



A bigger landscape

In David Hockney country
Pages 48-50

DAVID APPELEY / DREAMWORKS

Alert over dangers of cosmetic injections

Government pledge over breast implant costs

Fay Schlesinger, Chris Smyth, Sasha Magill
High street clinics are injecting patients with anti-ageing fillers that senior surgeons have said are dangerous and could do long term damage, an investigation by *The Times* has found. People who had facial fillers up to ten years ago are now coming forward with infections that can cause deformities, prompting calls for all permanent fillers to be banned in Britain. Barry Jones, a consultant plastic sur-

removed will not have to pay for the operation despite an expert review concluding that there is no evidence that routine removal is necessary.

"It has been a worrying time for these women," Mr Lansley said. The review found that available data was insufficient to establish whether the implants were more likely to rupture than other brands. Mr Lansley said that the health authorities would contact thousands of cancer patients who had the PIP implants on the NHS to say that if, after discussion with doctors, women want to have the implants removed, the state would pay.

He demanded that private clinics do the same for the women they gave PIP implants. Spire Healthcare, Britain's second largest private hospital chain, said it would treat women for free, but others are more resistant. But the NHS will have to pay for women treated by clinics which have gone bankrupt or refuse to co-operate. It insists that clinics have a legal duty to pay.

Anti-ageing fillers are injected into tens of thousands of people each year by practitioners who may have no qualifications. Some clinics offer same-day treatments of permanent facial fillers without any warning about potential dangers. Some are using a filler that senior doctors say has a 5 per cent complication rate.

'Dangerous' jabs still on offer to cure wrinkles

News, pages 8,9

geon, said: "Permanent fillers cause long-term, low-grade infections that cause discomfort and discharge. The evidence is that if you try to treat them surgically, you make them worse not better. There is no answer."

The revelations about the dangers of fillers came as Andrew Lansley tried to tackle the fears of 40,000 women with potentially faulty breast implants made by the disgraced French company PIP.

The Health Secretary said that patients who want their PIP implants



Jeremy Irvine, as Albert Narracott, rides Joey in Steven Spielberg's film. "It's a story that will, I hope, be loved but that's also provocative" Michael Morpurgo, Interview, pages 4, 5

Exclusive Where I found inspiration for War Horse, by Michael Morpurgo

Performance - turkeys / ridiculous art prostheses

IN THE NEWS

Fall in jobless a boost for Obama

President Obama was given a pre-election boost after figures disclosed that 200,000 Americans joined the workforce last month and the unemployment rate declined. There had been a 100,000 rise November. Page 66

Off with the head

Jamaica's new Government has vowed to get rid of the Queen as head of state. The island would mark the 50th anniversary of independence this year by moving towards republicanism. Page 28

Sequel: Year Two

The top seven films at America's box office last year were sequels and 26 more are scheduled for this year. People go less to the cinema in tough times and want familiar material. Page 35

Inside today

A brief history of a genius Birthday tribute to Stephen Hawking

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News Plastic surgery

High street clinics still offering women 'dangerous' jabs to smooth wrinkles

Fay Schlesinger, Sasha Magill, Laura Dixon

Some high Street clinics are offering patients a "dangerous" permanent facial filler, an investigation by *The Times* has learnt.

Bio-Alcamid, a wrinkle-smoothing gel which is not approved for use in the US and the long-term effects of which have been questioned in a medical trial in Spain, can "migrate" from where it is originally injected and cause lumps under the skin.

The most serious cases have seen women develop serious infections, sometimes as a result of routine dental treatment, that cause the body's immune cells to react to the product. The women have ended up in hospital.

Many senior doctors have already stopped using the treatment. Dr Sean Cummings, who administered Bio-Alcamid to hundreds of patients at his Freedom Health clinic in Harley Street, Central London, said he had stopped using it two years ago after witnessing one in 20 patients suffering complications.

