

# Shape of Thyroid Cartilage Influences Outcome of Montgomery Medialization Thyroplasty: A Gender Issue

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**Summary: Objective.** This study aimed to determine whether the shape of the thyroid cartilage and gender influence voice outcomes after a Montgomery thyroplasty implant system (MTIS).

**Methods.** A retrospective cohort study was performed on 20 consecutive patients who underwent MTIS. Voice outcome variables were the relative decrease in Voice Handicap Index (%) and the absolute increase in maximum phonation time (MPT) (in seconds). Material variables were the angle between the thyroid cartilage laminae ( $\alpha$ -angle), the size of the prosthesis, and a combination of both (the  $\alpha$ -ratio). Continuous variables were analyzed using medians and were compared between groups using the Mann-Whitney U test. Factors associated with the outcome variables were assessed by multivariable linear regression. A Pearson coefficient was calculated between material variables.

**Results.** The absolute increase in MPT between the pre- and postoperative period was significantly different between men and women, with a median absolute increase of 11.0 seconds for men and of 1.3 seconds for women ( $P < 0.001$ ). A strong inverse correlation between the  $\alpha$ -ratio and the absolute increase in MPT is observed in all patients, with a Pearson correlation coefficient  $R = -0.769$  ( $P < 0.001$ ). No factors were significantly associated with the relative Voice Handicap Index decrease in univariable or multivariable analyses. A better Pearson coefficient between the  $\alpha$ -angle and the prosthesis size was found for females (0.8 vs 0.71).

**Conclusion.** The MTIS is a good thyroplasty modality for male patients, but inadequate design of MTIS female implants leads to poor MPT outcomes. This represents a gender issue that needs to be further studied and eventually tackled.

**Key Words:** Thyroplasty–Montgomery implant–Voice outcome–Larynx anatomy–Gender.

## INTRODUCTION

Unilateral vocal fold paralysis (UVFP) causes insufficient glottis closure resulting in hoarseness as well as swallowing problems. If spontaneous recovery or compensation does not occur, treatment may be sought.

Medialization thyroplasty represents a recognized efficient treatment. It is considered as a standard treatment when long-lasting improvement is required.<sup>1,2</sup> Different types of techniques and materials have been proposed over the years. Among these, the technique and material named Montgomery thyroplasty implant system (MTIS) has gained interest for its facility of use and its short learning curve.<sup>3,4</sup>

The MTIS was designed to be a simplified implant technique. It provides a step-by-step surgical approach along with premolded soft silicone implants in six sizes; the range of sizes differs for male and female patients.<sup>5</sup> Voice results reported in the literature using the MTIS are comparable to those achieved with other techniques, so it appears that MTIS simplification is justified.<sup>6,7</sup>

However, practitioners who have expressed reservations on the use of MTIS argue that variability in shape of individual larynges will not be addressed sufficiently with only six sizes of implants per gender made available.

Thus, the primary aim of our research was to assess MTIS results retrospectively and investigate whether (1) the shape of the larynx represented by the angle between the two laminae of the thyroid cartilage (the  $\alpha$ -angle), (2) the size of the Montgomery prosthesis, or (3) a combination of both (the  $\alpha$ -ratio) correlate with subjective and objective voice outcomes.

With shape of the larynx being a gender-related feature, the secondary aim of our research was to analyze MTIS voice outcome for gender differences.

## MATERIALS AND METHODS

### Study design, patient selection, and intervention

The study protocol was approved by the Ethics Committee of Saint-Luc university hospital (number 2014/20MAI/256).

A retrospective study was performed on a cohort of 20 consecutive patients presenting a UVFP as defined by Rosen et al<sup>8</sup> between May 2011 and November 2014. Each patient presented a UVFP with a large glottis gap at videostroboscopic examination. No patient presented other features potentially affecting the quality of their voice except smoking habit before surgery. All patients were then treated with MTIS, with a minimum time period of 6 months between the initial diagnosis of UVFP and the surgery. Surgeries were performed according to the technique described by W. Montgomery and colleagues in 1993.<sup>5</sup> All MTISs were performed under light intravenous sedation and cutaneous local anesthesia with per-operative voice feedback as sole outcome control.

