Feature Article

Dermal Fillers – Is it Just a Matter of Time Before We Have ANOTHER Scandal in the Cosmetic Industry?

Dermal fillers are made of various kinds of natural and man-made or synthetic materials that have been developed over the years for injection into the skin in order to fill, plump, soften, volumise, augment or restructure an area of the face. In the main products have contained substances such as hyaluronic acid and collagen (human, bovine and porcine), but additional ingredients including polyacrylamides, poly-l-lactic acid, calcium hydroxylapatite, tri-calcium phosphate, polysaccharides, polymethylmethacrylate (PMMA), carboxymethylcellulose and polyethylene oxides, to name but a few, have all been developed (successfully and otherwise) within the dermal filler industry.

In general, as well as classifying dermal fillers according to their primary composition we can also split products into their temporary (resorbable) and permanent (non-resorbable) qualities, with most practitioners agreeing that after years of experience (and sometimes first hand complications) they now steer clear of the permanent ones. It is also agreed amongst experts that ideally a dermal filler product should be biocompatible, non-toxic, non-immunogenic, and non-migratory, yet as we have seen over the years this utopian idea isn't always achieved by the manufacturers and the end users, both clinicians and consumers, can find themselves akin to collateral damage when there are unexpected adverse events.

To that end, temporary hyaluronic acid (HA) based dermal fillers are now the second most popular non-surgical cosmetic procedure in the USA, according to annual ASAPS statistics, just behind of course, botulinum toxins, and despite a lack of coherent statistics for the UK, the picture is very much the same on this side of the pond.

Historical problems

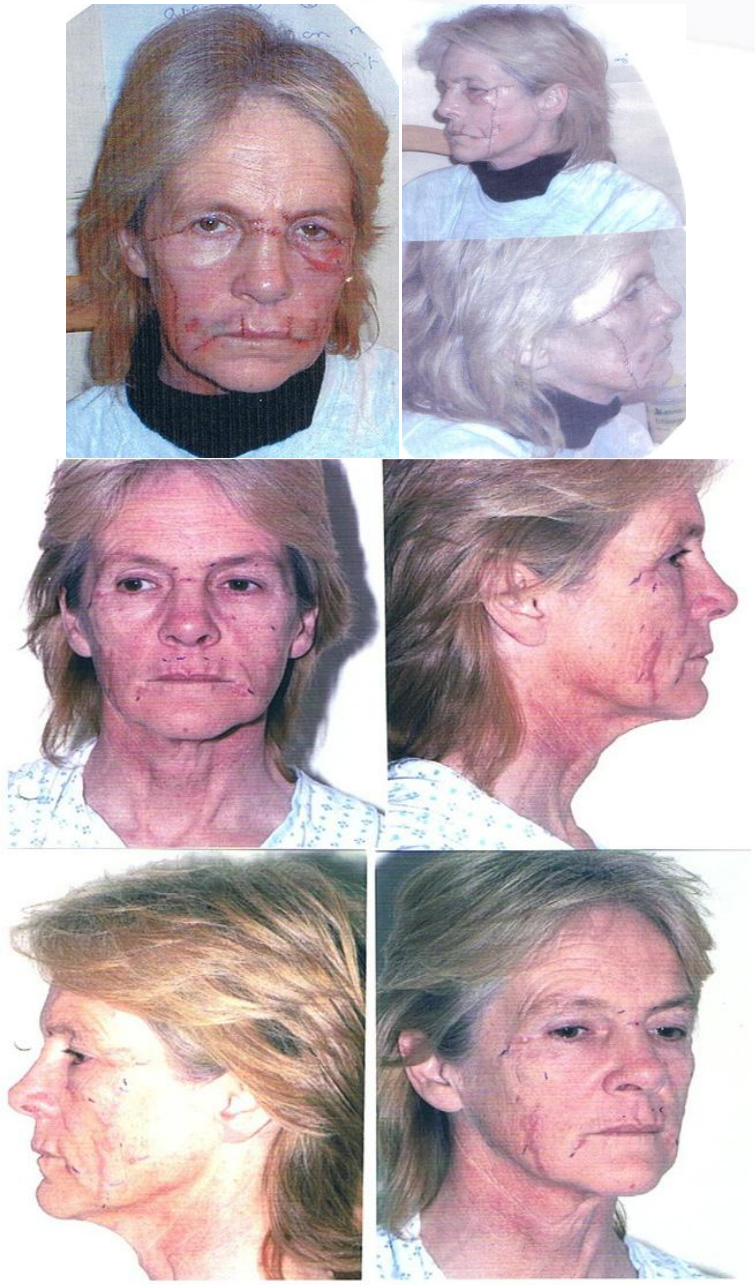
You don't have to go far on a surf around the Internet to come across websites and forums with distressing stories from angry and upset members of the public from around the world who have experienced sometimes horrific side effects from what were perceived to be genuine, approved, quality dermal filler products; brand names like Evolution®, Outline®, Bio-Alcamid™ and Dermalive® will be familiar to many of you.

