The Journal of Laryngology & Otology
April 2003, Vol. **117,** pp. 294–297

Use of polyethylene terephthalate and expanded-polytetrafluoroethylene in medialization laryngoplasty

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Abstract

Various materials have been used up to the present time in vocal fold augmentation. Although silicon has been the most frequently employed, the surgical difficulties encountered in shaping, positioning and placing this material have led to a search for a more easily applicable material. In our study, we investigated the local tissue reaction to implants in the laryngeal skeleton of 10 New Zealand rabbits in which we performed medialization laryngoplasty employing polyethylene terephthalate (PETP = Dacron®) and expanded polytetrafluoroethylene (e-PTFE = Gore-Tex®). When the local host tissue reaction to PETP and e-PTFE were compared, PETP was found to cause significant foreign body giant cell and histiocyte infiltration localized around fibres of the implant. The greater irregularity of the fibrous capsule formed in response to PETP and the density of foreign body giant cells around the PETP fibres suggested that resorption of the implant with time would decrease the degree of medialization.

Key words: Larynx; Surgical Procedures, Operative; Polyethylene; Polytetrafluoroethylene

Introduction

Unilateral vocal fold paralysis causes dysphonia during speech and aspiration during swallowing due to inadequate glottal closure. In some cases, in spite of the physiological compensatory mechanisms of the larynx, surgery may be indicated to correct glottal incompetence and restore vocal fold closure. Some surgical procedures which may have been used include Teflon® or fat injection into the vocal fold,[1] medialization laryngoplasty,[2] arytenoid adduction,[3] and reinnervation techniques.[4] The medialization laryngoplasty procedure (thyroplasty type I) described by Isshiki in 1974 is widely employed.[2] The success of this technique depends to a large extent on the surgical technique, the nature of the implant material used and its compatibility with the host tissue.[5]

Various materials such as autogenous cartilage,[6] silicon,[7] vitalium,[8] hydroxylapatite,[9] ceramic,[10] e-PTFE,[11] collagen compounds (Zyderm I, II) and Zyplast[12,13] and titanium[14] have been used for vocal fold medialization. An optimal implant for medialization laryngoplasty has not been found up to date, and clinical and experimental research studies are still being carried out on several alloplastic materials. Silicon is the most frequently employed material, but this has disadvantages such as shaping, positioning, placing and migration problems. Newer alloplastic materials are currently being employed in order to reduce these disadvantages and shorten the duration of surgery. In our study, we investigated the local host tissue reaction to implanted alloplastic material and compatibility of the material with the tissue in the larynx of rabbits in which we had performed medialization with e-PTFE (Gore-Tex®) and PETP (Dacron®). The degree of medialization with these alloplastic materials is not evaluated.

Materials and methods

All procedures and animal care were carried out in the Experimental Research Centre of the Medical Faculty of Kocaeli University in accordance with the regulations of the Ethics Committee. Ten three-month-old New Zealand rabbits were used in our study. The rabbits weighed 3.5 ± 0.5 kg. PETP and e-PTFE implant materials were used for medialization purposes. After six months the rabbits were sacrificed and a histopathologic evaluation was made.

Surgical technique

Following general anaesthesia with a combination of intramuscular ketamine hydrochloride (Ketalar®) 50 mg/kg and xylazine hydrochloride (Rompun®) 5 mg/kg, the operation site was shaved, cleaned and

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Accepted for publication: 8 January 2003.

prepared under sterile conditions. Two mls of two per cent lidocaine-adrenaline (Jetocaine®) injection was infiltrated under the skin of the neck. The skin and subcutaneous soft tissue was reached by making a midline vertical incision in the neck. On exposure of the laryngeal skeleton, the prelaryngeal fascia was opened. Two windows were opened on both sides by preparing a cartilage flap in the thyroid cartilage lamina, about 4 × 2 mm in size, with the base of the 'U' shape directed laterally, approximately at the level of the vocal fold. A strip of e-PTFE material was placed in the space produced by this window at the right side of all rabbits by elevating the perichondrium while keeping it intact. The cartilage flap thus produced was then laid in position and sutured with 7/0 prolene. The same procedure was carried out on the left side of the thyroid cartilage and an identical size of PETP strip was used as the implant material. The prelaryngeal muscles were sutured over the thyroid cartilage. The subcutaneous tissue was sutured with 4/0 chromic catgut and the skin with 4/0 prolene. Post-operatively, a single dose of antibiotics (cefazolin sodium 40 mg/kg) and steroid medication was given. The rabbits were sacrificed at the end of six months.

