr B wrote to Ms A on 15 January 1997. He informed her that blepharoplasty was one of the rejuvenative surgery options available and indicated it was:

> "[T]he standard operation done to remove excessive skin and fat pads from the eyelids and in selected patients a tightening of the capsulopalpebral ligament of the lower eyelid to the orbital septum to give the lower eyelid a shorter vertical height and more youthful appearance."

Dr B noted that laser resurfacing was better suited for the very fine ageing lines in the skin but was being used frequently for the lower eyelids. He also noted that while some surgeons believed swelling and bruising were reduced with the laser, he preferred to use a scalpel blade.

Dr B advised Ms A in the letter that the operation would be performed under local anaesthetic with sedation and that she might need to spend a night in hospital. He indicated that the consultation would cost $95.00, with a surgical fee of $1,500.00 plus GST.

Ms A wrote to Dr B on 7 February 1997 querying the cost of the procedure and whether upper eyelid surgery could be performed at his rooms.

Ms A consulted Dr B on 13 August 1997. Dr B advised the Commissioner that Ms A indicated she wanted her upper eyelids done but was actually concerned about hollowness and a tired look under her eyes. He advised that "lipo-infiltration was [his] interpretation of her request".

Ms A advised the Commissioner that Dr B talked about the various techniques available but was "gung ho" about lipo-infiltration and presented it as a very positive option. She said he made it sound like a very simple procedure and told her he would make a few cuts, take fat

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out of her stomach or leg and inject it under her eyes. She said he told her the fat would be sculpted like clay to achieve the desired look.

During the consultation Dr B established that Ms A was a smoker and indicated that she should not smoke for at least one month prior to surgery and for six weeks afterwards. Ms A said she knew, prior to any and every surgery, that people who smoke are told to stop and that this had to do with oxygen being received. She said she understood the instruction was so she would make a better and quicker post operative recovery. Ms A said she did not understand that the operation would not succeed if she smoked.

Dr B advised the Commissioner that smoking is considered a definite contra-indication for cosmetic surgery of any kind and that much of the consultation focused on this issue. He said he told her quite a lot about the risks of smoking, that there would be a lot of swelling with this technique and more bruising than would be experienced with standard cosmetic surgery techniques. Dr B indicated that the information provided to Ms A was recorded in a letter he sent to her immediately following the consultation. In that letter, which was dated 13 August 1997, Dr B noted that Ms A specifically wanted:

> "… correction of the lower eyelid and tear trough areas where you rightly perceive that there has been an increasing hollowing of the soft tissues of your lower eyelids which is consistent with the shrinkage of the fat layer of the face in this area with ageing".

Dr B noted that Ms A was a smoker and that this was a significant risk factor for any corrective surgery. He also commented on a "prominent superficial vein running obliquely across the lateral aspect of [her] right lower eyelid".

Dr B recorded a discussion about standard blepharoplasty, laser resurfacing and lipo-infiltration or lipostructure. He wrote:

> "Lipostructure has been popularised by [Dr D] from [overseas] and involves the harvesting by atraumatic technique of some of your own fat from either the lower abdomen or thighs and this fat is then refined in a Centrifuge and reinjected as small fat parcels in to the soft tissue layers of the region that needs structural support.
>
> In your case the infiltration of your own refined fat in to the infraorbital and eyelid regions would correct the contour deformity and also improve the texture of the skin and give the excess skin somewhere to go so that this has the overall effect of rejuvenating the appearance of the lower eyelids to produce a more youthful appearance. It may be necessary to remove the small superficial vein although I suspect that with infiltration of fat around this area the vein would be less prominent under the skin and a decision about this would need to be made at the time."

Ms A was advised in the letter that the surgery could be performed under local anaesthetic in Dr B's rooms, and that the bruising and swelling could take up to three or four weeks to resolve. She was advised that she would have to stop smoking for at least one month beforehand and six weeks afterwards because "one cigarette causes fifty minutes of tissue ischaemia [oxygen reduction] and this would almost certainly result in poor take of the small fat parcel grafts which would then lead to fat liquefaction [fat necrosis or dying tissue], infection and possible abscess formation".

