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## **The Montgomery Thyroplasty Implant System: A 360° Assessment**

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## **CHAPTER 1**

### **General Introduction and Thesis Outline**

### **Unilateral Vocal Fold Paralysis and the Montgomery Thyroplasty Implant System**

## **The unilateral vocal fold paralysis (UVFP)**

### **UVFP patients and impact on their quality of life**

UVFP with the paralyzed vocal fold in an abduction position results in glottic leakage during phonation.

Patients presenting with a UVFP and glottic air leakage will complain about the following symptoms:

- Breathy Voice
- Disability to project their voice, or in severe cases, even no voicing at all
- Shortness of breath when speaking (phonatory dyspnea)
- Dysphagia, mostly with liquids, due to inability to securely close the glottis during swallowing
- Inefficient cough due to glottic incompetence
- Constipation, due to inability to exert a Valsalva maneuver

The majority of the studies in the literature focus on voice symptoms, but these are not the only ones to consider. There is also a need for patient centered studies, that focus on patients' complaints and needs.

Dysphonia represents a significant disability that is comparable to conditions such as angina pectoralis, sciatica and chronic sinusitis. UVFP patients present the highest level of pre-treatment disability among dysphonic patients [1]

Hogikyan et al. investigated Voice-related Quality of Life (V-RQOL) following medialization thyroplasty (MT) for UVFP [2]. UVFP patients showed very low overall V-RQOL scores (32, 59 /100) in comparison to normal controls (97.95/100). After treatment with MT, the V-RQOL scores of UVFP patients, although improved, could not match the control group reaching a 73, 62/100 overall V-RQOL score.

### **Basic physiology**

Voice produced by a human transmitter, is energy transferred through a gas - the air - that will hit the tympanic membrane of a human receptor. This energy is produced by the lungs mobilizing and expelling air. This pressurized air will encounter a resisting obstacle represented by the closed vocal folds within the larynx and results in a buildup of pressure beneath the glottic plane. The sub-glottic air pressure increases up to the moment it forces the obstacle. The myoelastic properties of the vocal folds then come into play. These properties will alternatively open and close the glottis according to the Bernoulli's law. This will chop the air flow into pressure waves. These elementary acoustic waves are later modified within the resonance cavities of the upper respiratory tract into complex harmonics [3].

Vocal folds consist of a multilayer structure: (1) a surface epithelium, (2) a soft tissue space -the Reinke's space- (3) a lamina propria, a complex structure composed of collagen and elastin fibers (4) a vocal ligament (5) and a muscle, composed mainly of the vocalis portion of the thyro-arytenoid muscle. The integrity of this multi-layer disposition is key to the myoelastic oscillation of the vocal fold and also an important condition for successful voice production.

The primary condition for the myoelastic theory to occur however consists of adduction of both vocal folds in the midline in the glottic area.

Vocal folds could be seen as two sails. Their free edge can be fully deployed to offer a greater resistance to air -when voicing- or can be fully reefed when no resistance to the air passage -when breathing- is sought. These two sails, horizontally deployed, have a common fixed point anteriorly and a different mobile anchoring point posteriorly. The position of the posterior anchoring points will determine their respective degree of deployment. The anterior fixed point of the vocal folds corresponds to the anterior commissure located approximately at mid-height within the thyroid cartilage. Both mobile posterior points correspond to the vocal processes of the arytenoid cartilages.

In conclusion, the respective positions -in the three dimensions- of the vocal folds depend entirely on the positioning of the arytenoid cartilages.

The arytenoid cartilages are of particular interest. They are constantly in equilibrium on the articulatory facet of the cricoid cartilage. This equilibrium is maintained by tone and contractions of two antagonist muscles.

The Posterior Arytenoid Muscle (PCA) contraction pulls the arytenoid postero-medially. As a result, the vocal process will move externally and open the glottis or, reduce the sail surface to refer to our previous analogy. It will also slightly uplift the vocal fold posteriorly.