Even high profile 'celebrites' such as Dead or Alive singer Pete Burns, who received both Outline and Evolution in his lips, have suffered from traumatic complications involving surgical excision and reconstructive cosmetic work to get rid of the substances and trauma that they have caused. In this case the practitioner was the one paying the (out of court) damages and not the manufacturer.

At The Consulting Room™ we have had a number of emails from people within the UK, and as far away as Canada, reporting granuloma formation and migration with Bio-Alcamid. Well known UK cosmetic practitioner, Dr. Lisa Delamaine recently discussed her difficulties with this product in a **blog** for Consulting Room, in which she said; "*A few years ago I was looking for a solution for my patients who required cheek augmentation and volumising. At the time options for non-surgical treatments were limited. Then I was introduced to Bio-Alcamid, a polyacrylamide gel that according to the manufacturers would be the answer to my dreams. As it turns out it has been my worst nightmare*

It is a polyalkylimide gel that when injected in the correct volume and tissue plane becomes encapsulated by connective tissue. As a result this prevents the gel from migrating, being non-allergenic and pyrogenic and easy to remove if necessary or required. So you can imagine my horror when patients started to present months to years after their treatment with lumps all over their faces. As it turns out Bio-Alcamid does migrate, can cause low grade chronic infection and is extremely difficult to remove if possible at all. This has been the single most horrifying experience in my medical career and has bought me close to giving up the job I love and am good at. But the single most distressing thing about all of this is the total lack of support and advice from the manufacturers of Bio-Alcamid. In fact to this day, complete denial that there is anything wrong with their product."

One lady who contacted us following Dermalive implantation (60% stabilised hyaluronic acid plus 40% acrylic hydrogel (hydroxyethylmetacrylate - HEMA and ethylmetacrylate - EMA co-polymer) particles by volume) had to have the substance removed by a surgeon which led to significant scarring. She shared her photos with us as a warning to others. Again you don't have to go far on the internet to find similar images posted by other unfortunate people.



Another filler to appear on the scene with a big fanfare in January 2010 at IMCAS Paris was Novabel® by Merz Aesthetics, who were keen to promote the uniqueness of their product which was made from polysaccharide extracted from marine algae, but following some early UK trials and publicity, unfortunately many on well known UK tabloid journalists, the product was withdrawn from sale in June 2010 due to a few cases of adverse effects on those treated in the infra-orbital area. It is unlikely to return.

At the 2012 IMCAS meeting in Paris there was a consensus amongst a panel during a session that over 20% of people experienced oedema from tear trough treatment with dermal fillers, sometimes long term. Yet many practitioners still offer this as a treatment using dermal filler brands as manufacturers often mark the indication as appropriate for their products, yet they seldom train practitioners in this application. One Doctor at the meeting also mentioned that the injection of a dermal filler product into the temporal area had resulted in a case of blindness. Additional clinical papers back up such stories including a case in **South Korea** reported as recently as November 2011 of an HA filler used for nose augmentation which resulted in ocular ischemia with hypotony, with problems persisting after a 6 month follow-up. Similarly, a case reported in August 2011 in **Canada**, noted blindness and opthalmoplegia (eye muscle paralysis) following treatment of a peri-orbital region with subcutaneous poly-L-lactic acid. Such incidents, although rare are truly scary for any practitioner.