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Dr B offered to perform surgery on both Ms A's eyelids for $1,250.00, including GST.

Dr B subsequently sent Ms A an article written by Dr D. He also enclosed a hand written consent form.

Dr D's article, entitled "*The Technique of Periobital Lipoinfiltration*", discussed uses, preoperative manoeuvers, technique, postoperative care and evaluation of post-operative results. Complications identified by Dr D included underinfiltration (too little fat implanted), overinfiltration (too much fat implanted), migration (overfilling forcing implanted fat into an unplanned or improper location), clumping (caused by uneven filling) and infection (which Dr D recorded could often be traced to breaks in sterile technique). Other problems included bruising, oedema, induration [abnormal hardening of tissue] and "… prolonged erythema [flushing of the skin] at the incision sites".

The consent form provided by Dr B indicated:

> "The technique of lipostructure has been personally explained to me by [Dr B] and I completely understand the nature and consequences of the procedure. The following points have specifically made clear:
>
> 1. There will be small scars from the injection sites.
> 2. There will be swelling and bruising of the eyelids of the face which can persist for several weeks.
> 3. There is possibility of temporary injury to the nerves supplying the skin and muscles in the periorbital area.
> 4. Infection is possible in any type of surgery including lipostructure.
> 5. I agree that I will not smoke cigarettes for four weeks prior to surgery and for 8 weeks after surgery."

The consent form was signed by Ms A on 21 August 1997.

Ms A advised the Commissioner that she knew there would be bruising, swelling and possible nerve damage but "these were not presented as risks, more like side effects". She said she did not know what fat liquifaction was and that fat necrosis was never mentioned.

Dr B advised the Commissioner that "side effects and risks are all the same thing". He indicated that no surgery is free of side effects or risks and that risks are about "risk management". He said this is achieved by careful selection of patients for the operation plus making sure the surgeon is properly trained and that the surgery is performed in proper facilities. Dr B indicated that complications associated with the technique were listed in Dr D's article but he (Dr B) does not dwell on complications and does not want to talk a patient out of surgery unnecessarily. Dr B indicated that his consent form listed the complications, which are technique related and mostly avoidable, taken from Dr D's article.

Ms A advised the Commissioner that Dr B did not discuss Dr D's article with her. Dr B was unable to recall whether any discussion took place.

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Ms A advised the Commissioner that she decided to have lipo-infiltration because Dr B was so convincing and sold her on the procedure. She said he convinced her he was knowledgeable and capable and that it was a simple procedure.

Dr B advised the Commissioner that Ms A made the decision to have lipo-infiltration based upon his evaluation of her facial form, subcutaneous atrophy and a discussion of the options available, including standard blepharoplasty, laser resurfacing and the risks posed by her smoking history. He advised that lipoinfiltration offered the best choice for creating a more youthful appearance with respect to the lower eyelids and that a "modest skin only upper eyelid reduction would also be appropriate".

Ms A was asked to supply photographs of herself at ages 20 and 30 to enable Dr B to estimate and plan the surgical procedure.

Ms A wrote to Dr B on 26 August 1997 enclosing the photographs he requested. She indicated:

> "Thank you for the article on Lipoinfiltration. Also, thank you so much for your discounted fee. I do appreciate it.
>
> As I look at the photos I notice a difference between 20 and 33 years of age. The glamour shot is different again. I believe that at the time this glamour shot was taken, I was around 38. I do notice more fullness when I was 20 that's for sure.
>
> I hope these help you. I must admit a slight fear, but I know you will do a great job.
>
> …
>
> I do understand the smoking issue and may get acupuncture done. I'd rather do it this way to relieve the stress that I would experience if I was to do it cold turkey. I wouldn't want my mind and body to be stressed at the time of the Lipoinfiltration.
>
> [Dr B], I just have one question. When I lose weight it tends to start in my face and work its way down. I'm not planning to lose any, but if I did, how would that affect my face. Would my cheekbones drop and the fat that has been put under my eyes stay where it is? I have drawn a picture. I hope this question makes sense. …"

On 7 September 1997 Dr B wrote to Ms A. He thanked her for her photos and indicated:

> "These photographs are very interesting when compared to the most recent ones I have taken of you which show quite a significant loss of subcutaneous tissue in the tear trough area of your lower eyelids with a vertical lengthening of your lower eyelid as a result.
>
> There has also been a significant loss of subcutaneous tissue over the prominence of your cheek bones.
>
> I therefore believe that as recommended, lipoinfiltration with your own refined fat grafts would give you the best aesthetic improvement at this stage and the diagram that you have drawn in your letter asking about the separation between the tear trough and the cheek area; my response would be that with the lipoinfiltration we would hope to fill in this area

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> so that there is a smooth contour between your lower eyelid extending inferiorly on to your cheek prominence.
>
> Please do not hesitate to get back to me if you have any further questions about this."

Surgery was scheduled for 30 October 1997 but was postponed due to Dr B's planned overseas travel which meant he would not be available for post-surgical follow-up. Dr B's clinical record dated 30 October 1997 noted that Ms A had been making "great efforts to give up smoking over the last month and in fact has not had a cigarette for two weeks". Surgery was re-scheduled for 19 November 1997.

Ms A's surgery was carried out on 2 April 1998. Clinical notes recorded:

> "Fat was … harvested using [Dr D's] technique from both lower medial thighs and then refined in the centrifuge.
>
> A total of 3 ccs of refined fat was infiltrated in to each lower eyelid infraorbital region to correct the hollowness and contour defect. The fat was infiltrated both in the orbicularis layer and in the subcutaneous layer."

Ms A advised the Commissioner that she had one or two cigarettes in the two weeks prior to the surgery and did not smoke straight after surgery. She indicated that she would then have the "odd puff" but was not smoking chronically. Ms A said she was struggling but did "extremely well". She said that when she saw Dr B on 8 April 1998 he told her she was healing well and said "see what not smoking does". Ms A said she drank a lot of water and Dr B was pleased with how she was looking after herself.

Dr B said he suspected Ms A had been smoking post operatively. He said she admitted slipping up a couple of times but his recollection was that she was smoking according to her usual (10-15 per day) habit. Dr B advised the Commissioner that he warned Ms A there could be a loss of fat grafts if she continued to smoke and indicated that fat grafts can be lost up to three months after surgery because the process of revascularisation (the re-development of blood vessels within tissue) takes some time. The issue of smoking was not documented in the clinical notes.

Dr B's clinical notes recorded that Ms A's upper eyelid sutures were removed and that the area had healed well. It was noted that there was some obvious swelling and bruising of the lower eyelids consistent with lipo-infiltration. Photographs were taken and it was agreed that Ms A would return in one month's time. Dr B advised the Commissioner that Ms A admitted to having disturbed the right upper eyelid suture during the night by pulling on the thread near the eyebrow which caused a puckering and distortion of the scar compared to the left upper eyelid scar.

Ms A consulted Dr B on 17 June 1998. Dr B's clinical note recorded some minor asymmetry of the right supra-tarsal fold which he attributed to Ms A having pulled on the suture post-operatively. Dr B advised the Commissioner that it was evident Ms A had not kept to the 'no-smoking' policy and that Ms A confirmed this. He said he expressed his dismay at her

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"inability to co-operate with instructions" with respect to her interference with the sutures and that she was smoking when he had told her not to.

Ms A advised the Commissioner that this was three months after the surgery and that, while she was probably back to smoking 10-15 cigarettes a day, "this was way past the date [she] was told not to".

Dr B documented redness and queried fat parcels. He prescribed the antibiotic Augmentin. Dr B advised the Commissioner that with the degree of inflammation experienced by Ms A smoking was a definite contra-indication. He said he suspected the area was inflamed because of fat necrosis and took a biopsy of the area in order to confirm this.

Dr B advised the Commissioner that Ms A was very distressed and his aim was to try to get her through his period. He said he told her he thought the area would settle and that he wrote a letter to her afterwards because she made a "big deal" about her upper eyelid, which was a result of her pulling on a suture and causing distortion of the scar.