The routine clinical pathway of MTIS patients included a post-operative computed tomography (CT) scan of the larynx without

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Conflict of interest: The corresponding author has worked as surgical proctor for Bess Inc., Berlin, Germany since 2015.

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injection of contrast material performed 1 month after surgery to assess implant positioning and stability. The prosthesis was considered well positioned if (1) 90% or more of the intralaryngeal portion of the Montgomery prosthesis lay inside the inner perichondrium plane of the thyroid cartilage; (2) the anteroposterior plane of the prosthesis did not differ by 10° or more from the orientation of the opposite vocal fold; and (3) the implant was not located in the Morgani ventricle or the subglottic area.

Finally, patients who presented a major health event, such as a procedure-related complication, a new oncologic development or a new pulmonary disease between pre- and post-voice assessment were excluded from the analysis.

## Outcome measures and material variables

### Subjective and objective voice outcomes

Before surgery and 1 month after surgery, patients were asked to fill in a Voice Handicap Index (VHI) Questionnaire, and maximum phonation time (MPT) was measured.

The VHI-30 questionnaire was used. This is a 30-item self-administered questionnaire that allows patients to describe their voice state as well as the effects of their voice on their lives (a higher score implying a higher voice disorder impact on the patient's life). A validated native language VHI-30 questionnaire was used and filled in by patients without any guidance.<sup>9,10</sup> We chose the relative decrease in VHI as outcome to underscore the self-perceived improvement regardless of the preoperative baseline.

The objective assessment of a patient's voice improvement was evaluated by the absolute increase in MPT in seconds before and after surgery. The MPT measurement was performed according to the European Laryngological Society guidelines, with the longest attempt of three trials of /a/ phonations at comfortable pitch and loudness being recorded.<sup>11</sup>

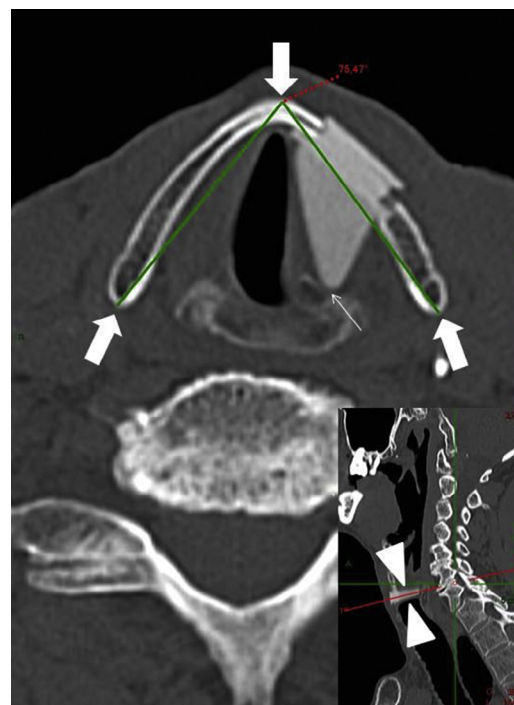
### Material variables

Three material variables were defined:  $\alpha$ -angle, the size of the prosthesis, and  $\alpha$ -ratio.

The  $\alpha$ -angle is the angle between the laminae of the thyroid cartilage and represents the shape of the larynx. The  $\alpha$ -angle was determined according to a CT-scan reading protocol, which was applied to each postoperative CT-scan. As shown in Figure 1, after optimal positioning of slice location on sagittal reformat through the axial oblique long axis of the Montgomery prosthesis, the angle between the posterior borders and the anterior midline points of the thyroid is electronically calculated using the angle calculation option of the postprocessing software.

For women, the available sizes of prosthesis are 6, 7, 8, 9, 10, and 11; for men, these are 8, 9, 10, 11, 12, and 13. All female prostheses have the same length but vary according to size in depth. The male prostheses are 2 mm longer and 2 mm thicker than the female prostheses but vary similarly in depth. The depth dimensions of the overlapping female and male sizes 8–11 are identical per gender.

The  $\alpha$ -ratio is the  $\alpha$ -angle (in degrees) divided by the size of the prosthesis<sup>6–13</sup> and represents the relationship, or congruence, between the shape of the larynx and the size of the prosthesis.