Histopathologic examination

The excised laryngectomy material was fixed in 10 per cent formaldehyde. Paraffin blocks were prepared by the routine tissue process. Five μm thick axial sections were obtained at 3 mm intervals in a cranial direction from the level of the vocal fold, keeping the implant in the centre. The sections were stained with haematoxylin and eosin and examined by light microscopy.

Six parameters were investigated in the histopathologic examination. These were: fibrous capsule formation, histiocyte infiltration, foreign body giant cell infiltration, eosinophil infiltration, neutrophil infiltration, and lymphoplasmacytic infiltration. In the histopathologic evaluation, morphological changes were classified on a scale from 0 to 5. According to this semiquantitative classification: 0 = no findings, no infiltration or capsule formation; 1 = slight; 2 = slight to moderate; 3 = moderate; 4 = moderate to severe; and 5 = severe changes.

Results

All 10 animals survived the six month post-operative period without any complications. No macroscopic infection was observed in the larynx of the sacrificed rabbits and there was no intraluminal or extralaryngeal extrusion of the implant material. The distribution of the local host tissue response to the two implant materials according to the animals is given in Table I. In the comparison of the fibrous capsule formation, histiocyte infiltration, foreign body giant cell infiltration, eosinophil infiltration, neutrophil infiltration and lymphoplasmacytic infiltration reactions to the implant materials, using the Chi-squared test, only histiocyte infiltration and foreign body giant cell infiltration parameters were significantly different ($p<0.05$). There was no statistically significant difference in the other parameters.

TABLE I
DISTRIBUTION ACCORDING TO ANIMALS OF THE HOST LOCAL TISSUE REACTION TO PETP AND E-PTFE

	FCD	HR	FBR	EI	NI	LPI
PETP 1	2	4	3	0	0	0
PETP 2	1	1	1	1	0	0
PETP 3	2	4	2	0	0	0
PETP 4	1	1	1	0	0	0
PETP 5	2	4	3	1	0	1
PETP 6	1	2	1	1	1	1
PETP 7	2	3	4	0	1	0
PETP 8	2	3	3	0	0	1
PETP 9	2	4	4	1	0	0
PETP 10	2	2	4	1	0	0
Mean PETP	*1.7*	*2.8*	*2.6*	*0.5*	*0.2*	*0.3*
e-PTFE 1	2	2	4	0	0	1
e-PTFE 2	2	4	3	0	0	1
e-PTFE 3	2	4	3	0	1	0
e-PTFE 4	1	2	1	1	1	1
e-PTFE 5	2	4	4	1	0	0
e-PTFE 6	2	4	3	1	0	0
e-PTFE 7	1	3	1	0	0	0
e-PTFE 8	1	3	4	0	0	0
e-PTFE 9	2	4	3	0	0	0
e-PTFE 10	2	4	3	0	0	0
Mean e-PTFE	*1.7*	*3.4*	*2.9*	*0.3*	*0.2*	*0.3*

Fibrous capsule development (FCD), Histiocytic reaction (HR), Foreign body reaction (FBR), Eosinophilic infiltration (EI), Neutrophilic infiltration (NI), Lymphoplasmocytic infiltration (LPI).
Semiquantitative classification: 0 = no findings, no infiltration or capsule formation; 1 = slight; 2 = slight to moderate; 3 = moderate; 4 = moderate to severe; and 5 = severe changes

https://doi.org/10.1258/00222150360600904 Published online by Cambridge University Press