In his letter to Ms A dated 17 June 1998, Dr B acknowledged her unhappiness with the asymmetry of her infraorbital regions. He recommended she regularly massage the area with Vitamin E or other moisturiser for three months to help soften the scars. He noted that if the infraorbital region did not settle down he would revise this at no extra charge.

Ms A consulted Dr B on 15 July 1998. Dr B advised the Commissioner that Ms A was not happy with the persisting lumpiness of the fat grafts and the relative asymmetry of her right upper eyelid. He said she had to be reminded that the asymmetry of her own doing. Dr B advised Ms A that these were minor complications and could be corrected under local anaesthetic in his office minor theatre, at no extra charge. Ms A was offered a second opinion but declined it.

Clinical notes record:

> "[Ms A] was reviewed again at […] on the 15.7.98. She still has some superficial fat deposits from the fat grafting of the left infraorbital margin and these are not shrinking and I think she would benefit from a lower lid blepharoplasty to tighten her lower eyelid skin and at the same time these redundant fat grafts could be trimmed. She would also need a minor right lower blepharoplasty and ligation of the superficial vein that is prominent here.
>
> The plan is to wait at least three more months and we will schedule her for surgery in October 1998 at the Rooms and she will need some oral sedation when she arrives.
>
> No further charge will be made for this surgery."

Ms A wrote to Dr B on 18 July 1998 complaining about the asymmetry of her left infraorbital region and detailing the effects her appearance was having on her life. She advised Dr B that she wanted her old face back.

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Dr B's clinical notes dated 22 July 1998 record:

> "[Ms A] wrote to me on the 18.7.98 with a lot of concerns about the asymmetry of her left infraorbital region where there is some superficial fat graft that has displaced and will probably need trimming in October. She also perceives some asymmetry of her right upper supratarsal fold where there was some concertinaring of the wound margins when she accidentally pulled on the suture post operatively and I have said I am happy to revise this for her as well.
>
> I phoned her at work today and she assured me that she does not want to sue me and that she does not want a second opinion. She accepts my advice about waiting for six months post op before attempting any further revision and she is also now happy about having it done here at the rooms under local anaesthetic because I think this will be safe and hospitalisation is not necessary."

Ms A was reviewed by Dr B on 9 September 1998. Dr B advised the Commissioner that it was decided Ms A would have her revision surgery at the private hospital under general anaesthetic, rather than at his rooms. He advised that, under the circumstances, he considered it a wise decision given her anxiety levels. Dr B stated that he made it clear to Ms A he would not charge her any further surgeon's fees but that hospital and anaesthetist fees would be her responsibility.

Clinical notes recorded:

> "I saw [Ms A] again on the 9.9.98 at the […] surgery where we discussed plans for her further periobital aesthetic surgery.
>
> She has agreed to have the surgery done under local anaesthetic with sedation at [the private hospital] on the 1.10.98 and the plan is to do bilateral lower eyelid skin only blepharoplasties with ligation of the superficial vein on the right lower eyelid and recontouring of the fat grafts to the left lower eyelid.
>
> She also wants a small excess of skin excised from the medial right upper eyelid scar."

The second surgery was performed on 1 October 1998. Dr B advised the Commissioner that he revised Ms A's right upper eyelid scar, coagulated a superficial vein in the right lower eyelid, resected the lumps of focal fat necrosis under the left lower eyelid and performed a conservative bilateral lower eyelid-skin only blepharoplasty.

The operation note also recorded:

> "The skin was very thin and she has been warned both pre and postoperatively to restrict all smoking activity because this will jeopardise the chances of healing of her eyelid incisions and also could end up with significant skin necrosis because of the thinness of her skin here."

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The Histology/Cytology Report dated 2 October 1998 indicated:

> "Clinical details:
> Previous fat grafts lower left eyelid.
>
> Macroscopic:
> Some irregular pieces of fatty tissue measuring up to 7mm.
>
> Microscopic:
> Sections show fibrous connective and adipose tissue with small amounts of striated muscle. Occasional microscopic cysts associated with multinucleated histiocytes are seen within the fatty tissue. The appearances are those of focal fat necrosis. The appearances are otherwise unremarkable and there is no evidence of inflammatory disease or neoplasia.
>
> Diagnosis: fatty tissue left lower eyelid – focal fat necrosis."

