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Tubular expanded polytetrafluoroethylene implants in glottal and neoglottal insufficiency: implantation technique in an animal model

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Abstract

The problem of the therapy of glottal and neoglottal insufficiency is still unsolved. The surgical techniques and the materials employed up until now are not completely free from possible partial or total failures, early or late complications, or the need of a second operation. The objective of the study is to introduce a new thyroplasty technique of inserting tubular expanded polytetrafluoroethylene (e-PTFE) into the larynx of an animal model, with the purpose of using it next in human laryngeal tissue augmentation. Seven 30 kg pigs had tubular e-PTFE implanted under endoscopic control into a vocal fold or laryngeal vestibule. The implants were secured by suture to the thyroid cartilage. Short-term results demonstrate the ease and effectiveness of this mini-invasive implant surgical technique. Long-term follow-up is underway in anticipation of applying this technique to human laryngeal tissue augmentation.

Key words: Laryngeal cartilages, surgery; Polytetrafluoroethylene; Glottis

Introduction

The term 'insufficiency' in medical jargon implies a defect of one or more of an organ's functions. Laryngeal insufficiency should be characterized by one or all of the following: respiratory, phonatory or sphincteric defects of the larynx. The literature uses the term 'glottal insufficiency' mainly as a synonym for incomplete glottal closure. This condition is clinically manifest as phonatory abnormality or aspiration.[1,2]

When the glottis is surgically altered, as it is in some types of functional laryngectomy, the resultant sphincteric incompetence may be defined as 'neoglottal insufficiency'. The post-operative anatomical and functional condition of the larynx depends upon the type (vertical or horizontal) and extent (partial or subtotal) of laryngectomy. In some cases, as cordectomy, there are only phonatory disturbances, while in other cases, such as subtotal laryngectomy, deglutition disorders take priority.[1,3]

The treatments currently employed in treating glottal and neoglottal insufficiency are imperfect. Reinnervation of the adductor muscles in case of paralyzed vocal fold has had mixed results which lack predictability.[4,5] Materials used until now in laryngeal framework surgery (autologous cartilage, silastic, hydroxylapatite) may undergo reabsorption, migration, or induce foreign body inflammatory reaction.[6–9] Injectable materials such as autologous fat, Teflon or collagen have also met with similar difficulties.[1,3,6,10-14]

Tubular or cylindrical e-PTFE tissue implants are used to augment soft tissue in facial plastic surgery because of their ease of removal, if that ever becomes necessary.[15–17] This work investigates the feasibility of applying tubular e-PTFE implants in the larynx to address glottal and neoglottal insufficiency. We have developed a mini-invasive laryngoplasty surgical technique with endoscopic guidance, for the laryngeal application of tubular e-PTFE in a live animal model. This paper presents our new technique; a companion work presents the histological, radiographical and videoendoscopic analysis of the stability and function of these implants.

Materials and methods

This work was performed on seven healthy two-month-old pigs with an average weight of 30 kg. The porcine larynx is morphologically and functionally similar to the human larynx (Figure 1). The main

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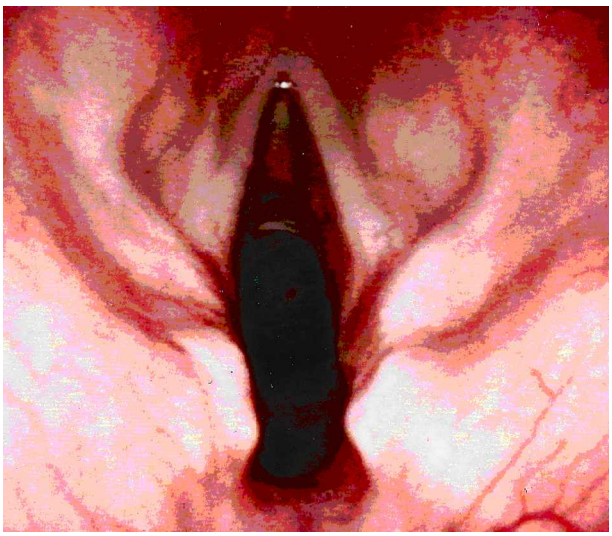