LCA

Inversely, the Lateral Crico-arytenoid (LCA) pulls the arytenoid antero-laterally. As a result, the vocal process will move inwards and close the glottis or unfold the sail. It will also slightly lower the vocal fold posteriorly. The LCA acts in conjunction with the inter-arytenoid muscle and the Thyro-arytenoid muscle (TA) that closes the posterior part of the glottis during high pitch voicing and airway protection.

The neurological control of these two antagonistic muscles (LCA and PCA) is remarkable as well as unique in the human body. Both muscles are innervated by the same branch of the Vagus nerve (X): the recurrent laryngeal nerve (RLN). Approximately 30% of the RLN neurons innervate the PCA, while 70% of the RLN neurons innervate the LCA-TA complex. Accordingly, there is clearly a predominance of adductive innervation within the RLN [4].

During voicing, the adducting LCA-TA complex is activated through the RLN to close the glottis. Inversely, during breathing the abducting PCA is activated through the same RLN to allow air passage.

Coordination between breathing and voicing, as well as symmetrical coordination of vocal folds motion depend on motor cortex, pontine reticular formation and brainstem nuclei control (nucleus solitarius and nucleus ambiguus) [5].

### Definition of vocal fold paralysis

According to Rosen et al., a vocal fold paralysis is defined as “*an immobile vocal fold due to a neurogenic etiology, the cause can be either a central nervous system pathology (i.e. lateral medullary infarct) or peripheral nervous system abnormality (X or RLN)*” [6].

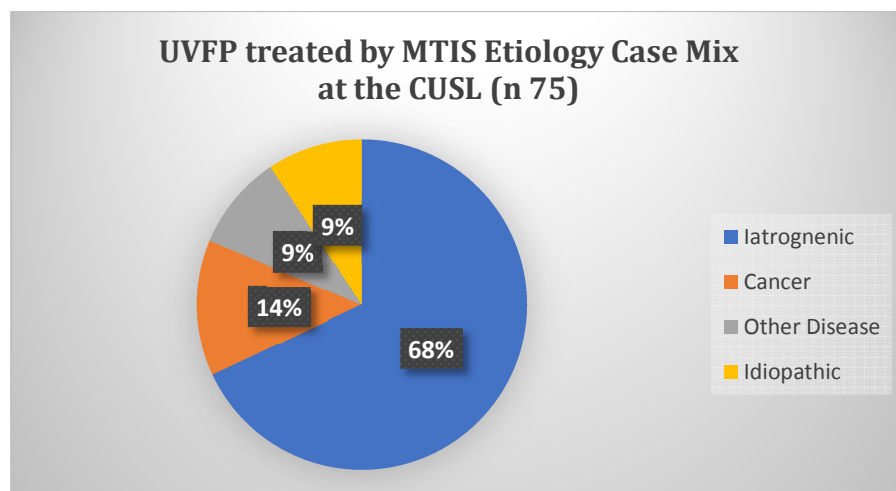
In common clinical practice, the neurogenic origin of UVFP is supported by the clinical history. The history will reveal the presence of pathology or a medical intervention affecting the neural control of the affected side of the larynx [7]. Laryngeal electromyography (LEMG) may be useful to confirm the neurogenic origin of UVFP, specifically when medical history does not provide evident causes of neurogenic damage or when a Crico-arytenoid joint pathology is suspected.

The etiology case mix of UVFP will largely depend on local disease incidence, treatment pathways and referring patterns.

Up to 75% of UVFP can be of iatrogenic origin [8].

Figure 1 represents the case mix of etiologies of patients that benefited of a MT at the cliniques universitaires Saint-Luc (CUSL) in Brussels between 2004 and 2018 (n:75).

It is important to note that 82% of the iatrogenic labelled etiologies were related to cancer surgery (esophagus, pulmonary and thyroid gland cancer).