Ms A wrote an undated letter to Dr B following the 1 October surgery. She indicated:

> "I received your letter explaining the revision procedure that was done in my second operation. My eyes are healing well and I am now pleased with these most recent results."

Ms A complained about second hospital bill and asked Dr B to take responsibility for it. Dr B wrote to Ms A on 12 October 1998 indicating:

> "…
>
> At no time have I undertaken to be responsible for the hospital and anaesthetic costs which you have incurred during the admission of the 1.10.98 and it clearly states in my notes that I was prepared to make no extra surgical fee for the revisional surgery and this is documented in my notes on the 15.7.98 and again on the 9.9.98 when you agreed to have the surgery done under local anaesthetic with sedation at [the private hospital] because of your fear of having any further procedures done under local anaesthetic. As it turned out the Anaesthetist felt that it was more appropriate for you to have a general anaesthetic because of your level of anxiety and as well as the second hospital bill you should expect to receive a second anaesthetic bill from [Dr E]. …"

Ms A advised the Commissioner that she did not receive a second anaesthetic bill from Dr E.

On 15 October 1998 Ms A wrote to Dr B advising that she intended to take the matter before the Small Claims Court.

Ms A requested a second opinion from the New Zealand Foundation for Cosmetic Plastic Surgery regarding Dr B's surgery and was interviewed and examined by Dr C on 30 October 1998. Dr C documented in his report that Ms A was satisfied with the result of the surgery on her right upper and lower eyelids but was not happy with the result of her left lower eyelid revision. Dr C recorded that Ms A complained of a residual lump and a small concavity at the junction of the eyelid skin with the orbital margin and that a 2.5mm diameter rounded fat deposit was visible beneath the eyelid skin. Dr C also documented a small indentation in the

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eyelid where the skin appeared to be adherent to the underlying muscle and a mild degree of post-inflammatory hyper-pigmentation of the eyelid skin, consistent with the recent revision surgery. Dr C formed the opinion that it was too early to make a decision about the result of the second operation. He indicated:

> "[Ms A] must be patient and wait at least three months, preferably six, before contemplating any further surgery. Scar formation in the early phase of wound healing can be exaggerated and scar maturation and resolution may take upwards of six to twelve months. Any area that has been reoperated on may take even longer to settle. The patient's smoking habit is a known risk factor and can adversely affect wound healing due to impairment of blood supply and cellular toxins. The superficial fat deposit may spontaneously reduce in size and become less noticeable. Likewise the small indentation may improve as the scarring softens. There may not be any need for further surgery. I have offered to review [Ms A] over the next few months but I would encourage her to settle her differences with [Dr B] and allow him to monitor her progress. …"

Dr C also noted:

> "[Dr B] has provided [Ms A] with sufficient written and verbal information for her to sign a consent form that she 'completely understands the nature and consequences of the procedure'. He has stressed the necessity to stop smoking to reduce complications. He has documented his operative procedures in detail. He has seen the patient on several occasions following surgery and has also kept in contact by phone and letter. The degree of detail in the notes is far above average and would indicate to me that he is careful and conscientious in his assessment, treatment and followup. It is difficult for me to equate this attention to detail and informed consent with negligent surgery. Complications can occur with virtually any operation, despite preventive measures. Surgery, especially cosmetic, is not an absolute science. [Dr B] has attempted to the best of his ability to correct [Ms A's] concerns. [Ms A] remains unhappy. I would not recommend any more surgery just yet and would suggest that [Dr B] obtains one or more opinions from overseas experts in eyelid surgery before deciding on a plan of action."

Dr B advised the Commissioner that Ms A has not presented for further follow-up with him, is unrealistic about her responsibilities regarding the doctor-patient relationship, post operative instructions and the continued harmful effects of smoking on her general health and facial appearance.

Ms A consulted Dr F, a second plastic and reconstructive surgeon on 20 January 1999. Dr F advised:

> "I do not see a great deal of hope in trying to re-operate to remove the fat. It would be very difficult technically to get the contour exactly right and furthermore the scar of the healing operation may tend to pucker up the thin eyelid skin even further and create new different contour irregularities."