FIG. 1
Endoscopic view (using a 08 10 mm telescope) of normal porcine larynx.

differences are the larger size of the laryngeal ventricles and the oblique arrangement of glottal and ventricular bands in relation to the laryngeal and tracheal cavity. Moreover in the porcine larynx the anterior commissure is located on a lower plane in relation to the vocal processes of the arytenoid cartilages. The point of attachment of the vocal folds to the thyroid cartilage in a two-month-old pig is situated 3 mm above the lower edge of the thyroid cartilage. Thus, the vocal folds rise at an inclination of 40 degrees from their anterior attachment to the arytenoids.

In this trial laryngeal implants of e-PTFE tissue tubes were used. The outer diameter is 2.5 mm, the inner diameter is 1 mm, the length is 30 mm. A characteristic feature of these implants is to allow variations of length without changing the outer and inner diameters.

One laryngeal implant was performed in each animal. The body of the implant was located under the vocalis muscle, corresponding to the vocal fold in two animals, under the mucosa in the ventricular band in three animals and under the mucosa in the laryngeal vestibule above the ventricular bands in two animals.

The insertion was performed under inhalation general anaesthesia after curare administration. Anaesthetic induction was achieved via intramuscular injection of ketamine HCl (8 mg/kg), xilazine HCl (2 mg/kg), atrophine sulphate (1 mg) and diazepam (2 mg). This was followed by forane/oxygen three per cent via oro-facial mask. Paralysis was achieved by giving pancurionium bromide (one intravenous 4 mg vial followed by another 2 mg if necessary). The anaesthetic maintenance phase was sustained by the administration of forane/oxygen three per cent by inhalation, after standard oro-tracheal intubation, and propofol/ketamine/glucose five per cent by infusion.

Each animal was given antibiotics and steroids pre- and post-operatively (enrofloxacine 5 mg/kg by intramuscular injection just prior to the operation and for five days after; methylprednisolone 250 mg by intramuscular injection just prior to the operation and again the day after. Normal feeding is resumed the day after the operation.

Surgical technique

After median longitudinal cervical incision of skin, subcutaneous tissues and platisma, the midline raphe of the strap muscles was identified and the strap muscles were reflected laterally. A tracheotomy was then performed between the second and third tracheal rings after dividing the thyroid isthmus. Finally, the thyroid cartilage on the side of implantation was exposed.

The implant insertion was carried out using specially designed surgical instruments under endoscopic control. These included an external cannula, a trocar, an intermediate guide and an internal guide or carrier (Figure 2).

A small thyrotomy was created by a surgical drill or trocar just lateral to the anterior midline of the thyroid cartilage using endoscopic control. Using the external cannula and the trocar, a sub-mucosal tunnel was created either into the ventricular band or the laryngeal vestibule. In cases of vocalis