**FIGURE 1.**  $\alpha$ -Angle calculation. After optimal positioning of slice location on sagittal reformat through the axial oblique long axis of the prosthesis (arrowheads on right bottom insert), the angle between posterior borders and anterior midline points (arrows) of the thyroid cartilage is electronically calculated using the angle calculation option of the post-processing software. Observe close contact between prosthesis and the arytenoid cartilage (thin arrow).

### Statistical analyses

Continuous variables were analyzed using medians [P<sub>25</sub>; P<sub>75</sub>], and were compared between groups using the Mann-Whitney test. Variables that were assessed in simple linear regression were the gender and the material variables (the size of the implant, the  $\alpha$ -angle, and the  $\alpha$ -ratio).

Factors associated with the outcome variables in simple linear regression were assessed by multivariable linear regression. A stepwise model was used to determine the final multivariable model by keeping only the contributing variables. The variance inflation factor was also used to avoid multicollinearity. Eventually, a simple Pearson correlation coefficient was calculated between material variables, and between these variables and the outcomes variables.

All analyses were performed using R software Version 3.2.1 (Free software Foundation Inc., Boston, MA). A *P* value < 0.05 was considered statistically significant.

## RESULTS

One male patient presented bone metastases and mandibular osteonecrosis within the time frame between pre- and postevaluation. This patient was excluded from the analyses. No complications, such as infection, bleeding, prosthetic extrusion, or protrusion were found. All in all, 19 patients were included in the analyses, 11 being women (57.9%, *n* = 11/19). Etiology of UVFP was distributed as follows: lung neoplasm (6)

**TABLE 1.**  
**Characteristics of Outcomes and Material Variables and Differences Between Males and Females (N = 19)**

Variables	Total (N = 19)	Males (n = 8)	Females (n = 11)	P Value
	Median [P <sub>25</sub> ; P <sub>75</sub> ]	Median [P <sub>25</sub> ; P <sub>75</sub> ]	Median [P <sub>25</sub> ; P <sub>75</sub> ]	
Baseline characteristics				
Age (years)	63.0 [52.5; 73.0]	72.0 [60.5; 75.3]	60.0 [45.5; 66.5]	0.173
Outcome measures				
VHI (/120)				
Before surgery	52.0 [45.5; 69.0]	49.5 [46.3; 70.8]	59.0 [45.0; 69.0]	0.836
After surgery	11.0 [7.5; 18.5]	11.0 [8.0; 13.8]	13.0 [6.5; 19.5]	0.868
Relative decrease (%)	76.6 [66.5; 88.4]	80.1 [72.2; 88.3]	73.9 [66.5; 89.3]	0.680
MPT (s)				
Before surgery	5.0 [4.2; 10.3]	5.0 [4.5; 6.0]	6.7 [4.2; 11.0]	0.508
After surgery	12.2 [7.7; 16.3]	19.5 [13.8; 22.0]	8.0 [6.9; 11.6]	0.005
Absolute increase (s)	3.2 [1.2; 9.5]	11.0 [8.9; 17.0]	1.3 [-0.2; 2.9]	<0.001
Material variables				
$\alpha$ -Angle	68.0 [61.2; 77.2]	62.5 [59.6; 66.8]	74.7 [67.2; 80.9]	0.021
Size of the implant	9.0 [8.5; 10.0]	10.0 [9.0; 11.0]	9.0 [8.0; 9.0]	0.033
$\alpha$ -Ratio	8.2 [6.5; 8.7]	6.2 [6.0; 6.9]	8.6 [8.4; 8.8]	<0.001

Abbreviations: 95% CI, 95% confidence interval; MPT, maximum phonation time in seconds; VHI, Voice Handicap Index.

post-thyroidectomy (5), post-mediastinoscopy (3), post-aortic surgery (2), post-skull base surgery (2), and idiopathic (1).

Table 1 shows the results of the outcome and material variables and their differences between genders. At baseline, the median [P<sub>25</sub>; P<sub>75</sub>] VHI score and MPT were 52.0 [45.5; 69.0], and 5.0 [4.2; 10.3] seconds, respectively, with no significant differences between genders (Table 1). All three material variables were significantly different between genders, as demonstrated in Table 1.