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Independent advice to Commissioner

The advisor commented as follows in respect to the Commissioner's written questions:

"… There are no binding specific written guidelines issued by any professional body to my knowledge for rejuvenation surgery of the eyelids. The specific standards that I would apply are:

Consultation and Examination:

This involves taking a case history and obtaining information about the past and present health, medication requirements, smoking and tendency to bleeding. Enquiry is made into the reasons for requiring the surgery and patient expectations.

The examination involves a thorough check of the eyelids and surrounding areas, including the eyebrows and the orbits. Particular note is made of excess skin and excess swelling, loss of subcutaneous fat, lack of tone in the eyelids and visual acuity. Following this a full discussion takes place involving the methods of treatment and their advantages and disadvantages.

For eyelid rejuvenation the basic treatments are to remove excess of skin and excess orbital fat, if that is a problem. Other aspects of the treatment can include a forehead lift to elevate the eyebrows and tighten the upper eyelids and the injection of fat to fill out hollow areas. All treatments have their advantages and disadvantages and these should be discussed with the patient. The consultation and examination is documented and this can be augmented by the drawing of diagrams and the taking of photographs.

Surgery:

Surgery is done in an appropriate facility and much eyelid surgery can be done under a local anaesthetic as an outpatient in a day stay facility. Where there are concerns about patient apprehension a general anaesthetic is advised.

Post operatively the patient is reviewed regularly until wound healing is complete and the sutures removed. Usually patients are reviewed some weeks after surgery to assess the results once the swelling and bruising has subsided.

Were these standards followed?

I believe they were. There had been considerable correspondence between [Ms A] and [Dr B] before surgery and well documented records. The initial concern of [Ms A] was to have her upper eyelids treated but the consultation notes indicate that she wanted her under eyelids done and not the upper eyelids at the moment.

Is Lipoinfiltration a recognised and acceptable technique?

The technique of injecting fat into parts of the body to improve appearance has been advocated increasingly in the last 10 or so years. Considerable refinements of the technique, especially in handling the fat, and injecting small amounts only have produced

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acceptable results. [Dr D] from [overseas] ran a course in [another country] on this technique some years ago and I note that [Dr B] attended this course.

What level of training is required before lipoinfiltration can be offered cosmetically?

There is no specific training requirement for offering new techniques. This is mainly up to the Practitioner offering the technique. I would, however, expect that anyone offering such a technique would have considerable experience of liposuction surgery and had attended meetings and courses in which the procedure was discussed, demonstrated and the advantages and disadvantages considered.

Was [Dr B's] level of training and experience reasonable?

Yes. He has indicated that his initial experience of lipoinfiltration or lipostructure, was with accident cases with a gradual move towards aesthetic patients.

What should a consumer contemplating lipoinfiltration be told about the expected risks?

This is the normal informed consent process. I note in [Dr D's] article the complications are discussed. It is not easy for a layperson reading such an article to understand medical terminology and such information requires discussion with the Surgeon.

Could the effect [Ms A] desired have been achieved using any other technique?

Not to my knowledge.

What caused the lumpiness?

There are several reasons for this. The eyelid skin is extremely thin and any accumulation of the fat cells into little globules will be quite recognisable under the thin skin. If the skin were thicker it would have a better chance of disguising minor irregularities. Fat necrosis is a complication of fat injections. Sometimes the fat can become thickened or calcified into small lumps and this appears to be a not uncommon complication with fat injections, although the newer methods of fat preparation for injection, as described in [Dr D's] article, are supposed to reduce the chances of this happening.

Could the lumpiness be related to the Surgeon's technique?

This is possible, although I think that the reasons given in the previous paragraph contributed to this.

Could smoking have contributed to or caused the lumpiness?

It may have had a part to play in reduced blood supply to the infiltrated fat thus causing the necrosis.

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Was massage an acceptable remedy?

Massage after eyelid surgery has been strongly recommended for a number of years and its main advocate is [Dr G] who was a Visiting Professor some years ago and who popularised this technique. It was, however, for persons who have had the basic excisional type of blepharoplasty in order to reduce swelling and tightness. Massage would certainly help reduce the swelling but would not eradicate the residual fatty lumps.

