MORPHOLOGICAL EVALUATION OF THE VIABILITY OF SILICON-LAVSAN TRACHEAL PROSTHESES

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The main radical method of treatment of tumors and cicatricial stenosis of the trachea and main bronchi is resection with end-to-end anastomosis. In some cases, however, when there are extensive lesions, a restorative operation is impossible and a prosthesis must be fitted. To replace circular defects of the trachea, in experimental practice biological transplants of the trachea [1, 7] and alloplastic prostheses [3-6] have been used. The results of previous investigations show that a search must be made for new materials and improvements to the design of prostheses for the respiratory tract. One such prosthesis has been produced.

To demonstrate the possibility of clinical use of the silicon-lavsan prosthesis, it was subjected to experimental trials. The study of repair processes at the boundary between tissue and implant is particularly important.

EXPERIMENTAL METHOD

A new Soviet silicon prosthesis with lavsan cuffs (Fig. 1) has been produced in the Department of Pulmonary Tuberculosis, I. M. Sechenov First Moscow Medical Institute, in conjunction with a constituent unit of the Ministry of the Electrotechnical Industry (Fig. 1). Prostheses were implanted into the thoracic part of the trachea in the region of its bifuration in 108 mongrel dogs weighing 18-32 kg. The prosthesis was anastomosed with the divided ends of the trachea and main bronchi with interrupted sutures, the thread being taken through all layers of the wall, taking in two-thirds of cartilaginous ring and of the lavsan cuff. Lavsan was used as the suture material. The region of the cranial and caudal anastomoses of the trachea, with the lavsan cuffs, the capsule around the prosthesis, and the lung tissue were studied at intervals from 7 days to 3 years after implantation. Histological sections were stained with hematoxylin and eosin and by Van Gieson's method, by Brachet's method for RNA, and with toluidine blue at neutral pH for glycosaminoglycans [2].

EXPERIMENTAL RESULTS

Seven days after implantation of the prosthesis a marked inflammatory reaction was observed in the tracheal wall close to the anastomoses: the tissue was edematous and saturated with fibrinous exudate containing a few neutrophils. The capillaries and small blood vessels were dilated and packed with blood cells; diapedetic hemorrhages were present. The terminal portions of the mucous glands were in a state of destruction. Meanwhile foci of active proliferation of connective-tissue cells and the formation of new capillary loops could be seen in the trachea. Actually in the region of the anastomoses between the fibers of the synthetic cuffs organization of fibrin was taking place. Here there were many young fibroblasts, newly formed capillaries, and undifferentiated cells. In the external portion active pyroninophilic fibroblasts and thin, winding fuchsinophilic fibrils predominated. They were firmly adherent to the surrounding cellular tissue, which was rich in blood vessels and lymphoid formations. A connective-tissue capsule with a double-layered structure

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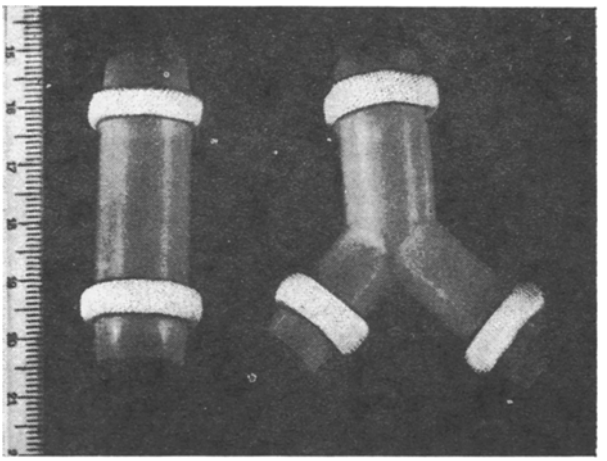

Fig. 1. Linear and bifurcation silicon-lavsan tracheal prostheses.

surrounded the prosthesis: the inner layer contained many cells and had fibrin on the surface, the outer layer consisted mainly of collagen fibers. In some parts the layered structure of the capsule was disturbed and cells and fibers were arranged haphazardly. The capsule was intimately connected to the well vascularized cellular tissue.

