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CASE REPORT

Polydimethylsiloxane for injection laryngoplasty: two cases necessitating tracheotomy

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Abstract The surgical treatment of glottic insufficiency due to lesions of the recurrent laryngeal nerve has become a routine procedure in the last few decades. In particular, injection laryngoplasty with polydimethylsiloxane (PDMS) has proved to be an easy, effective and safe method for vocal fold medialization. It is a biologically inert substance having almost ideal properties as a filler; complications related to its intralaryngeal use such as migration, or granuloma formation are extremely rare and allergic reactions have not been reported as yet. We discuss two cases representing the first description of acute severe complications after injection laryngoplasty with PDMS.

Keywords Glottic insufficiency · Injection laryngoplasty · Polydimethylsiloxane · Complications

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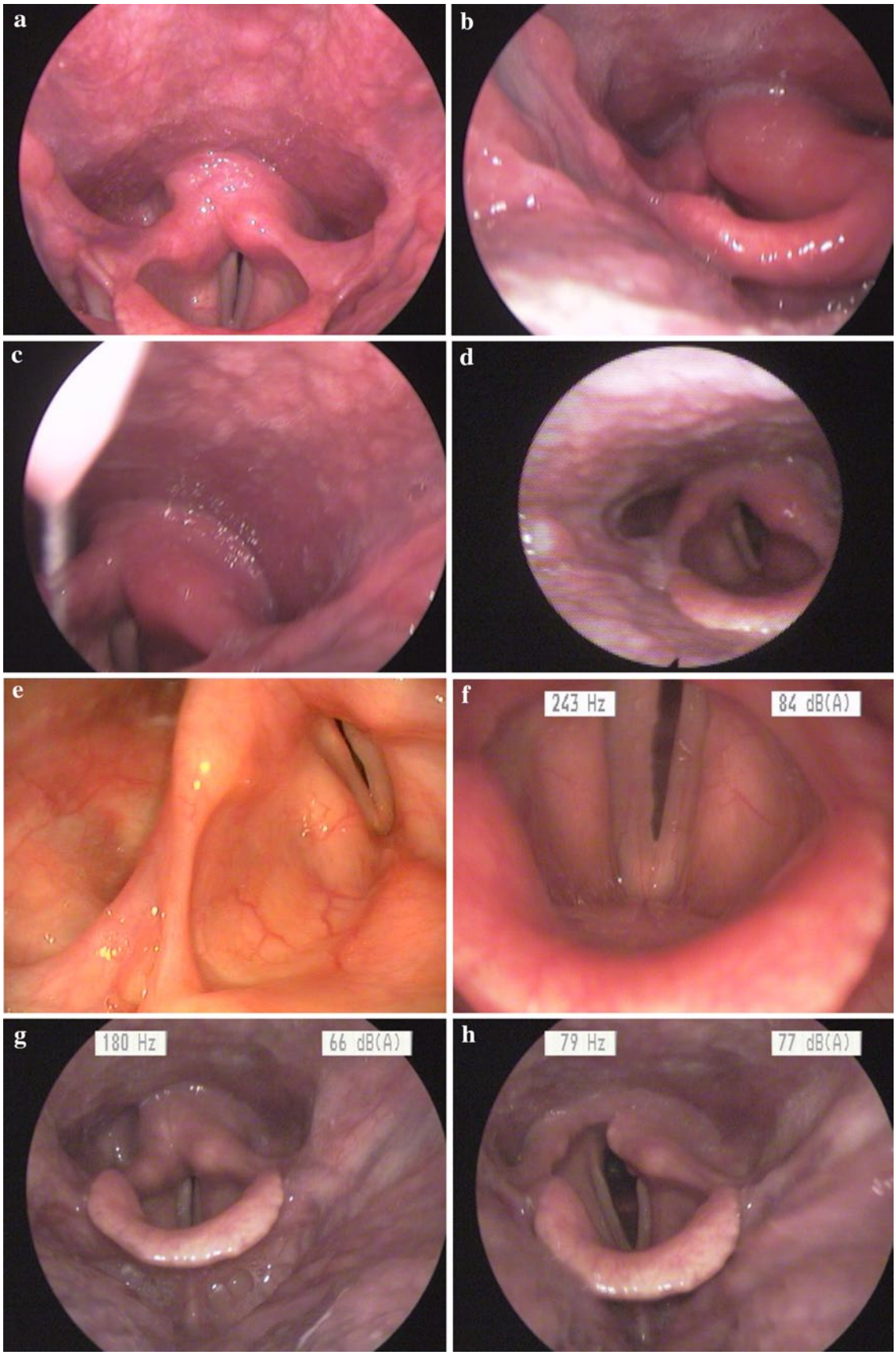
Introduction

Polydimethylsiloxane (PDMS) (VOX® Implants) has been used for injection laryngoplasty since 1993 [1]. This biologically inert and stable substance has proved to be safe and effective for obtaining adequate voice results due to glottic insufficiency [2]. Adverse reactions or complications after intralaryngeal use of PDMS are extremely rare. We report two cases with acute inflammatory complications after vocal fold medialization using PDMS.