Could further surgery correct the residual lump and concavity?

Without seeing the patient it is not possible to give a definite answer to this. Based on the information supplied, she has already had two procedures on the lower eyelids and there will be a certain amount of underlying scarring resulting from these. Further surgery would create more scar tissue and getting the contour exactly right would be difficult as the thin overlying skin will tend to show up any minor irregularities."

My advisor also commented that there is a growing trend to blame smoking for the development of fat necrosis, which is caused by a lack of, or impaired, blood supply to the transplanted fat. He indicated that there are other reasons for fat necrosis occurring, but that these reasons are not always understood.

Response to Commissioner's Provisional Opinion

Dr B responded to the Commissioner's provisional opinion as follows:

"…

I agree with everything documented except for the last two pages 23 and 24.

Right 6 states that every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive including … an explanation of the options, risks, benefits etc.

[Ms A] in my opinion received a reasonable amount of information, was encouraged to read and reflect on this carefully and in fact had a 6 month pre-operative period in which to further discuss this with me both verbally and in writing as you have correctly documented.

[Ms A] is an intelligent woman, and she received from me all knowledge, technical details and specific risks known about lipo-infiltration by [Dr D's] method available at that time. I first saw her at a medical clinic in […] and not having [Dr D's] article in my possession then undertook to include it with my initial detailed consultation letter to her.

I dispute the claim that a layperson would have difficulty understanding the specific details in [Dr D's] article relating to known complications. This article is a review article based on his 10 year experience [overseas] with this technique for fat grafting. It was published in Operative Techniques in Plastic Surgery which is a quarterly journal

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characterised by sound explanation of the indications, techniques and potential complications of a number of reconstructive and cosmetic procedures.

Your own description of the complications section of the article on page 5, 4th paragraph as a layperson testifies to the clarity of the article … **underinfiltration (too little fat implanted), overinfiltration (too much fat implanted), migration, clumping and infection.** My consent form focused on the specific morbidities relating to the technique of adding fat to the soft tissues and especially to the risk factor of smoking. There is extensive scientific evidence now in the plastic surgery literature relating to the dangers of smoking on the healing of all tissues but specifically to grafts and I would be happy to provide your advisor with a bibliography provided by a leading plastic surgeon [overseas].

Right 7 refers to the right to make an informed choice and give informed consent.

[Ms A] claims she was not fully informed despite the documents of material presented to her, which complimented the verbal discussion. She broke the agreement regarding the most serious risk factor (smoking) which I went to all reasonable lengths to inform her of. She claims that she would not have consented to having lipoinfiltration if she had known what the potential unsatisfactory results could have been. I contend that I would not have agreed to the surgery if I could have predicted that she would not comply with the clear pre and post-operative instructions.

I have had considerable experience with the technique of lipo-infiltration now and to date have had no problems with non-smoking patients. The fundamental principle of fat grafting as with skin and cartilage grafting is that the implanted graft must become revascularised and this depends on the healthy ingrowth of tiny blood vessels which the inhalation of nicotine and other toxic chemicals in cigarettes opposes. The fat grafts, which are not adequately revascularised, die and become hard lumps of fibrotic soft tissue felt and seen under the skin.

I strongly disagree with your opinion that I did not meet my obligations to ensure that [Ms A] was fully informed and I refer you to the opinion expressed by an independent colleague [Dr C] who has personally examined and consulted with [Ms A].

These are my comments and you will note that they dispute your provisional opinion and preliminary conclusions."

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Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4
Right to Services of an Appropriate Standard

2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.

RIGHT 6
Right to be Fully Informed

1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including –
b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option;

RIGHT 7
Right to Make an Informed Choice and Give Informed Consent

1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

3 Provider Compliance
1) A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.
2) The onus is on the provider to prove that it took reasonable actions.
3) For the purposes of this clause, "the circumstances" means all the relevant circumstances, including the consumer's clinical circumstances and the provider's resource constraints.

