Facial fillers are assumed to be safer than surgery, but Britain has become the testing ground for many unproven products

Injections that plump the skin and fill out wrinkles - known as “fillers” - sound safe, quick and cheap. They’re approaching the popularity of Botox, with tens of thousands tempted every year because they are seen as less risky than surgery, says Mintel, the market research company.

But if you thought that because they are available everywhere from the high street to Harley Street, they are tightly controlled and proved safe, you’d be very wrong. When it comes to dermal fillers, Britain is the Wild West, where safety regulations are flimsy and knowledge of long-term effects can be non-existent.

Take a look through your Yellow Pages or go online and you’ll find dozens of clinics that offer dermal fillers. You might find one, as we did, that advertises injections with Dermalive - “a new form of hyaluronic gel thick enough to enhance cheekbones, fill out deep nose-to-mouth lines and inverted scars, or make a weak chin look more pronounced”.

The clinic is registered with the official vetting body, the Healthcare Commission, and its website assures us that Dermalive “satisfies all safety, reliability and efficiency requirements in accordance with European standards and is EEC approved”.

Dermalive is not used in the US

It all sounds reassuring, until you know three things. First that Dermalive, though promoted here, is not allowed to be marketed as a filler in the United States and that it is the subject of controversy in Canada, where people who say they have suffered bad reactions are trying to launch legal action against the makers and distributors. Secondly, that registration with the Healthcare Commission means only that general standards of care at the premises - not quality or safety of individual treatments - have been vetted. And finally, that “European standards” are currently so ill-adapted to fillers that British cosmetic doctors think they are virtually worthless.

At clinics all over the country, beauty therapists with minimal training can inject synthetic substances with long-lasting, but often scantily researched, effects. So lax are British filler regulations that safety-conscious American authorities are using us as a testing ground for
products before allowing them to be used in the US, according to the consumer body Which?, now campaigning for tighter regulation here.

Nick Lowe, a dermatologist and doctor, and one of Britain’s most authoritative voices on cosmetic treatments, says that there are more than 100 fillers that contain a substance called hyaluronic acid in the UK, but only six in the US, where the Food and Drug Administration (FDA) conducts long-term safety and efficacy assessments before allowing products to be marketed. Britain has no equivalent system and the public is unaware that some products are more proven than others.

“An over-enthusiastic capitalist might say that we need all these new substances, but a sane clinician would say that we actually need only four or five that have been well tested,” says Dr Lowe. “Fillers are released in Europe without sufficient scrutiny and education on the best way to deliver them.”

**Minimum checks for European safety mark**

The Government’s drug regulating body (the Medicines and Healthcare products Regulatory Agency, or MHRA) controls only substances that have a medical use and are prescription only, such as Botox. But this doesn’t apply to most fillers and the only checks are minimum safety and efficacy ones for a European “CE” mark. “The legislation is incredibly weak, allowing companies to self-certify or use independent testing laboratories,” says Jenny Driscoll, of Which?

One bizarre anomaly is that an injection of water into the skin can be administered only by a qualified doctor while injections of permanent fillers containing synthetic gels and “microspheres” can be administered by anyone, anywhere.

Independent studies have reported short-term complications from several permanent fillers, the most common being “granuloma”, or inflamed and lumpy tissue. Although manufacturers stress that such complications are rare, the problem isn’t so much that we know permanent fillers are risky, simply that we don’t know enough about them at all.

**Ill-effects of temporary fillers can wear off**

Many injectable fillers are temporary, made of collagen or hyaluronic acid, which can be reabsorbed into the body. This means their effect wears off after a year or so, and that any ill effects are likely to be temporary. The substance can also be dissolved or removed if anything goes wrong. Each treatment costs between £150 and £750, depending on what area is being treated.

Permanent fillers such as Dermalive and Artecoll, are also based on hyaluronic acid and collagen but include synthetic particles and gels that won’t be absorbed by the body. These fillers may be appealing because they remove the need for regular “top-up” jabs, but doctors are worried that there is not enough research to show how people look or feel ten years on.
Ron Myers, who is a consultant to the cosmetics industry, is concerned that though permanent fillers may be effective for patients who have lost large amounts of tissue after major surgery, there is limited information demonstrating their long-term value in “facial rejuvenation”. He is worried that permanent fillers may make people look strange when the shape of their faces changes as they age. “Areas of filler may start to stand proud,” he says. “Total facial contouring is the new buzzword; fillers are being injected in all areas of the face, including under the eyes. Even experienced practitioners can have problems getting a natural-looking result here.”

