The Montgomery Thyroplasty Implant System: A 360° Assessment

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CHAPTER 6:

« Shape of thyroid cartilage influences outcome of Montgomery medialization thyroplasty. a gender issue.”

Abstract

Objective:

This study aimed to determine whether the shape of the thyroid cartilage and/or the gender influence voice outcomes after Montgomery thyroplasty (MTIS).

Methods:

A retrospective cohort study was performed on 20 consecutive patients that underwent MTIS. Voice outcome variables were the relative decrease in VHI (%) and the absolute increase in MPT (sec.). Material variables were the angle between the thyroid cartilage laminae (α-angle), the size of the prosthesis and a combination of both (the α-ratio). Continuous variables were analyzed using medians, and were compared between groups using the Mann-Whitney test. Factors associated with the outcome variables were assesses by multivariable linear regression. A Pearson coefficient was calculated between material variables.

Results:

The absolute increase in MPT between the pre and post-op period was significantly different between males and females, with a median absolute increase of 11.0 se. for males and of 1.3 sec. for females ($p<0.001$). A strong inverse correlation between the α-ratio and the absolute increase in MPT is observed in all patients, with a Pearson's correlation coefficient $R=-0.769$ ($p<0.001$). No factors were significantly associated with the relative VHI decrease in univariable or multivariable analyses. A better Pearson coefficient between the α-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.

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 (1, 2). Different types of techniques and materials have been proposed over the years. Amongst these, the technique and material named Montgomery Thyroplasty Implant System (MTIS) has gained interest for its facility of use and its short learning curve (3, 4).

The MTIS was designed to be a simplified implant technique. It provides a step-by-step surgical approach along with pre-molded soft silicone implants in six sizes; the range of sizes differing for male and female patients (5). 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 (6, 7).

Opponents of the MTIS, argue that only 6 sizes of implants per gender could never be sufficient to match the variability in shape of individual larynges.

The primary aim of our research was to assess MTIS results retrospectively and investigate whether (a) the shape of the larynx represented by the angle between the two laminae of the thyroid cartilage (the α-angle), (b) the size of the Montgomery prosthesis or (c) a combination of both (the α-ratio) correlate with subjective and/or objective voice outcomes.

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

Material 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.* (8) between May 2011 and November 2014. Each patient presented a UVFP with a large glottis gap at video-stroboscopic 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 diagnostic of UVFP and the surgery. Surgeries were performed according to the technique described by W. Montgomery and colleagues in 1993 (5). All MTIS 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 postoperative CT scan of the larynx without injection of contrast material performed one month after the surgery in order to assess implant positioning and stability. The prosthesis was considered well positioned if: a) 90% or more of the intra-laryngeal portion of the Montgomery prosthesis lay inside the inner perichondrium plane of the thyroid cartilage; b) the antero-posterior plane of the prosthesis did not differ of 10° or more with the orientation of the opposite vocal fold; and c) the implant was not located in the Morgani's ventricle or the subglottic area

Finally, patients who presented a major health-event, such as a procedure-related complications, 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 one month after surgery patients were asked to fill in a Voice Handicap Index Questionnaire (VHI) and maximum phonation time was measured (MPT).

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 (9, 10). We chose the relative decrease in VHI as outcome in order to underscore the self-perceived improvement regardless of the pre-op baseline.

The objective assessment of a patient voice improvement was evaluated by the absolute increase in MPT in seconds before and after the surgery. The MPT measurement was performed according to the European Laryngological Society guidelines, recording the longest attempt of three trials of /a/ phonations at comfortable pitch and loudness (11).

Material variables

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

The α-angle is the angle between the laminae of the thyroid cartilage and represents the shape of the larynx. The α-angle was determined according to a CT-scan reading protocol which was applied to each post-operative 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 post-processing software.

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

The α-ratio is the α-angle (in degrees) divided by the size of the prosthesis (6-13) and represents the relationship, or congruence, between the shape of the larynx and the size of the prosthesis.

(Figure 1).

Statistical analyses

Continuous variables were analyzed using medians [P_{25}; P_{75}], 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 α-angle, and the α-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 multicolinearity. Eventually, a simple Pearson's correlation coefficient was calculated between material variables, and between these variables and the outcomes variables.

All analysis were performed using R software Version 3.2.1 (Free software Foundation Inc., Boston, Massachusetts, USA). A p-value < 0.05 was considered statistically significant.

