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CONSULTING ROOM

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FEATURE ARTICLE

Who is to Blame for
Dermal Filler Complications?

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Who is to Blame for Dermal Filler Complications?

Over the past few years the medical aesthetics industry has observed unparalleled growth, driven primarily by a reduction in stigma associated with treatments and heightened consumer awareness[1]. In 2014 total sales of aesthetic products exceeded $6.8 billion, which is expected to expand by 11.5% per year to $11.9 billion by 2019.[2,3] Although the US and Brazil constitute the largest markets, the UK market, valued at £725 million in 2014, continues to hold a strong position in global aesthetics.[4]

Although procedures such as breast augmentation continue to be popular, it is injectable treatments such as botulinum toxin and dermal fillers that continue to drive its growth, which grew in the UK from 33.7% to 34.5% between 2013 to 2014.[4]

As the market continues to grow, so does investment, of which the main advantage seems to be the evolution of medical education programmes, particularly for injectables, delivered either by large manufacturers or experienced injectors. Despite this, complications appear to have increased in incidence, likely due to the growth of procedural numbers. This has led to increasing debate regarding the safety of treatments by the public, and the products themselves by providers. The latter is demonstrated by a steady increase in related content at major aesthetic congresses and within the medical literature.[1,5] A particularly comprehensive paper was authored by De Boulle and Heydenrych, which outlined the key steps and considerations in the prevention, recognition and management of complications associated with dermal fillers.[5]

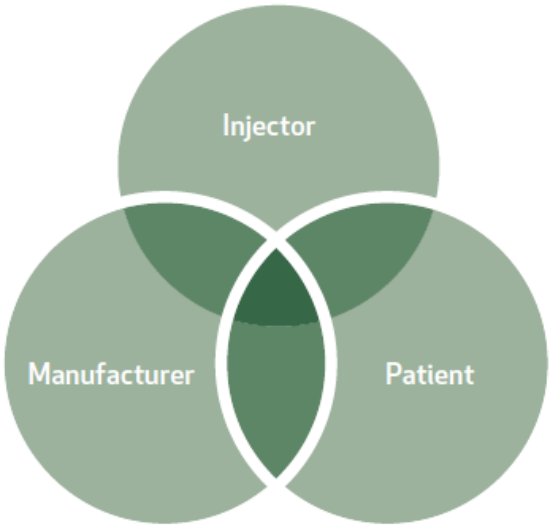

Figure 1. Relationships in the evolution of complications

The purpose of this article by **Consulting Room Guest Writer Mr Benji Dhillon** is not to describe how to identify and manage complications, but to serve as a discussion on where responsibility lies in their prevention, as well as posing some considerations in their aetiology. In order to do so three variables have been identified and addressed:

Injector

Consequent to increased demand there are more injectors in the UK versus five years ago, leading to a competitive aesthetics landscape. Three important questions are therefore important to consider.

In a bid to compete, and prevent turning away patients, are injectors treating unsuitable patients?

As health care professionals (HCPs) we are responsible for ensuring that our patients are suitable for treatment either based on indication or their medical history. “Normalisation” has led to more considerers with a greater number of co-morbidities. Although the majority of injectors will be aware of the more common contra-indications and precautions to treatments, such as avoiding injecting into areas of active infection or inflammation, there are others which are not so apparent.

These may not serve as complete contra-indications but should be considered carefully and the risks communicated in full. These include diabetes and immunosuppression with risk of infection, and bleeding disorders or the use of anti-inflammatories within 48-72 hours of treatment (before and after), which increases the risk of bruising. The medical history should also explore any recent mild illnesses, dental procedures (two weeks pre or post treatment) or dental pathology.[5] There is increasing evidence that such infections or procedures may potentiate bacterial colonisation of filler material leading to biofilm formation.[6]

Are injectors expediting their development and compromising key clinical steps to manage busier lists?

A thorough understanding of basic techniques is essential to optimising outcomes and preventing complications. Novice injectors should allow sufficient time to familiarise themselves with the nuances of 'simple' techniques before they expose themselves to substandard, and potentially dangerous outcomes with more advanced ones in the tear trough or nose.

With greater numbers of patients leading to busier lists are we also compromising good aseptic technique? Key steps that should never be omitted include removing all makeup, preparing the skin with appropriate solutions such as chlorhexidine, and preventing gloves and swabs touching other areas outside the zone of treatment. Technical considerations that can also be compromised when rushing to complete a treatment are speed of injection, and depth of placement. Taking time to plan and deliver treatments is therefore essential. A thorough understanding of anatomy should be attainted prior to treating patients. This is central to avoiding vascular occlusion, the most severe of complications. Intravascular injection or external compression can lead to necrosis if not recognised and treated appropriately. Its sequelae not only lead to life changing events for the patient (Figure 2) but can expose the injector medico-legally.

