Unexpected outcome (positive or negative) including adverse drug reactions

Complications of facial fillers: resource implications for NHS hospitals

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Summary

Facial rejuvenation seeks to reverse the negative sequelae of multiple factors but most importantly of genetic predisposition, sun damage and smoking. With the advent of the so-called 'non-surgical' techniques, and perhaps fuelled by these austere times, volumetric facial augmentation using dermal fillers has soared in popularity among both patients and practitioners. However, legislation has yet to keep pace with the change in clinical practices leaving patients poorly informed and with no protection against unscrupulous suppliers and unregulated practitioners. When things go wrong, patients often turn to the National Health Service (NHS) to rectify both the acute and chronic sequelae resulting in potentially difficult ethical and resource implications. Here, we report one of an increasing number of cases presenting to our NHS craniofacial service with acute filler-related complications.

BACKGROUND

Volumetric 'non-surgical' facial augmentation has a long history spanning over two centuries. Following well-publicised disasters after facial injection with paraffin derivatives in the early 20th century, it was not until 1962 that the use of silicone for cheek augmentation was described.¹⁻³ Since that time, a number of alternative materials have been developed and marketed and, most recently, hyaluronic acid (HA) fillers have massively increased their market share. The popularity of these HA-based fillers among patients and practitioners alike is probably due to their non-permanent nature and perceived improved safety profile, together with aggressive direct consumer marketing.

Patients seeking these 'non-surgical' procedures often fail to realise how poorly regulated this industry is, particularly outside the US. The US regards all dermal fillers as medicines and, consequently, requires them to be approved by the Federal Drug Administration. However, in Europe, fillers are regarded as medical devices requiring only Conformité Européenne (CE) certification. In the UK, a register of practitioners performing these treatments was introduced by the Independent Healthcare Advisory Service in 2011. However, this register remains voluntary and, in our experience, public awareness of the register remains poor.

Finally, even though regulation of these treatments remains poor (especially in the UK), access to unscrupulous suppliers via the internet is still available to individuals who wish to avoid the costs of professional treatment. Self-administration is fraught with dangers not least because there is usually no information provided regarding the type, composition and sterility of the material for injection actually supplied. We present the interesting case of a 31-year-old patient who presented to our hospital following the self-administration of an injectable filler material sourced from abroad on the internet. Issues regarding clinical management and potential resource implications will be discussed.

CASE PRESENTATION

A 31-year-old patient presented to our accident and emergency unit with a 24 h history of right facial pain and swelling with associated systemic malaise. The patient reported having self-injected approximately 10 ml of a filler material into the left and right nasolabial folds in two instalments over the previous 4 days. The patient had ordered this facial filler material (which the patient assumed to be HA-based) through the internet from a source in Brazil (figure 1). Previous, multiple-site, self-administered facial treatments from the same source had been performed during the last 12 months without complication. Sterile injection equipment had been purchased from Brazil and the patient denied needle sharing.

Hours after the second administration, the patient described a gradual increase in localised erythema, oedema

Figure 1 (A) Clinical photograph after treatment for 2 days with intravenous antibiotics and repeated needle aspirations. (B) Evidence a fluctuant, erythematous, indurated and painful swelling persists.

and pain. Attempts to remove the material by gentle massage and expression through the injection site were unsuccessful.

The patient's medical history included current hormone replacement therapy (oestrogen+anti-androgen). The patient had undergone breast augmentation and was awaiting male-to-female gender reassignment surgery. A background of poly-drug misuse was disclosed.

On examination, the patient was systemically well and all the observations were within normal range. A 4×3 cm swelling with associated induration was noted over the right cheek extending to the right lower eyelid. No discharge or punctum was visible. The swelling was fluctuant but did not transilluminate. Intraoral examination revealed a tense swelling distorting the buccal mucosa. Dental health was reasonable. Reactive ipsilateral submandibular and cervical lymphadenopathy was also noted. No functional compromise was reported.

INVESTIGATIONS

Blood tests were normal apart from a leucocytosis (12×10^9 cells/l) neutrophilia suggesting bacterial infection, and a mild elevation in the C reactive protein (27 mg/l). Microbiology swabs and transoral pus aspirates were taken and sent for microscopy, sensitivity and gram stain. The non-labelled bottle containing the filler substance was sent for analysis. All the cultures were negative; no organisms were grown and only skin flora was found. Tests for acid fast-bacilli and HIV were also negative. Finally, the blood results also returned to within normal range 24 h after the commencement of intravenous antibiotic therapy.

Subsequent nuclear magnetic resonance spectroscopy and mass spectrometry of the unlabelled filler material was performed courtesy of the NMR Centre, Imperial College, University of London. The results confirmed that the sample was principally of silicone oil base (most likely a polydimethylsiloxane). Purity was estimated at 95% with trace contaminants.