Case reports

Case 1

A 50-year-old woman suffered from recurrent nerve paresis of the left vocal fold after surgery for a benign lesion of the thyroid gland 1 year earlier. After unsuccessful voice therapy, injection laryngoplasty was performed using PDMS (VOX® Implants, Uroplasty BV, Hofkamp 2 6161 DC Geleen, The Netherlands). In the first 24 h after surgery, a progressive swelling of the aryepiglottic fold and arytenoid region occurred which increased despite corticosteroid therapy. On the third post-operative day, the patient was tracheotomized because of dyspnea due to a narrow laryngeal entry (Figs. 1b–d, 2a–c). Afterwards, the laryngeal swelling gradually diminished and she could be decannulated on the 14th day after initial surgery. The tracheostoma was surgically closed on the 60th post-operative day. Her laryngeal status normalized and she had a better voice quality compared to that before laryngoplasty. At the last clinical control 22 months after initial surgery, her laryngeal status was unremarkable and the patient was satisfied with her voice (Figs. 1e, 3a, b).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◀ **Fig. 1** Case 1. **a** Pre-operative laryngeal status at phonation. **b** Sixth post-operative day after injection laryngoplasty with PDMS on the left side. **c** Tenth post-operative day. **d** Fourteenth post-operative day. **e** Twenty-two months after injection laryngoplasty with PDMS on the left side (phonation). Case 2. **f** Pre-operative laryngeal status. **g** Six weeks after laryngoplasty (phonation). **h** Six weeks after laryngoplasty

Case 2

A 64-year-old woman presented with recurrent nerve paresis of the left vocal fold after surgery for a benign lesion of the thyroid gland performed 5 years earlier. She had end-stage breast cancer with rib- and skull metastases and received monthly fulvestrant (Faslodex®) and bisphosphonate (Pamifos®) therapy. Repeated injection laryngoplasties 3 and 4 years before with bovine collagen (Zyderm II®) in the left vocal fold yielded unsatisfactory voice performance (Fig. 1f). Nine days after vocal fold augmentation with PDMS (VOX® Implants), she developed a paralaryngeal abscess on the side of the injection. Despite combined intravenous antibiotic therapy with metronidazol + cefuroxim together with corticosteroids, her condition worsened and intubation was necessary. Twelve days after laryngoplasty, a tracheotomy was performed because of intractable laryngeal swelling after an unsuccessful extubation attempt (Fig. 2d, e). Simultaneously, abscess drainage was carried out. Culture of pus taken intra-operatively revealed *Streptococcus constellatus* (*Str. milleri*). Upon improvement in her laryngeal status, surgical closure of the tracheostoma was carried out 50 days after laryngoplasty (Fig. 1g, h). The patient was lost to follow-up 3 months after initial surgery so that her clinical status could not be further assessed.

