## Resorbable Device for Costal Cartilage Graft Fixation in the Surgical Treatment of High Tracheal Stenosis

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Tracheal stenosis is a condition where the trachea narrows or becomes constricted as a result of a laryngotracheal trauma, prolonged tracheal intubation, high tracheostomy or systemic diseases. A possible treatment for tracheal stenosis is tracheal reconstruction with costal cartilage grafts that are implanted into the anterior tracheal wall. In order to secure the graft cartilage to the tracheal sidewalls we can use differnt synthetic resorbable materials, such as polylactic acid and polyglycolic acid, that allow anchoring of the costal cartilage to the tracheal wall. The aim of this paper is to present a fixation device for fixing the cartilage graft on the tracheal side walls. This device is designed using a synthetic resorbable material and allows anchoring of the costal cartilage to the tracheal wall using microscrews made of resorbable material.

Keywords: tracheal stenosis, costal cartilage, resorbable material

The etiology of high tracheal stenosis includes: laryngotracheal trauma, prolonged tracheal intubation, high tracheostomy, but other causes may be involved, such as systemic diseases, chemotherapy or radiotherapy. Also, thacheal stenosis may be idiopathic [1].

Diagnosis is achieved by endonasal fiberscopic or bronchoscopic examination. High quality imaging represented by CT scanning will help locate the area of stenosis. During endoscopic examination targeted biopsies may be taken.

The trachea is a single organ with a length of 10-12 cm for an adult, a diameter of 13-16 mm to 16-20 mm in men and women, respectively. It consists of 16-20 horseshoeshaped cartilages and the posterior region is membranous. Vascularization of the cervical trachea is provided by the upper and lower thyroid arteries.

Depending on the degree of stenosis, high tracheal stenosis treatment is represented by endoscopic approach or cervical external approach.

We prefer to carry out tracheal stenosis plasty using costal cartilage grafts that are implanted into the anterior tracheal wall. This reconstructive procedure will create a larger diameter of the tracheal injured area, that will allow proper ventilation of the patient. Costal cartilage has good

stiffness and can be easily modeled on the size and curvature of the defect that must be reconstructed. In the current stage, in order to secure the graft cartilage to tracheal sidewalls, a number of non resorbable surgical suture threads (30-40 shots) are used. Surgical suture using threads does not offer high stability or a perfect sealing and involves a significant operative period.

**Experimental part** 

The absorbable materials we propose to make up the fixture are polylactic acid and polyglycolic acid.

Polyglycolic acid is a polymer with high consistency crystals, dark brown, with a melting point of 224-2280°C. The temperature for crossing the polyglycolic acid products in transparent color is 360°C. It has no methyl radical, which confers hydrophilic properties and a rate of degradation faster than that of polylactic acid.

Polylactic acid is an off-white semi-crystalline polymer with a temperature of transformation into translucent products of 570°C. It has a boiling temperature of 174-1840°C. The lactic acid asymmetric molecule creates two stereoisomers, L and D. Isometric L is found in human metabolism. If the polymer consists only of L-isomer, then it is called poly L lactic acid (PLLA).

Endoscopic	External approach
LASER Surgery	Laryngo-tracheal plasty using:
	- costal cartilage
	- mucosa
Dilation	Resection/tracheal anastomosis
Injection near the stenotic area of topic	Stents
corticosteroids , Mitomycin C	

Table 1
SURGICAL TREATMENT OF HIGH TRACHEAL
STENOSIS

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Fig. 1. Sagittal section, traumatic laryngotracheal stenosis - no laryngotracheal axis patency



Fig. 3.Normal laryngo-tracheal axis.

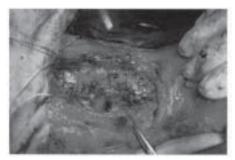


Fig. 2. Fixing the costal cartilage graft with 56 suture stiches to the tracheal wall

If the polymer contains both isomers, it is called steriopolymer - poly D, L lactic acid (PDLLA). The methyl radical contained makes the polylactic acid to be hydrophobic and resistant to hydrolysis.

The fixing device will be achieved by melting and casting in a mold the material we want to fabricate. To provide high rigidity for the fixing device, ribbing can be added by molding the same material along the fixture. This will confer similar mechanical properties of the metal. Absorbable screws will be poured using a device that compresses material so that screws with increased rigidity can be obtained.

The biodegradation of the fixing device is done in two phases:

The first phase is carried out by the invasion of water molecules entering the polymer lysing links. The second phase is the phagocytosis of the polymer fragments made by the macrophages. Polyglycolic acid degrades rapidly because it is hydrophilic. Polylactic acid degrades slowly because it is hydrophobic.

The hydrolysis converts polyglycolic acid into glycolic acid and polylactic acid into lactic acid. These products are metabolized in the citric acid cycle to carbon dioxide and water excreted in the urine and breath. Cellular enzymes favor the degradation of polylactic and polyglycolic acids.

Polyglycolic acid is quickly lysed, in about six weeks loses it's mechanical properties and is completely resorbed 3-12 months after mounting.

