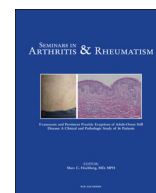


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Inflammatory, immune-mediated adverse reactions related to soft tissue dermal fillers ☆, ☆ ☆, ★, ★ ★

Jaume Alijotas-Reig, MD, PhD^{a,b,c,*}, Maria Teresa Fernández-Figueras, MD, PhD^{d,e}, Lluís Puig, MD, PhD^{f,g}

^a Ageing and Systemic Autoimmune Diseases Research Unit. Service of Internal Medicine-I. Aging Basic Research Unit, Molecular Biology and Biochemistry Research Centre for Nanomedicine (CIBBIM-Nanomedicine), Vall d'Hebron University Research Institute (VHIR), Barcelona, Spain

^b Centro de Investigación Biomédica en Red Bioingeniería, Biomateriales y Nanomedicina (CIBER-BBN), Instituto de Salud Carlos III, Madrid, Spain

^c Department of Medicine, Universitat Autònoma, Barcelona, Spain

^d Pathology Department, Trias I Pujol University Hospital, Barcelona, Spain

^e Universitat Autònoma, Barcelona, Spain

^f Dermatology Department, Sant Pau University Hospital, Barcelona, Spain

^g Department of Medicine, Universitat Autònoma, Barcelona, Spain

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ABSTRACT

Background: An increasing number of persons seek medical solutions for esthetic indications and for diverse pathological conditions, such as malformations, trauma, or cancer. Despite manufacturers' and different authors' claims that fillers are non-immunogenic or that complications are uncommon, unwanted adverse reactions do occur.

Objectives: To review the literature regarding the multiple types of immune-mediated adverse reactions related to medical dermal filler injections/prosthesis.

Methods: A comprehensive MEDLINE, PubMed, and Google Scholar electronic database search was performed (2000–January 2012). Selected articles published before 2000 referring to general concerns regarding the studied topic were also included. The search provided almost 300 articles. Finally, 235 studies were selected and included.

Results: All known fillers present in the market have been shown to be able to provoke early- and late-onset inflammatory adverse reactions. Their true prevalence is unknown but appears to be significant. The majority of the late-onset adverse effects are inflammatory and immune-mediated in nature. Edema, granulomas, sarcoid-like disorders, and panniculitis are the findings most commonly seen. Rarely, systemic granulomatous and autoimmune diseases, and to lesser extent acute hypersensitivity reactions can be seen.

Conclusions: All implanted, injected, and blood-contact biomaterials trigger a wide variety of adverse reactions that may appear early or late and range from local to systemic. Most fillers act more as adjuvants than as direct T-cell activators, on a background of genetic predisposition. Their treatment has not been the subject of well-designed studies. Management of both acute and systemic reactions is often difficult and requires anti-inflammatory and occasionally immunosuppressive therapy.

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1. Introduction

An ever-increasing number of persons seek medical solutions for their aging skin, for purely esthetic and cosmetic indications

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☆☆All authors agree with the contents of the article and also to having their names included in the list of authors.

*The authors also state that they do not have any commercial or any other type of interest that may have influenced the drawing up and the results of this paper.

***We had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

* Correspondence to: Josep M^a de Segarra, 2-F, 08190-Sant Cugat del Vallès, Barcelona, Spain. Tel.: +34 93 489 4194.

