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Vocal fold medialization: Which are the available fillers in France in 2010?

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Introduction

Surgical treatment of unilateral laryngeal paralysis is based on three procedures: thyroplasty, which may be associated to arytenoid adduction; medialization by intracordal injection; and reinnervation. Injection medialization has been revived by the advent of new methods of percutaneous injection by cervical route under local anesthesia. Such minimally invasive methods allow ambulatory management and are suitable for more fragile patients [1–3]. They were developed following improvements in filling materials in plastic surgery: the international literature abounds in materials with varying pharmacologic properties and life expectancies. The present study is an update on the cordal medialization fillers available in France in 2010.

Material and methods

A review was performed on the international literature for the period 2001–2010. The articles studied described techniques of medialization by injection of exogenous substances, whatever the injection method (laryngoscopy, cervical route or nasofibroscope). The list of substances retrieved was then compared to the French health products safety agency (AFSSAPS) data.

Results and discussion

The list of products found in the literature and their characteristics is shown in Table 1.

The development of these cordal medialization fillers is promising for ambulatory management of unilateral laryngeal paralysis. Several substances have been used for vocal fold augmentation, but in France at present only polydimethylsiloxane (Vox Implant[®], Medtronic, France) is available (official marketing authorization [MA]) for medialization by intracordal injection. Injection is performed under direct laryngoscopy; the percutaneous

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Table 1 List and life expectancies of substances described in the literature and French Marketing Authorizations (MA).

Material (nature and brand-name)	Possible injection modalities	Life expectancy	MA in laryngology	MA in plastic surgery
Silicone (Vox Implant®) [4,5]	Suspension laryngoscopy	Definitive	Yes	No
Bovine collagen (Zyplast®) [1]	Suspension laryngoscopy, cervical route	Short: 3 to 6 months	MA in laryngology, but marketing stopped in France in 2010	
Human collagen (Cymetra®, Cosmoderm®, Cosmoplast®) [1,3,6]	Suspension laryngoscopy, cervical route	Short: 3 to 6 months	Not available in France	
Calcium hydroxyapatite (Radiesse®) [6,7]	Suspension laryngoscopy, cervical route ±	Long: 6 to 24 months	No	Yes
Hyaluronic acid large particles (Perlane®) [8]	Suspension laryngoscopy, cervical route	Long: 6 to 24 months	No	Yes
Hyaluronic acid Small particles (Restylane®, Hylaform®) [1,3]	Suspension laryngoscopy, cervical route	Short: 3 to 6 months	No	Yes
Polyacrylamide hydrogel (Aquamid®) [9]	Suspension laryngoscopy, cervical route	Definitive	No	Yes
Bovine gel (Gelfoam® poudre) [10]	Cervical route, naso-fibroscope	Very short: 1 to 3 months	No Used in surgery (hemostasis)	
Methylcellulose (Radiesse voice gel®) [1,3]	Suspension laryngoscopy, cervical route	Very short: 1 to 3 months	Not available in France	

MA: Marketing authorization.

cervical attitude is inappropriate here due to the very long life expectancy of silicone, making any malpositioning irreversible [7]. Injection should be very deep into the thyroarytenoid muscle in the paraglottic space.

Collagen has no longer been marketed in France since the summer of 2010. Bovine collagen (Zyplast®) required performing a test dose to the forearm to rule out allergy. There was a risk of autoimmune disease such as dermatomyositis or polymyositis. No complications were reported with processed human collagen (Cymetra®, Cosmoderm®), but this is not available on the French market.

Fillers developed for esthetic applications, such as polyacrylamide hydrogel (Aquamid®, FerrosanA/S) [9], hyaluronic acid (Perlane®, Restylane®, Hyladerm®) [8], or calcium hydroxyapatite (Radiesse®) [6,7], were used with success by certain authors, but do not come in a form suitable for laryngology (no MA for this indication).

Methylcellulose exists in a form suitable for laryngology and is authorized in certain countries but not in France (no MA for this indication).

Finally the rapid resorption characterizing Gelfoam® (Gelfoam®, Pfizer, France) in the form of a paste reconstituted from powder would make it an interesting filler in case of recent paralysis with unpredictable evolution: compensation by the healthy contralateral vocal fold or spontaneous

reinnervation could be expected, but again this substance has no MA in this indication [10].

Market authorization for these resorbable products in France would enable ambulatory management of laryngeal paralysis, and the consequent prevention of inhalation pneumopathy would doubtless have a positive impact on health costs. At the present time, the cost of Vox Implant® is to be weighed against that of other medialization techniques using autologous material (fat, fascia temporalis) or of thyroplasty; comparison should also take surgery time (and hence theater costs) into account.

Conflict of interest statement

None.

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