Dr John Curran, president of the British Association of Cosmetic Doctors, says that permanent fillers concern cosmetic doctors. “The evidence behind them isn’t there. If I saw colleagues using products like Dermalive and Artecoll, I’d say that they fell below the standard required of a doctor and might refer them to the General Medical Council.”

Artecoll, which is available throughout the UK, is a good example of the British being guinea-pigs for the more wary US market. Artecoll, a permanent filler made of collagen and tiny synthetic beads, evolved from a substance called Arteplast, first made available to Europeans in the early 1990s. After reports of granuloma, it was reformulated, renamed and launched in Europe in 1994, gaining a CE mark.

In America, meanwhile, the FDA tracked European developments closely. In February 2003 it convened to discuss the risks and benefits of Artecoll on the basis of European evidence, before approving in 2006 Artefill, a new version for the American market - with strict conditions that it should be used only by doctors trained in its use, and only in particular circumstances. There are no such strictures in Britain.

Artes Medical, the maker of Artefill, says it has never manufactured or distributed Artecoll. The Dutch company behind Artecoll, Rofil Medical, says the product has been on the market 15 years. “A lot of research has been done and there are numerous studies available,” said product manager Maud Kas. “Artecoll has to be injected into the skin at the proper depth and used for the indicated areas of the face. Adverse events can always happen, but this goes for all dermal fillers. We find Artecoll one of the best documented and safest products on the dermal fillers market.”

Meanwhile, Dermatech, the manufacturer of Dermalive, has proved difficult to contact. Its distributor, Vivier Pharma in Canada, was given the opportunity to comment on the product’s safety and efficacy but decided not to.

Three years ago the Department of Health said that it would look at the need for additional regulation of aesthetic fillers, asking the MHRA and Healthcare Commission to steer the process. Then, last year, it changed its mind. Instead, it asked for a voluntary self-regulation scheme from the industry itself, led by the private health industry’s body the Independent Healthcare Advisory Services (IHAS), supported by the Healthcare Commission.

Calls from Body&Soul to the commission, however, reveal that it believes the responsibility
for regulation is now with the IHAS alone. The IHAS says that dermal filler regulation cannot be fully addressed unless the MHRA classifies fillers as medicines rather than medical devices so that they become, like Botox, regulated under the Medicines Act. The MHRA, however, says there is no evidence that the assessment process for this type of product “is not sufficiently rigorous” and that the only moves to change regulations are at European level, where a consultation is being held on medical devices directives.

**Self-regulation is starting, say clinics**

Amid this complex cat’s cradle, Sally Taber of the IHAS says that self-regulation of cosmetic and aesthetic clinics is beginning to take shape. She wants to develop a quality assurance mark, which will be granted only to clinics where doctors, nurses and dentists administer cosmetic procedures, rather than hairdressers and beauticians. That way, any practitioner suspected of behaving irresponsibly, or using products that have not been sufficiently tested, can be referred to their professional regulator, such as the General Medical Council.

But it’s all going to take time. Despite the Government’s supposed awareness of a problem that required action three years ago, nothing has happened - and is unlikely to happen for years. Which means that it’s up to us to be very careful, to follow the advice of doctors and industry experts (see box) and to remember that although it might look like Harley Street, it could actually be Dodge City.

**Lucia van der Post, the weekly style columnist for times2, puts her faith in fillers and a New York surgeon**

Plastic surgeons have a wonderfully graphic metaphor to describe how our faces age. Imagine, they say, a balloon. As the air slowly seeps out of it, so its surface begins to wrinkle. Blow it up and the surface fills out and it becomes smooth again.

That, they say, is what happens to our skin. It wrinkles and, worse, becomes misshapen, because the face loses volume. Ergo...if you can replace the lost volume, the skin will plump out again, the wrinkles disappear and we’ll look a little bit more like our old - or perhaps I should say our younger - selves. Forget the knife, is the new mantra; fillers is where modern anti-ageing warfare is waging its newest battle.

But choose your filler and your aesthetician carefully. Yan Trokel, a New York surgeon who has developed a unique method of “filling in” the deflating skin called the Y-Lift, uses nothing but hyaluronic acid (the brand he uses is Juv?derm, a temporary filler).