Polylactic acid undergoes slow degradation, loses its mechanical properties at 48 weeks and is absorbed slowly in 5-7 years postoperatively. This polymer does not cause inflammation in the perimeter, unlike the polyglycolic acid.

If the implantation device is not strengthened with ribbed polymer, the implant may break at the force of 200 N. The area of the implant attachment is not subject to such forces, neither during swallowing, nor even when the movements are performed by the rotation of the head, so that the strengthening ribbing of device is not required.

The method of attachment of the costal cartilage above the tracheal wall is the following:

- costal cartilage is harvested from one or more distal ribs to have a sufficient amount of material [2].
- the costal cartilage is cleaved and a cartilage graft with thickness of about 3 mm is shaped.
- a cervical incision is performed in the anterior cervical region, where the laryngotracheal segment is found.
  - the trachea shall be cut along the vertical axis.
- the device is inserted into a water bath heated at 700°C for 10 s; It becomes malleable and it can be modeled on the curvature and shape of the patient's trachea.

The time when the fixture is malleable is about 10-15 s, then it becomes rigid again.

- the costal cartilage graft is fixed with absorbable selftapping microscrews in the middle of the mounting bores
- the fixation device with cartilage grafts previously fixed, is placed at the tracheal wall defect.
- the combination device / cartilage graft is secured with self-tapping microscrews of 1.5 mm to the lateral walls of the trachea. The number of fixing screws is 8.



Fig. 4. Multiple fracture lines in the trachea.

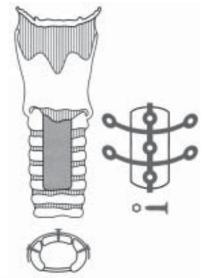


Fig. 5. Resorbable fixation device for the cartilage graft fixated covering the tracheal defect

For sealing purposes we recommend using tissue adhesives at the costal cartilage/tracheal cartilage interface. The ensemble is wrapped in fascia and muscular structures. The muscular plan of the anterior cervical region is rebuilt, the muscular-cutaneous flap is placed in the normal position and sutured.

The fixing device does not allow the cartilage graft to dive, so it is not necessary to use an intra-tracheal mentor for epithelialization. Tracheostomy is maintained for a period of six weeks, during which repeated endoscopic examinations are performed to ensure the patency of the reconstruction area [3,4].

An alternative to the cartilage graft may be harvesting a vascularized flap of sternocleidomastoid muscle by keeping the superior vascular pedicle (from the occipital artery). Harvesting the caudal portion of the composite flap is done by keeping a 3/2 cm clavicle cortical bone and skin on the distal end of the muscle at that level. The muscular-skeletalskin composite is rotated so that the skin is sutured inside the tracheal mucosa. The clavicle cortical fragment is fixed to the tracheal defect with the imagined fixing device described above with absorbable screws. Sternocleidomastoid muscle vasculature ensures the viability of the flap [5].

Installation of a tracheal mentor for epithelialization is not required.

## **Results and discussions**

The original resorbable device for fixing costal cartilage graft gives the surgeon the possibility of a good quality graft fixing for carrying out the laryngotracheal plasty.

The use of a glycolic polyacid fixing device will lead to a

The use of a glycolic polyacid fixing device will lead to a rapid resorption of the material in approximately 3-12 weeks. We believe that this type of device made of polyglycolic acid is suitable for pediatric patients, where rapid absorption of the fixture allows enlargement of the trachea. The fixing device made of lactic polyacid seems appropriate for use in adults. Slow absorption recommends it's use in this direction. Advanced age patients, at which tissue repair processes are slow, need an extensive cartilage costal graft fixation and integration for a long time.

## **Conclusions**

The original, resorbable device for fixation of cartilage grafts during laryngothacheal costal cartilage plasty has the following qualities:

- it offers a quality graft fixation

- is reabsorbed, a particularly important feature for the pediatric population, that is growing

- quick workmanship that results in a significant

decrease of surgery and anesthesia time.

- heating the device for 10-12 s in a water bath of 700°C leads to a malleable material maintained approximately 10-15 s, which allows the surgeon to model the device on the shape and curvature of the patient's trachea.

The device replaces the minimum of 40 sutures necessary to secure costal cartilage and leads to a decrease in operative time of about 2 h.

The device does not allow "sinking" into the trachea and the cartilage graft no longer needs a supportive mentor maintained. This way decreases the risk of infection.

Degradation products are represented by  ${\rm CO_2}$  and water,

and are eliminated through urine and breath.

Because of the low forces the cartilage graft is subjected to, the casting method is one in which the device does not require reinforcement ribbing with the same material.

The use of self-tapping absorbable 1.5 mm screws,

The use of self-tapping absorbable 1.5 mm screws, without requiring the drilling of the tracheal wall and of the cartilage graft in advance, translates into a lower operating time and lower costs.

The use of a vascularized composite flap made of sternocleidomastoid muscle, clavicle cortical bone and skin coverage will lead to faster healing, low hospitalization and early reintegration of the patient.

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