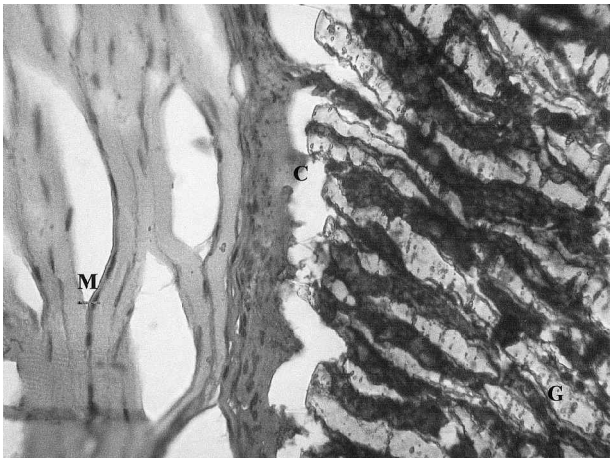

FIG. 1
Fibrous capsule (C) formation between striated muscle fibres (M) and partially calcified e-PTFE implant (G) (H & E; ×400).

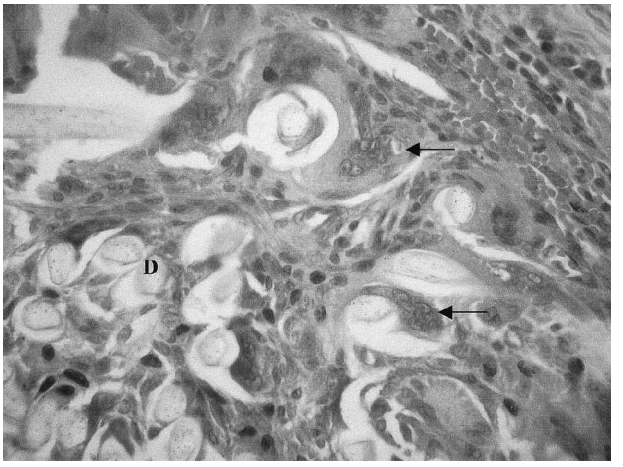

FIG. 2
Inflammatory reaction composed of histiocytes and multinucleated foreign body giant cells (arrows) around PETP implant fibres (D) (H & E; ×400).

Discussion

In the treatment of unilateral fold paralysis, which may cause dysphonia and aspiration, various surgical approaches such as Teflon® or fat injection into the vocal fold,[1] medialization laryngoplasty,[2] arytenoid adduction,[3] and reinnervation techniques[4] are employed. The most widely used method is medialization laryngoplasty. Utilization of alloplastic implants in medialization laryngoplasty is not new, but the earlier procedures generally used autogenous tissue. After the 1960s, with the introduction of biocompatible and completely inert materials to medical practice, such materials began to be used as alternatives. The implant materials which have been used in medialization laryngoplasty to date are: autogenous cartilage,[6] silicon,[7] vitalium,[8] hydroxylapatite,[9] ceramic,[10] e-PTFE,[11] and titanium.[14] Although so many implant materials have been used, each implant material has its disadvantages as well as its advantages, and this had led clinicians to search for an ideal implant material with fewer problems. In our study, we investigated the tissue compatibility of a new material by comparing e-PTFE, which has been previously tested both experimentally and clinically and found suitable, with a completely untried PETP.

