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Clinical Record

Foreign body reaction to polymethylsiloxane gel (Bioplastique™) after vocal fold augmentation

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Abstract

Statement of problem: The consequences of vocal fold paralysis include voice change, airway problems and difficulty swallowing. Medialisation procedures using injected material have been used for many decades, with varying outcomes, mainly secondary to lifespan, tissue reaction or migration. Newer materials have recently become clinically available which are easier to manage and supposedly less likely to elicit foreign body reaction.

Method of study: Case report.

Results: We report a case of foreign body reaction and possible migration of polymethylsiloxane gel (Bioplastique™), one such material, after vocal fold injection. To our knowledge, this is the second such case described.

Conclusions: This case highlights the fact that the risk of foreign body reaction and migration is still present for this material, albeit low. We also highlight the fact that, although this material can cause foreign body reactions and may possibly migrate, it is removable by microlaryngoscopy via the microflap technique, with vocal improvement.

Key words: Vocal Cord Paralysis; Otorhinolaryngological Surgical Procedures; Larynx; Bioplastique; Foreign Body Reaction

Introduction

Vocal fold paralysis can occur at any age, due to a variety of causes. It occurs most commonly following iatrogenic surgical injury, but can also result from: endotracheal intubation; blunt chest or neck trauma; tumours involving the skull base, neck or chest; and viral infection.

The consequences of vocal fold paralysis include: voice changes (ranging from hoarseness, breathy voice, effortful phonation and air wasting to diplophonia); airway problems (including shortness of breath with exertion, stridor, and ineffective or poor cough); and difficulty swallowing (including aspiration).

Vocal fold medialisation procedures have been carried out for many years; different techniques and materials have been used, with variable success, limitations and complications. The main aim of treatment for vocal fold paralysis is to improve voice quality and prevent aspiration. Commonly used injectable materials include fat, collagen, polytetrafluoroethylene (Teflon®), calcium hydroxyapatite, gelation sponge (Gelfoam®) and, more recently, polymethylsiloxane gel (Bioplastique™; Uroplasty BV, Geleen, Netherlands).

Bioplastique is a biphasic material and consists of solid silicone particles (ranging in size from 100 to 400 μm) suspended in a polyvinylpyrrolidone carrier. The material elicits a low-grade inflammatory reaction once injected. Collagen subsequently encapsulates and localises the silicone and, as deposition progresses, it replaces the organic component of the material in a ratio slightly higher than 1:1. The carrier itself is removed by the body and excreted by the kidneys in under four weeks. It has been observed that particles of less than 60 μm can be engulfed by macrophages and transported to regional lymph nodes. The inability of Bioplastique to migrate or to be carried by the lymph to the lymph nodes is based on this theory.

Bioplastique has been used successfully in aesthetic plastic surgical procedures,[1] to seal leakage around speech valves[2] and to treat faecal incontinence (injected into the anal sphincter),[3] all with good long term results.

Bioplastique is commonly used in Europe for vocal fold augmentation procedures, and its safety is well documented.[4,5] A recent study by Hamilton *et al.*[6] has shown that results for Bioplastique, with regards to voice performance, are comparable to those for Isshiki thyroplasty, and that Bioplastique is possibly more suitable for patients with limited life expectancy, as it was quicker to use and had few complications.

Animal studies have shown no evidence of migration or malignant change, and minimal local tissue reaction,[7,8] thus enhancing the evidence for Bioplastique's efficacy and clinical use.

We report a case of foreign body reaction and presumed migration of injected Bioplastique after vocal fold augmentation, requiring removal. To our knowledge, this is only the second[9] reported case both of a clinical foreign body reaction to Bioplastique and of removal through a conventional microflap approach.

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Case report

A 66-year-old man with a six-year history of left vocal fold paralysis thought to be secondary to a viral aetiology was referred to our centre. He had previously been treated with four medialisation procedures (three Bioplastique vocal fold injections and a thyroplasty with expanded polytetrafluoroethylene (Gore-Tex®; WL Gore & Associates, Phoenix, Arizona)) at his referring centre, with only transient improvement in his voice.