DIFFERENTIAL DIAGNOSIS

- Concomitant skin-based pathology with supra-added infection
- Acute exacerbation of chronic granulomatous reaction secondary to multiple filler injections

TREATMENT

On presentation and after appropriate samples were obtained, treatment was commenced with intravenous antibiotics (benzylpenicillin and flucloxacillin). Conventional surgical management with percutaneous incision and drainage under general anaesthesia was advised but declined by the patient for fear of leaving a poor facial scar. The patient did consent to needle aspiration via an intraoral route and topical anaesthesia. This was performed daily for 4 consecutive days before the abscess did not clinically re-collect. On each occasion, 5–8 ml of frank pus was aspirated.

Since the patient stated that an HA-based filler was obtained, the intralesional injection of hyaluronidase was considered. Hyaluronidase degrades HA by lowering its viscosity and increasing its permeability within the tissues. However, given the ambiguous composition of the

unlabelled filler, it was decided that administration of a biologically active substance into the wound was ill-advised. This decision was subsequently vindicated by chemical analysis (the results of which were only available after the patient had left hospital).

OUTCOME AND FOLLOW-UP

Once the patient's clinical condition had settled and the abscess had been aspirated to dryness, the patient subsequently self-discharged. The inpatient length of stay was five nights. The patient failed to attend the outpatient review appointment that had been arranged.

Two months later, the patient re-presented with a similar erythematous fluctuant swelling in the contralateral nasolabial area. The patient denied any repeated self-administration of fillers. Again, the patient refused to consent to percutaneous incision and drainage, and a similar clinical course ensued with multiple needle aspirations of the acute abscess.

The total cost to the health service of these two clinical episodes was £2060 and £1968. The EBITDA for the hospital was +£624 and +£178, respectively. The EBITDA (earnings before interest, taxes, depreciation and amortisation) represents the money that the hospital retains after paying the costs of patient care.

DISCUSSION

Soft tissue augmentation is not a new phenomenon; it dates back to the beginning of the 20th century.^{1 2} Following well-publicised disasters after facial injection with paraffin derivatives in the early 20th century, it was not until 1962 that the use of silicone for cheek augmentation was described.^{3 4} Since that time, a number of alternative materials have been developed and marketed. The popularity of these fillers among patients and practitioners alike is probably due to their perceived improved safety profile, together with aggressive direct consumer marketing.

Volumetric 'non-surgical' facial augmentation has taken the industry by storm, and over the past 10 years, these non-invasive fillers have been easily available to the public. However, legislation has yet to keep pace with the change in clinical practices leaving patients poorly informed and with no protection against unscrupulous suppliers and unregulated practitioners. Parallel to this, the rate of globalisation has also been astounding, fuelling endless possibilities for 'cosmetic tourism',⁴ for those seeking cheaper aesthetic treatments abroad. Nonetheless, when things go wrong, patients often turn to the National Health Service (NHS) to rectify the acute and chronic situation resulting in potentially difficult ethical and resource implications and the case we present highlights this dilemma. We report this case to highlight one of an increasing number of cases presenting to our NHS craniofacial service with acute filler-related complications.

Outside the USA, the industry producing tools and applications of 'non-surgical' aesthetic procedures is very poorly regulated, with approvals only requiring a CE certification. The purchase of medications over the internet is entirely unregulated and this poses an even greater problem as this case highlights. Our patient erroneously assumed she had purchased a hyaluronic based filler when, in fact, subsequent chemical analysis showed this to be

Figure 2 Unlabelled filler material purchased over the internet and self-administered by the patient. Subsequent analysis showed it to be 95% silicone oil.

contaminated silicone oil (figure 2). This extends to the physician or beauticians administering the fillers with no way of assessing their techniques and complication rates.

The use of fillers is associated with normal sequelae that are not the same as complications. These sequelae include swelling, echymosis, postinjection pain and transient visibility of filler.⁴

Complications are often divided into three categories (table 1).^{5–7}

There is no ideal product on the market and fillers are generally categorised as temporary, semipermanent or permanent. The distinction is very important because although the permanent fillers last longer, they carry a much higher risk of complications that are challenging to treat.^{7–10}

Permanent filler complications can be present many years after injection with a high level of unpredictability deeming them a less popular choice for the physician and the patient. Unfortunately, abnormal filler complications are not uncommon, forcing patients to seek help to improve their appearance.^{4 5 11–13} A survey among UK plastic surgeons, carried out by the British Association of Aesthetic Plastic Surgeons in 2009, revealed that approximately 40% of surgeons were seeing 1–3 patients/year with permanent facial filler complications.¹⁴

With patients presenting with the complications of fillers to their local NHS for help, advice and emergency treatment, the role of the NHS needs to be defined. Will it be considered on a case-by-case basis, or do guidelines and standards of treatment need to be outlined? Will the NHS limit its treatment to only the 'acute' cases? These are all unanswered questions that need to be addressed to help guide units such as ours on how to proceed.

