ELSEVIER

Biomaterials 20 (1999) 1997–2005

Biomaterials

Biocompatibility of a novel tissue connector for fixation of tracheostoma valves and shunt valves

A.A. Geertsema[a,*], H.K. Schutte[a], M.B.M. van Leeuwen[b], G. Rakhorst[a], J.M. Schakenraad[c], M.J.A. van Luyn[d], G.J. Verkerke[a]

[a]*BioMedical Engineering, Division of Artificial Organs, Faculty of Medicine, University of Groningen, Bloemsingel 10, 9712 KZ Groningen, Netherlands*
[b]*BioMedical Engineering, Division of Biocompatibility, Faculty of Medicine, University of Groningen, Bloemsingel 10, 9712 KZ Groningen, Netherlands*
[c]*Bioscan BV, Prof. Bronkhorstlaan 10, 3722 MB Bilthoven, Netherlands*
[d]*Cell Biology and Biomaterials, Faculty of Medicine, University of Groningen, Bloemsingel 10, 9712 KZ Groningen, Netherlands*

Received 23 March 1999; accepted 13 May 1999

Abstract

Rehabilitation after laryngectomy often includes the use of a shunt valve and a tracheostoma valve to restore voice. To improve the fixation method of these valves, a new tissue connector has been developed, basically consisting of a ring that will be integrated into surrounding tracheal soft tissue. The valves can be placed in the ring. To test the principle of the tissue connector, a prototype consisting of a subcutaneous polypropylene mesh and a percutaneous titanium stylus was implanted into the backskin of 10 rats by a two-stage surgical procedure. We reasoned that if a firm connection can be realized with the skin, a firm connection with the trachea will also be possible. The subcutaneous part was implanted first, followed by the percutaneous part after 6 weeks. The complete tissue connector with surrounding tissue was removed 8 weeks later and examined histologically. The principle of the new tissue connector proved to be effective: hardly any epithelial downgrowth appeared, and adhesion of soft tissue was demonstrated. No infection or severe inflammation reaction was detected. The tissue connector seems appropriate for its intended use.

Keywords: Tissue connector; Percutaneous implants; Polypropylene mesh; Titanium; Two-stage surgical procedure; Laryngectomy

1. Introduction

The surgical treatment of a malignancy in the larynx sometimes leads to a total laryngectomy. This is often seen as a life-saving operation, as the malignancy is taken away by removing the larynx surgically, including vocal folds and epiglottis. The trachea is directed to a tracheostoma in the neck. To restore voice, the surgeon inserts a shunt valve in the tracheoesophageal wall, and sometimes a tracheostoma valve [1,2] is glued on the skin around the tracheostoma (Fig. 1). Voice becomes possible by producing a rapid airflow, which closes the tracheostoma valve; expired air then flows via the shunt valve through the upper esophageal sphincter (pseudoglottis), which starts to vibrate (comparable to belching) and creates voice to make speech possible. The functioning of these valves is often hampered due to air leakage as a result of poor fixation. To overcome these fixation problems, a new tissue connector was developed to establish an adequate fixation of these valves to the tracheal mucosa. The tissue connector basically consists of a ring intended to be integrated into surrounding soft tissue. Thereafter, the valves can be placed in the ring (Fig. 2). This concept can also be used for the fixation of a total artificial larynx, which is being developed at the University of Groningen [3].

The new tissue connector is considered to be a permucosal implant, as the tissue connector pierces the tracheal mucosa. Permucosal implants anchored by osseointegration, which are applied in the field of dental surgery to replace teeth, are commonly made of titanium [4]. The same implant system is used for percutaneous implants such as the bone-anchored hearing aid (BAHA) [5–7], orbital epistheses and auricle prostheses [8–10]. The resemblance between skin and mucosa can explain

* Corresponding author. Tel.: + 31-50-363-2463; fax: + 31-50-363-3139.
E-mail address: a.a.geertsema@med.rug.nl (A.A. Geertsema)

0142-9612/99/$ - see front matter
PII: S0142-9612(99)00102-7

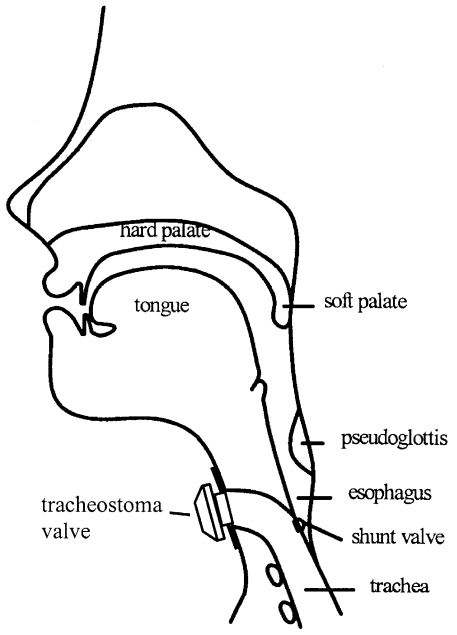

Fig. 1. Rehabilitation after laryngectomy with shunt valve and tracheostoma valve.