Whenever I go to IMCAS in Paris, I'm always amazed at the number of NEW dermal fillers that I see being promoted in the exhibition hall; Brand X, Y & Z are added to the seeming over supply of products now available for European clinics and practitioners to buy, as the market appears to have been saturated for years now.

Yet it can be argued that more danger lies in counterfeit or generic products, most often manufactured in China and sold either direct to physicians around the world (dare we say unscrupulous ones with cost saving and not their patients in mind), most commonly via unsolicited fax and email messages, or direct to consumers through online retailers who will kindly give you all the DIY kit, including a helpful video, and let you get on with it in front of your bathroom mirror! Who knows what substances are in these, let alone the potential complications from self-injection by a non-medic.

In a recent interview with The Times newspaper Sally Taber, Head of the Independent Healthcare Advisory Services (IHAS) said; “The next thing will be that a patient will have a dangerous dermal filler that's come in from China and it will be 'How on earth did we let this happen?' We need to work together to cut out some of the appalling practice."

So is it just a matter of time before this erupts like the PIP scandal?

Chatting to a Doctor at IMCAS 2012, they summed up the recent furore concerning PIP breast implants by saying that “patients receiving these have lost trust in their Surgeons, and Surgeons have lost trust with the suppliers”. No relationship or industry can function effectively where there is a lack of trust on either side; more parallels can also be drawn with the banking industry where mistrust between the public and banks is equal to the mistrust between the banks themselves.

So are we ‘this’ close to a public dermal filler scandal?

No one is suggesting that dermal filler manufacturers might be embarking on fraudulent or illegal activity such as has been seen with the PIP breast implant manufacturer who post CE Mark approval deliberately substituted the medical grade silicone used in production for a cheaper industrial grade concoction, but there is nothing really to stop it happening again.

With so many dermal filler manufacturers out there, all with CE Mark approved products and a lack of scrutiny by the European CE regulators as demonstrated with PIP, (a 10 day warning was given of impending inspection so operations could be easily switched back to approved parameters), it could be quite simple and tempting in such a price sensitive marketplace for someone to cut corners.

And what would happen if a batch of a product was found to be contaminated or adulterated? What could even be done? Not a lot. With no central register of dermal filler treatments it would be practically impossible to link up affected batch numbers with patients; individual clinics would be required to check their own data and for most that would be an admin nightmare and difficult to gather as even electronic patient record software is not designed to pull out records of patients by product batch numbers. Even if all the people affected were ‘found’, unlike a breast implant which is an encapsulated object which can be removed, filler substances are simply not easy to remove – think of all the horror stories in America where industrial silicone has been injected into unsuspecting people who have either died or faced agonising surgery to have it removed.

If what the PIP company did was done by a well-known and widely used dermal filler manufacturer the consequences simply wouldn’t bare thinking about and would make the 50,000 affected PIP patients look like a drop in the ocean!

It’s not just the products which are to blame; providers might not be all they’re cracked up to be either...

Dermal fillers can provide fantastic results in the right hands, and disastrous, sometimes permanent disfiguration in the wrong ones. For consumers buying cosmetic treatments like dermal fillers, most will reasonably trust (without questioning) that the clinics offering these treatments have practitioners that:

1. Are appropriately “qualified” to deliver dermal filler treatments.
2. Have been adequately trained and assessed in the use of dermal fillers for all of the areas that they inject (i.e. lips, tear troughs, mid-face volumising etc.).
3. Are using the right products for the correction required.
4. Are using hygienic methods for delivery (i.e. not saving partially used syringes of fillers from previous patients!)
5. Are adequately insured.
6. Buy CE Mark approved products from approved distribution routes.

In turn the practitioner or clinic must trust that:

1. Their supplier has gone through the proper testing and European registration process for their filler product.
2. The product is manufactured according to the registration standards requirements.
3. The batches are being regularly checked and monitored for quality.