Fazel Fatah, president of the British Association of Aesthetic Plastic Surgeons who used it for serious facial reconstruction, has also stopped. "Anyone who has a permanent filler must be made aware that in the long term they can have problems, including infections or reactions to the materials," he said.

But when *The Times* rang one beauty clinic in Leeds and arranged an on-the-spot consultation about fillers this week, the reporter was offered Bio-Alcamid with no warnings of the possible long-term effects.

A doctor recommended "temporary" fillers for first time use rather than Bio-Alcamid, but said it could be an option for more experienced filler users. In ten years' practice, he said, he had never had any problems with any fillers.

Dr Cummings said his decision to stop using Bio-Alcamid coincided with a large price increase in about 2009, when there were well-publicised concerns about its effects. He suspects that the rise in price may have been an attempt by the makers, Polymekon, to prevent further use.

Polymekon, based in Brindisi, Italy, appears to have ceased to operate. Its website and telephone lines are down and its main distributor in Britain said that it no longer stocked the product.

Dr Cummings said that most practitioners, who do not have to be doctors, learned to use Bio-Alcamid during a single afternoon observation session at a lecture theatre in London, though he requested three training sessions at his own clinic.

He said: "There have been polarised views. Some people say it is safe enough to use and I have had some good results. I have seen complications in the range of 4.5 to 5 per cent, which is not safe. I have stopped using it."

Previously, Polymekon has said that

A new pout at lunchtime?

First person Laura Dixon

Alongside the usual eyebrow shaping and waxing, many salons are now offering facial fillers. Lip jobs. Cheek jobs. Not surgery, but still something that can change the shape and nature of your face.

The Times rang a number of beauty clinics in Leeds to inquire about getting "a bit of work" done, asking in particular about bio-alcamid, a permanent filler that a number of doctors have expressed serious concerns about.

I thought fillers were the preserve of the over-50. Wrong: apparently lots of young-ish women are getting them, for bigger lips and fuller cheeks. The doctor in one clinic said that I could choose something "conservative" or something "really nice" — depending on the amount of filler. They brought out five fillers, four of them temporary and one packet of bio-alcamid, to explain the pros and cons of each.

Temporary fillers, which last between four months and a year, cost about £250 when used on the lips. One of the cheaper products is £200, but it is usually accompanied



Treatments seem remarkably easy

by a few days' swelling. Cheek fillers cost from £400 to £600. There are, the doctor noted, lots of places that offer even cheaper products, "but if you go to the pound shop you don't get M&S".

This doctor recommended the temporary fillers for first-time use, but did not mention any possible complications with the long-term injection. In ten years' practice, he said, he had never had any problems with any of the fillers.

But it is not always doctors carrying out the treatment. In two beauty salons visited this week it is nurses who do the injections.

It all seems remarkably easy: a lunchtime appointment, a new pout.

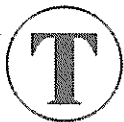
the gel itself had a 1 per cent rate of complication and does not migrate. It claimed that most problems were likely to have involved poor administration or subsequent procedures introducing bacteria into the implants.

The Medicines and Healthcare Products Regulatory Agency (MHRA) said that it had no specific concerns over the product, providing it was used according to the manufacturer's instructions. But the British Association

Online today

Tell us your experience of plastic surgery

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tion of Dermatologists called yesterday for the MHRA to reclassify fillers as medicines, rather than the current "devices", and regulate them more tightly so that only qualified practitioners can administer them.

The Times investigation also discovered that GPs were routinely carrying out minor cosmetic surgery in private clinics without qualifications other than their general practitioner's certificate.