Irrespective of the negative microbiology cultures, this case clearly demonstrates the risk of peri-prosthetic infections due to poor aseptic technique, contaminated

instruments or nonsterile filler material as the patient experienced both early and late complications. More specifically, the unknown filler substance used by the patient was identified as polydimethylsiloxane, which can lead to chronic long-term sequelae including severe granulomatous reactions which are very difficult to treat.^{11 15}

It also highlights the dilemma of maintaining aesthetic appearance in a patient disfigured by complications of fillers when trying to manage such cases where surgical incision and drainage is the gold standard. Patients' refusal of further disfiguring incision and drainage, the advised course of treatment, results in prolonged hospital stay and considerable cost to the unit, which are not often reflected in the Healthcare Resource Group (HRG) codes. Treating complications of a procedure such as this is always more costly than the initial treatment.

In the modern health service, the financial and resource implications of treating patients with complications of cosmetic procedures cannot be ignored. Currently, the numbers are small; in the last 15 months, our unit saw 12 patients with infected facial fillers—the largest incidence in the reported literature. However, this is likely to increase as the popularity of facial fillers continues to increase.

The HRG code that each episode maps determines the hospital income for the treatment of these patients. Typically, this falls under 'JC04C: intermediate skin procedures'. For the patient presented here, this totalled £4028. The EBITDA represents the money that the hospital retains after paying the costs of patient care. For this patient, the total EBITDA was +£802. Interestingly, for the series of 12 patients treated by our unit in the last 15 months, the total cost and EBITDA were £38 454 and +£8223, respectively.

These data demonstrate that, at present, the hospital does not incur a direct financial loss during the treatment of these patients. However, two factors suggest that this may not continue. Commissioning Groups may refuse to pay for such treatments reducing income and, for the reasons discussed above, the cost of treating these patients may increase due to additional resource requirements such as prolonged inpatient stays, multiple-imaging investigations and drainage procedures.

CONCLUSION

The literature is populated with case reports; literature reviews and editorials on facial fillers and referrals for management of the complications of dermal fillers are increasing. The British Association of Aesthetic Plastic Surgeons attributed this to the lack of information being provided to patients regarding the risks and side effects, the fact that unqualified practitioners are administering fillers with poor technique and that the lack of

Table 1 Filler complications

Immediate (0–2 days postprocedure)	Early (3–14 days postprocedure)	Late (>14 days post procedure)
<ul style="list-style-type: none"> ▶ Under/over correction ▶ Vascular compromise ▶ Implant visibility (superficial injection) 	<ul style="list-style-type: none"> ▶ Persisting nodularity ▶ Angioedema ▶ Infection ▶ Injection site discolouration ▶ Persistent discolouration 	<ul style="list-style-type: none"> ▶ Persistent erythema and telangiectasia ▶ Migration ▶ Persistent scarring ▶ Immune-mediated granuloma formation

strict regulation in the UK has allowed unproven substances to be used.¹⁴

Therefore, it is vital that patients are assessed thoroughly and the contents used should be formally evaluated in order to tailor the management of the patient accordingly. Furthermore, raising patient awareness about the dangers of fillers is necessary to get a handle on this ever-growing market.

Learning points

- ▶ Dermal filler complications presenting to the National Health Service are likely to increase in frequency owing to the unregulated nature of this industry both in the UK and abroad.
- ▶ Clinicians treating filler complications should remain sceptical about the real composition of the injected materials.
- ▶ Patients may decline conventional surgical techniques of abscess drainage for aesthetic reasons resulting in additional pressures on clinical provision and resource management.
- ▶ Prevention is better than cure: doctors and governments must raise patient awareness about the dangers and potential complications of 'non-surgical' facial rejuvenation.
- ▶ It is time that the UK followed the lead of the US and re-classified dermal fillers as medicines rather than medical devices.

Competing interests None.

Patient consent Obtained.

Provenance and peer review Not commissioned; externally peer reviewed.

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Please cite this article as follows (you will need to access the article online to obtain the date of publication).

Hachach-Haram N, Gregori M, Kirkpatrick N, Young R, Collier J. Complications of facial fillers: resource implications for NHS hospitals. *BMJ Case Reports* 2013;10.1136/bcr-2012-007141, Published XXX

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