**Figure 1: MTIS etiology case mix at the CUSL between 2004 and 2018.**

## **Type of nerve lesions and natural history of re-innervation**

Only a relatively a small percentage of UVFPs has a central nervous origin. In most cases the lesion is to be found in the peripheral nerve. Three types of peripheral nerve damage of increasing gravity can be distinguished: (1) neurapraxia, (2) axonotmesis and (3) neurotmesis.

- neurapraxia consists of temporary damage of the myelin sheath. The axons themselves are intact and thus nerve conduction will usually recover within the six weeks. LEMG shows reduction of action potential amplitude.

- axonotmesis consists of more severe damage to the axons and the myelin sheath but the perineural infrastructure consisting of the endoneurium, perineurium and epineurium is preserved. LEMG performed two-three weeks after injury, shows signs of de-innervation such as fibrillation potentials and sharp action potential waves. Recovery appears usually after 6 to 9 months.

- neurotmesis consists of severe damage of axons and myelin sheath associated with a severe injury of the nerve infrastructure. It has a poor prognosis, usually with incomplete or no nerve function recovery at all.

In all these types of nerve injuries there will be a spontaneous tendency toward re-innervation. Once the nerve disruption is overcome, the nerve will regrow at a pace of 2 – 4 mm/day [9].

Whether this reinnervation will be complete and result in appropriate nerve function and movement, remains uncertain. The more severe the nerve lesion is, the smaller the chance of recovery will be.

In clinical practice the severity of the nerve damage is seldom known. Arviso et al. described the natural history of a cohort of 42 patients presenting with a UVFP (2/3 of iatrogenic origin, 1/3 of idiopathic origin). All patients were treated with early (< 3 months) TA injection laryngoplasty (IL) with a temporary material. Twenty-four percent (24%) recovered a full vocal fold motion, 10% recovered a partial vocal fold motion, 40% recovered no vocal fold motion but had a satisfactory compensated voice and finally 29% had no recovery of motion or voice [10].

From Arviso's paper, we can conclude that the natural history of the re-innervation is highly unpredictable. Nevertheless, it is fair to assume that, after UVFP, approximately one third of patients will recover vocal fold motion, one third of patients will recover a satisfactory "compensated voice" with no motion and one third of the patients will not recover motion nor voice.

Young et al. confirmed this concept of "compensated voice" accounting for 21% of their patients, recovering a normal VHI-10, despite lack of recovery of motion. [11]

Mau et al. recently published a study investigating time as a prognostic factor for UVFP recovery [12]. They published a large case series with a de novo mathematical model. The novelty was to take severity of nerve damage into account. A mathematical recovery model based on nerve damage severity was compared to the natural history of 44 UVFP patients that recovered voice. They distinguished neurapraxia lesions, in which the nerve is stretched but the sheath remains intact, from other more severe nerve damage. They postulated that neurapraxia patients' recovery would follow a deterministic bell shape curve with a small dispersion, centered on a 2-3 weeks post-injury latency. In the other group of patients with a more severe nerve lesion, the new nerve sprouts have to cross the site of injury. This occurrence of this "cross-over" stage will follow a probabilistic decreasing recovery/time curve. In a second stage, a neural grow to the target muscle will follow a deterministic bell-shaped recovery/time curve with a larger dispersion centered on a 3 months post-injury latency. The fusion of all these three curves matched completely with the voice recovery latencies – with or without vocal fold motion- of this group of 44 UVFP patients.

