## Volume and position change of Gore-Tex® after bilateral medialization thyroplasty assessed by MRI

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To measure the change in the volume and the position of Gore-Tex® after bilateral medialization thyroplasty in patients with vocal fold atrophy with or without sulcus by post-operative MRI.The results of this study will be used to 1) optimize the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

## Summary

## ID

NL-OMON54926

**Source** ToetsingOnline

#### **Brief title**

Volume and position change of Gore-Tex® after medialization thyroplasty

## Condition

- Other condition
- Head and neck therapeutic procedures

**Synonym** glottic insufficiency, voice disorder

**Health condition** 

stemaandoening

#### **Research involving**

Human

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## **Sponsors and support**

Primary sponsor: Leids Universitair Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

### Intervention

**Keyword:** bilateral medialization thyroplasty, Gore-Tex® implant, laryngeal framework surgery (LFS), non-paralytic glottic insufficiency

## **Outcome measures**

#### **Primary outcome**

Change in implanted Gore-Tex® in volume and position.

#### Secondary outcome

voice parameters: VHI-30 questionnair, maximum phonation time (MPT), dynamic

range, fundamental frequency (F0), melodic range.

## **Study description**

#### **Background summary**

Non-paralytic glottic insufficiency is a common form of dysphonia affecting both voice quality as vocal function and causing substantial patient\*s burden. There are several underlying causes including hypomobility, paresis and atrophy (with or without scarring) of the vocal folds. The surgical treatment to improve glottic closure is medialization of the vocal folds. This may be achieved by bilateral vocal fold injection with a filler, such as autologous fat or calcium hydroxyapatite, or by bilateral medialization thyroplasty.

Several factors contribute to the optimal voice result after bilateral medialization thyroplasty; an important factor is the underlying cause, but also surgical factors play a major role, such as the optimal window position and the amount of (over)correction of the implant.

Gore-Tex® is one of the most used implant materials for bilateral medialization thyroplasty.As it is a soft and malleable material, it is held to change in volume and position after implantation. This change in volume and position may lead to suboptimal post-operative voice outcome.

### **Study objective**

To measure the change in the volume and the position of Gore-Tex® after bilateral medialization thyroplasty in patients with vocal fold atrophy with or without sulcus by post-operative MRI.

The results of this study will be used to 1) optimize the peroperative (over)correction, in order to 2) optimize the post-operative voice results.

#### Study design

Observational study

Patients will undergo two MRI-scans (no contrast); first MRI one day after surgery and second MRI three months after surgery.

#### Study burden and risks

Burden associated with participation consists of undergoing a MRI without contrast. The first MRI scan will take place on day 1 postoperatively during admission. The second scan will be combined with regular outpatient control 3 months after surgery. Time investment per patient is estimated between 90 and 120 minutes. Serious adverse event that can occur with MRI-scanning is the presence of magnetic sensitive materials. Patients will be screened according to local guidelines in our hospital. Patients who are not able to undergo MRI scanning will not be included in this study.

## Contacts

**Public** Leids Universitair Medisch Centrum

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## **Trial sites**

## **Listed location countries**

Netherlands

## **Eligibility criteria**

**Age** Adults (18-64 years)

## **Inclusion criteria**

- Adult >18 years old
- Glottic insufficiency caused by vocal fold atrophy with or without sulcus
- Consented for bilateral medialization thyroplasty with  $\ensuremath{\mathsf{Gore}}\xspace{\mathsf{Tex}}\xspace{\mathbbmathbb{R}}$  under local anaesthesia
- No contraindication for MRI
- To be able and willing of giving informed consent

## **Exclusion criteria**

- Patients undergoing unilateral medialization thyroplasty
- Patients with medical history of phonosurgery
- Patients with revision thyroplasty
- Patients with medical history of head and neck malignancy
- Patients with other causes of glottic insufficiency (paralysis, hypomobility, paresis, vocal fold scar)
- Patients not fit for bilateral medialization thyroplasty under local anesthesia
- Patients not able to undergo MRI scanning, e.g. metal implants, claustrophobia

## Study design

## Design

# Study type: Observational non invasiveMasking:Open (masking not used)Control:Uncontrolled

Primary purpose:

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Treatment

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	24-09-2021
Enrollment:	10
Туре:	Actual

## **Ethics review**

Approved WMO	
Date:	05-07-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

## **Study registrations**

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register CCMO **ID** NL72655.058.20