The fibrous capsule which develops around the inserted implant is a barrier which forms between the host tissue and the implant material. After insertion of the implant, and following the local inflammatory response, the amount of collagen increases around the implant and a capsule develops. In our opinion this barrier, by isolating the alloplastic implant, is an important factor in enabling the implant to remain in the host for a long period without being resorbed. According to our study, there was no statistically significant difference between the capsule formation in response to the two implants. However, the capsule formed with PETP was more irregular than that formed with e-PTFE, and the continuity of the capsule was indistinct in places (Figure 1). It was observed that the phagocytic cells, which entered through the capsule defect, formed foreign body giant cells around the PETP fibrils, which were more loosely woven compared to the e-PTFE fibrils, and completely surrounded them (Figure 2). The animal studies in the literature report the e-PTFE caused limited fibrous tissue production and minimal capsule formation.[15] When a fibrous capsule does not form around the alloplastic material, it is thought that histiocytes and foreign body giant cells increase resorption of the material by phagocytosis. However, the materials used in our study have been used for several years in cardiovascular and plastic surgical procedures without any major problems. Fibrous capsule formation has another advantage in that it allows the implant to be easily removed when desired. Paniello investigated changes in the tissue around the vocal fold and cricoarytenoid joint by removing the implant one month after performing medialization laryngoplasty using silicon in dogs. He stressed that this surgical procedure should not be carried out in cases where there was a possibility that nerve function might return.[16] In another investigation, Whitmore compared PETP and e-PTFE as graft material in the sclera of rabbits. While e-PTFE could be easily removed from the capsule-like covering in the sclera, it was observed that PETP was firmly bound to the underlying tissue. It was stated that, due to the hydrophobic character and small pore structure of e-PTFE, it only allows a small amount of fibrous tissue into the material. In contrast, PETP has a loose network structure so that surrounding reactive tissue can easily penetrate into the implant, and fixation to tissue is stronger.[17] Besides the risk of resorption, fixation to tissue is a desirable property in some surgical procedures. In medialization laryngoplasty, the silicon is generally implanted between the thyroid cartilage and the cartilage perichondrium and is therefore in a relatively stable area. It has been reported in the literature, however, that the use of silicon in medialization leads to complications such as

https://doi.org/10.1258/00222150360600904 Published online by Cambridge University Press

unwanted extrusion into the laryngeal lumen or disturbance of the quality of sound due to migration.[7]

Histiocytes and foreign body giant cell infiltration shows that the host has locally sensed the implant as foreign body. Significant difference was observed in our study in the comparison of the two groups. Foreign body giant cells were found completely surrounding the PETP fibres (Figure 2). In another study on PETP using 14 goats, a percutaneous dialysis catheter containing PETP was compared with a titanium catheter. Inflammatory cells, macrophages and foreign body giant cells were detected surrounding the implant and as a result it was concluded in this study that PETP was inferior to titanium as an implant material.[18]

When the general characteristics of materials such as PETP and e-PTFE are considered, they are seen to have some advantages from the surgical aspect. PETP and e-PTFE are flexible and soft and since they are used in strips they can be added as required.[19,20] For this reason they can more easily attain the shape of the replaced tissue and may be increased to the required size. In addition, because they are soft materials they can withstand manipulation and it is unnecessary, within limits, to open a regular cartilage window during surgery.[11] When rigid materials such as silicon, hydroxylapatite and titanium are too small or too big for the space produced, they should be prepared again. In addition, silicon may be broken easily while being shaped or a piece may break off. This involves preparation of a new implant.[7,9,14] For these reasons, the use of PETP and e-PTFE during operation is much easier and more practical. The short duration of the operation, which is carried out under local anaesthesia, makes it easier for the patient to tolerate.[11,19,20] Furthermore, since PETP and e-PTFE are synthetic materials, the risk of infection with hepatitis and human immunodeficiency virus (HIV) as with homografts is not a problem.[15]

Conclusion

The local host tissue reactions to PETP and e-PTFE materials were compared. Only histiocyte infiltration and foreign body giant cell infiltration was found to be significantly different. The greater irregularity of the fibrous capsule that developed around PETP and the density of the foreign body giant cells surrounding the PETP fibres indicate that the implant would be resorbed with time. For this reason, although PETP was compatible with the host tissue in clinical study, it may decrease in mass with time and this would lead to a decrease in medialization. Since both materials are easy to use during surgery, they are worthy of further research. Increasing the number of experimental animals and the length of the post-operative period to evaluate long-term resorption results will enable us to reach a definite conclusion regarding the results of our preliminary study.

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Dr G. Keskin takes responsibility for the integrity of the content of the paper.
Competing interests: None declared