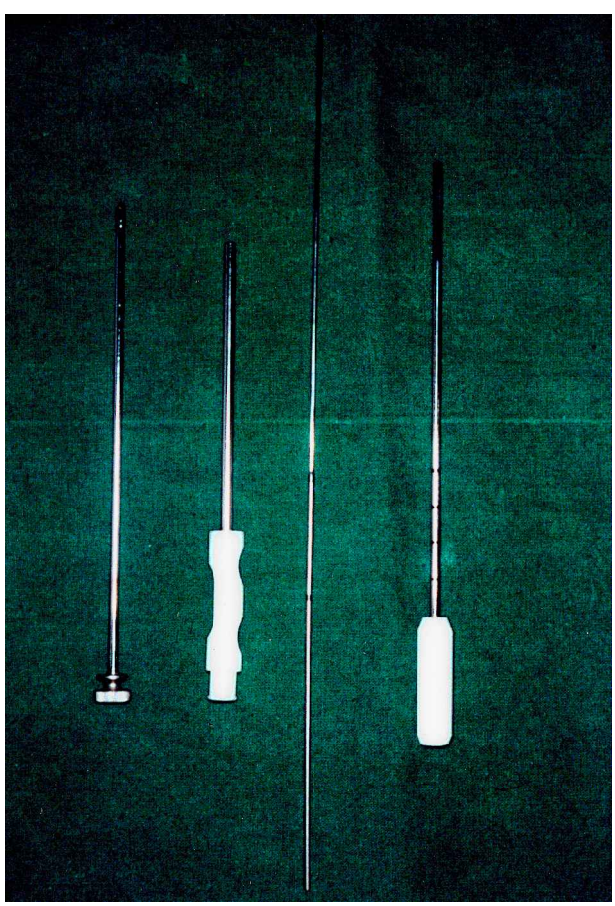

FIG. 2
Surgical instrumentation. From left to right: trocar, external cannula, internal guide and intermediate guide.

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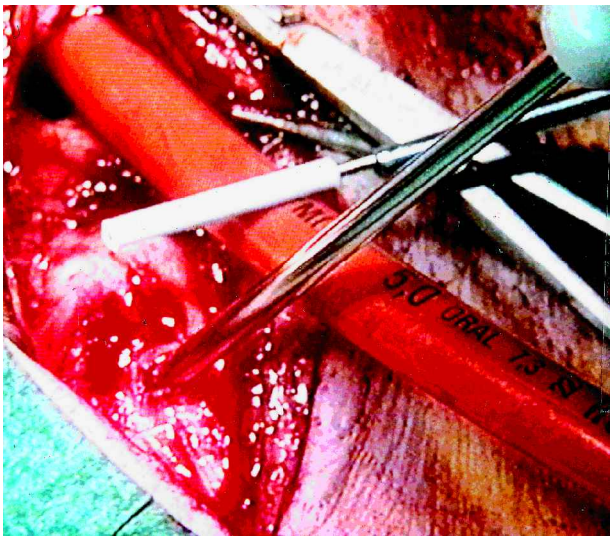

FIG. 3

Completed tunnelling. The external cannula is positioned in the implant seat. The e-PTFE tube is mounted on the internal guide and kept in place by the intermediate guide.

implantation, a tunnel was created under the vocalis muscle. The tunnel was further expanded by using the outer cannula and attached trocar.

After the removal of the trocar, a e-PTFE tube was mounted on the internal guide which in turn is placed within the intermediate guide and outer cannula. The unit was then inserted through the thyrotomy into the tunnel created by the outer cannula and the trocar (Figures 3 and 4). Under endoscopic control (using a 08 10 mm telescope), the implant was then positioned as desired (Figure 5).

After the implant had been correctly placed, the outer cannula was withdrawn, allowing the surrounding connective tissues to grip the external surface of the laryngeal implant and the intermediate guide. Next, the internal guide was pulled back, keeping the contact between the implant and the intermediate guide. Finally, the intermediate guide was extracted

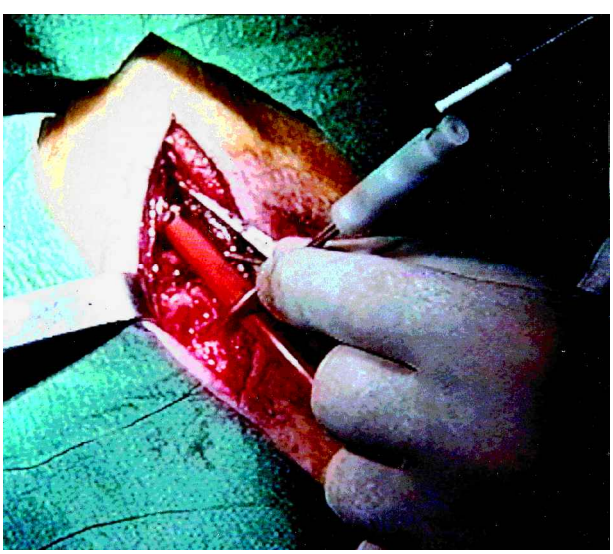

FIG. 4

Inserting the e-PTFE tube into the external cannula.

