

newsletter

Injectable dermal fillers

Aesthetic practices – and with them the demand for dermal filler injections – are booming given the insatiable need for enduring beauty. However, the risk and safety profile of long-lasting cosmetic dermal filler products has not yet been fully established.

Description, Application

Dermal fillers, or soft-tissue fillers, are substances injected to fill facial imperfections, such as wrinkles, creases and concave scars, as well as to enhance the fullness, volume and shape of facial tissue (eg lips). Injection sites include the face and other areas of the body, such as the hands, feet and neck.

Cosmetic procedures are manifold and can basically be broken down into surgical and non-surgical procedures. As a non-surgical procedure, the injection of dermal fillers is one of the most popular methods and is used mainly in the US, Latin America and Europe. Injectable dermal fillers also have several medicinal areas of use, eg in ophthalmic surgery, treatment of osteoarthritis of the knee or in the treatment of HIV-drug induced lipoatrophy. Medicinal use is comparably small and restricted to a limited range of treatment.

Classification

Table 1: Classification of injectable dermal fillers by persistency

Resorbable < 1 year	Semi-permanent 1-2 years	Permanent > 2 years
Own fat	CaHA – Calcium hydroxylapatite	PMMA –
Collagen – bovine		Polymethylmetacrylate
Collagen – human	PLA – Polylactic acid	PAAG –
	DEAE – Sephadex particles (Dextran)	Polyacrylamide gel
	PVA – Polyvinyl alcohol	Polyacrylamide
Collagen – porcine	Chitosan	
HA – animal	HEMA –	
HA – bacterial	hydroxyethylmethacrylate	
	Cultivated human fibroblasts	

HA, also known as hyaluronan, is a glycosaminoglycan, which is a naturally occurring, hydrophilic linear polysaccharide that is a major component of the extracellular matrix of epithelial, connective and neural tissues.

Temporary fillers (or resorbable fillers) are made of collagen or HA, both of which are natural substances that can be reabsorbed by the body. This means their effect wears off after approximately one year, thereby requiring patients to receive periodical top-up injections. The HA fillers most widely used in clinical practice today are non-animal based.

Semi-permanent and permanent injectable fillers are used to correct deep facial creases and restore volume in large areas. They are injected deep within the soft tissue for more long-lasting and large volume correction. Permanent fillers are also based on collagen or HA but include synthetic particles and gels that are not absorbed by the body (eg HA combined with PMMA).

Regulation

In the European Union, injectable filler substances are certified as medical devices, and as such require a CE marking (Conformité Européenne), a mandatory conformity mark on many products placed on the single market in the European Economic Area (EEA). The certification indicates that some degree of clinical evaluation has been performed, albeit limited. This approach to conformity enables manufacturers to use what is called "SELF DECLARATION", where the manufacturer itself declares conformity by signing the "Declaration of Conformity (DOC)" and then affixing the CE marking to its product. Self-certification means that the product being sold in Europe is declared as complying with the Medical Device Directive (MDD). According to the classification of medical devices, a notified body (NB) confirms that the company complies with the MDD and grants a product marketing authorisation (MA). Notified bodies can be governmental authorities or private corporations. International regulations vary with regard to market approval. In the US, fillers must be approved by the FDA as independent governmental agency. This means an additional effort for the manufacturer (regarding the proof of product safety and efficacy) to attain market approval for its product. Consequently, over 140 injectable fillers are available on the UK/European market compared with only few in the US. The massive growth of the industry, fuelled by exponential demand, demedicalisation through advertising and lack of regulation, has led to dentists, nurses and beauticians offering filler injections on the high street. There is currently no requirement for any certified training or a background in facial plastic surgery.

Side effects, Risk evaluation

Side effects can be distinguished between local, mostly procedure-related, rather mild and transient events (eg lumps, swelling), and delayed (weeks to years), adverse reactions (eg inflammatory granuloma, migration of the filler within the face). Serious complications include severe systemic reactions, swelling of the tongue, difficulty breathing, anaphylactic shock and hives. Most notably, permanent products have a heightened adverse reaction profile. According to the IQUAM (International Committee for Quality Assurance, Medical Technologies & Devices in Plastic Surgery), all permanent soft tissue fillers are associated with the risks of infection and granuloma formation, which may lead to major disfigurement. Relatively high volumes of injected permanent fillers, especially hydro gels, are reported to cause severe irreversible damage and have therefore generated substantial concern. Surgery is often needed to fully resolve the side effects of permanent filler. Most of the complications and claims to date are the consequence of treatment performed by inexperienced and unqualified practitioners or physicians with insufficient knowledge of the procedure (eg injection technique and preparation of the product).

Treatment is often performed in "unsafe" facilities (in settings other than a doctor's office) where patients are more prone to infection due to insufficient hygienic precautions. Furthermore, dermal fillers are often used in an off-label manner, with many patients receiving injections in positions that are not indicated (eg in the hands, neck or feet).

**Information for
the underwriter**

Despite the substantial increase in products available for soft-tissue augmentation, well-performed clinical studies are scarce, and long-term clinical safety data are lacking. These products are subject to less stringent regulation than drugs. Although "permanent fillers" promise a lasting solution to wrinkles, their long-term effects are often not known. What's more, the most adverse event reports involve injections by untrained personnel and injections in sites other than those for which the filler has approval (off-label use).

Against this background and the fact that more products of this type are being evolved and will be put onto the market in the next few years, the insurance industry may very rapidly find itself faced with major claims for various damages. This is particularly likely as patient numbers are set to increase rapidly and the already large pool of potential claimants is set to widen more and more. The insurance industry has so far been confronted mainly by single-loss events affecting medical malpractice portfolios. This may change, however, as other lines of business might be affected in the future. Injectable dermal fillers, specifically permanent fillers, represent a long-tail risk with cumulative loss potential. Synthetic products tend to last longer, but are considered to entail a higher risk of lumping or migration.

Predominantly healthy people seeking cosmetic treatment are the most exposed. An individual technical risk evaluation of injectable dermal fillers may be helpful with regard to proper risk management.

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