The absolute increase in MPT between the pre- and postoperative period was significantly different between males and females, with a median [P<sub>25</sub>; P<sub>75</sub>] absolute increase of 11.0 seconds [8.9; 17.0] for men and of 1.3 seconds [-0.2; 2.9] for women ( $P < 0.001$ ) (Table 1). Finally, the relative VHI decrease between pre- and postoperative measurements was not different between men and women ( $P = 0.680$ ), with a median [P<sub>25</sub>; P<sub>75</sub>] VHI relative decrease of 76.6% [66.5; 88.4] for all patients (Table 1).

Factors associated with the absolute increase in MPT, in simple linear regression were gender, the size of the implant, and the

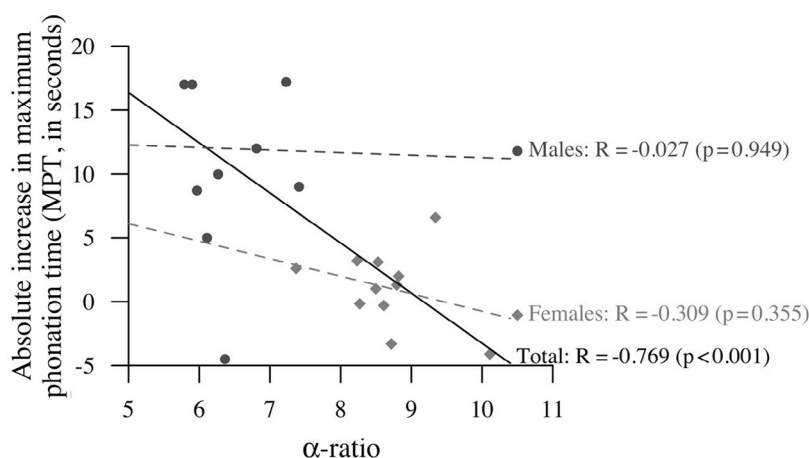
$\alpha$ -ratio (Table 2). In multivariable linear regression, gender was significantly associated with this objective outcome, with the absolute increase in MPT being higher in men than in women ( $\beta$  [95% confidence interval] = 9.13 [5.00; 13.27],  $P < 0.001$ ). The size of the implant remained in the model although it was not a significant factor ( $P = 0.104$ ).

Using the Pearson's correlation, a strong inverse correlation between the  $\alpha$ -ratio and the absolute increase in MPT was observed, with a Pearson's correlation coefficient  $R \leq 0.001$  (Figure 2). When splitting by gender, a significant correlation between the two variables was no longer observed, with an  $R = -0.309$  for women ( $P = 0.355$ ) and an  $R = -0.027$  for men ( $P = 0.949$ ).

This confounding factor—the gender—explains why the  $\alpha$ -ratio is highly associated with MPT increase in the univariable analysis ( $P = 0.001$ ) but is no longer observed to be so in the multivariable analysis when adjusting for gender through the stepwise model.

**TABLE 2.**  
**Variables Associated With the Absolute Increase in MPT and the Relative Decrease in VHI Between Preoperative and Postoperative Periods in Linear Regression (N = 19)**

Variable	Univariable Analysis		Multivariable Analysis	
	$\beta$ [95% CI]	P Value	$\beta$ [95% CI]	P Value
Absolute increase in MPT (s)				
Gender: males vs females	10.90 [7.20; 14.60]	<0.001	9.13 [5.00; 13.27]	<0.001
$\alpha$ -Angle	-0.22 [-0.53; 0.10]	0.163	Rejected by stepwise model	
Size of the implant	3.15 [1.13; 5.16]	0.004	1.30 [-0.30; 2.89]	0.104
$\alpha$ -Ratio	-3.93 [-5.59; -2.26]	0.001	Rejected by stepwise model	
Relative VHI decrease (%)				
Gender: males vs females	6.66 [-16.13; 29.46]	0.546	Rejected by stepwise model	
$\alpha$ -Alpha	0.39 [-0.75; 1.52]	0.479	1.05 [-0.34; 2.44]	0.128
Size of the implant	6.70 [-1.50; 14.90]	0.103	Rejected by stepwise model	
$\alpha$ -Ratio	-3.23 [-12.07; 5.61]	0.451	-9.33 [-19.17; 2.51]	0.123



**FIGURE 2.** Graph showing the linear regression line and Pearson's correlation coefficient (R) between the  $\alpha$ -ratio and the absolute increase of MPT for the total cohort (continuous line) and by gender (dotted lines).