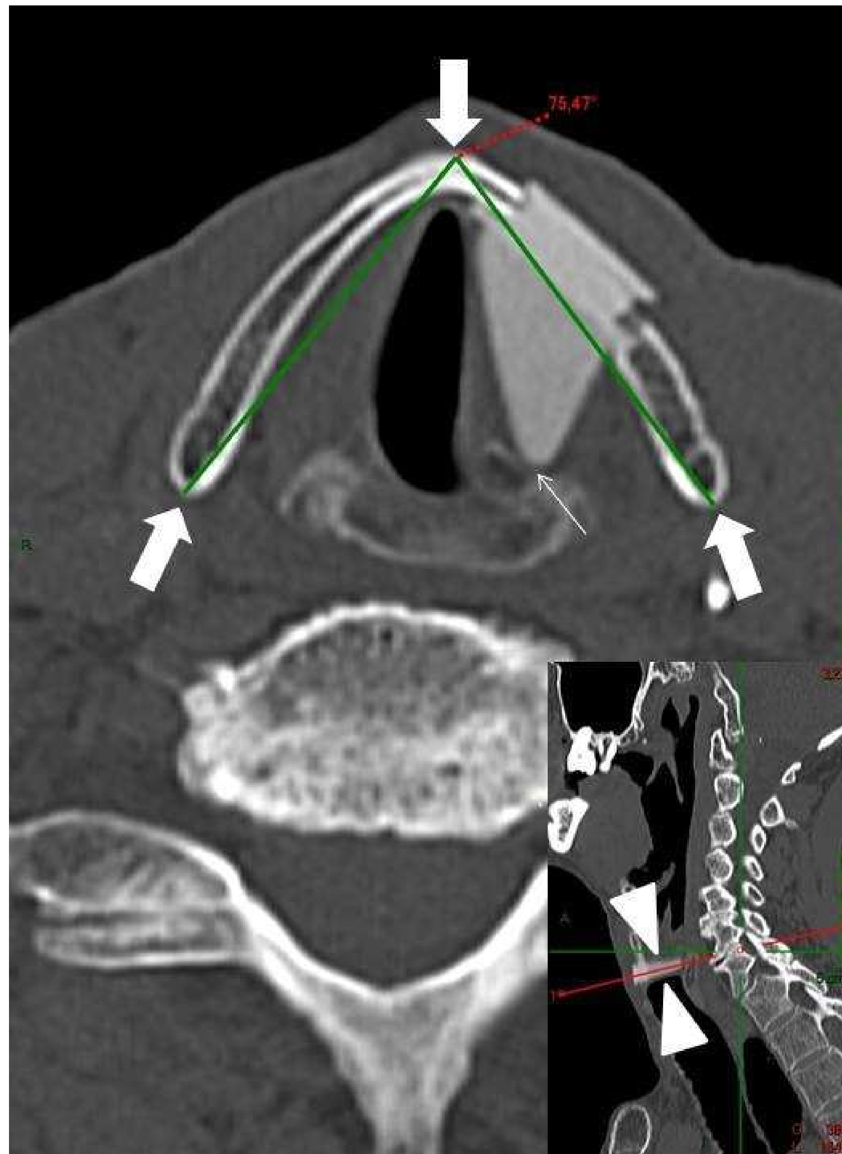

Figure 1: α-angle calculation. After optimal positioning of slice location on sagittal reformat through the axial oblique long axis of the prosthesis (arrowheads on right bottom insert), the angle between posterior borders and anterior midline points (arrows) of the thyroid cartilage is electronically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

Results

One male patient presented bone metastases and mandibular osteonecrosis within the timeframe between pre and post evaluation. 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 females (57.9%, n=11/19). Etiology of UVFP was distributed as followed: lung neoplasm (6), post-thyroidectomy (5), post-mediastinoscopy (3), post-aortic surgery (2), post-skull base surgery (2) and idiopathic (1).

Table 1 shows results of the outcome and material variables and their differences between genders. At baseline, the median [P_{25}; P_{75}] VHI score and MPT were 52.0 [45.5; 69.0], and 5.0 [4.5; 6.0] seconds, respectively, with no significant differences between genders (Table 1). All three material variables were significantly different between genders, as demonstrated in Table 1.