In reality in the UK, because dermal filler treatments are regulated as medical devices, no formal separate regulation is required in order to set up an injection service, the manufacturers have no control over the commercially organised training programmes and little control over distribution of their product; it's becoming increasingly possible for someone to fall into the hands of a non-medically qualified practitioner who is using products derived from the Internet after a few hours "training" with limited or no insurance cover.

The **Treatments You Can Trust** register of cosmetic injectable providers can help lead people through to clinics that operate to a certain level in terms of standards, but it still doesn't guarantee a good result and it's not a mandatory scheme.

Many people have discussed this for a number of years, but the market has run away with itself without proper checks and balances relating to the basics in how these products are used. Company representatives will tell you that even some people who have been involved in the industry for a number of years may still be poor injectors as there simply isn't any validation of injection practice going on.

It's easy for people to kid themselves that they're doing it 'okay', but when you hear stories of scary complications such as blindness, it brings it home somewhat. Knowing how to use a product (or a number of products) for a wide range of indications is paramount, a training course on naso-labial lines isn't going to make a practitioner skilled in contouring lips, treating under the eye or attempting deep volumisation, all of these indications are potentially difficult and fraught with problems so a lack of adequate training in the main and cross product use (assuming training in one product applies to any new product they decide to buy and use) is something to be taken seriously.

Other problems are starting to arise from the practice of product layering, both intentionally and by a lack of adequate patient history taking or patient knowledge of previous product use. Practitioners are known to have layered, for example, Sculptra, Radiesse and HAs without really knowing what, if any, problems might occur; the manufacturers simply don't know either as there is no evaluation of scientific data on this practice being carried out. The assumption that if 'Product A' is safe and so is 'Product B' and thus if you use them both in the same place it'll be fine, is perhaps a little naive, if not a little irresponsible as we simply don't know that to be true. Additionally with stories of HAs being mixed into the same syringe as botulinum toxins, we might as well be going back to the days of alchemy as practitioners seem to be experimenting somewhat to find 'gold' within cosmetic injectable treatments!

Add to that the cut-throat nature of competition within the industry and the drive of marketing a new technique, something different to distinguish themselves from other clinics and practitioners, the kudos of being an industry leader and all the opportunities for training revenue that it can bring and practitioners will 'play' somewhat to come up with the next best use, method or combination treatment. Often this is embraced by the manufacturers themselves, who get swept along in a media frenzy and back the practitioner and their new 'fantastic thing' without always knowing the scientific implications behind it.

Surely the industry is 'this' close to a fall-out...

So how can we raise standards and protect consumers?

In the United States there are currently 16 Food & Drug Administration (FDA) **approved dermal filler brands/products**, (6 of which are no longer commercially available due to obsolescence). Approved brands include Restylane/Perlane, Juvéderm (Ultra, Ultra Plus, XC), Belotero Balance, Elevess, Sculptra Aesthetic, Radiesse, Prevelle Silk and Captique. Several of these are not available in the UK as yet and other well known brands are marketed under slightly different names, and/or compositions. That is to say, those which are approved by the U.S. regulator can be commercially marketed and sold by manufacturers and distributors and then used by practitioners on patients. The use of all other, non-approved products (unless specially dispensated within a clinical trial environment) would be considered to be illegal and practitioners could face prosecution.

However, when it comes to the UK and Europe, we simply don't have an exact number of the 'approved' or CE Marked dermal filler products that are available to buy and use within the European Union; estimates range dramatically from 150 to 250 individual product brands stemming from all over the world. In the UK, there are approximately 16+ known brands in widespread use, available through the primary pharmacy supply chain.

