Polydimethylsiloxane Injection Laryngoplasty for Unilateral Vocal Fold Paralysis: Long-Term Results

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Summary: Objectives. To analyze the long-term objective, perceptive, and subjective outcomes after endoscopic polydimethylsiloxane (PDMS) injection laryngoplasty in unilateral vocal fold paralysis.
Study design. A retrospective study carried out between January 2008 and January 2012.
Setting. Head and Neck Department, University Hospital of Modena, Modena, Italy.
Methods. This was a retrospective analysis of 26 patients with unilateral vocal fold paralysis who underwent endoscopic injection of PDMS under general anesthesia. A voice evaluation protocol was performed for all patients, which included videolaryngostroboscopy, maximum phonation time, fundamental frequency, analysis of the harmonic structure of the vowel /a/ and the word /aiuole/, Grade of Dysphonia, Instability, Roughness, Breathiness, Asthenia, and Strain scale, and Voice Handicap Index. The protocol was performed before surgery, in the immediate postoperative period, and at least 3 years after surgery. The mean follow-up period was 73 months (range 39–119 months).
Results. The statistical analysis showed a significant improvement ($P < 0.01$) for all of the objective, perceptive, and subjective parameters by comparison between the preoperative and long-term follow-up data; moreover, no statistically significant difference was found between the postoperative and long-term follow-up data. This indicates that injection laryngoplasty with PDMS guarantees long-lasting effects over time. No complications were reported in our series.
Conclusion. Injection laryngoplasty with PDMS can be considered to be a minimally invasive and safe technique for the treatment of unilateral vocal fold paralysis. Moreover, it allows very good and stable results to be obtained over time, avoiding repeated treatments and improving the quality of life of the patients.
Key Words: Vocal fold paralysis–Polydimethylsiloxane–Speech therapy–Injection laryngoplasty–Endoscopic injection laryngoplasty.

INTRODUCTION

Vocal fold paralysis is the result of congenital, viral, neurological, traumatic, iatrogenic, or neoplastic injuries to the vagus or the recurrent laryngeal nerve.[1,2] If no etiology is found, it is defined as idiopathic.[3] The paralyzed vocal fold can be in adduction or in a paramedian or lateral position. In unilateral vocal fold paralysis (UVFP), a vocal fold fixed in adduction does not cause important symptoms, as the contralateral vocal fold well compensates the gap; however, a vocal fold in a paramedian or lateral position causes inadequate phonation with breathlessness of voice and hoarseness, associated with possible swallowing disease and bolus inhalation because of glottic incompetence. This condition has a negative impact on the quality of life of the patient because of both phonatory dysfunction and psychological impact. Difficulties in communication interfere with everyday social life and sometimes with work activities, for example, for singers, teachers, etc.

In these cases, therapy is necessary. Voice therapy is attempted as early as possible, and in the case of poor phoniatric results, phonosurgery is performed.[4] The goal of surgery is the medialization of the paralyzed vocal cord to reduce the glottic gap and to restore the quality of voice as much as possible so as to improve the quality of life of the patient with stable results over time. Two main surgical approaches are performed: type I thyroplasty[5] and injection laryngoplasty.[6,7] The first approach requires an external incision and is more invasive, whereas injection laryngoplasty is a rapid and less invasive endoscopic procedure. It consists of the injection of a substance in the lateral part of the paralyzed vocal cord to increase its volume and medialize the cord with a reduction in the glottic gap.[7] Materials used need to be biocompatible and many have been tried up to now. The first materials used (fat, bovine collagen, hyaluronic acid, cartilage) were rapidly reabsorbed,[8] whereas others were poorly biocompatible (paraffin oil, Teflon).[9] A slowly reabsorbable material, calcium hydroxylapatite (Radiesse Voice), has allowed good results to be obtained, but over time, it can dislocate or it is reabsorbed although slowly. In 1989, a new biocompatible nonreabsorbable material, polydimethylsiloxane (PDMS), was introduced in surgery. It was first used in plastic surgery and urology.[10,11] Since 1993, it has been used in laryngology, with the expectation of results that would be stable over time. However, only a few studies have reported the use of PDMS for the treatment of UVFP.[12–18] Most of the studies only considered subjective evaluations, such as the GIRBAS (Grade of Dysphonia, Instability, Roughness, Breathiness, Asthenia, and Strain) scale[19] or the Voice Handicap Index (VHI).[20]

Moreover, there are no long-term results in the literature. Our previous study documented the short-term functional results and compared objective and subjective voice measures after endoscopic laryngoplasty with injection of PDMS (Vox Implants, Bioplasty BV, Geleen, The Netherlands) for the treatment of UVFP and verified PDMS biocompatibility in the vocal fold. It showed an improvement in results after a 4-month follow-up in

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comparison to preoperative performances.[4] The aim of this study is to document long-term functional results after injection laryngoplasty with PDMS in patients with UVFP after at least a 3-year follow-up period, in comparison to preoperative and immediate postoperative results.

MATERIALS AND METHODS

Patient selection

This was a retrospective analysis of patients who underwent injection laryngoplasty with PDMS at the ENT Department of the University Hospital of Modena between January 2008 and January 2012. In that period, 42 patients with UVFP underwent endoscopic injection of PDMS.