**Figure 2** shows the camel back-shape (in red) of this time to recovery curve.

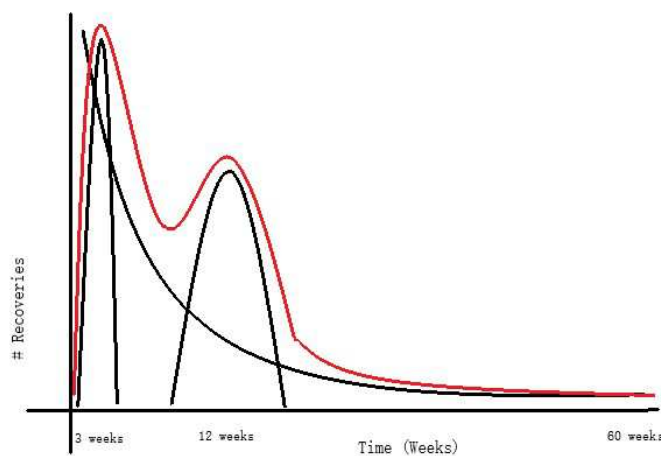


Figure 2: Voice recovery versus time (weeks) after nerve lesion. According to T. Mau et al. Laryngoscope 2018

They concluded that their model predicts that 86% of patients that will eventually recover a voice after UVFP will recover within 6 months, and 96% within 9 months.

No recovery of vocal fold motion could be observed after 7.5 months.

### **UVFP Treatment options**

The basic principle of UVFP treatment is to medialize the paralyzed vocal fold in order to improve glottic closure during phonation.

Many treatments, based on different approaches, have been proposed in the literature to treat UVFP:

- **Approach #1:** injecting a substance into the TA muscle and thus augmenting the paralyzed side. This is called **Injection Laryngoplasty (IL)**. There are numerous substances available on the market, both permanent and transient.
- **Approach #2:** surgical modification of the larynx cartilaginous framework.
  - **Medialization Thyroplasty (MT) or Isshiki's Type 1 Thyroplasty** consisting of creating a window within the thyroid cartilage and pushing the vocal fold inward to close the glottic gap. An implant allows the permanency of this framework modification. Many materials have been proposed by many authors in the past. They are listed below.

Medialization Thyroplasty can be complemented by arytenoid procedures such as:

- Arytenoid adduction (AA) consisting of suturing the arytenoid to the anterior portion of the thyroid ala in order to rotate the posterior anchor of the VF and thus close the (posterior) glottic gap. AA can be combined with IL or reinnervation as well.
- Arytenoidopexy (AP) consisting of suturing the crico-arytenoid joint in order to modify the position of the posterior anchor of the VF and thus close the glottis gap. AP can be combined with IL or reinnervation as well.

The need for such complimentary approaches is still debated and appears to depend on the medialization technique or implant that is used [13-15].

- **Approach #3:** restoring tonus by non-selective or selective reinnervation of TA. Several techniques have been proposed:
  - End to end suturing of proximal and distal stumps of the injured nerve (X or RLN) [16]
  - Anastomosis between the Ansa Hypoglossi and the distal stump of the injured nerve (X or RLN). This anastomosis can be non-selective (on the common trunk of the distal stump of the RLN) or selective, with separate grafting of the PCA (abductory) branch and the TA branch [17,18].
  - Muscle (Omo-hyoid muscle) and nerve (Ansa Hypoglossi) “en bloc” grafting into the PCA or the TA [19].

Arytenoid procedures can also be combined with re-innervation procedures [20]

- **Approach #4:** guiding inevitable re-innervation so that abductory impulse will eventually activate the abductory muscle (PCA), and adductory impulses will activate the adductory muscles (LCA-TA). Experiments have been performed injecting neutropic agents and stem cells supposedly secreting neutropic agents in the target muscle (PCA or TA) [21].
- **Approach #5:** electric stimulation by pacers has been attempted within the frame of research protocols [22].
- **Approach #6:** voice therapy has been proposed as treatment for UVFP. Results, however, remain modest and do not match surgical approaches results in terms of Maximum Phonation Time (MPT) and modified Voice Handicap Index (VHI-10) improvement [23]. Drawing conclusions about voice therapy efficiency for UVFP remains difficult because of lack of outcome indicators and interventions standards [24].

Approaches number 1, 2 and 3 have been the subject of numerous publications showing their benefits and can be considered as gold standards of treatment. Siu et al. published, in 2015, a systematic review that compared outcomes in surgical interventions of UVFP [25]. According to this review there is no evidence suggesting superiority of any of these approaches in terms of voice outcomes. They also conclude that reinnervation may be best reserved for infants and children.

