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Tissue augmentation using Bioplastique® as a treatment of leakage around a Provox® 2 voice prosthesis

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Abstract
Rehabilitation of voice and speech after laryngectomy with valve prosthesis has become a well-established practice in recent years. The formation of tracheo-oesophageal fistula (TOF) and the subsequent management of the patient with a voice prosthesis can be associated with a number of problems and complications.

We report a new technique of the use of injectable Bioplastique® in the treatment of persistent leakage around Provox® 2 voice prosthesis. Our experience in two cases has shown that it is a relatively simple and effective procedure in stopping the leak around the valve immediately and is without any short-term complications.

Key words: Tracheo-oesophageal Fistula; Prostheses and Implants; Treatment Complications

Introduction

Rehabilitation of voice and speech after total laryngectomy and pharyngolaryngectomy with voice prosthesis has become an established technique after its introduction by Singer and Blom in 1980.[1] The Provox® voice prosthesis was introduced 10 years later in 1990 and is now commonly used for voice rehabilitation.[2]

The use of an indwelling prosthesis is associated with a number of problems including leakage through, or around, the prosthesis, extrusion of the prosthesis, candidal overgrowth, tract stenosis etc.[3]

We describe two cases of chronic leakage around a Provox® 2 valve that could not be managed by replacement with valves of different sizes and insertion of a feeding tube through the fistula. The leakage was successfully treated with injection of Bioplastique® around the tracheo-oesophageal fistula (TOF). This article is the first to report the use of injectable Bioplastique® for reducing the size of the TOF, for treating the intractable leakage around the voice rehabilitation prosthesis.

Case reports

Case 1

A 68-year-old male had undergone total laryngectomy for carcinoma of the larynx. He had primary tracheo-esophageal puncture with insertion of Provox® 2 voice rehabilitation prosthesis by the front-loading technique. He successfully achieved good speech. After two years, however, he developed problems with leakage around the valve. This was unsuccessfully managed with insertion of Provox® 2 valves of varying sizes and also by passing a nasogastric feeding tube through the tracheo-oesophageal fistula to narrow it down.

As all other techniques had failed, we proceeded to augment the soft tissues around the TOF using injectable Bioplastique®. The patient has been followed up for the last 11 months and there has been no further leakage.

Case 2

A 76-year-old gentleman had undergone total laryngectomy followed by radiotherapy for carcinoma of the larynx. He had successful secondary tracheoesophageal puncture performed with insertion of a Provox® 2 voice prosthesis using a front-loading technique. He starting having continued problems with leakage around the valve four years after the tracheoesophageal puncture. He underwent tissue augmentation with injection of Bioplastique®. The procedure was performed under general anaesthesia on the patient's demand. There has been no further leakage for more than eight months.

The procedure. The procedure was carried out as a day case. One patient did not need any anaesthesia while

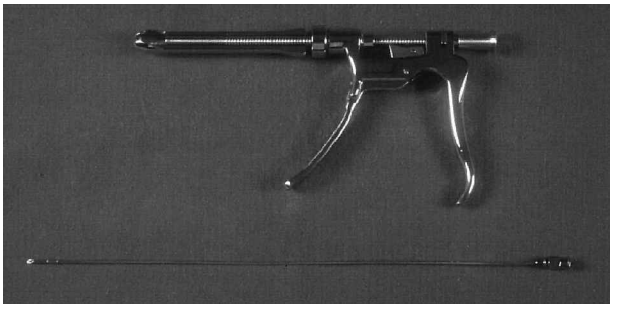

Fig. 1
Bioplastique® injection gun with ratchet mechanism.

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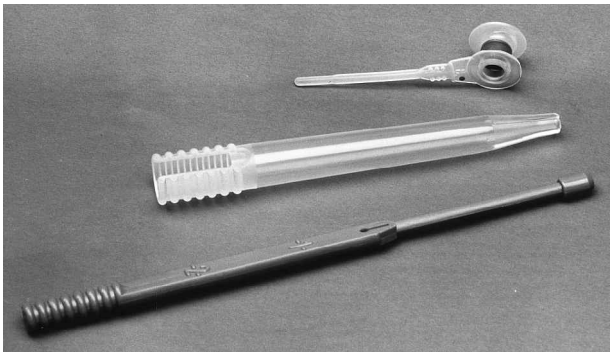

FIG. 2
Provox® 2 voice rehabilitation prothesis and introducer.

another patient was given general anaesthesia on his demand. The leaking valve was removed and 0.4 ml of Bioplastique® was injected at three sites (2, 6 and 10 o'clock positions) around the TOF using a 20 gauge needle and a special gun with a ratchet mechanism designed to inject exact quantities. A new size 8 Provox® 2 valve was re-inserted which fitted snugly in the tracheo-oesophageal wall.