Figure 2: Glabella necrosis following hyaluronic acid injection[4].

Most events are completely avoidable if the simple step of aspiration is performed and repeated at all times for any injection point. Only the most experienced injector should be able to omit this. Even so, they too run the risk of being complacent. The variability of vascular anatomy, although small, can play too great a role in the potential for a negative outcome. As important as prevention is being equipped to recognise and treat the problem. Cardinal signs are pain and blanching of the skin. If these are observed - stop injecting immediately and infiltrate the area with hyaluronidase immediately along with other agents to promote blood flow to the area.[5]

Are practitioners injecting greater volumes of products in one sitting in an attempt to achieve more visible, immediate outcomes?

The use of greater volumes, although at times necessary to achieve the desired effect, raises an interesting notion regarding the potential for longer-term complications. Biofilm for some time has been hypothesised as a potential cause of late issues with dermal fillers.[5] Essential to its formation is the adhesion of bacteria to a substrate surface[7], an increase of which allows for a greater surface area of biofilm formation.[8]

Although the correlation between dermal filler surface area and the type and incidence of complications has not been studied in detail, it is interesting to note that an upper recommended limit is often set by manufacturers on the volumes injected. Guidance by manufacturers ranges from 2-6mls per patient per treatment[9,10], and the independent medical literature advises on using not more than 0.5mls per bolus.[11]

Patient

Although the majority of preventative measures are the responsibility of injectors, patients also play a vital role. Suitable post procedure instructions must be provided and communicated effectively to ensure an understanding of their importance. Important points for patients to adhere to are the avoidance of the use of cosmetics (given their bacterial contamination) for at least 24 hours. Although this time limit is arbitrary, it does allow enough time for wound closure of multiple injection points. However if patients are insistent upon wearing makeup, advice must therefore entail using new brushes or pots of make-up.

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Manufacturers

HCPs are responsible for evaluating and understanding the quality of products they are being sold and using. Despite common perception, there are sufficient safeguards to ensure the appropriate approval of medical devices within the EU. However the role of manufacturers has recently been debated in the evolution of 'unexplained' late stage (> four weeks) complications. When considering this, it is vital we take into account the manufacturing standards that most achieve and exceed, as well as the fact that there are a multitude of causative variables that the injector is responsible for. It has been argued that methods or techniques previously used with older products with no issues, have led to complications with newer ones. However aren't all products essentially different? We should take time to ask manufacturers of these differences and understand how we must adapt our techniques to ensure we do not compromise on good results with a potentially more advanced product.

If complications do occur it is essential that the injector, performs a root cause analysis. Were there any unknown minor illnesses close to the time of injection, any dental work unknown to have occurred or any other comorbidities that were not reported by the patient in the medical history? Despite this there are times when even the best technique and patient selection still result in adverse outcomes. These (as well as all complications) should be reported to the manufacturer. How can they be held accountable and initiate an investigation if they do not know about it? A reputable manufacturer will have a safety department (details are often within the box), to which you should report such events, unfortunately something HCP's often completely ignore.

Conclusion

Over the coming years innovation will continue at a pace and new products will be brought to the market. It is imperative that as a group, we continue to implement only the highest standards of what is clinical care. So who really is to blame? The answer is not clear but we should recognise that simple steps implemented by the injector can avoid the large majority of complications. This requires that we do not become complacent. Mr Olivier Branford, a UK based Plastic Surgeon, recently tweeted an interesting graph (Figure 3), which perfectly summarises how aware of our own limitations we should be.

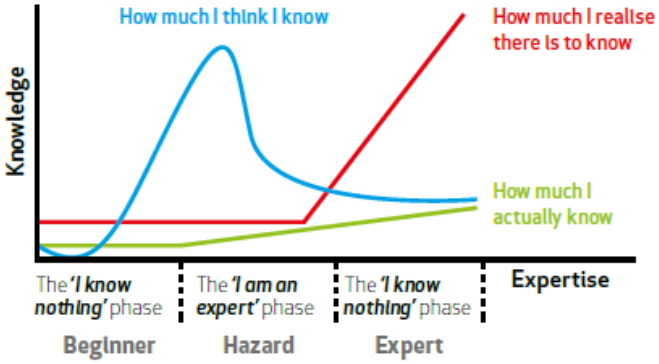

Figure 3. Adaptation of knowledge/expertise graph (Source unknown)

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