Table 1 summarizes the strengths and weaknesses of each approach according to Siu et al.

<b>Approach</b>	<b>Strengths</b>	<b>Weakness</b>
<b>IL</b>	can be performed office-based, does not impeach later MT (temporary measure)	may require multiple injections
<b>MT</b>	instantaneous result, simple technique	long-term result may fade away due to progressive vocal fold atrophy, requires operating room time
<b>AA or AP</b>	may be useful correcting large posterior horizontal or vertical glottic gaps	technically challenging, more risk of complications compared with MT
<b>Reinnervation</b>	prevent TA atrophy long-term results are good	technically challenging long latency before voice result, requires operating room time

Table 1: Strengths and weakness of UVFP treatments. (IL: injection laryngoplasty, MT: medicalization thyroplasty, AA: arytenoid adduction, AP: aytenoidopexy, TA: thyro-arytenoid muscle)

Approaches 4 and 5 are not considered as gold standards. Larynx pacing and use of neurotrophic agents remains largely experimental to date.

Approach 6 is mostly considered as a support effort to the IL, MT and reinnervations procedure. Efficiency of voice therapy as sole intervention remains uncertain and is subject to further investigations.

## Medialization thyroplasty

### Techniques

As mentioned earlier, MT, also called Type 1 Thyroplasty referring to Isshiki's classification [30, 31], represents a standard treatment for paralyzed vocal fold in abduction [32].

The basic principle of MT consists of pushing the paralyzed vocal fold inwards through a fenestration created of the lateral ala of the thyroid cartilage. Many materials have been proposed over the years since the first interposition of cartilage performed by Dr Payr in 1915 [33].

Table 2 summarizes the different materials used around the world. Some materials need larger or smaller cartilage fenestration. Some are pre-molded and provided by the industry, others are self-carved per-operatively by the surgeon. Finally, some are self-anchored others need stitches in order to be stabilized.

Type of implant & technique	Designer (if applicable)	Reference article
<b>Medtronic Silastic Implant™</b>	J.L. Netterville	<b>Netterville</b> JLStone RE, Luken ES, Civantos FJ, Ossoff RH (1993) Silastic medialization and arytenoid adduction: The Vanderbilt experience. A review of 116 phonosurgical procedures. Ann Otol Rhinol Laryngol 102:413-424
<b>Hard Silicone MTIS™</b>	W. Montgomery	<b>Montgomery</b> WW, Blaugrund SM, Varvares MA (1993) Thyroplasty: a new approach. Ann Otol Rhinol Laryngol 102:571-579
<b>Hydroxyapatite VoCom™ implant</b>	C. W. Cummings	<b>Cummings</b> CW, Purcell LL, Flint PW (1993) Hydroxylapatite laryngeal implants for medialization. Preliminary report. Ann Otol Rhinol Laryngol 102:843-851
<b>Titanium implant™</b>	G. Friedrich	<b>Friedrich</b> G (1999) Titanium vocal fold medialization implant: introducing a novel implant system for external vocal fold medialization. Ann Otol Rhinol Laryngol 108: 79-86
<b>Gore-Tex™ (Polytetrafluoroethylene)</b>	None/ surgeon-specific technique	<b>McCullogh</b> TM, Hoffman HT. (1998) Medialization laryngoplasty with expanded polytetrafluoroethylene. Ann Otol Rhinol Laryngol 107:427-432
<b>Self-carved Silastic block</b>	None/surgeon-specific technique	<b>Benninger</b> MS, Manzoor N, Ruda M.(2015) Short and Long-term Outcomes after silastic medialization laryngoplasty: are arytenoid procedures needed? J Voice, Vol. 29N 2, 236-40 <b>Shingal T, Anderson J, Chung J, Hong A, Baratha A</b> Effect of medialization on glottic airway anatomy: cadaver model (2015) J Voice Vol 30, N6, 757.e1-757.e6

Reports reveal good results for all the materials described in table 1, showing low re-intervention rates.

