PMFA News and Hamilton Fraser Cosmetic Insurance have teamed up to provide a series of articles that will give examples of claims that occur from different procedures.

In our February/March issue we featured a case that involved complications following the use of botulinum toxin as part of a training course. You can read the case in the magazine or on our website www.pmfanews.com (page 33).

Conclusion to the case provided by Hamilton Fraser

The case was settled with admission of liability. The following payments were made:

Damages to claimant - £50,000
Claimant's legal costs - £80,000
Clinician's defence fees - £13,298.

Comments on the case

Dalvi Humzah, Consultant Plastic Reconstructive & Aesthetic Surgeon, Aesthetics Sub-Editor, _PMFA News_:

This case highlights many issues: 1) Consent – for patients / models; 2) Responsibilities of trainers / practitioners for models / patients on an ongoing continuity of care; 3) Procedural issues; 4) Causation. The use of abobotulinumtoxin A in aesthetics is an approved procedure – with the product available in 125 unit vials. Addressing the procedural issues, details regarding treatment should document: patient preparation (skin prep), vial(s) used, dosage, areas treated and post treatment advice given. This would mirror the standard of care given by any competent medical practitioner in their clinical practice and would be expected to be provided by those responsible for the training being provided. Any 'off-label' uses would need to be clearly identified and recorded.

In the consent process it should be made clear to the model / patient that they are part of a training course and the contingency plans as to who would have the duty of care and responsibilities in the event of an adverse event. I bring these points up not only as an issue of this particular case but also as a leaning point now that there appears to be an explosion of training 'Academies'; those involved in these should consider these issues.

In relation to causation and an objectively verifiable morbidity that is co-incidental to the treatment given – this would need, in the true sense of medical practice, evidence-based / expert opinion to link these events together. This avenue may lead to expert opinions being sought.

So what is the practitioner's responsibility, the trainer's, and the insurance company's advice? We open the doors to further discussion and to use these cases as learning aids for all of us involved in delivering training and trainees treating 'models' as part of their learning process.

Dr Sabine Zenker, Dermatologist, Munich, Germany:

Systemic side-effects and adverse events associated with the therapeutic and cosmetic use of botulinum toxin are extremely rare. If systemic side-effects happen, the spread of toxin could potentially lead to botulism-like features, starting as dry eye, accommodation difficulty, dry mouth, gastrointestinal disturbances, dysphagia and lastly breathing difficulties, as well as muscle weakness (Blackie et al. 1990, Crowner et al. 2010). Data on the therapeutic use of BoNT-A, indicates the risk for systemic effects is related to total injection dose and injection frequency. Repeated use of 600 units of Botox® with three-monthly follow-up injections for hypertonicity and movement disorders, may lead to an increased risk of those general side-effects (Crowner et al. 2010). Data is quite rare. A big retrospective study of 4103 injections for the treatment of lines of the upper face with a minimum of three treatment cycles showed no evidence of cumulative adverse events (Binder 2006, Rzany et al. 2007). With BoNT-A accurate dosing, accurate delivery, right dilution, right placement, etc. have extreme implications on the final result, especially when it comes to delicate indications, where overdosing will show and where tiny doses are needed (Meso-Botox). In the case reported, the patient was treated with Onabotulinumtoxin A using 164U. Neither the indication, nor the area, the injection technique or other aspects for this treatment are reported, which makes it difficult to substantially comment on this case. Generally speaking, an overall amount of 164U BoNT-A for a cosmetic indication seems to be adequate. Unfortunately, the patient did develop unspecific systemic reactions 24 hours after the treatment which lasted for several months. According to the literature, and to my knowledge, this might happen even though it is very rare, especially in cosmetic applications where we use far lower doses than for therapeutic indications. Even in lower doses and after repeated treatments without any negative effect in the past, side-effects can happen. But such reactions are most likely related to the administered drug itself rather than to the technique. Most importantly it is necessary to do a full examination and documentation in order to exclude potential other causes of the problems the patient experienced. The immediate reaction and medical advice given to the patient were correct. Cosmetic treatments in general, and especially treatments with BoNT-A, have to be done in a safe and aesthetically appealing way. Experience, as well as proper medical education, is demanded of any practitioner.

Doris de Beer, Managing Director, TSK Laboratory, The Netherlands:

TSK Laboratory Europe B.V. recently released the new 3DOSE unit dose injector from VLOW Medical, a disposable injector that helps to inject accurate units of toxin. During the development phase, VLOW Medical collaborated with several key opinion leaders to identify the key challenges with standard injection methods. Further market testing was performed by TSK with a large demographic group of experienced doctors. These tests, in which the actual unit dose was measured using a high sensitive scale, showed that what doctors thought they inject is most often more than what they actually inject. An inaccuracy of up to 20% was measured and even when the user is focused on the graduations, doctors couldn't consistently inject small volumes. Another observation was that most doctors had trouble in determining how much ml is equivalent to one unit dose based on their standard dilution procedure. It is known that different toxin brands cannot be used interchangeably and it can also be questioned if it is clearly understood by all users how to accurately dilute toxin, especially when switching between Botox® units and Speywood units. Because of the introduction of new BoNT injection devices, there are increased discussions about the importance of accurate BoNT-A injections and how this impacts the clinical outcome. As a manufacturer and provider of injection equipment tools we don't have the clinical expertise to comment on possible side-effects of the medication itself.