In all patients, the endoscopic injection was performed 1 year or more after the onset of the palsy. Before surgery, most of the patients underwent early speech therapy (within 6 months after the onset of the palsy) without sufficient improvement. All of these patients did not show satisfactory voice improvement, due either to delayed voice therapy or to incomplete voice treatment. Among them, we only included patients with at least a 3-year follow-up after the procedure. Of the 42 patients, only 26 had 3-year follow-up functional results (two patients moved abroad, for one patient the cricoarytenoid junction block was completely resolved after surgery, and 13 patients did not complete the requested follow-up period). The study population was composed of 15 women and 11 men with a mean age of 60 years (range 28–85 years).

The etiology of vocal cord palsy in our 26 patients is presented in Figure 1.

Injection technique

Laryngoplasties by endoscopic injection were all performed by microlaryngoscopy under general anesthesia. A good laryngeal exposure is required. The procedure requires two injection points. The first injection point is into the thyroarytenoid muscle laterally and deep into the vocal fold apophysis, to medialize the vocal process and the posterior third of the vocal cord (Figure 2A); the second injection point is lateral to the middle third of the thyroarytenoid muscle, near to the internal surface of the thyroid cartilage, to medialize the anterior and medial third of the vocal fold, with a result that is as effective as external laryngeal frame surgery (Figure 2B).

To avoid an overdose of injected material, a maximum of 2 mL of Vox Implants was injected in each patient. After injection, we performed a redistribution of textured silicon by modeling the vocal fold with an aspirator or a Bouchayer forceps as necessary.

Further details about the injection technique have already been described in our previous study.[4]

Voice evaluation

We collected data about the patients before surgery (some days before surgery or on day 0 immediately before surgery), within the first weeks after surgery, and at least 3 years after surgery.

Speech-language pathologists and otolaryngologists evaluated all patients with questions about their medical history and an instrumental voice evaluation protocol. Analysis of the results followed the protocol of subjective and objective evaluations of dysphonia proposed by Dejonckere et al,[21] and approved by the European Laryngological Society since 2001. In Italy, a simplified revision of this protocol was introduced in the Official Relation of XXXVI National Congress of Italian Society of Phoniatrics and Speech Therapy.

All patients underwent videolaryngostroboscopy (VLS) (Mediastroboscope-Atmos, Atmos Medizin Technik GmbH & Co. KG, Leutkirch, Germany) to evaluate the position of the vocal cord (median, intermediate, lateral) and the edge of the vocal fold (bowing, concave, linear).

Acoustic (CSL Model 4300B-KAY, Elemetrics Corp., Lincoln Park, NJ) and aerodynamic analyses of the voice were performed to establish maximum phonation time with a sustained vocal /a/ (MPT), fundamental frequency (Fo), and the quality of voice with the analysis of harmonic structure of the vowel /a/ and the word /aiuole/ according to the classification of Yanagihara.[22] All VLS and acoustic analyses were digitally recorded.

Furthermore, a perceptive evaluation of the patients' voices has been made using the GIRBAS scale[19] that assesses six vocal

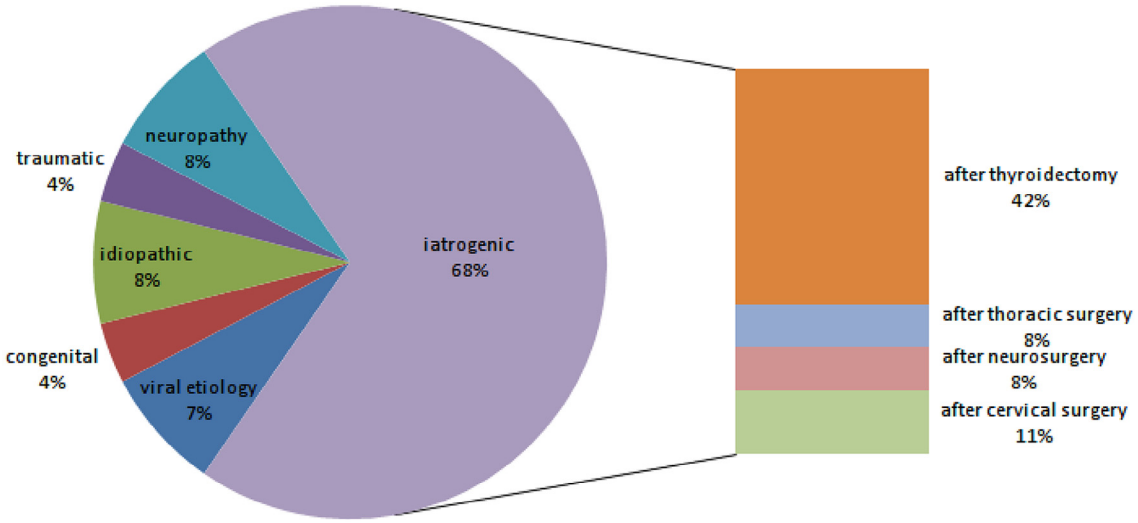

FIGURE 1. Etiology of vocal cord paralysis in our 26 patients.