Discussion

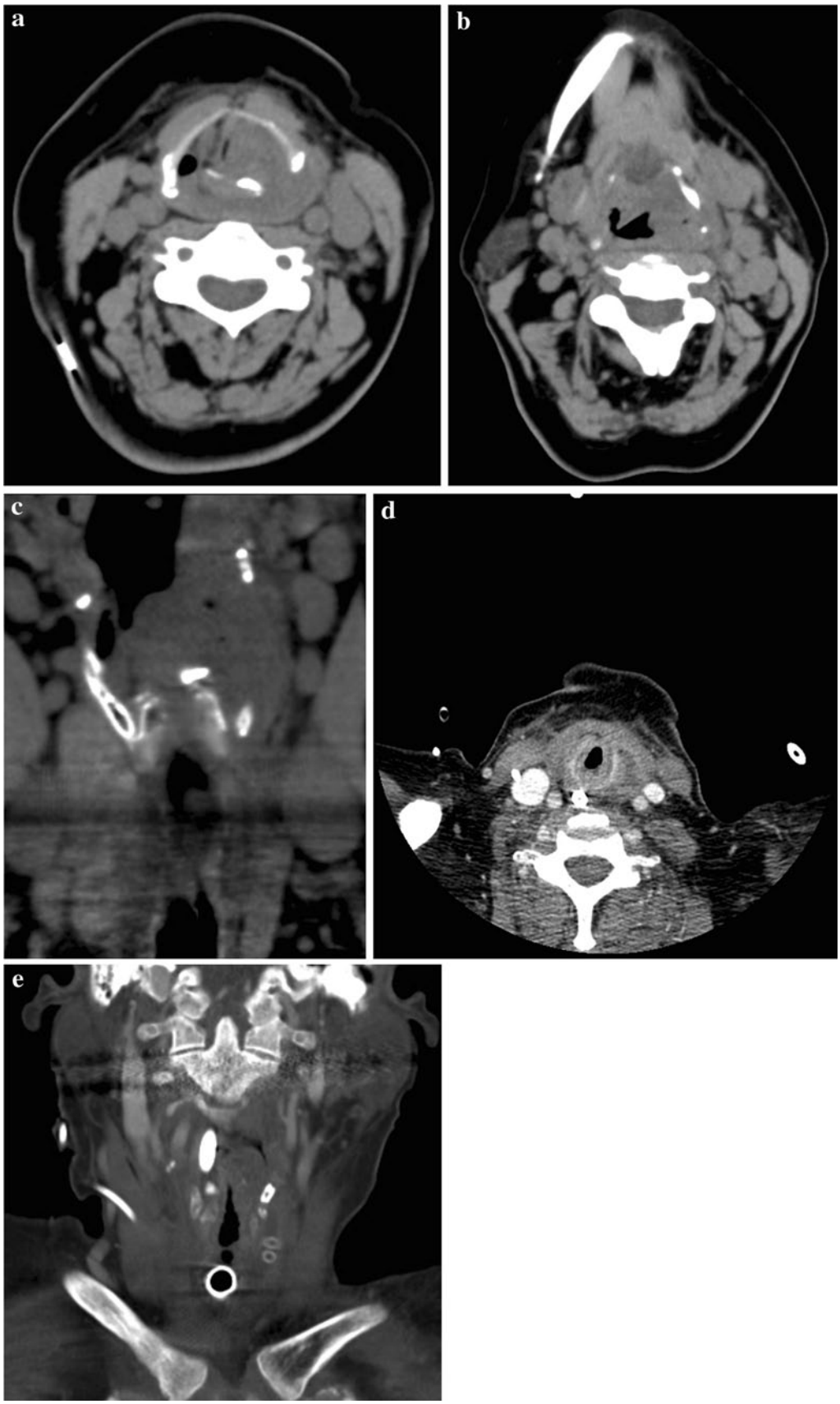
The use of PDMS over two decades for injection laryngoplasty has demonstrated that it is a near ideal biological substance for medialization of the paralyzed vocal fold [2–4]. PDMS is not resorbable and remains in place even several years after injection, ensuring a persistent effect on vocal cord augmentation [2]. Allergic reactions associated with this material have not been observed and foreign body reactions have only sporadically been reported [5, 6]. However, a chronic inflammation with granuloma formation has been described related to its dermal use for cosmetic reasons [7]. Interestingly, partial explantation of PDMS from the human larynx 7 years after injection showed no inflammatory cells histologically but did show scar tissue encapsulating the silicone [8].

To date, only one case of acute inflammatory reaction has been published related to the intralaryngeal use of PDMS [5]. In this case, injection material was surgically removed during cordotomy 8 days after initial surgery. Histopathological examination showed inflammatory cell infiltrates accompanied by foreign body granulomas without giant cell formation [5]. From these histological findings, an abnormal foreign body reaction was hypothesized. However, specific type IV hypersensitivity to the components of the silicone implant could be excluded in the case reported by Baijens et al. [5].

Our two cases are the first reports of acute laryngeal swelling following injection laryngoplasty with PDMS. The clinical course of both patients is unique and differs from the history of previously reported cases with complications. First, progressive laryngeal swelling in our cases developed from the start not just at the injection site but rather in the entire larynx on the side of the injection (Figs. 1b, c, 2a–e). Because of airway compromise, tracheotomy was necessary in both cases on the third and ninth day after initial surgery, respectively. In our case 2, extralaryngeal development of inflammation caused an abscess which had to be drained (Fig. 2d, e). As in the case described by Baijens et al. [5], post-operative laryngeal swelling could not be controlled by empiric broad-spectrum antibiotic therapy or corticosteroids in our cases. Second, despite the fact that injected PDMS was not surgically removed, laryngeal swelling gradually diminished over the following weeks and the tracheostomas could be surgically closed.