The second in the series looks at laser hair removal.

The case in question

The most frequent claims that Hamilton Fraser Cosmetic Insurance have had to deal with over the last five years have been related to the removal of hair and tattoos by laser.

This case, which presented in 2016, concerns laser hair removal. It underlines the problem of how to ensure patients are as honest as possible so that treatment can be delivered safely and with the lowest risk of complications.

The patient had purchased a series of sessions of laser hair removal. Five sessions had been completed successfully with no concerns. On the sixth session a different therapist performed the treatment. Immediately after the treatment the patient advised the therapist that they were experiencing pain in both of their thighs. That evening, the patient attended their nearest A&E department as the thighs became very red, swollen and extremely painful. The nurse at the hospital stated that the patient had suffered first degree burns. A large blister developed on the left thigh which left a large scar. Solicitors acting for the defence noted that the patient record detailed the settings used on the sixth appointment were identical to the previous five sessions (level 755nm, 14mm, 25ms, 15j). The patient was type II on the Fitzpatrick Scale and had undergone a test patch at the start of the course of treatments. At the beginning of the sixth session, the therapist confirmed that there had been no recent sun exposure. However, it subsequently became apparent that the patient had been on her honeymoon 10 weeks previously and had undergone significant sun exposure. This highly relevant information was not disclosed to the therapist who stated that she would not have proceeded with treatment if she had been aware of this.

Editor's comment

The removal of body hair by laser or intense pulsed light is a popular procedure because in general it is simple, safe and effective. The chromophore is melanin which is made in the melanocytes and distributed throughout the epidermis in melanosomes located in the keratinocytes. The melanocytes are concentrated in the hair shaft bulb area. An effective energy setting is one that will cause selective damage to the hair bulb but spare the epidermis.

The 755nm alexandrite laser is regarded as a good wavelength for all skin types including the type II Fitzpatrick skin. When a patient signs up for a course of treatment it is important to emphasise that the test patch is to determine the optimum energy level for the course. Both implicit and explicit must be the understanding that the condition of the skin does not change. Of major concern is sun exposure where there may be an increase in epidermal melanin causing absorption of the laser energy and local thermal effects. It is important to ensure that there are no topical preparations that could also interfere with the distribution of the laser energy, e.g. artificial tanning creams.

There are several issues illustrated by this case:

1. When a patient signs up for a series of treatments is it better to obtain consent for the series, or consent for each treatment? I would be interested to hear different views on this. When performed in an institutional setting the usual practice seems to be consenting for each treatment.
2. Who delivers the information? Who signs the consent and who treats the patient? Again, practices vary and in some settings a doctor sees and assesses the patient, obtains the consent and performs the test patch and then hands over to the laser therapists to perform the treatment sessions. What is the feedback loop in this arrangement? Does the doctor review the response after each treatment or does the therapist alter the laser parameters? Each clinic needs to have clear protocols to ensure continuity of care.
3. Pre-and post-treatment photographs can be very useful to monitor response but also to provide baseline information particularly when the therapist changes. Lighting and positioning should be constant and with current technology it is easy to give each patient a digital record of their treatment.
4. The interval between sun exposure and laser treatment is important. Typically three to four days is sufficient but if a patient has undergone prolonged sun exposure and gained a tan then the options are to either wait for the tan to fade or to recalibrate the dosage. Waiting is far better and so information about the effects of tanning should be emphasised at the outset.
5. In the initial consultation, the nature of the treatment needs to be explained and the importance of maintaining a constant skin colour should be emphasised. It would be helpful to include in the consent that the patient understands the importance of skin colour and that they will inform the therapist of any changes of relevance. These should be listed.
6. If a sessional consent is obtained this need not be a fully detailed information exchange but there could be a tick box exercise to identify any changes since the last treatment. Something physical and signed has more weight than a "he said, she said" debate months later.
7. It is always important to consider technical issues in the laser machine. Regular servicing is essential and machines that record outputs of calibration data and treatment data provide hardcopy evidence that can be of relevance when outcomes are not satisfactory.
8. Once a complication has occurred it is important to check and re-check all available information but I would suggest not trying to shift blame onto the patient. The failure of a patient to volunteer information can be seen as a failure of the therapist to seek it. Only if there is clear, unequivocal evidence from contemporaneously signed documentation that a patient has deliberately concealed relevant information should the integrity of the patient be questioned.
9. One final point is that scars go through several maturation stages in terms of colour (redness), texture and pigmentation. Regular support and reassurance can help a patient through a critical period and once an area of damaged skin has returned to normal colour, texture and pigmentation any compensation should be proportionately decreased. Scar maturation does take time and a period of 18 months to two years may be needed for a final result to become apparent.

Email jennifer@pinpoint-scotland.com with your comments