Opinion: No breach

In my opinion Dr B did not breach Right 4(2) of the Code of Health and Disability Services Consumers' Rights as follows:

Right 4(2)

Ms A originally wrote to Dr B requesting information about upper eyelid surgery. During a consultation on 13 August 1997 Dr B determined that Ms A was concerned about a tired look under her eyes and recommended lipoinfiltration to correct this. I accept the advice of my independent plastic and reconstructive surgeon that lipoinfiltration is a recognised and acceptable technique and that Dr B was properly qualified to undertake the procedure. The

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effect Ms A desired could not have been achieved using any technique other than lipoinfiltration.

My advisor informed me that fat necrosis is a recognised complication of fat injections and can occur independently of the surgeon's technique. It is caused by a lack of blood supply to the fat cells, although the technique described by Dr D and utilised by Dr B is supposed to reduce the chances of this happening. In my opinion Dr B provided services in accordance with professional standards and did not breach Right 4(2) of the Code of Health and Disability Services Consumers' Rights.

Opinion: Breach

In my opinion Dr B breached Rights 6(1)(b) and 7(1) of the Code of Health and Disability Services Consumers' Rights as follows:

Right 6(1)(b)

Ms A complained that she was not told of possible complications of lipo-infiltration. While Dr B provided her with a copy of Dr D's article which outlined complications associated with lipo-infiltration my advisor commented that this was difficult information for a layperson to absorb and its contents should have been discussed with Ms A. Dr B did not do this.

Dr B indicated that he does not dwell on complications and does not want to talk a consumer out of surgery unnecessarily. He provided a consent form which listed some of the complications contained in Dr D's article and which Ms A signed. It indicated there would be small scars from the injection sites, that swelling and bruising of the eyelids would occur, that temporary injury to the nerves supplying the skin and muscles in the periobital area could occur and that infection was possible. In signing the document Ms A undertook that she would not smoke cigarettes for four weeks prior to surgery and for eight weeks afterwards. Dr B informed Ms A that smoking was contra-indicated because a single cigarette causes 50 minutes of tissue ischaemia, which would almost certainly lead to poor uptake of the fat grafts leading to fat liquefaction (fat necrosis), infection and possible abscess formation. The parties disagreed on how well Ms A adhered to the no-smoking policy. My advisor informs me that fat necrosis is a complication of lipoinfiltration and that, while smoking may contribute to a reduction in blood supply leading to necrosis, the lumpiness experienced by Ms A, and diagnosed as fat necrosis after histological investigation, could have been caused by other factors. There is no evidence in Dr B's clinical notes that Ms A was informed of this possibility, independently of his advice that complications could develop if she did not stop smoking for a period of time, both pre- and post-operatively. Right 6(1)(b) sets out the information a consumer can expect to receive without having to ask. The onus was on Dr B to show that this information had been provided, as indicated by Clause 3(2) of the Code. In my opinion Dr B did not fully explain the risks associated with lipoinfiltration and breached Right 6(1)(b) of the Code of Rights.

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Right 7(1)

Ms A complained that had the possible complications been explained, she would not have had the procedure performed. In the absence of information indicating Dr B fully explained all the risks, including those outlined in Dr D's article and that tissue breakdown can occur independently of the smoking risk, I conclude that despite Ms A signing a consent form acknowledging the risks had been explained to her, Dr B did not meet his obligations to ensure she was fully informed. Ms A was therefore not able to make an informed choice about the proposed surgery. In my opinion Dr B breached Right 7(1) of the Code by providing services to Ms A without sufficiently informing her about the potential complications of the procedure and allowing her to make an informed choice and give informed consent.

Actions

I recommend that Dr B takes the following actions:

- Apologises in writing to Ms A for his breach of the Code. This apology is to be sent to the Commissioner's office and will be forwarded to Ms A.
- Reads the Code of Health and Disability Services Consumers' Rights.
- Ensures that consumers are fully informed about the risks associated with lipoinfiltration, independent of the smoking risk, as part of his informed consent procedure.
- Refunds Ms A's initial surgical costs.

Other actions

A copy of this report will be sent to the Medical Council of New Zealand, the New Zealand Foundation for Cosmetic Plastic Surgery and ACC, with the request that it reconsiders Ms A's eligibility.

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