On the patient's first visit, he was observed to have a breathy voice. Stroboscopy revealed fullness in the mid-membranous region of the left vocal fold, which was impeding the mucosal wave (Figure 1). His right vocal fold was mobile and there was also some degree of abduction and adduction of his left vocal fold, and it was thought that the viral process may have resolved to some extent. The patient's voice quality was assessed pre-operatively using the grade–roughness–breathiness–asthenia–strain score, as follows: grade = three, roughness = three, breathiness = two, asthenia = one and strain = two.

Our clinical suspicion was of misplaced Gore-Tex material. At suspension microlaryngoscopy, however, the fullness was felt more likely to be due to Bioplastique. A biopsy using the microflap technique confirmed foreign material.

Post-operatively, the patient underwent speech and language therapy, with only minimal improvement in his voice.

On review after a few months, the fullness was still present in the mid-membranous portion of the patient's left vocal fold, albeit less obvious. He underwent a further suspension microlaryngoscopy, with removal of further foreign body from his left vocal fold via microflap (Figure 2). Histological analysis showed multiple irregular areas of translucent, acellular material surrounded by a prominent foreign-body reaction composed of multinucleated giant cells, histiocytes and fibroblasts (Figure 3). The acellular material was non-birefringent under polarised light (Figure 4), in contrast to the intense birefringence seen with Teflon;[10] thus, the histological picture was that of a granulomatous reaction to Bioplastique.[11]

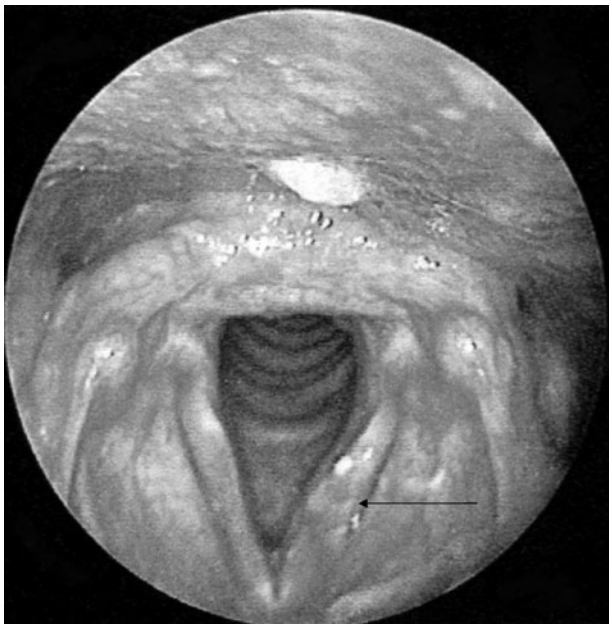

FIG. 1

Pre-operative appearance showing fullness (arrow) in mid-membranous portion of left vocal fold.

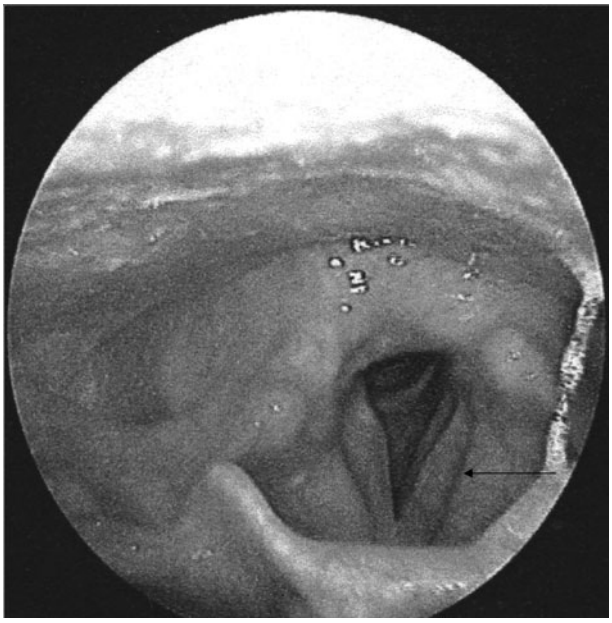

FIG. 2

Post-operative appearance showing improved left vocal fold appearance (arrow).

Post-operative voice assessment showed the following scores: grade = two; roughness = one; breathiness = two; asthenia = one and strain = zero. This represented an overall improvement in the patient's voice quality, and, clinically, he felt that his voice quality had improved.

At the time of writing, the patient was undergoing further speech therapy.