Unfortunately, the lack of standardized voice outcome indicators impedes proper comparison between materials and techniques so that, to our best of knowledge, none of these can be declared to be superior to others [25].

In 2018, the choice of the technique and material that is used for a MT is left to the discrepancy of the surgeons. Their choice is usually based on their own experience and training.

## The Montgomery Thyroplasty Implant System (MTIS)

### The pioneer, entrepreneur and generous spirit of William W. Montgomery MD



William W. Montgomery MD

Proctor VT, 1923 - Brookline, MA 2003

William W. Montgomery was a Harvard surgeon and an innovator. This is how he was he described in his New York Times Obituary the 15<sup>th</sup> of November 2003[26].

He was also fond of sharing his knowledge and inventions with anyone who asked for it. As Joseph B. Nadol Jr, one of his former residents, stated in The Lancet in 2004, he had a *“rather uncanny ability to make things seem simple...his hypotheses were always how to make surgery better, safer, more reliable...and easier”* [27].

These principles were followed when developing the MTIS [28,29].

It was all about developing a system that was reliable, safe as well as easy to use. Its easiness of use was aimed at being able to share the technique as widely as Dr. Montgomery possibly could. From a patient’s perspective, the larger the number of surgeons performing MTIS is, the better the accessibility to the technique will be.

W. Montgomery was also a woodcrafter and his first prototypes were simply crafted in Vermont’s maple wood (FIGURE 3). As a former war-surgeon during the nineteen-fifty Korean conflict, his motto could certainly be stated as “keep it simple and efficient”.

The reality of this philosophy will be tested by this thesis.



FIGURE 3: Original Montgomery's Implant carved by William W. Montgomery in maple wood. (Courtesy of S. Montgomery)

**The Medialization Thyroplasty technique known as the Montgomery Thyroplasty Implant System™ (MTIS).**

This technique and type of implant is widely used and available all over the world. Its frequency of use is increasing with its reported short learning curve and excellent post-operative voice outcomes. The MTIS provides not only a pre-molded hard silicone implant, but also a step-by-step operative procedure.

The MTIS procedure:

The procedure is performed under light sedation and local anesthesia. Particular attention is offered to overweight and/or apneic patients for which sedation must be titrated in order to avoid any tongue ptosis causing apnea and desaturation. An anesthesiologist is present within the OR during the entire procedure. Oxygen and cardio-pulmonary parameters are monitored continuously.

The patient lies on his back with a neutral positioning of the head. Oxygen is administered through a nasal probe fixed with tape.

In our experience, we do not systematically use visual feed-back of the larynx with simultaneous trans-nasal video-endoscopy. The patient's voice is the sole feed-back indicator. Video-endoscopic feed-back is reserved for difficult or unclear cases.

All surgical steps correspond to the step-by-step surgical procedure described by Dr. Montgomery's initial paper and provided with the implants, sizer set and surgical instrument set by Boston Medical Inc. [34]. These steps are filed at the Federal Food & Drugs Administration (FDA) and have not been modified since their initial filing .

## **Rationale and outline of the thesis**

At the time of starting this work, a review of the literature focusing on MTIS for UVFP retrieved fifteen studies [36-50]. Only 2 teams have published large series evaluating the results of MTIS for treatment of UVFP, one of which was performed by Montgomery himself. Both teams concluded that MTIS represented an efficient, safe, reliable and reproducible technique that superseded the results with Gore-Tex. Laccourreye et al. also evaluated the results after 2 years of follow-up and found that the good results were maintained over this period.

One of the unwritten but outspoken criticisms, on MTIS is the following: “How could the individual shape of individual larynges be addressed sufficiently with only six sizes of implants per gender made available?” Some laryngologists also complain about the incidence of re-do surgeries they have been confronted with after MTIS surgeries. Nevertheless, a growing number of MTIS implants are used in the US each year [35].