No factors were significantly associated with the relative VHI decrease in univariable or multivariable analyses.

Table 3 shows the correlation observed between material variables by gender, as measured by Pearson's correlation coefficient. A strong inverse correlation is found between the size of the prosthesis that has been used and the  $\alpha$ -angle. The Pearson's correlation coefficient appears to be higher for female than for male individuals.

## DISCUSSION

Although the MTIS has gained interest for its facility of use and its short learning curve, it has been argued that the range of pre-molded silicone implants must be too small to match the variability in shape of individual larynges. Self-carved silicone bloc prostheses would therefore be more efficient. However, comparison between techniques of medialization thyroplasty is tedious because of the large variety of voice outcome indicators that have been used to assess UVFP surgical treatments in the past. In a recent systematic review comparing outcomes of interventions for UVFP, MPT and VHI appeared to be the most used and validated voice outcome measures.<sup>12</sup> MPT is a common, easy-to-perform aerodynamic test that has been shown to be particularly useful in evaluating voice outcome after medialization thyroplasty.<sup>13</sup> The VHI-30 developed by Jacobson in 1997 is of particular interest in cases of UVFP.<sup>14</sup> Indeed, using the VHI, Benninger et al showed that patients with vocal fold paralysis had the highest level of pre-treatment disability among voice patients.<sup>9</sup> In addition, Maertens

and de Jong showed that gender and profession did not have a significant influence on the total VHI scores.<sup>15</sup>

Three studies looking at the results of thyroplasties performed with self-carved silicone bloc (1) as a sole procedure; (2) using MPT and VHI as voice outcome variables; and (3) assessed within the same time frame as in our study are available in the recent English written literature.<sup>16-18</sup>

Compared with the total sample absolute increase in MPT described in these three studies (see below), our male patients performed very well (11 seconds), whereas our female patients performed poorly (1.3 seconds). In one of these studies, the results were stratified per gender and showed slightly better absolute increase in MPT for women than for men.<sup>17</sup> It should also be noted that the higher the number of patients included in these studies, the better the absolute increase in MPT, thus raising the question of a possible longer learning curve of the self-carved silicone bloc technique compared with the MTIS (2.7 seconds for  $n = 10$ ,<sup>16</sup> 8.7 seconds for  $n = 32$ ,<sup>17</sup> and 14.2 seconds for  $n = 78$ <sup>18</sup>).

Gender differences were also not found in voice outcome results after injection laryngoplasty.<sup>19</sup>

In their inaugural initial paper on MTIS outcomes, McLean-Muse et al already noted a gender-related discrepancy, reporting an absolute MPT increase of 11 seconds for men and 5.6 seconds for women.<sup>6</sup> Unfortunately, later reports on MTIS outcomes by Laccourreye's team did not stratify the results of their study per gender.<sup>7,20</sup>

On the other hand, the relative decrease in VHI in our study was large and similar for both genders. This is in accordance with the findings of many publications that showed there was no correlation between VHI and voice laboratory measurements, with the notable exception of the average airflow rate in connected speech for UVFP.<sup>21-23</sup> Two hypotheses can be postulated to explain this discrepancy between objective and subjective voice results after MTIS. One is that an MTIS is a "forgiving surgery"; a slight improvement of MPT causes an important degree of satisfaction. The second is that patients simply may not value an increase in MPT as much as surgeons do.

Likewise, two hypotheses can be made to explain the post-operative absolute increase in MPT difference between genders:

**TABLE 3.**  
Pearson Coefficient Between Material Variables by Gender

	Size of the Prosthesis	$\alpha$ -Ratio
<b>Males</b>		
$\alpha$ -Angle	0.71	0.13
Size of the prosthesis		-0.61
<b>Females</b>		
$\alpha$ -Angle	0.80	0.48
Size of the prosthesis		-0.15

(1) the preoperative choice of implant size was for some reason systematically less appropriate for women than for men and (2) there is a certain inadequacy between female larynx anatomy and the available choice of prosthesis size, a concern that is not present in male implants.