The Y-lift is so-called because Dr Trokel believes that the perfect face shape is a Y; two good cheekbones forming the top of the Y and the chin forming the base. As we age, the “Y” becomes wider and looser. To restore it, he has developed a titanium instrument that he uses to lift the muscles, fascia and fat underlying the skin. Once lifted, he injects the hyaluronic acid to “hold” them and the skin in their newly uplifted positions. No knife. No general anaesthetic. No weeks of hiding behind scarves and dark glasses. It takes about half an hour, so a lunchtime does nicely.
Since I am a fan of Dr Jules Nabet and Joanne Evans’s treatments at the Soma Centre, a medispa in West London where Dr Trokel performs his Y-lift procedures in London, I was invited to try it. I pored over the pictures of “befores” and “afters” done by Dr Trokel in the US. The results seemed to me subtle yet significant. Jawlines became firmer, cheekbones were higher, faces were generally smoother, lines less obvious.

I decide to go for it. Dr Trokel starts with pain-killing injections, something like the ones dentists use. The following “lifting” feels odd and is not something you would want to endure every day. The instrument - which I imagine to be like a very fine crochet hook, though I never saw it - is inserted under the skin and a little “hoicking” done. Then the fillers are injected.

After about 30 minutes it is all over. I am left with a bruise on my chin and a couple of slight (invisible) bumps on the outside of each cheekbone. Dr Trokel leaves for New York that night, having done 30 or more Y-Lifts (news of the treatment has spread like wildfire), so I visit Dr Nabet, his London partner, the next day for a check-up. He declares the results “fabulous”.

Me? At first I’m not too thrilled as I have several big events to go to, all with a large bruise on my chin. I play it straight and explain that my husband hasn’t socked me one; I’ve had a “procedure”. Every woman is riveted. They behave like wildebeest desperate to get to the better grazing on the other side of a crocodile-filled river. They’re nervous, fascinated and yet longing to go for it.

Ultimately I’m very pleased. My cheekbones look more pronounced, my jawline firmer. These are small, definite improvements for which I’m grateful.

The curious thing, though - which must be depressing for the surgeons - is that after about a week you forget what you looked like before and take it all for granted. But, then, isn’t that the best compliment of all?

Dr Trokel will be at The Soma Centre, Royal Garden Hotel, Kensington, London W8 (020-7938 2195), on December 9 and 10. A Y-lift costs £2,000 and lasts about two years. www.imageispower.com

What cosmetic doctors use on themselves

Dr Tracy Mountford, 46, cosmetic doctor

I use... Restylane, a temporary filler, in my nose-to-mouth lines and around my lips. Collagen is good, but like most practitioners I’ve moved to Restylane as it lasts longer - six to nine months rather than three to four. Avoid...using someone who isn’t medically trained. Be cautious. www.cosmeticskinclinic.com

Dr Vicki Dondos, 34, cosmetic doctor
I use...Restylane. It is made by one of the big pharmaceutical companies, has been around the longest and has the most data. Avoid...new things. There are good new products and fillers on the market but wait for the data to come through on them. Be patient. www.medicetics.com

Dr Hilary Allan, 47, cosmetic doctor

I use...Juv?derm Ultra, a temporary filler. It’s good for feathery lips and deep frown lines. Avoid...permanent fillers. I’ve seen them cause major problems, such as lumps or puckers in the skin. Faces can change a lot over ten years. Fillers that look good when you’re in your forties can look ridiculous when you’re in your fifties. www.woodfordmedical.com

Dr Elisabeth Dancey, 49, cosmetic doctor

I use...temporary fillers based on hyaluronic acid, the natural hydrating agent found in our eyes, joints and skin. Esth?lis for fine lines on the top layers of skin, Surgiderm for nose-to-mouth lines, Restylane for eye sockets and Voluma for cheeks. Avoid...artificial products. Natural compounds that are found in your bodycan be dissolved if anything goes wrong. www.elisabethdancey.co.uk

Dr Tamara Griffiths, consultant dermatologist

I use...Restylane on my patients. I don’t use any fillers on myself, although I’m sure my time will come! Out of all the temporary fillers Restylane has been around the longest. Avoid...using fillers if you have allergies or autoimmune diseases such as lupus or rheumatoid arthritis - the chances of developing an allergic reaction are higher.

Before you begin

You have far more protection if you have treatment administered by a doctor

Make sure you know what filler is being used, why, and whether it is permanent or temporary.

Do you research. Go to www.consultingroom.com or www.which.co.uk/cosmetic.

Make sure you understand what your practitioner means when he or she uses the term “semi-permanent”.

Your practitioner should have a training certificate from the manufacturer of the filler, and the testimony of happy clients.

Ask who makes the filler: big companies such as sanofi-aventis, Q-Med and Allergen are more likely to have had extensive trials.

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