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Viscoaugmentation as a treatment for leakage around the Provox® 2 voice rehabilitation system

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Abstract

Tracheo-oesophageal puncture for voice restoration is a well-established technique post-laryngectomy. A number of complications can occur with the creation of a tracheo-oesophageal fistula (TOF) and in the subsequent management of the patient with an indwelling voice rehabilitation system.

This article is the first to report the use of Hylaform®, a colourless viscoelastic gel, to treat an intractable case of leakage around a Provox® 2 voice prosthesis. The procedure which required no anaesthesia resulted in no further leak around the valve to the present day, now more than four weeks post-viscoaugmentation.

Key words: Tracheo-oesophageal fistula; Voice; Prosthesis; Complications

Introduction

There are several voice prostheses available for voice rehabilitation post-total laryngectomy (Natarajan *et al.*, 1994). The first useful device for establishing tracheo-oesophageal speech post-laryngectomy was described in 1980 (Singer and Blom, 1980) with the Provox® voice prosthesis being introduced 10 years later (Hilgers and Schouwenberg, 1990).

Complications include problems at the site of the TOF and those relating to the prosthesis itself, ie these include candidal overgrowth, extrusion of the prosthesis, leakage through or around the valve etc. (Garth *et al.*, 1991; Laccourreye *et al.*, 1997).

A case of chronic leakage around a Provox® 2 voice rehabilitation system is described in a patient who had suffered over many months. Replacement with new valves including different sizes was ineffective.

This article is the first to report the use of Hylaform®, a polysaccharide gel, to reduce the size of the TOF. The procedure is a simple and straightforward one requiring no anaesthesia and resulted in an immediate resolution of the patient's symptoms. There has been no further leakage around the valve – now more than four weeks post-viscoaugmentation.

Case report

A 62-year-old male who underwent laryngectomy for radionecrosis in 1992 had a successful tracheo-oesophageal puncture performed in 1993.

Since early 1998 however, the patient has had continued problems with leakage around the valve, unsuccessfully managed with insertion of different sized prostheses and thickening of feeds.

The patient was admitted as a day case in October of this year and the procedure described below was performed in the operating theatre. There was no requirement for anaesthesia. The patient's size 6 Provox® 2 valve was removed to reveal a large fistula. Hylaform® was supplied to us in a 1.0 ml glass syringe with protective sleeve and needle-locking device (Figure 1). 0.5 ml of Hylaform®, judged to be the correct volume, was injected circumferentially around the TOF with a 25 gauge needle to act as a space-occupying supplement. A new size 6 Provox® 2 valve was re-inserted. The prosthesis sat snugly in the tracheo-oesophageal wall with no leak observed through the fistula when tested by swallowing water.

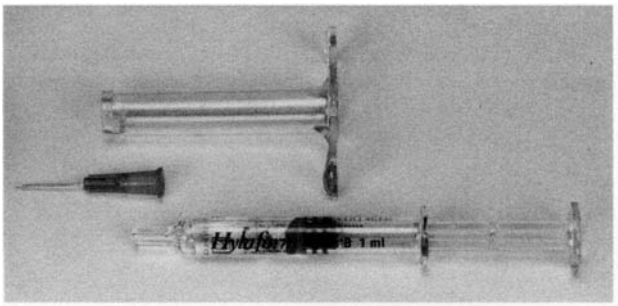

Fig. 1

Hyaloform® in glass syringe with protective sleeve and needle-locking device.

Discussion

The Provox® 2 prosthesis is composed of medical grade silicone rubber and is available in different lengths (4.5, 6.0, 8.0, 10.0 and 12.5 mm) but with a fixed outer diameter of 7.5 mm (Provox® 2 voice rehabilitation system – Physician's and patient's manual).

The complication of leakage around a Provox® 2 voice rehabilitation system may be transient and improve spontaneously. If not, leakage around the valve may be due to an incorrectly sized valve. The importance of measuring the thickness of the party wall with the manufacturer's measuring tool is therefore important. Should the size of the prosthesis be correct and leakage

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still occur around the valve, the underlying abnormality is an enlargement of the TOF.

This complication may be treated by removal of the valve and the introduction of nasogastric feeding or insertion of a rubber catheter through the fistula to actively encourage shrinkage. A purse string suture may alternatively be placed around the fistula. Failure of these conservative treatments normally necessitates surgical closure of the fistula and later repuncture if desirable (Garth *et al.*, 1991; Provox® 2 voice rehabilitation system – Physician's and patient's manual).

The authors describe a new technique using Hylaform®, which is both simple and effective, for treating intractable cases of leakage around the low resistance indwelling Provox® 2 voice rehabilitation system. Hylaform®, a viscoelastic polysaccharide gel distributed by Collagen (UK) Ltd, is more commonly used as an intradermal injection for the immediate correction of wrinkles, folds and scars. It is available in both 0.5 ml and 1.0 ml amounts in a single use 1.0 ml glass syringe (Hyalform® viscoelastic gel – Physician package insert). The cost of the 1.0 ml syringe as supplied to us was approximately £120.

Hylaform® viscoelastic gel was introduced three years ago. It is derived from a highly purified source of hyaluronan (hyaluronic acid) of avian origin which has been cross-linked to optimize its viscoelasticity and persistence (Hyalform® viscoelastic gel – Physician package insert). Hyaluronan is, in fact, obtained from the cocks' comb – the comb or crest on a cocks' head (personal communication).

Unlike collagen, which is derived from cow hide, there is no misplaced anxiety regarding theoretical transmission of the agent responsible for new variant Creutzfeldt-Jakob disease (CJD). Three per cent of the population are allergic to cow hide and therefore skin testing is mandatory. The duration of the skin test is 28 days as delayed hypersensitivity reactions have been reported. Even if the skin test is negative, there is still a one per cent risk of a hypersensitivity reaction to the injected collagen (personal communication). The resultant inflammatory sequelae in the tracheo-oesophageal wall would obviously be deleterious.

No such skin testing is needed with Hylaform® and its immediate safe application is assured provided there is no history of food intolerance to eggs, poultry etc, ie no known allergies to substances of avian origin (personal communication).

According to the manufacturer's product information leaflet, repeat injections may be required after five to 12 months, ie a duration of action similar to that of collagen.

It is the author's opinion that the cost of the injection in this patient, which has so far negated the need for further Provox® 2 valve changes, (also approximately £120) may be justified.

Conclusion

Successful prosthetic voice rehabilitation post-laryngectomy necessitates a multi-disciplinary team approach. The use of an indwelling prosthesis has a number of recognized complications, but the long-term results of vocal rehabilitation via this method are favourable.

In this article, the authors describe a new technique of viscoaugmentation. It is hoped that this report, outlining another method of managing leakage around a Provox® 2 valve, will improve the care of patients with these indwelling prostheses.

The authors recognize that although their experience with this new technique is in its infancy, they believe that viscoaugmentation in the treatment of leakage around indwelling voice prostheses is a valuable new asset in an ENT surgeon's armamentarium.

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