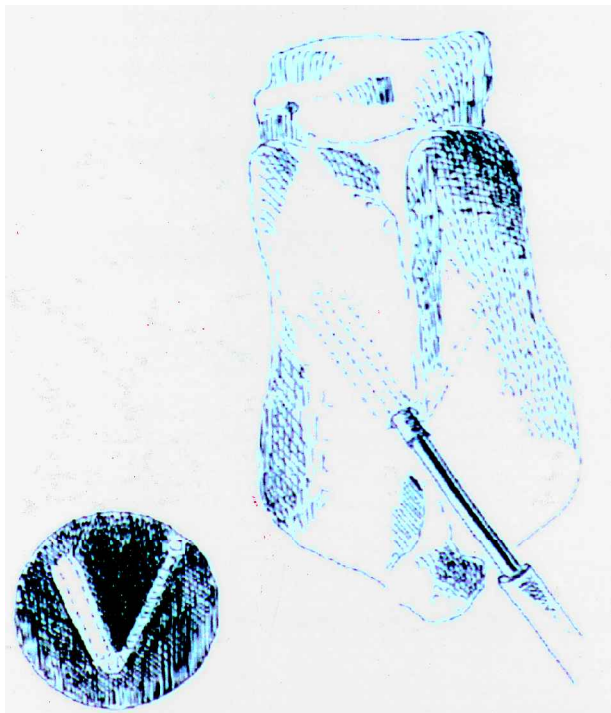

FIG. 5

e-PTFE tube correctly positioned under the vocalis muscle of the right vocal fold.

(Figure 6). The proximal end of the implant (protruding from the thyroid cartilage) was divided into two tips that were fixed by non-absorbable suture to the thyroid cartilage (Figures 7 and 8). Then the temporary tracheotomy was closed by suturing the subcutaneous and cutaneous layers.

Results

In six of the seven animals implantation of tubular e-PTFE was successful. During the process of insertion one animal was noted to have a mucosal tear of the ventricular band. This was thought to be due to technical error at the time of surgery. This tear was

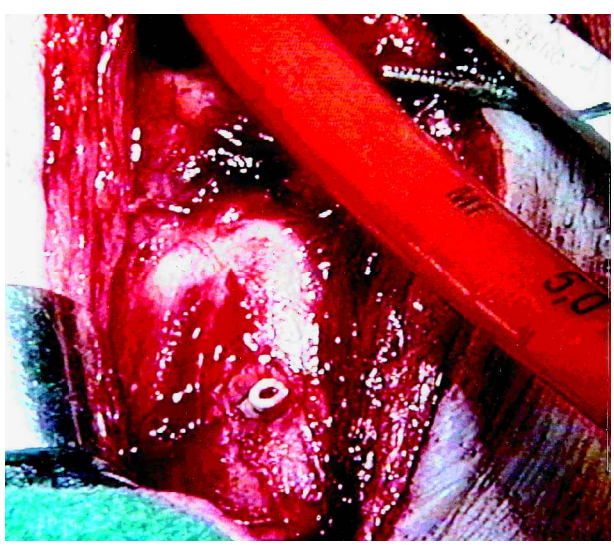

FIG. 6

e-PTFE tube in place, with its proximal end protruding from the thyroid cartilage after retracting the three guides.

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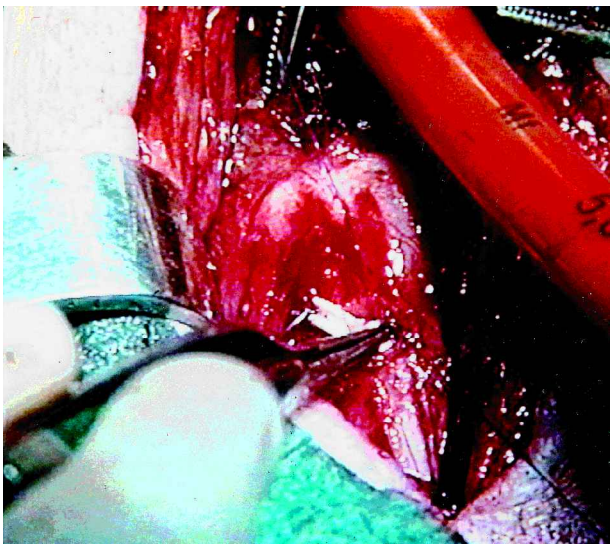