Intermediate and long-term indirect laryngoscopic findings in case 1 showed no signs of any granuloma of the vocal cords, and this patient had a satisfactory voice quality (Figs. 1e, 3a, b). In case 2, laryngeal status improved in a similar fashion (Fig. 1g, h). Because of the lack of granuloma formation in our cases, the hypothesis of a delayed-type hypersensitivity is very unlikely.

Our routine surgical technique for PDMS laryngoplasty under general anesthesia involves injections in the middle and posterior third of the true vocal cord between M. vocalis and thyroid cartilage with a single use, sterile, flexible needle for vocal cord rehabilitation (VMN-720) and Vox-1.0 implants (Uroplasty BV, Hofkamp 2 6161 DC Geleen, The Netherlands). Surgery was performed in each of our two cases by the last author (S.D.) who has extensive experience in surgical voice restoration and an uneventful previous series of 18 cases of PDMS laryngoplasty. Hypothetically, incorrect placement or oozing of injection material through the cricothyroid or thyrohyoid ligament may result in paralaryngeal fluid accumulation that mimics abscess formation. However, in case 2, an obvious paralaryngeal abscess was explored intra-operatively. Post-operative local inflammatory reactions due to airway pathogens or injection material contaminated with bacteria are other possible explanations. Indeed, the risk of infection by injection laryngoplasty is relatively low in comparison with external approaches (thyroplasty) [2]. Production faults with the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◀ **Fig. 2** Case 1. **a–c** Sixth post-operative day after injection laryngoplasty with PDMS on the left side. Non-enhanced CT-scans of the neck (patient refused to have an MRI or contrast material) in axial (**a**, **b**) and transverse (**c**) plane: swollen soft tissue on the left side in the region of true and false vocal fold propagating extralaryngeally in the tongue base and pre-epiglottic space. Marked narrowing of the laryngeal lumen with complete obturation at the level of the glottis. Case 2. **d** Contrast-enhanced CT-scan in the axial plane showing a paralaryngeal abscess on the left side at the level of the cricoid cartilage. **e** Contrast-enhanced CT-scan in the coronal plane showing a massive supraglottic swelling. Tracheostomy tube in the trachea, drain in the left paralaryngeal space

injected PDMS cannot be excluded but it is very difficult to examine this retrospectively. There was a 7-month interval between the two cases and the patients may have been injected with PDMS from the same batch. Interestingly, laryngeal swelling did not respond to antibiotic therapy and there was even a progression into a paralaryngeal abscess in case 2. Highly elevated C-reactive protein (CRP) blood level before surgical drainage (maximum 119.5 mg/dl) suggests a bacterial infection in case 2. In case 1, CRP blood level was moderately elevated (17 mg/dl) before