Discussion

The main aim of treatment of vocal fold paralysis is to improve vocal fold closure with concomitant improvement in voice quality and efficacy of cough production. Factors that need to be taken into account when deciding which material to use include the general health and probable lifespan of the patient, degree of compensation, and pulmonary status.

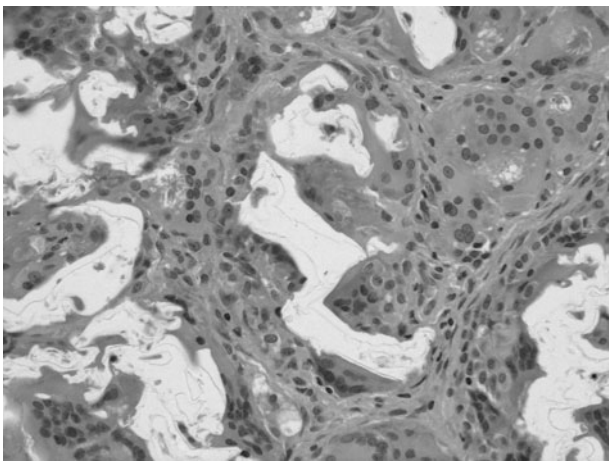

FIG. 3

Medium power photomicrograph of the left vocal fold biopsy, showing the Bioplastique™ as irregularly shaped, translucent masses surrounded by a multinucleate giant cell reaction (H & E; original magnification ×250).

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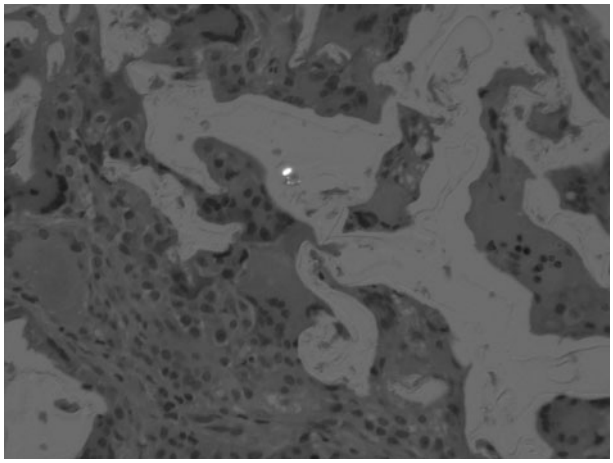

FIG. 4

Medium power photomicrograph of the left vocal fold biopsy taken under polarised light, showing the absence of birefringence, characterising the material as Bioplastique™ (H & E; original magnification ×250).

Foreign body reactions and migration caused by injected materials have been described in the literature. Tissue foreign body reaction to Teflon has been well documented;[12–14] more recently, such reactions have been reported to Radiesse (Bioform, San Mateo, California, USA).[15] There have been reports of migration of Bioplastique after treatment for ureteric reflux[16] and granuloma formation[17] following aesthetic surgery. However, to our knowledge, the current report represents the second published case of Bioplastique material, used for vocal fold augmentation, migrating and causing a foreign body tissue reaction.

Bioplastique granulomas can be confirmed histologically, as the material exhibits irregularly shaped, cystic spaces of varying size containing jagged, translucent foreign bodies that are non-birefringent under polarised light.[11] These specific histopathological findings allow the correct diagnosis to be made, despite sparse clinical information.

- **Bioplastique™ is commonly used in Europe as an injectable material for medialisation treatment of vocal fold paralysis. Its safety and efficacy as a permanent material are well documented**
- **This case highlights the fact that foreign body reaction and migration are still possible with this material, albeit rare**
- **Although this material can cause foreign body reactions and may possibly migrate, it is removable by microlaryngoscopy via the microflap technique, with potential vocal improvement**

Clinicians need to be aware of the possibility of Bioplastique migrating and causing foreign body reactions. In our case, it was difficult to be absolutely certain that the Bioplastique material had actually migrated, rather than been injected into the wrong site or undergone inadvertent medialisation due to the Gore-Tex, as the initial surgical procedures were all performed in another centre. However, as there has been evidence of migration at other sites,[16] this possibility must be considered.