Liposuction, fat grafting and breast augmentation using injectable gels are among the invasive procedures carried

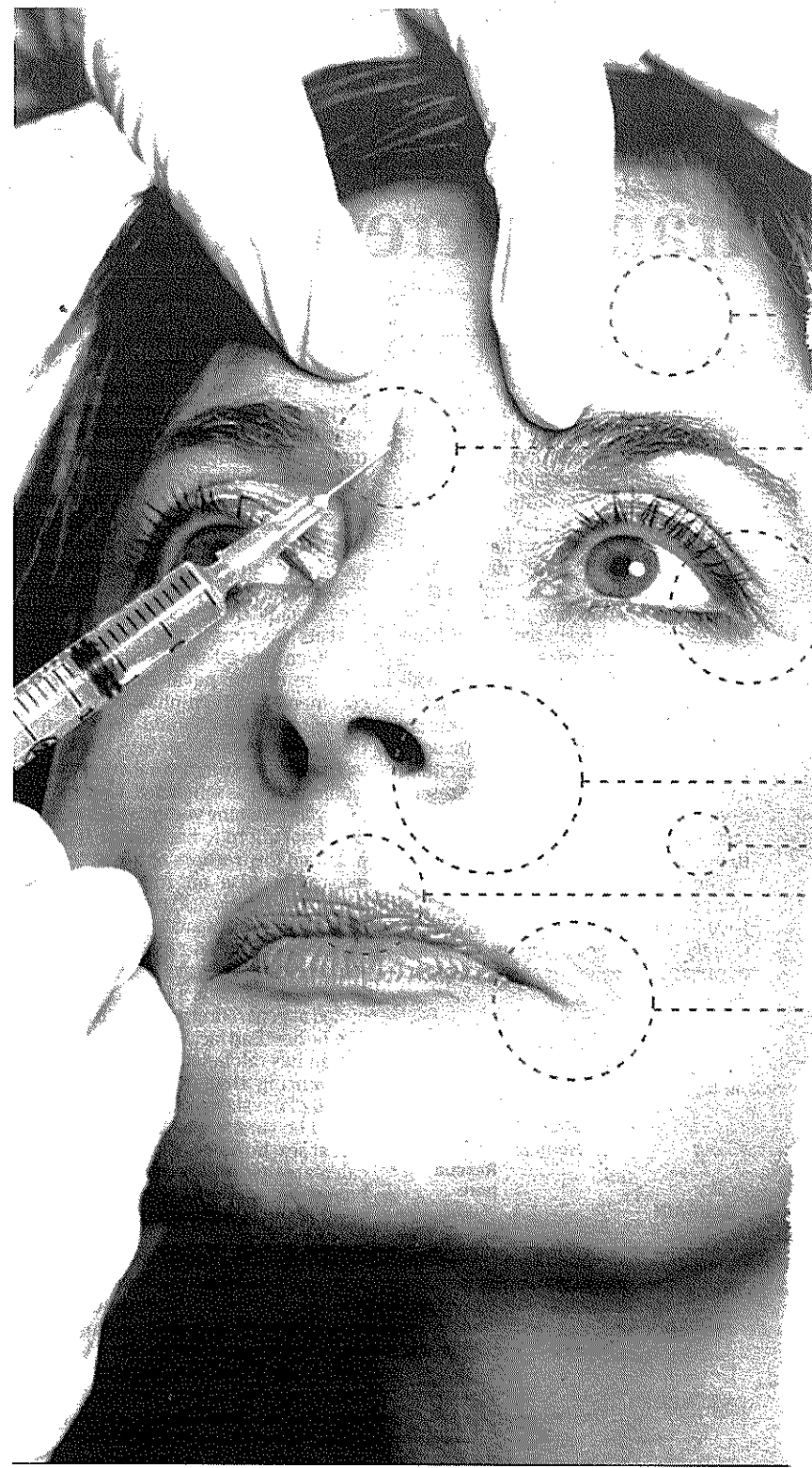
out in Harley Street clinics by GPs, it has emerged. In the private sector, there is no requirement for cosmetic surgeons to have anything beyond basic medical training.

Nigel Mercer, a consultant plastic surgeon and former president of the British Association of Aesthetic Plastic Surgeons, said that anecdotal evidence suggested that there were at least a hundred people carrying out cosmetic surgery in Britain who would not meet the stringent requirements to practise under the NHS.