In the USA, FDA approval of dermal filler products is based on the review of data collected from controlled clinical studies that evaluated the safe and effective use of the products when injected into the naso-labial folds. Some of the temporary products are approved for the 'correction of moderate to severe facial wrinkles and skin folds' which

includes marionette lines and crow's feet. The FDA has also approved one filler for lip augmentation in patients over the age of 21. However they have not approved dermal fillers to augment (volumise) or alter the shape of cheeks or noses or rejuvenate the hands. This increased regulation over the EU in itself doesn't represent the Holy Grail of safety nets as complications may occur from a filler product which is perfectly suited to use in the naso-labial region but would be ill-advised to be used in say the lips or infra-orbital regions and many U.S. practitioner will use an approved filler in an off-label indication.

In Europe, fillers are classified as medical devices and thus clinical trial data requirements are much less rigorous, certainly when compared to our medicines regulations, in fact the CE marking relates more to the production methods of the product than it does its safety and efficacy when used in humans. Because of this some people within the industry are therefore advocating that UK practitioners should only use those products which are also FDA approved, more clinical data, more evidence of safety and long term efficacy has got to be good, right? Yet many of the now FDA approved dermal fillers only got their body of evidence for approval application from decades of use and trial data in the European market, take Restylane as a prime example.

So there are clearly issues with both regulatory models and neither is perfect.

Additionally there have been calls by the industry for dermal fillers to be reclassified as medicines (prescription only) which would make them subject to much stricter regulations in the UK and Europe, both in terms of product scrutiny as well as providers. This would need legislative changes on a European level for the UK to be able to implement this, something which it is feared by many to be an impossible task.

When it comes to practitioners offering dermal fillers it's a simple case of 'who' and 'how'. Who should be providing such treatments in the first place and how should they be adequately trained in order to do so.

Predominantly dermal fillers have always been provided in the UK by Doctors (including Dermatologists and Cosmetic Surgeons), Dentists and Registered Nurses. This stance is very much backed by the main manufacturers of well-known brands. Yet there is currently no legislation to uphold this practice and 'anyone' can offer them to the public, with little to no recourse.

With no real regulation in this area, BABTAC, the industry body for Beauty Therapists is now making a case for them to been seen as reputable practitioners when it comes to dermal fillers, quoting those with experience in electrolysis and micropigmentation as the most 'qualified' to undertake filler treatments. Their magazine for February/March this year stated; "BABTAC is keen to be involved in the development of a level 4/5 (NVQ) qualification for suitable practitioners, including therapists to train practitioners to have all the necessary skills to carry out safe and effective injectable cosmetic procedures".

Conversely the recent public draft of the new European CEN Standard for Aesthetic Surgery Services is causing widespread controversy as this document currently states that Nurses and Dentists should be excluded from providing dermal fillers, unless under the supervision of a medical Doctor.

So if Europe wants even the medics split down the middle and only Doctors to perform dermal fillers treatments, surely the beauty therapists stand little chance of acceptance. But again, when the standard, once ratified, comes into existence, it too won't be a mandatory requirement, just a 'best practice' aim for those clinics wishing to be heads above the rest.

So what are the practical solutions?

At the start of 2012, the Treatments You Can Trust Governance Group announced 7 challenges that it would be targeting in the future. Some of these related to dermal fillers and included the reduction in the number of dermal fillers available in the UK market, citing the worry that stricter guidelines are not in place to evaluate the safety data relating to dermal filler products. The restriction of the foreign supply of dermal fillers to the UK, where they noted that non-CE marked dermal fillers or even counterfeit versions of established leading brand names are also promoted via Internet shops from the Far East providing additional concerns regarding patient safety. And the need to track the use of dermal fillers amongst appropriately qualified providers, pointing out that several manufacturers including Merz, Lifestyle Aesthetics and Allergan all have on the side of the boxes of their respective dermal filler brands that they should only be supplied to Doctors and Nurses. The challenge is how this distribution can be monitored to restrict the use of their products by Beauty Therapists.

As discussed there is currently no formalised, approved training in dermal fillers and manufacturers lost control of this many years ago as private training course companies and independent Doctor/Nurse trainers took over. Although the Treatments You Can Trust scheme and insurers such as Hamilton Fraser will only recognise competence from qualifications obtained from certain number of 'approved' trainers for inclusion in the injectors

register or for medical indemnity insurance, this doesn't mean that there isn't a wide range of courses available out there with no agreed guidelines, verification of ability or a control on product supply and insurance for attendees.

