

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25743

Bron

NTR

Verkorte titel

MRIGT

Aandoening

voice disorder, glottic insufficiency

Ondersteuning

Primaire sponsor: Prof. Dr. P.P.G. van Benthem Head of department of ENT Head- and Neck surgery

Overige ondersteuning: ENT departement

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-06-2021
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	14-09-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9731
Ander register	METC LLD : METC NL 72655.058.20

Resultaten