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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25743

Source
NTR

Brief title
MRIGT

Health condition

voice disorder, glottic insufficiency

Sponsors and support

Primary sponsor: Prof. Dr. P.P.G. van Benthem Head of department of ENT Head- and Neck surgery
Source(s) of monetary or material Support: ENT departement

Intervention

Outcome measures

Primary outcome

Assessment of change in Gore-Tex® volume and position after bilateral medialization thyroplasty .The volume and position of the implants will be visually rated on fused MRIs at post-operative day 1 and 3 months. Change in volume of Gore-Tex® implant will be quantified in ml and in %. Overlap of the segmented volumes in MRI images will be quantified

using the Jaccard index (representing the percentage overlap between two volumes).

Secondary outcome

subjective and objective voice parameters: VHI-30 [8], maximum phonation time (MPT), dynamic range, fundamental frequency (F0), melodic range.

Study description

Background summary

Rationale:
Dysphonia caused by non-paralytic glottic insufficiency can be treated by surgical medialization of the vocal folds. Gore-Tex® is one of the most widely used implant materials for correcting the glottic gap in uni- or 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. In clinical practice surgeons tend therefore to introduce a surplus of material to (over)correct for this post-operative change.

Objective:
Main objective: to assess the change in Gore-Tex® volume and position after bilateral medialization thyroplasty by post-operative imaging (MRI).

Study design:
Observational study. Patients will undergo two MRI scans (without intravenous (iv) contrast administration), first MRI one day postoperative and second MRI three months postoperative.

Study population:
Patients undergoing bilateral medialization thyroplasty with Gore-Tex® (age 18-99) without contraindications for MRI. N=10

Intervention (if applicable):
No intervention.

Main study parameters/endpoints:
1. Change in implanted Gore-Tex® volume in ml and in %.
2. Shift in position of the implant in relation to thyroid cartilage.

Study objective

Dysphonia caused by non-paralytic glottic insufficiency can be treated by surgical medialization of the vocal folds. Gore-Tex® is one of the most widely used implant materials for correcting the glottic gap in uni- or 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 design

Observational study. Patients will undergo two MRI scans (without intravenous (iv) contrast administration), first MRI one day postoperative and second MRI three months postoperative.

Intervention

assess the change in Gore-Tex® volume and position after bilateral medialization thyroplasty by post-operative imaging (MRI).

Contacts

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Eligibility criteria

Inclusion criteria

- Adult >18 years old
- Glottic insufficiency caused by atrophy with or without sulcus
- Consented for bilateral medialization thyroplasty with Gore-Tex® under local anaesthesia
- No contraindication for MRI (see addendum 1)
- 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
- patient with other causes of glottic insufficiency (paralysis, hypomobility, paresis, vocal fold scar)
- patients with a contra-indication to MRI (see addendum 1)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2021
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-09-2021
Application type:	First submission

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	ID
NTR-new	NL9731
Other	METC LLD : METC NL 72655.058.20

Study results