One GP-turned-cosmetic surgeon told *The Times* that minor surgery with local anaesthetic was entirely safe, as long as GPs knew to draw the line and did not attempt breast implants.

Mike Comins, of The Private Clinic in Harley Street, said his liposuction and fat grafts — commonly the transfer of fat from the abdomen to the breasts — are equivalent to GPs carrying out minor procedures such as mole removal for the NHS. Dr Comins, 46, worked part-time as a GP and moved into private cosmetic procedures 12 years ago but has not completed further formal qualifications.

He said: "I don't call myself a cosmetic surgeon, and I only carry out minor invasive procedures that I can do absolutely safely. I have carried out over 3,000 procedures. Whatever my background I am a doctor and I adhere to the GMC guidelines."



When things go wrong

Lisa Stredwick 'They can't treat clients as guinea pigs'

For eight years after she had dermal filler injected into her lips, Lisa Stredwick was happy: she had a temporary fuller smile from a reputable clinic in return for £800 and no side-effects.

But in 2007, the Pilates teacher noticed a cold-sore-like mark on her upper lip. When she returned to the Central London clinic that had treated her nearly a decade earlier, the practitioner "went white as if they had seen a ghost", she said.

Ms Stredwick, now 42, had a major infection that grew in size despite treatment with steroids. It was then she discovered that, contrary to what she had understood, the two dermal fillers were permanent.

In 2008, she paid £5,000 for an operation to remove the filler and hard granulomas — immune cells



that had developed around the product because of the infection.

But the way the filler spreads means it will never be fully removed. Doctors have told her it was designed for other areas of the face.

Ms Stredwick, married and from East London, has been left permanently scarred along her top lip and still has six-weekly injections to help the healing process. "The clinics have to know they can't treat clients like guinea pigs," she said. "If we don't know the long-term effects of a filler, it shouldn't be allowed."

GRAPHIC: PAUL ERYANT FOR THE TIMES

JEAN-PAUL FELSISHER / REUTERS

Where fillers are used

- Forehead lines
- Frown furrows
- Crows feet
- Nose to mouth grooves (nasolabial folds)
- Acne pits
- Lip lines
- Marionette lines

Dermal fillers are gels injected into the skin to reduce wrinkles and facial lines and create smoother, plumper-looking skin

Oc No Dec
1 1 19

They can be temporary — naturally breaking down a few weeks or months before — or permanent, meaning they remain under the skin and do not need to be topped up

Permanent ones are very difficult to remove and have led to reports of lumps and infections

CE

They only have approval with a CE mark, as seen on teddy bears or toasters



Boxes of silicone gel breast implants and prosthetic testicles in the PIP building

Deserted warehouse gives up secrets of a suspect company

Laura Pitel finds the abandoned French factory at the heart of the scandal littered with silicone products

In a rundown alley in an unglamorous corner of Provence lies all that is left of the French company now at the centre of a global health scandal.

Boxes of silicone implants are strewn across the floor of the abandoned warehouse. Pots of gels and powders dot the counters, and thousands of documents and folders lie in heaps.

Prosecutors in Marseilles have now opened a criminal investigation into Poly Implant Prothèses and this week a judge visited the company's former headquarters. But many are asking why the warehouse, which closed last year, has not been sealed off as a crime scene.

Anyone can walk into the building on an industrial estate in the borough of Six-Fours-les-Plages. A group of travellers have set up camp in the car park and put up a makeshift kitchen in one corner.

In the warehouse, a large box of prosthetic testicles confirmed claims made in recent days by former employees that the company produced not only breast implants but also male products.

The company also appears to have been developing fillers for facial wrinkles. In one room there were several boxes of syringes marked "PIP", containing a clear, colourless liquid. Corresponding documents found nearby showed that the company had paid for clinical trials of a product, described as a "wrinkle-filling gel", to be carried out on rats. There were nothing to suggest that the product had reached the market either in France or Britain and an online search produced no results.