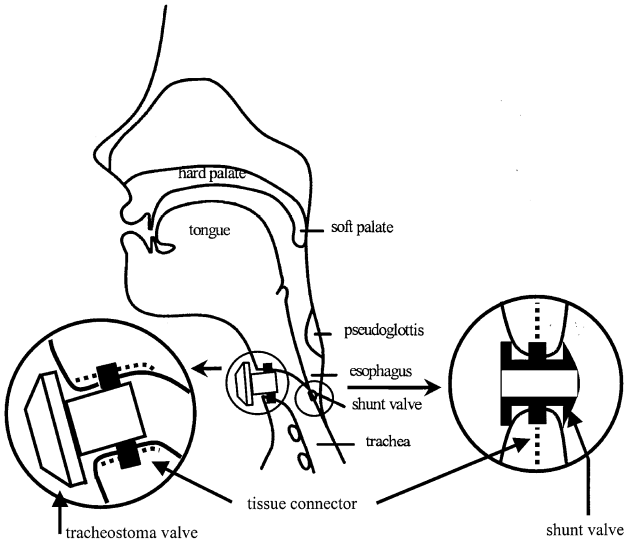

Fig. 2. Application of the tissue connector for fixation of a tracheostoma valve (left) and a shunt valve (right).

the success of this implant system for both percutaneous and permucosal implants.

However, our tissue connector is not located near bone, but in soft tissue making stabilization by osseointegration impossible. To find a solution for the permucosal tissue connector, percutaneous devices stabilized in soft tissue must be considered. One of the main failing mechanisms of these implants is epithelial downgrowth along the implant, which finally results in extrusion by marsupialization [11]. Formation of an effective epidermal seal at the implant–skin interface could prevent epithelial downgrowth. Several soft-tissue-anchored percutaneous implants made of different kinds of material have been developed to form such an epidermal seal [12–18]. These soft-tissue-anchored percutaneous implants can be applied for a permanent access to the body, such as left ventricular assist devices (LVAD) [15], continuous ambulatory peritoneal devices (CAPD) [19–21], percutaneous devices to deliver insulin into the abdominal cavity of patients with diabetes [22] and percutaneous devices for enteral feeding and drainage [23].

Jansen et al. [24,25] developed a new two-stage technique. As a first-stage operation a titanium fiber mesh was implanted in subcutaneous tissue. A five-week healing period was applied to ensure a sufficient stabilization, so that a second-stage installation of a percutaneous implant would be successful [26]. This technique favors the functionality of percutaneous implants in soft tissue.

A good alternative for the titanium mesh might be polypropylene (Marlex®) mesh for initial fixation. Polypropylene mesh is used clinically for repair of the abdominal wall [27,28] and for tracheobronchomalacia [29,30] as well as experimentally for tracheal defects [31,32].

Application of horizontal microgrooves for percutaneous implants might be effective for preventing epithelial downgrowth. Several studies have shown that surfaces with uniform multiple parallel grooves can enhance cell adhesion by confining cells in grooves and by mechanically interlocking them [33]. Chehroudi et al. showed that percutaneous dental implants with parallel grooved surfaces resulted in an inhibition of epithelial downgrowth [34,35].

For our application we developed a new tissue connector constructed from a new material combination, consisting of a polypropylene mesh for a subcutaneous anchorage and a titanium part for the percutaneous implantation. The aim of this study is to test the biocompatibility of this novel tissue connector. These parts are implanted by a two-stage surgical procedure. For simplicity we did not use a tracheal model, but the new tissue connector was implanted into the backskin of rats. We reasoned that if a firm connection can be realized with the skin, a firm connection with the trachea will also be possible.

2. Materials and methods

2.1. Implants

The configuration of the tissue connector (TC) is shown in Fig. 3. It consists of a subcutaneous polypropylene mesh (Bard® Marlex® mesh, Bard Benelux N.V., Leuven, Belgium) with a centrally fixed titanium ring and a percutaneous part (stylus). The titanium used is an