On the 15th day moderate hypertrophy of the epithelium was observed in the mucous membrane of the trachea and slight fibrosis in the submucosa. Around the glands and blood vessels there were foci of histio-lymphocytic and plasma-cell infiltration. Cells of the hyaline cartilage showed signs of dystrophy. Nearer to the anastomoses, the tracheal walls became thicker on account of proliferation of granulation tissue around the cuffs. Compared with the previous time this tissue had a more mature structure and it gradually penetrated into the pores of the cuff, filling them. The granulation tissue in the zone of the anastomoses was fibrous in type, consisting mainly of collagen fibers, well vascularized, and merging directly with the mediastinal cellular tissue. A gradual decrease in the number of cells and conversion of granulation tissue into fibrous tissue were observed in the capsule around the prosthesis.

After 30 days the surface epithelium in the region of the tracheal wall was virtually completely restored and the lumen of the glands contained secretion, evidence that they were functioning. Small fibrous changes were observed in the submucous layer. Connective tissue at this time filled the pores of the lavsan cuff and encapsulated the entire prosthesis. Fragments of cartilage were compressed, ischemic, and showed partial degradation; cellular infiltration was weak around the suture material, natural reparative changes typical of tissue — implant contact were present in the anastomosis (Fig. 2). The tracheal epithelium gradually disappeared closer to the cuffs or underwent hypertrophy due to the appearance of a mechanical obstruction impeding its growth. The capsule around the prosthesis gradually condensed and became thicker.

After 3 months the tracheal wall close to the anastomoses showed partial sclerosis and was lined with cylindrical epithelium. Diffuse histiocytic and plasma-cell infiltration was observed. The mucous glands were actively functioning and secretion was entering the lumen of the trachea. The epithelial lining ended by the cuffs, and areas of erosion were formed. The submucosa merged directly with the connective tissue surrounding the allograft. From the point of view of its structural features, this tissue can be conventionally divided into two layers. The outer layer was formed by coarse, highly convoluted collagen fibers with a minimal number of cells. Glycosaminoglycans, many capillaries, and small vessels of the arteriole and venule type appeared in the intercellular substance. In the inner layer cells (macrophages, fibroblasts, endotheliocytes, neutrophils) predominated over fibers. Macrophages were adsorbed on the lavsan threads, and giant cells, partially resorbing the cuffs, also appeared.

From 6 to 8 months after the operation foci of necrosis of the mucous membrane and, to some extent also, of the submucosa, were found in the tracheal wall near the anastomosis. In some places the mucous membrane was desquamated and replaced by granulation tissue with many vascular cells. Here also marked degenerative changes were observed in two of the

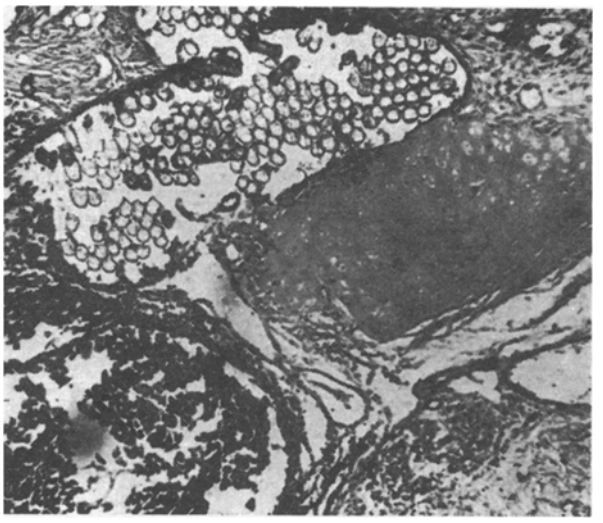

Fig. 2. Invasion of cuff of prosthesis by connective tissue on 30th day after operation: ischemia and replacement of areas of cartilage, encapsulation of suture material. Stained with hematoxylin and eosin. Here and in Fig. 3, 100 ×.

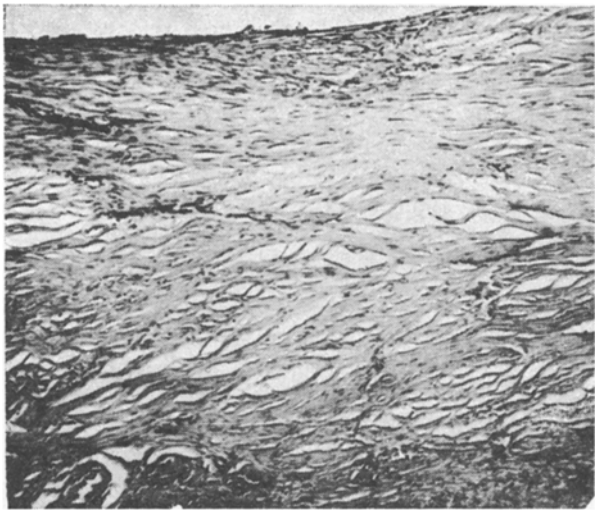

Fig. 3. Fibrous capsule surrounding tubular part of prosthesis 3 years after operation (Van Gieson).