There is a discrepancy, between the frequency of use and the limited number of publications on MTIS. This constituted the trigger of this thesis.

Within the global context of the recent “Implant Files Scandal”, the questions we should ask ourselves are: is MTIS a good medialization system? What are its advantages and disadvantages? Is it not high time for a 360° assessment?

## **Research Questions**

### ***Subsidiary Question: How do you assess MTIS voice outcome?***

Anyone who would like to compare different treatment modalities of UVFP is confronted by the lack of standardized voice outcome measures and differences in reporting of outcome data [25]. This is also true for the MTIS related literature. To evaluate their results, for example, Montgomery and Laccourreye used MPT [42,48], Hartle et al. used acoustic parameters [40], Borel et al. used the VHI score [43], Cesari et al. a new electro-acoustic data set [44] and Almohizea et al. investigated per-operative Peak Direct Subglottic Pressure [36].

Voice outcome indicators had to be chosen to evaluate MTIS performance. Accordingly, a literature review was launched (STUDY 1, chapter 2). The aim of the review was to assess the most frequent Voice Outcome Indicators (VOI) that were used in the recent English literature. Subsequently a second study subjected these frequently used VOIs to the surgeon’s opinion (STUDY 2, chapter 3).

***Question 1: Is the MTIS a simple technique? What is its “learning-curve”?***

In 2015, before the launching of the thesis, G. Desuter reported the results of a retrospective study that focused on MTIS learning curve. MTIS provides good outcomes even when performed by a novice surgeon. Over time with growing experience of the surgeon, operating times shorten and voice outcomes are maintained. [51].

***Question 2: does the MTIS offer permanent results?***

As Siu’s review suggested that voice improvement after MT could fade away with time due to the vocal fold atrophy caused by ageing and that the 2 years follow-up of Laccourrey’s paper could not answer this question [25, 42], we launched a European multi-centric cross-sectional study to evaluate very-long term (> 2 years) VHI-30 scores of MTIS patients (STUDY 3, Chapter 4).

***Question 3: Does the MTIS make additional arytenoid cartilage surgery unnecessary? In other words, does the MTIS also achieve posterior glottis closure?***

The 1993 initial paper of Montgomery stated that “the design of the implant will close the posterior commissure”. This closure should be related to optimal voice improvement. Neither data nor technique was available at the time this thesis was started, to be able to test this statement. Considering the progress of medical imagery techniques and pre-operative planning software, we expected an imagery study assessing the relationship between MTIS implants and the arytenoid cartilage. As a matter of fact, an imagery study has now recently been published and shows a positive influence of the arytenoid position and closure using the MTIS [52]. We opted for a non-irradiating approach to assess the posterior glottis. With a team of engineers from the Free University of Brussels, we launched a post-mortem study to evaluate the possibilities of assessing height and position of the vocal process, using a new endoscopic laser-based measuring device (STUDY 4, chapter 6). This work will eventually help evaluate the effect of the Montgomery implant on the posterior glottis.

***Question 4: Considering the large variation in laryngeal anatomy, do 6 sizes of implants per gender allow satisfactory treatment of all the UVFP patients?***

To answer this question, we launched a study comparing Thyroid cartilage shapes per gender with voice outcomes (STUDY 5, chapter 6)