Variables	Total (N=19) Median [P_{25}; P_{75}]	Males (n=8) Median [P_{25}; P_{75}]	Females (n=11) Median [P_{25}; P_{75}]	p-value
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 (sec.)				
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 (sec.)	3.2 [1.2; 9.5]	**11.0 [8.9; 17.0]**	**1.3 [-0.2; 2.9]**	**<0.001**
Material variables				
α-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
α-Ratio	8.2 [6.5; 8.7]	**6.2 [6.0; 6.9]**	**8.6 [8.4; 8.8]**	**<0.001**

VHI: Voice Handicap Index 30 score; MPT: maximum phonation time

Table 1: Characteristics of outcomes and material variables and differences between males and females (N=19)

The absolute increase in MPT between the pre and post-op period was significantly different between males and females, with a median [P_{25}; P_{75}] absolute increase of 11.0 sec. [8.9; 17.0] for males and of 1.3 sec. [-0.2; 2.9] for females ($p<0.001$) (Table 1). Finally, the relative VHI decrease between pre and post-operative measurements was not different between males and females ($p=0.680$), with a median [P_{25}; P_{75}] 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 the gender, the size of implant and the α-ratio (Table 2). In multivariable linear regression, the gender was significantly associated with this objective outcome, the absolute increase in MPT being higher in males than in females (β [95%CI] = 9.13 [5.00; 13.27], $p<0.001$). Size of the implant remained in the model although it was not a significant factor ($p=0.104$).

Variable	Univariable analysis		Multivariable analysis	
	β [95%CI]	**p-value**	**β [95%CI]**	**p-value**
Absolute increase in MPT (sec)				
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
α-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*	
α-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*	
α-Ratio	-3.23 [-12.07; 5.61]	0.451	-9.33 [-19.17; 2.51]	0.123

95%CI: 95% confidence interval; MPT: maximum phonation time in seconds; VHI: voice handicap index

Table 2: Variables associated with the absolute increase in MPT and the relative decrease in VHI between pre-op and post-op periods in linear regression (N=19)

In the Pearson's correlation a strong inverse correlation between the α-ratio and the absolute increase in MPT was observed with a Pearson's correlation coefficient of R=-0.769 (p<0.001) (figure 2). When splitting by gender, a significant correlation between the two variables was not observed anymore, with an R=-0.309 for females (p=0.355) and an R=-0.027 for males (0.949).

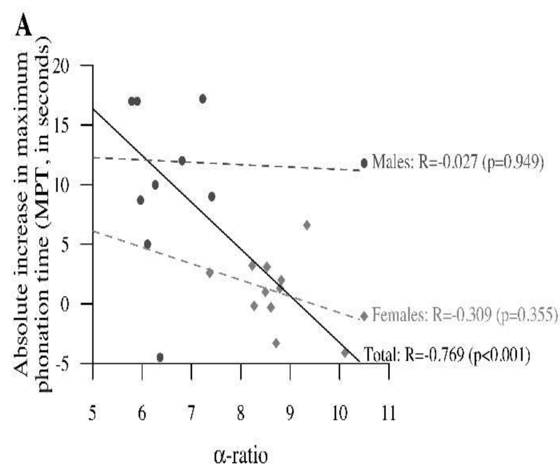

Figure 2: Graph showing correlation line and R^2 between the α-ratio and the absolute increase of MPT for the total cohort (continuous line) and by gender (dotted lines)

This confounding factor -the gender- explains why the α-ratio is highly associated with MPT increase in the univariable analysis (p=0.001) and is not anymore in the multivariable analysis when adjusting for gender through the stepwise model.

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 correlation is found between the size of the prosthesis that has been used and the α-angle. The Pearson's correlation coefficient appears to be higher for female than for male individuals.

	Size of the prosthesis	α-Ratio
Males		
Alpha angle	**0.71**	0.13
Size of the prosthesis		-0.61
Females		
Alpha angle	**0.80**	0.48
Size of the prosthesis		-0.15

Table 3: Pearson coefficient between material variables by gender

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 due to 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 utilized and validated voice outcome measures (12). MPT is a common, easy to perform aerodynamic test that has been shown to be particularly useful in evaluating voice outcome after medialization thyroplasty (13). The VHI-30 developed by Jacobson in 1997 is of particular interest in cases of UVFP (14). Indeed, using the VHI, Benninger et al. showed that patients with vocal fold paralysis had the highest level of pretreatment disability among voice patients (9). In addition, Maertens et al. showed that gender and profession did not have a significant influence on the total VHI scores (15).

Three studies looking at the results of thyroplasties performed with self-carved silicone bloc, (i) as a sole procedure; (ii) using MPT and VHI as voice outcome variables and (iii) assessed within the same timeframe as in our study; are available in the recent English written literature (16-18).

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

Gender differences were also not found in voice outcome results after injection laryngoplasty (19).