FIG. 7
Suturing the e-PTFE tube to the thyroid cartilage.

purposefully left untreated and the implant was left in place so that we could follow the animal's clinical course and determine the effect of this complication. We were particularly interested in assessing the stability of the anchoring suture to the thyroid cartilage under these adverse conditions. There were no other intra- or post-operative complications. Dyspnoea or stridor was not noticed in any animal, even after tracheotomy closure. There was no evidence of movement or extrusion of the implant over the period of study of six months.

In one animal (that had a mucosal tear at the time of initial implant placement) the distal end of the implant was found exposed in the laryngeal ventricle. However, there was no evidence of foreign body granuloma, active infection, reabsorption or loosening of the implant from the thyrotomy site. In all cases there was no evidence of foreign body reaction, increased vascularity, migration, reabsorption or infection.

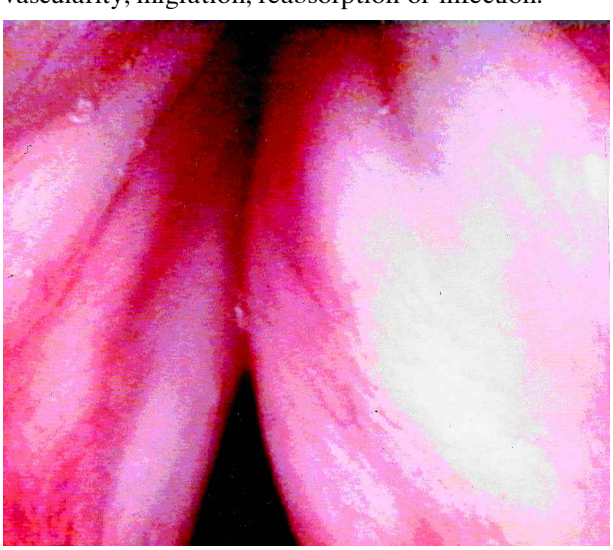

FIG. 8
Endoscopic view (using 08 10 mm telescope) of the implant positioned in the right ventricular band.

Discussion

We report a new surgical technique for placing tubular e-PTFE implants for soft tissue augmentation of the larynx in a porcine model. The objective of our experiment is to evaluate the suitability of these specially designed e-PTFE implants in an animal model. In a companion publication we will report the histological, videoendoscopic and radiographic computed tomography (CT) and magnetic resonance imaging (MRI) results of these implantations.

Our results demonstrate the feasibility of placing soft tissue augmentation implants, designed for stability and biocompatibility, with a straightforward, mini-invasive surgical technique. The live endoscopic visualization by the operator affords an accurate view of the seat of implant before and during the different phases of the operation. Moreover it allows the visualization of the tissue augmentation effect caused by the correctly positioned implant.

The purpose of these preliminary studies is to evaluate the stability of a tubular e-PTFE implant. By preserving normal laryngeal motility and sensation in the experimental model, the implant is subjected to maximal dynamic stresses. Future experimentation possibilities include implanting animals after recurrent laryngeal nerve section to evaluate the ability of these implants to augment the malpositioned or atrophic vocal fold.

Conclusions

We present a new minimally-invasive, thyroplasty technique to place a permanent tissue augmenting e-PTFE tubular implant. The technique affords accuracy of placement via endoscopic guidance. The accuracy and ease of this technique combined with e-PTFE's inherent stability in human tissue make this a promising avenue for further investigation in an attempt to solve the problem of glottal and neoglottal insufficiency by augmentation of removed or paralyzed tissue.

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