E-mail addresses: 16297jar@comb.es, jalijotas@vhebron.net (J. Alijotas-Reig).

or for diverse medical conditions, e.g. malformations such as Poland's syndrome, trauma, cancer, orthopedic, urological, or ophthalmological conditions. Only for esthetic reasons, more than 10 million of fillers have been injected in the United States in 2009, according to the American Society of Aesthetic and Plastic Surgery [1]. Currently, physicians have many different types of dermal and subdermal fillers, which may be classified according to their origin and average persistence in tissue [2,3]. Besides, an increasing number of new dermal fillers is currently available (Table 1). The properties of an ideal filler—namely to be safe, neither allergenic nor immunogenic, effective, injectable with reproducible technique and results, with high potential for use and low for abuse, noncarcinogenic, nonteratogenic, nonmigratory, cost effective, physiologic, and permanent—are not entirely accomplished by any of the available materials. Even though

Table 1
A non-comprehensive list of dermal fillers used at present and in the past

Composition	Commercial name	Permanence: Short (< 3 months) Medium (3–12 months) Long (12–24 months) Very long (> 24 months)	Source	Type of reaction*	Microscopical clue for identification	Reference*
Adipose-derived mesenchymal stem cells	No name	Very long duration	Autologous	ND	ND	ND
Agarose gel	Easy agarose	Medium	Synthetic	ND	ND	ND
Alginate	Novabel	Medium	Biological (sea algae)	GR [†]	Surrounding bluish deposits of variable size and shape with a blurred or spiky perimeter	[170]
Calcium hydroxylapatite (CaHA)	Beautyfill/Radiesse/Radiance	Considered of medium duration but it can last very long	Synthetic	Granulomas, clumping, migration	Bluish round structures	[78,79]
Collagen	ZydermI [®] /Zyderm II [®] Zyplast [®] /Evolence [®] Fibroquel [®] Permacol [®] /Cosmoderm [®] Cosmoplast [®] /Fascian [®] / Cymetra [®] Resoplast/Sunmax i-plus/ Endoplast/Dermatogen	Short to medium duration	Biological (Human, Bobine, Porcine)	Non-specific inflammation. FB or granuloma annulare-like GR. Necrosis	Non-human collagen polarizes different than human	[78]
Dextranomers + HA	Matridex/Redexis/Reviderm	Medium–Long	Biological HA is from bacteria) + Synthetic	Granulomas or non-specific chronic inflammation (delayed inflammatory reaction)	Spherical particles of dextrans	[171,172]
Fat		Very long duration	Autologous	Fat necrosis, Fibrosis Hypertrophy	Fat necrosis and granulomatous inflammation	[158]
Gelatin powdered and aminocaproic acid	Fibrel	Long	Synthetic	ND	ND	ND
Hyaluronic acid in different forms*	See table	Short to medium duration	Biological (animal or bacterial)	Granulomas, rare infections, occasional delayed inflammatory reactions	Bluish material (Alcian blue positive with better definite borders in "bioengineered molecules"	[7,24]
Hydroxyethylmethacrylate/ethylmethacrylate	DermaLive/DermaDeep	Very long	Synthetic	GR	Polygonal translucent structures	[7,79]
Paraffin		Very long duration (Non-biodegradable)	Synthetic	FB-GR	Large cystic vacuoles of different size (Swiss cheese appearance	[159,160]
Polyacrylamide hydrogel (PAAG)	Beautical (Outline)/Bio-Alcamid/ Aquamid/Bio-formacril	Very long	Synthetic	FB-GR	FB-GR, collections surrounded by palisades of macrophages	[79]
Polyalkylimide	Bio-alcamid	Very long	Synthetic	Irregular encapsulation, dystrophic calcification, acute inflammation	Bluish material (Alcian blue positive) similar to HA	[8]
Polycaprolactone (PCL)	Ellanse	Very long	Synthetic	ND	ND	ND
Polydimethylsiloxane (Silicone oil)	Silikon 1000/Surgisil PermaLip/ Fluid silicone 350cs/Silskin 1000cs	Very long duration	Synthetic	Non-specific inflammation. FB-GR	Pseudoxanthomatous cells and pseudolipoblasts. Slightly birefringent translucent material inside microvacuoles	[79]
Polyethylene glycol (PEG) di-acrylate	Remake [®]	Long (16 m)	Synthetic	Commented on websites	ND	< www.simplycosmeticsurgery.com/fillers > (accessed 07.03.12)

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