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 sec. for males and 5.6 sec. for females (6). Unfortunately, later reports on MTIS outcomes by Laccourreye's team did not stratify their results per gender (7, 20).

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 (21-23). Two hypotheses can be postulated to explain this discrepancy between objective and

subjective voice results after MTIS. One is that a MTIS is a “forgiving surgery”; a slight improvement of MPT causing 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: (a) the per-operative choice of implant size was for some reason systematically less appropriate for females than for males; b) there is a certain inadequacy between female larynx anatomy and the available choice of prosthesis size which is not present in males.

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

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

The fact that α-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 anatomical changes are of particular interest: (a) the male larynx outgrows the female one in the antero-posterior dimension (b) the α-angle between the thyroid laminae decreases more in males than in females. Our study results, showing significant larger α-angles values in females, are in line with literature data (24, 25). As a matter of fact, all dimensions of the laryngeal framework are greater in males except for the thyroid angle (α) which is higher in females. 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 (a) the oblique line mark or (b) the posterior border of the laminae mark. The “oblique line” technique gives bigger figures (mean of 77° for males; mean of 91° for females) (26) and is mostly used in post-mortem anatomical studies (26-29).

Because the determination on the –sometime absent- oblique line can be tedious to identify on CT scan images (see the example of figure 1), we opted for the second measuring technique.

Ideally, this anatomical 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 intra-laryngeal portion of the implant is 2 mm longer in males (14 mm for males versus 12 mm for females), 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 female. A too long implant could also possibly create a conflict with the homolateral arytenoid cartilage (Figure 1 thin arrow).

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 pre-operative planning strategy from our results. Indeed, by performing a rule of three with the calculated α determined on a pre-operative CT scan of the larynx, and seeking for a value of α-ratio of 8 and below, one could try to determine the smallest implant that would be needed to appropriately impact the MPT. It is adamant to remind these readers that the determination of a, CT based, pre-operative planning was not the aim of our study and would require further prospective studies in order 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.

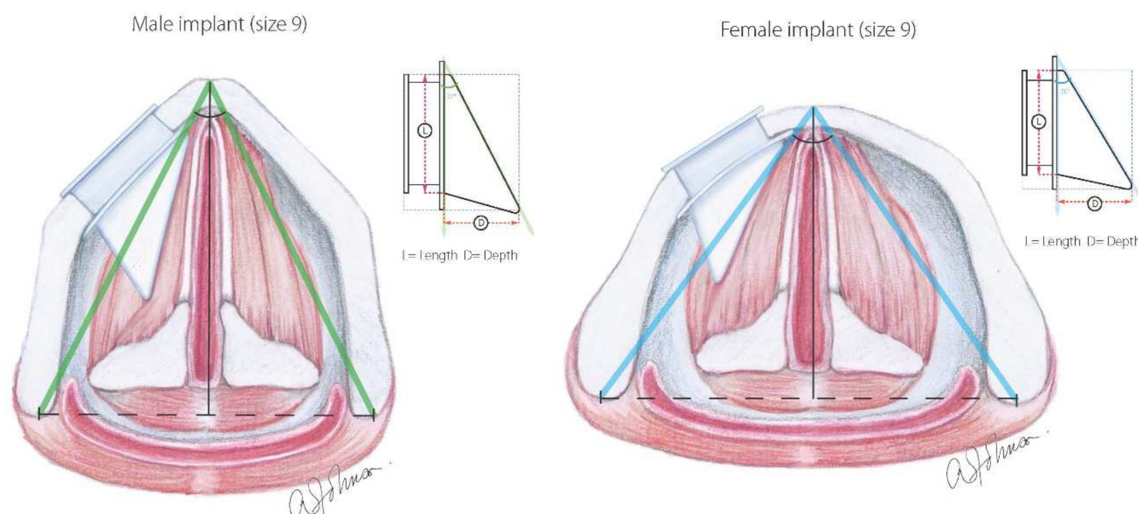

Figure 3: Male anatomy of the larynx, horizontal cut through the glottis plane (above), and Female larynx anatomy, horizontal cut through the glottis plane (below), both with a n°9 prosthesis inserted. Technical characteristics such as Length (L = 12mm for female, L=14mm for male), Depth (D= 9mm for both genders) and angle between middle plate and free edge of the prosthesis (27° for male and 30° for female) 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.

Conclusion

This study is the first publication demonstrating 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 supports the idea that 6 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 α-ratio and the absolute increase in MPT supports the hypothesis of a female implant design that does not compensate gender-related anatomical 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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