Discussion

The Provox® 2 is a self-retaining voice prosthesis made up of a low resistance medical grade silicone rubber. It is available in different lengths (4.5, 6.0, 8.0, 10 and 12.5 mm) but has a fixed outer diameter of 7.5 mm).[4]

Wetmore *et al*.[5] and Garth *et al*.[3] found leakage around the fistula to be a problem in five of 63 and two of 119 patients respectively. The leakage around the valve may be temporary and can resolve spontaneously. If it continues, the size of the valve should be checked. It is important to measure the thickness of the party wall with the manufacturer's measuring tool. If the leakage occurs around the correct sized valve, the underlying problem is an enlargement of the TOF.[6]

Various techniques have been described to reduce the fistula size and prevent leakage. The valve can be removed and replaced with a small gauge rubber catheter to allow the fistula to contract. Alternatively a nasogastric tube can be passed through the nose after removing the valve altogether, thus allowing an open fistula to contract without irritation from a catheter.[4] Cautery to the fistula may stimulate contracture. A purse string suture may be placed around the fistula.[3] Viscoaugmentation using injection of collagen[3] and Hylaform viscoelastic gel[6] has been described. Failure of these methods will require surgical closure of the fistula and later re-puncture if required.[7]

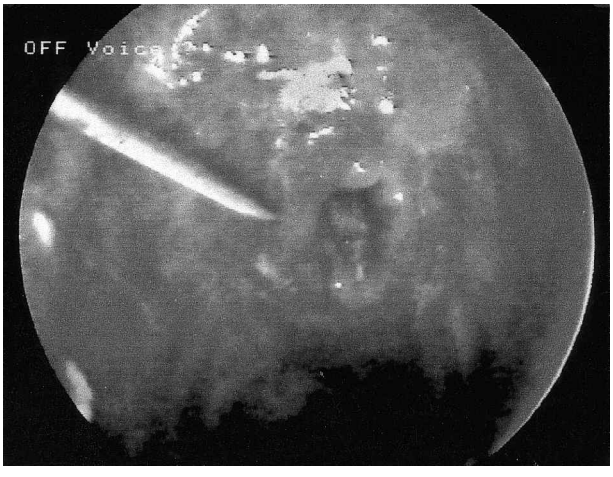

FIG. 3
Injection of Bioplastique® around a tracheo-oesophageal fistula.

We describe a new simple and effective technique for the treatment of persistent leakage around the Provox® 2 valve by injecting Bioplastique® around TOF. Bioplastique® was introduced in 1989.[8] It is manufactured by Bioplasty in the Netherlands and is distributed by Xomed in UK. It is commonly used for subdermal administration in the augmentation and restoration of soft tissue defects and contour deficiencies in the areas including the malar region, nasal bridge, the nasal tip, the chin and mandibular lining.[9] It is also used in urology for the treatment of vesicoureteral reflux and urinary stress incontinence.[10] In Laryngology Bioplastique® is used for vocal cord medialization.[11]

The Bioplastique® implant suspension is available in a 1.0 cc polypropylene syringe with a tip shield cap over the delivery end. As the suspension becomes tacky on exposure to air the syringe is double packaged and heat-sealed to form a complete moisture and microbial contamination barrier.[8] Injection of the suspension is accomplished using an administration gun incorporating a ratchet mechanism, which releases a fixed small quantity of implant.[7] The cost of each prepacked vial of Bioplastique® suspension is £300.

Bioplastique implant consists of textured polydimethylsiloxane elastomers (PDMs), a member of the silicone family of polymers, suspended in a bioexcretable polyvinylpyrrolidone (PVOP) hydrogel. The mean particle size is 200 μm, with the minimum size being 100 μms. Bioplastique® is held in place at the implantation site when body fluids, are exchanged for the hydrogel carrier and host fibroblasts subsequently deposit collagen around the particles. The hydrogel is removed by the reticulendothelial system and excreted unchanged from the body through the kidneys.[8]

Viscoaugmentation using injection of collagen[3] or Hylaform[6] around a TOF has been described in the literature. Collagen has some drawbacks as an injected agent. It is derived from cowhide and therefore carries a theoretical risk of transmitting the agent responsible for new variant Creutzfeldt-Jakob Disease (vCJD).[6] Injection of collagen can precipitate a hypersensitivity reaction to foreign protein in up to three per cent of patients treated, making skin testing prior to injection mandatory. As delayed hypersensitivity reactions are reported skin testing is necessary at least 28 days before the injection. In spite of a negative skin test, the hypersensitivity reaction can still occur in one per cent of the patients.[12] It can affect tracheo-oesophageal wall adversely as a result of inflammation.[6]

Hylaform viscoelastic gel is also not free of allergic potential. It is derived from hyaluronic acid of avian origin (cock's comb). Therefore its use is unsafe in patients with known allergies to substance of avian origin such as food intolerance to eggs, poultry etc.[6]

Injection of Bioplastique® does not cause a hypersensitivity reaction. The large particle size (average 200 μm) prevents Bioplastique® from being phagocytosed. Hence it does not serve as an antigen.[13] As skin testing is not required prior to injection of Bioplastique® its clinical use is facilitated and unlike Hylaform it can be safely injected in patients with known allergy to substances of avian origin.

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Bioplastique® is non-toxic and does not cause irritation of the mucous membranes. A foreign body reaction to Bioplastique® is usually very mild and does not involve granuloma formation, but even if granuloma formation occurs it does not seem to cause clinical symptoms.[13]

Unlike collagen and Hylaform the augmentation effect with Bioplastique® is permanent. Repeated injections may be required with collagen[12] and Hylaform[6] because of resorption by the body. No such repeat injection is required with Bioplastique® making its benefits cost effective.

Conclusion

Voice rehabilitation using a prosthetic tracheo-oesophageal valve has become common after laryngectomy. Useful voice is achieved in a high proportion of cases, and complications are infrequent.

We describe a new technique of injection of Bioplastique® around a TOF to tackle the problem of intractable leak around the Provox® 2 valve.

Although our experience is currently limited we feel that tissue augmentation using Bioplastique® is a valuable and safe technique for the treatment of intractable leakage around Provox® 2 voice rehabilitation prosthesis.

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