The first hypothesis is ruled out by a better Pearson coefficient between the  $\alpha$ -angle and the size of the implant for the female population of the cohort (0.8 vs 0.71) (Table 3). In other words, the chosen prosthesis was comparatively slightly bigger for women than for men. Accordingly, the female “undertreatment” is not related to surgeon’s decisions.

The second hypothesis is supported by the inverse linear correlation between MPT improvement and  $\alpha$ -ratio. All female patients of the cohort have a high  $\alpha$ -ratio associated with disappointing voice outcomes in terms of MPT. In fact, women are doubly penalized when it comes to the  $\alpha$ -ratio calculation. They present not only a higher numerator ( $\alpha$ -angle) but also a lower denominator (size of implant) than men.

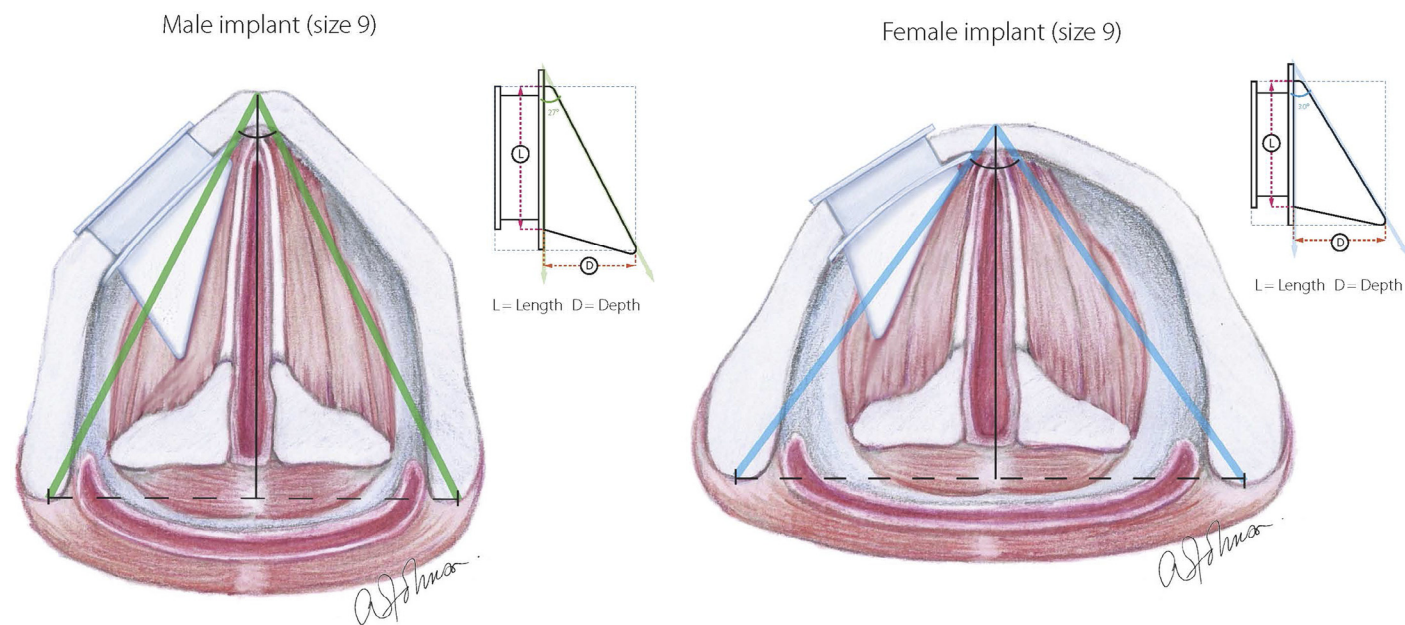
The fact that  $\alpha$ -ratio—representing the relationship between larynx shape and prosthesis size—is deemed the underlying causal factor for poor MPT in this hypothesis but was not identified as a significant factor in the multivariable analysis is explained by the strong overlap between gender and larynx shape ( $\alpha$ -angle) in our cohort.