We also feel that clinicians need to be aware that removal of portions of this material is achievable via microlaryngoscopy and microflap technique, as shown in this case, with reasonable improvement in voice. This differs from the problems encountered while attempting to remove Teflon granulomas endoscopically.[18]

Conclusion

Bioplastique is an injectable material which is commonly used in Europe for medialisation in cases of vocal fold paralysis. Its safety and efficacy as a permanent material are well documented. The current case highlights the fact that foreign body reaction and migration may still be possible for this material, albeit rare. We also highlight the fact that, although this material can cause foreign body reactions and may possibly migrate, it is removable by microlaryngoscopy via the microflap technique, with potential vocal improvement.

References

1 Ersek RA, Gregory SR, Salisbury AV. Bioplastique at 6 years: clinical outcome studies. *Plast Reconstr Surg* 1997;**100**:1570–4
2 Rokade AV, Mathews J, Reddy KT. Tissue augmentation using Bioplastique® as a treatment of leakage around Provox® 2 voice prosthesis. *J Laryngol Otol* 2003;**117**:80–2
3 Tjandra JJ, Lim JF, Hiscock R, Rajendra P. Injectable silicone biomaterial for faecal incontinence caused by internal anal sphincter dysfunction is effective. *Dis Colon Rectum* 2004;**47**:2138–46
4 Alves CB, Loughran S, MacGregor FB, Dey JI, Bowie LJ. Bioplastique medialisation therapy improves the quality of life in terminally ill patients with vocal cord palsy. *Clin Otolaryngol Allied Sci* 2002;**27**:387–91
5 Bihari A, Meszaros K, Remenyi A, Lichtenberger G. Voice quality improvement after management of unilateral vocal cord paralysis with different techniques. *Eur Arch Otorhinolaryngol* 2006;**263**:1115–20
6 Hamilton DW, Sachidananda R, Carding PN, Wilson JA. Bioplastique™ injection laryngoplasty: voice performance outcome. *J Laryngol Otol* 2007;**121**:472–5
7 Dewan PA, Byard RW. Histological response to injected Polytef and Bioplastique in a rat model. *Br J Urol* 1994; **73**:370–6
8 Nijhuis PH, van den Bogaard TEP, Daemen MJ, Baeten CG. Perianal injection of polydimethylsiloxane (Bioplastique implants) paste in the treatment of soiling: pilot study in rats to determine migratory tendency and locoregional reaction. *Dis Colon Rectum* 1998;**41**:624–9
9 Baijens L, Speyer R, Linssen M, Ceulen R, Manni JJ. Rejection of injectable silicone 'Bioplastique' used for vocal fold augmentation. *Eur Arch Otorhinolaryngol* 2007; Jan 9
10 Rajkumar K, Khalil HS, Elloy M, Sheffield E, Baldwin DL. Histopathological changes in the human larynx following expanded polytetrafluroethylene (Gore-Tex®) implantation. *BMC Ear, Nose and Throat Disorders* 2005;**5**:1–6
11 Rudolph CM, Soyer HP, Schuller-Petrovic S, Kerl H. Foreign body granulomas due to injectable aesthetic microimplants. *Am J Surg Pathol* 1999;**23**:113–17
12 Lewy RB, Millet D. Immediate local tissue reactions to Telfon vocal cord implants. *Laryngoscope* 1978;**90**:281–6
13 Stone JW, Godfrey EA. Human larynx injected with Telfon paste. Histological study of innervation and tissue reaction. *Arch Otolaryngol* 1967;**86**:98–109
14 Boedts K, Roels H, Kluyskens P. Laryngeal tissue responses to Teflon. *Arch Otolaryngol* 1967;**86**:562–7
15 Tanna N, Zalkind D, Glade RS, Bielamowicz SA. Foreign body reaction to calcium hydroxylapatite vocal fold augmentation. *Arch Otolaryngol Head Neck Surg* 2006;**132**:1379–82
16 Dewan PA, Hoebeke P, Ehall H, Chow CW, Edwards GA, Terlet J. Migration of particulate silicone after ureteric injection of silicone. *Br J Urol* 2000;**85**:1–2
17 Lackgren G, Wahlin N, Stenberg A. Endoscopic treatment of children with vesico-ureteric reflux. *Acta Paediatr Suppl* 1999;**88**:62–71
18 Ossoff RH, Koriwchak MJ, Netterville JL, Duncavage JA. Difficulties in endoscopic removal of Teflon granulations in the vocal fold. *Ann Otol Rhinol Laryngol* 1993;**102**:405–12

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