And what if you were trained a decade ago? No one asks you to retrain. Many practitioners will attend conferences each year or small group workshops where they can top up their CPD points but this isn't a requirement in order to offer dermal fillers to the public. When the FACE meeting first started, almost a decade ago it was all about filling lines and folds, now it's all about volumising and facial structure rather than just tracing a line with a needle and syringe. If practitioners don't retrain and continue to learn this can only breed poor practice and complacency.

To reduce the risk of trauma and potential harmful effects from the administration of dermal fillers, particularly for HA use, many are now advocating the use of blunt cannulae instead of sharp needles. A cannula will glide along connective tissue fibres instead of actually puncturing them like a needle, thus are considered to be less traumatic and less invasive as it's more difficult to damage a blood vessel with a blunt cannula. Similarly, some practitioners are now using assisted injection systems such as Nordson's Artiste, or the Anteis injection system as an additional tool to help deliver product into the skin. These new delivery options are not liked by all experienced practitioners, and may not be suitable for all indications, but may well prove to be a useful solution to reduce the incidence of complications.

And what about learning about problems? How many practitioners for example learn about the effective use of hyaluronidaise for the dissolution of HA fillers? How many practitioners know what to do when a complication arises from a filler product or who the experts are to turn to for help? The implementation of a referral service may mean that unfortunate patients get a satisfactory resolution much quicker.

As well as learning about problems and how to deal with them, there is an argument for learning from problems. A centralised reporting mechanism for adverse events occurring through the use of the many dermal filler products may stop continued use of products by unsuspecting practitioners who have just been sold the next 'Bio-Alcamid'.

The European CEN Standard for Aesthetic Surgery Services addresses the requirements for clinical aesthetic practice, (both surgical and non-surgical) to ensure patient safety. It notes that a registration for all practitioners performing aesthetic medical procedures is highly recommended for the future. It goes on to say that formal training recognised and approved by a national competent authority responsible for medical training and education is the only controllable guarantee that the practitioner has the competence and knowledge to perform aesthetic medical procedures. As previously discussed, currently 'practitioner' refers only to medical doctors.

The standard goes on to discuss training and says that a practitioner undertaking procedures such as dermal fillers shall have at least two years of general clinical experience and at least three years of specific training in those procedures they intend to do. Ongoing the practitioner shall improve continuously his/her professional knowledge and attend at least 2 CME accredited scientific events per year relevant to aesthetic medical procedures.

There is much to debate on this subject and to that end a session on the Saturday at FACE 2012 will look at the new European standard, the regulation of dermal fillers from a U.S. and European perspective, followed by a roundtable debate on the practical approaches to raising standards in dermal filler treatments.

Unless we get things sorted within this field, we are definitely in danger of adverse media publicity, sooner rather than later!

Ron Myers, Director Consultingroom.com Ltd, FACE Media Ltd and MediZen Ltd
After a career in the pharmaceutical industry, which included being involved in the launch of Botox® in 1994, Ron, with his business partner Martyn Roe, set up a consultancy business called Aesthetic Business Services. They helped to develop Wigmore Medical's "one stop shop" concept for aesthetic supplies, and launched the FACE and BODY Conferences. Ron and Martyn also own **www.consultingroom.com** – launched in 2003, and now the largest specialist aesthetic membership website in the UK, alongside dedicated training website **www.cosmetictraining.co.uk**, and multimedia portal – **www.cosmeticvideos.co.uk**.

They also part-own MediZen – a Midlands based cosmetic clinic and clinical trial centre which, in conjunction with their other activities, gives them a very broad overview of the cosmetic industry.
Other activities include web marketing and consultancy services - **www.consultingroomservices.com**, their annual Golf Tournament: **www.consultingroomgolf.co.uk**, and popular SMART IDEAS events – **www.smartseminar.co.uk**.

If you have any comments or suggestions regarding this article, please email
clinicarea@consultingroom.com