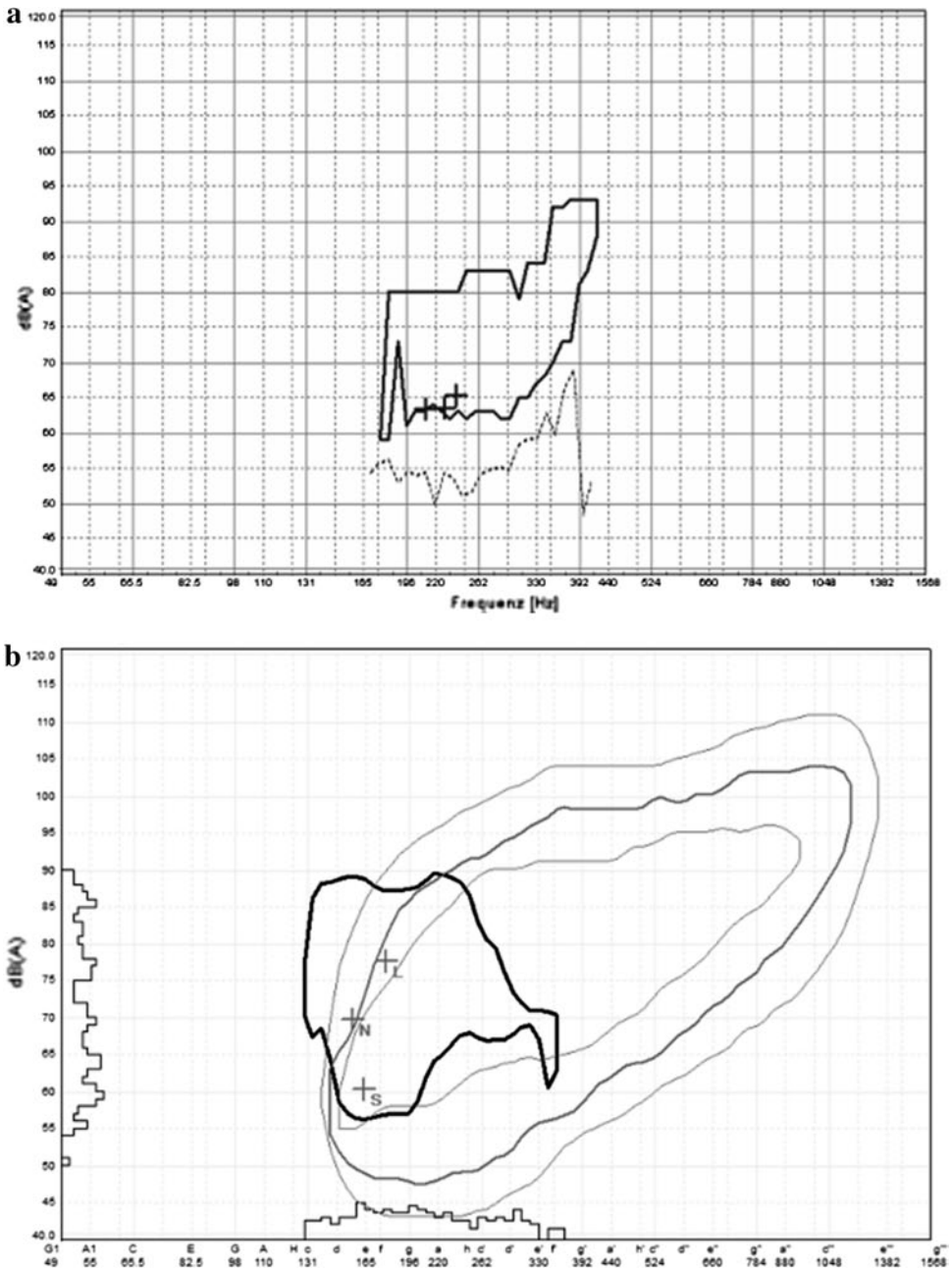

Fig. 3 Case 1. **a** Pre-operative voice field measurement (Datalogger 322 sound level measuring device, Voltcraft, Conrad Electronic SE, Hirschau, Germany; software: lingWAVES 2.34.08, LingCom GmbH, Forchheim, Germany). Dysphonia severity index (DSI): −1.1; maximal phonation time (MPT): 8.9 s (data not shown on the diagram). **b** Voice field measurement 22 months after PDMS injection laryngoplasty (Datalogger 322 sound level measuring device, Voltcraft, Conrad Electronic SE, Hirschau, Germany; software: lingWAVES 2.50.0041, WEVOSYS, Forchheim, Germany). *S* pitch level of low voice; *N* pitch level of normal voice; *L* pitch level of loud voice. *DSI* dysphonia severity index: 3.6; *MPT* maximal phonation time: 21.0 s (data not shown on the diagram)

tracheotomy. *Streptococcus constellatus* was isolated from the abscess in case 2. These Gram-positive cocci are part of the normal flora in the oral cavity and respiratory tract and as pathogens are strongly associated with abscess formation [9]. Patients who have had previous surgery or have a history of immunodeficiency are at higher risk for infections involving these microorganisms [9]. Case 2 had been receiving chemotherapy because of her disseminated breast cancer, consequently, we postulate that she was prone to infections with the abovementioned bacteria. Prophylactic empiric peri-operative antibiotic therapy is reasonable in cases with presumed immunodeficiency, however, it was not performed in case 2. While no antibiotic resistance of bacteria was noted, abscess formation required surgical drainage in case 2. This is a common therapeutic problem concerning infections with *S. constellatus* [9].

In summary, the pathomechanism of these severe complications is still unclear. However, clinicians need to be aware of the possibility of such disastrous post-operative courses and the discussion material presented above may be beneficial for future patients having PDMS laryngoplasty.

Conclusion

Despite the generally safe use of injectable PDMS in laryngoplasty, it is necessary to inform patients pre-operatively about possible unusual adverse reactions involving silicone or inflammatory processes with the resulting need for tracheotomy. In our experience, acute post-operative swelling after injection laryngoplasty with PDMS cannot be influenced by antiphlogistic or antibiotic therapy but spontaneous improvement in laryngeal status occurs within weeks, even without surgical removal of the injection material. In contrast to the early post-operative progress of laryngeal swelling, granuloma formation could not be clinically confirmed in our two cases and intermediate and long-term voice quality results were favorable. We recommend prophylactic peri-operative antibiotic therapy to patients with immunodeficiency scheduled for PDMS laryngoplasty. Further investigations are needed to clarify the pathomechanism of such undesirable complications following intralaryngeal use of PDMS.

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Conflict of interest None.

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