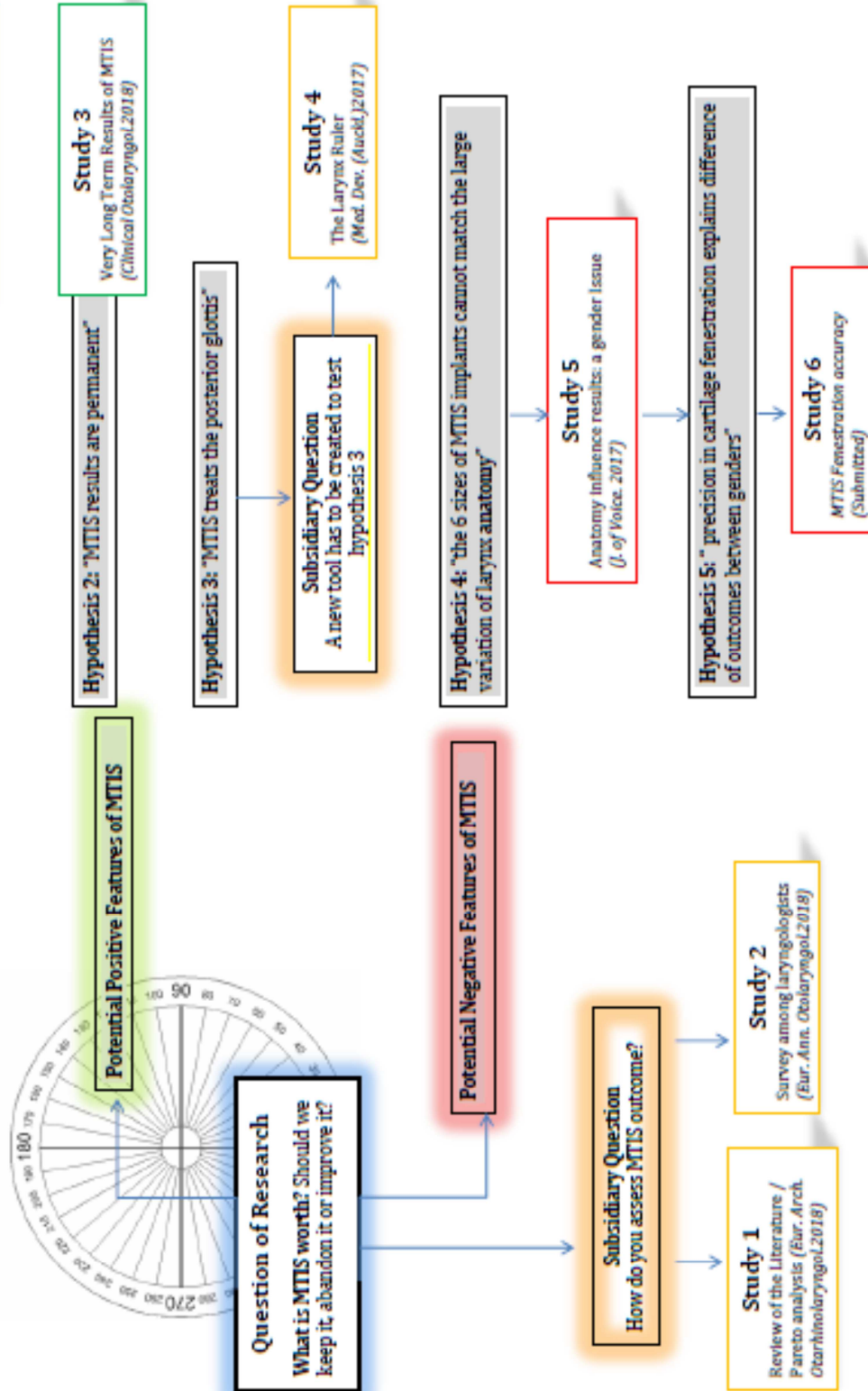
***Question 5: What is the accuracy of cartilage fenestration by following the “instruction for use” provided by the MTIS?***

As many opinion leading laryngologists complained of having to deal with a significant number of unsatisfied MTIS patients due to wrongly placed implants, we launched a study that looked at the accuracy of MTIS cartilage fenestration and the influence of the position of fenestration on voice outcomes (STUDY 6, chapter 7).

Figure 4 represents a flow chart representing the various questions of research and their rationale.

"The Montgomery Thyroplasty Implant System: A 360° Assessment"

FLOWCHART



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**The author of this thesis has been proctoring for Bess Inc., Berlin, Germany, in 2015-17.**

This allowed the author to enlarge his experience with the MTIS in many different operating theaters and settings around the world.

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