It is a difficult time for the residents of Six-Fours. The revelation that PIP was using industrial-grade silicone in its breast implants has left many asking how a company could have created a fraudulent health product for so long.

"It went on for ten years. That's a very long time," said Dr Arnaud Rochebilière, a plastic surgeon based in the neighbouring city of Toulon.

One former employee offered a clue. "The bosses at the factory were given 15 days' notice ahead of an inspection," he

said. "They had time to clear away anything suspicious. I don't know whether that is normal practice or if they were getting something in return."

Jean-Claude Guidicelli, a Toulon-based lawyer for ten women with PIP implants, is convinced it was not only those at PIP who knew what was going on. "Everyone knew these implants were defective," he said. "All the regulatory authorities in France were aware. Everyone respected the web of silence."

His theory? "There's lots of money involved. Up to a high level. It was a case of money first, virtue later."

But some of PIP's former workers have been left upset by the implication that they knew what was happening but failed to act. "I don't want to speak any more," said one when called by *The Times*. "I've been threatened on the phone. The patients' blogs tell us we are murderers." He said that claims that all the employee knew about the use of authorised silicone were untrue. "That's false. We were not aware of anything. We are not chemists."

Another worker said: "Most employees had no idea. The implants are impossible to tell apart. Put two together and they're exactly the same — they look the same, they feel the same."

So far, scrutiny has fallen mainly on Jean-Claude Mas, the company's multi-millionaire founder. Yesterday his reputation was not enhanced after a transcript of comments he made to French police last year were leaked. In them he said that victims were only suing him for the money and he described the plaintiffs as psychologically "fragile".

Mr Mas, 72, who is expected to face trial for aggravated fraud, added: "I knew the [silicone] gel was not authorised but I used it deliberately because the PIP gel was less expensive. The formula was perfect, it is better than that used to make the authorised gel."

He also said he had told staff to "hide the truth" about the make-up of the implants from TÜV, the German firm that was responsible for disbursing compliance certificates to PIP and the rest of the industry.

Another former employee warned: "You have to know that Mr Mas was not the worst. There were the executive director and managers around him who knew everything but went on the same way, and even worse. Lots of money was involved."

Additional reporting Marie Tourres and Adam Sage

Sarah Payne 'It's like having a time-bomb in your face'

Sarah Payne, a former beauty clinic manager, was injected with Bio-Alcamid in her cheeks to lift and give the area volume.

A few months later she began to notice small lumps in her cheekbone area. She had the filler removed, but more lumps continued to appear. Ms Payne went on to have an MRI scan, which revealed that the product had disintegrated, and that parts of it had spread to the area directly around

her eyeball. She had an operation carried out by three surgeons to remove the Bio-Alcamid, but parts of it remain and she is anxious about the long-term consequences this may have.

"It's like having a time-bomb in your face. You don't know what's going to happen," she said.

"There is no redress. Nobody will take responsibility. That is the real problem. There are so many people out there [practising]. You just have to have insurance, you don't have to have a qualification. It is a minefield.

"I say always go to a practitioner, never a practice. You can have somebody working for a branded group and you don't even know who they are. How can you be going around changing people's faces when you don't even understand it?"

Inside today

'Cosmetic surgery clinics behaved as irresponsibly as banks. This scandal should end the vogue for painful artifice' Janice Turner

Opinion, page 22



Barrie Fairbairn 'I was put in hospital for infections'

Barrie Fairbairn, a solicitor from Leicester, lost part of his nose from an infection after being injected

with the filler Bio-Alcamid. The £1,000 procedure in 2005 was designed to smooth deep folds from his nose to the corners of his mouth. The filler apparently restricted the blood supply, causing tissue to die and an infection. Antibiotics cleared it up but he has a deformed right nostril, sleeping problems and depression.

He estimates that private medical investigations and time off work cost him £25,000. "I was hospitalised twice for infections. It made me really poorly."