Until puberty the laryngeal dimensions do not differ between genders, but during puberty the male larynx follows a different developmental path under the influence of testosterone. Two of these anatomic changes are of particular interest: (1) the male larynx outgrows the female one in the anteroposterior dimension and (2) the  $\alpha$ -angle between the thyroid laminae decreases more in men than in women. Our study results, showing

significant larger  $\alpha$ -angle values in women, are in line with literature data.<sup>24,25</sup> As a matter of fact, all dimensions of the laryngeal framework are greater in men except for the thyroid angle ( $\alpha$ ), which is higher in women. This difference of angle between laminae can be measured in different ways. If the anterior commissure represents always the summit of the triangle, its sides can be determined whether using (1) the oblique line mark or (2) the posterior border of the laminae mark. The “oblique line” technique gives bigger figures (mean of 77° for men; mean of 91° for women)<sup>26</sup> and is mostly used in postmortem anatomic studies.<sup>26–29</sup> Because the determination on the—sometimes absent—oblique line can be tedious to identify on CT scan images (Figure 1), we opted for the second measuring technique.

Ideally, this anatomic discrepancy between male and female larynxes should be compensated for by adjusting the implant design to these gender differences. However, female and male Montgomery implants hardly differ. The length of the intralaryngeal portion of the implant is 2 mm longer in men (14 mm for men vs 12 mm for women), but the depth of female and male prosthesis are the same from size 8 (8 mm) to size 11 (11 mm). Moreover, the angle between the middle plate, embedding the prosthesis within the cartilage, and its free edge are similar for both genders.

If the larynx is seen as an isosceles triangle, the classical female larynx presents an open (obtuse) anterior angle and a shorter height. The obtuse anterior angle means that there is more distance to be covered by an implant between the thyroid lamina and the midline (Figure 3). Unfortunately, the MTIS implants set does not provide deeper implants for women. An implant that is too long could also possibly create a conflict with the homolateral arytenoid cartilage (Figure 1, thin arrow).



**FIGURE 3.** Male anatomy of the larynx, horizontal cut through the glottis plane (above), and female anatomy of the larynx, horizontal cut through the glottis plane (below), both with a n°9 prosthesis inserted. Technical characteristics such as length ( $L = 12$  mm for female prosthesis,  $L = 14$  mm for male prosthesis), depth ( $D = 9$  mm for both genders), and angle between middle plate and free edge of the prosthesis ( $27^\circ$  for male prosthesis and  $30^\circ$  for female prosthesis) between the middle plate and the free edge are indicated aside for each prosthesis. Note the obtuse anterior angle and the shorter height of the female larynx in comparison with the male larynx, and the lower adductive potential of the female prosthesis. MPT, maximum phonation time; VHI, Voice Handicap Index-30 score.

Intuitively, it seems that female implants should be shorter and deeper to the midline. However, a definite recommendation for an ideal shape for female implants goes beyond our study's aim. Likewise, some readers could be tempted to infer a preoperative planning strategy from our results. Indeed, by performing a rule of three with the calculated  $\alpha$  determined on a preoperative CT scan of the larynx, and seeking for a value of  $\alpha$ -ratio of 8 and below, one could try to determine the smallest implant that would be needed to appropriately impact the MPT. It is important to remind these readers that the determination of a CT-based, preoperative planning was not the aim of our study and would require further prospective studies to be validated. Finally, two weaknesses of the present study must be mentioned. The small size of the cohort and the use of only two outcome measurements limit the confidence in the conclusions made from this study and call for further studies on the same topic.

### CONCLUSION

This study is the first to demonstrate a relationship between the shape of the larynx and voice outcome after MTIS. Excellent results were found for male patients. These results are comparable with those obtained by experienced surgeons carving silicone blocs. This study supports the idea that six sizes of implants can match the results—whether objective or subjective—of custom-made, self-carved silicone implants.

On the other hand, poor voice outcome results were found for female patients in terms of absolute increase in MPT.

The inverse linear correlation between the  $\alpha$ -ratio and the absolute increase in MPT supports the hypothesis of a female implant design that does not compensate gender-related anatomic differences.

Our findings show that the MTIS is a good thyroplasty modality for male patients, but inadequate design of MTIS female implants leads to poor MPT outcomes. This represents a gender issue that needs to be further studied and eventually tackled.

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