cartilaginous rings located nearer to the anastomosis. Some cartilage cells were in a state of destruction and signs of karyolysis were present. The ground substance contained moderate amounts of glycosaminoglycans. The muscular coat showed atrophy. The tracheal wall was infiltrated with macrophages, plasma cells, lymphocytes, and a relatively few neutrophils. All these changes occurred in a limited region of the tissue close to the cuff, i.e., in the zone of continuous contact between mucous membrane and end of the prosthesis.

From 1 to 3 years after the operation, at a distance of 1.5-2 mm above the anastomosis all layers of the trachea were fibrosed, with partial atrophy of the cells composing it. Near the anastomosis the epithelium was flattened and showed some features of the stratified squamous type. Signs of chronic inflammation with histio-lymphocytic and plasma-cell infiltration, and also stasis of erythrocytes in the capillaries, were found in the submucosa. The cartelaginous rings had areas of lysis, no glycosaminoglycans were detected, the perichondrium was virtually absent and was replaced by granulation tissue. Hyperplasia

of capillaries, weak fibrosis, and moderate cellular infiltration of the same character as in the submucosa were observed in the advantitia. In the region of the cuff sluggish granulations were observed, with vasculitis, foci of resorption of collagen fibers, and a decrease in the number of fibroblasts and in the RNA content in their cytoplasm, with predominance of macrophages and other monocytic cells. Tissue of this kind is characteristic of sluggish inflammation. It virtually did not turn into mature fibrous tissue but remained retarded in its development, delaying the course of the repair process. The capsule formed around the silicon prosthesis was 3-5 mm thick and the intima was not connected with it. Inflammatory changes here were mainly perivascular and were mild in degree (Fig. 3). A few macrophages accumulated on the inner surface. Fibrocytes and capillaries were present between the partially separated layers of collagen bundles and fibers. Capillaries, together with larger blood vessels, predominated in the outer layer of the capsule.

At all times of observation starting with the 7th day the lung tissue was free from recent inflammatory changes and the alveolar passages and bronchioles had a free lumen and thin walls. Only small areas of connective tissue, formed at the site of previous inflammatory foci, were observed. In some animals with secondary autoinfection 1 month after the operation the mucous membrane in the intact portion of the trachea showed hyperplasia. Increased histio-lymphocytic infiltration was observed in the submucosa, and neutrophils also appeared closer to the cuff. The latter infiltrated the granulation tissue diffusely and formed small perivascular concentrations. In some cases the neutrophilic filtration was considerable in degree and the granulation tissue was separated from the cuff.

On the whole, the study of the time course of repair after implantation of the silicon tracheal prosthesis with lavsan cuffs showed that in the course of 2 weeks an active inflammatory reaction took place around the prosthesis: edema of the submucosa, degeneration of the mucous glands and cartilaginous rings, and cellular infiltration of the tissues took place. Pores of the lavsan cuffs were filled with fibrous exudate mixed with neutrophils. Along the line of contact of the trachea with the cuff and in its vicinity desquamation of the epithelial lining was present and the defect was filled with developing granulation tissue. Between the anastomoses and along the whole length of the prosthesis a granulation tissue capsule formed. Later, directly in the region of the anastomosis the cuff and suture material were surrounded by granulation tissue, and later by fibrous tissue with minor cellular infiltration. The epithelium near the anastomosis was hypertrophied and in some cases it acquired the features of stratified squamous epithelium, but actually along the line of anastomosis the epithelium was absent. At the later stage, chronic indolent inflammation continued in the thickness of the tracheal wall around the cuffs and, to a lesser degree, in the capsule; this inflammation was local in character and gave rise to no marked changes in the lung tissue, and was fully compatible with life of the experimental animals. By the time of publication of this paper 14 animals with implanted prostheses have survived for 6-43 months. A favorable time course of repair around the implant in the majority of the animals provides grounds for recommending this silicon prosthesis for clinical trials.

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