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The Montgomery Thyroplasty Implant System: A 360° Assessment

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CHAPTER 8:

General discussion, summary and future perspectives

General discussion:

The ultimate goal of this work is to contribute to the improvement of the voice, and consequently the quality of life, of the patient suffering from dysphonia due to paralysis of a vocal cord.

Basically, there are three kinds of surgical treatments for UVFP considered effective in the literature. Regardless of their duration of effectiveness, these are: injection laryngoplasty, non-selective reinnervation and laryngeal framework surgery including arytenoid modifications.

Temporary injection laryngoplasty appears to be highly effective in an early phase, all be it temporary. Some authors even attribute to it, an effectivity beyond the time of substance resorption. This hypothesis that injection augmentation thyroplasty perhaps stimulates reinnervation, induces adaptation of the central nervous system and/or gives rise to long-term beneficial laryngeal adaptations remains disputed and is the subject of studies in progress.

Improvement of voice results with a non-selective nerve transfer using the ansa cervicalis is based on reinitialization of reinnervation and recovery of tonus. Reports show more favorable results than those obtained during the initial spontaneous reinnervation, but results also appear somewhat unpredictable. Such reinnervation procedures are regularly combined with temporary injection augmentation, using various injectable materials. It then becomes less clear to what intervention the final effect can be attributed: injection, reinnervation or the combination of both?

Laryngeal framework surgery is generally considered as the "gold standard" for the treatment of UVFP, the technique is effective and relatively simple. Such a surgical procedure, as medialization thyroplasty, practiced since the first intervention by *Payr* in 1915, whatever its exact technique or the implant used, does not have to prove its effectiveness, the number of the studies underlining its good results are numerous.

So, *ite missa est*? Has everything been said? Are we satisfied on the pretext that some postoperative voice quality indicators have only a 5% chance of being identical to their preoperative value ($p < 0.05$)?

Regarding laryngeal medialization framework surgery, this thesis puts this complacency back into question. A specific type of thyroplasty -the MTIS- was chosen for two reasons; firstly, because the author had good experience with the technique, secondly the MTIS not only represents a type of implant but also a codified surgical technique, supposed to reduce the variability related to the surgeon.

The author of this thesis has also made an effort to use alternative and innovative research techniques in order to *critically consider the nature of the knowledge claims of their discipline (sic)*[1]. The originality lies in the choice of the Pareto technique as

literature review, in the technique of the e-mail survey as to the use of voice indicators by practitioner, in a proof-of-concept study of an innovative (perhaps even disruptive) endoscopic measuring technique, and finally in the development of a new concept, the α -ratio with the use of virtual CT scan reconstruction to study the interactions between thyroid cartilage morphology and post-operative voice results.

Only one non-innovative research technique –a classical multi-centric cross-sectional study- was used, applied in the case of the long-term results. In the latter case, is it then a coincidence that its conclusions are as expected and gender differences did not become apparent?

Such innovative approaches, called for by the scientific community [2], offer alternative perspectives of the same reality. They allowed, as ambitioned, to further improve what is perceived as already satisfactory.

Here within lies the basis of our research.

Regarding the Voice Outcome Indicators

The literature review and the survey of surgeons (Studies 1 and 2, Chapter 2 & 3) indicate that two VOIs are widely used: the MPT and the VHI-30. These are both VOIs that are easily accessible. Nevertheless, the methodology to collect MPT should be further standardized. VOI acoustic measurements such as Jitter and Shimmer, although widely cited in literature and acclaimed important by speech-language pathologists, appear less relevant to surgeons. The survey among surgeons shows an interest in aerodynamic measurements - MeAF in particular - for UVFP assessment. This is in line with the work of Dastolfo et al. who consider the average airflow in the all-voiced sentence as a disease-specific VOI for UVFP [3].

Finally, two frequently used VOIs, should not be part of a minimum UVFP set of outcome indicators. These are the fundamental frequency (F0) and the estimated subglottic pressure (ESGP). Although frequently reported, F0 and ESGP do not change as a function of UVFP treatment (Study1). The same seems to be true of the Peak Direct Subglottic Pressure (PDSP) that shows a poor agreement rate between PDSP and Choice of Implant Size (62.5%) [4].

One of the possible reasons why F0 and ESGP are not relevant is that it does not only reflect the severity of the UVFP but rather a combination of the severity and the way the patient tries to overcome the limitation.

TAKE HOME MESSAGE 1:

Most commonly used VOIs to determine the effectiveness of surgical UVFP treatment are: MPT and VHI. MeAF is a VOI deserving further investigations.

Regarding the Advantages of the MTIS

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

An article, published in 2015, by G. Desuter et al. showed the easiness of the technique. The post-operative voice outcomes are good from the first patient on and remain at the same level [5]. Only the operating time improves with increasing experience of the surgeon. In conclusion; yes, the MTIS is a simple operating procedure.

Question 2: Does the MTIS offer permanent results?

Although MT is considered a definitive treatment of UVFP by the majority of authors [6], some have expressed doubts about the permanence of its benefits in the very long term [7]. According to these authors, glottic atrophy would cause a reappearance of symptoms. Our multi-centric cross-sectional study demonstrates the opposite (Chapter 4). It shows particularly stable results over the years. These results are independent of the patient's gender, his age at the time of the procedure and the size of the implant. The work of Ryu et al. had already reached the same conclusions regarding the medialization thyroplasties realized with self-carved silastic implants [8]. Our work shows that the same is true for MTIS. To conclude, the MTIS must be considered as offering a permanent result and can be presented as such during the pre-operative discussion with the patient.

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

The authors expected to see this issue addressed by other teams during the course of this thesis. Indeed, Storck et al. answered this question by superimposing pre and post-operative 3D images with an imagery software (MIMICS) [9]. They concluded that MTIS can, in the case of a paralyzed vocal fold, adequately close the posterior glottis by imposing a postero-superior gliding movement of the arytenoid on the shoulder of the crico-arytenoid joint.

The authors, together with engineers, have chosen a non-irradiating and cheaper approach. An on-board laser measuring system on a flexible video-endoscope was developed and tested. In conducting a "proof of concept" study on human post mortem larynx, the question was whether this type of instrument would be clinically applicable and whether it had sufficient resolution to determine difference in height and position between vocal folds. The answer is affirmative and the Larynx Ruler is expected to be tested in clinical practice in the coming years.

TAKE HOME MESSAGE 2:

MTIS is a simple technique, offering permanent results with the possibility of treating posterior glottal gaps in most UVFP configurations.

Regarding the limitations of the MTIS

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

Study 5 (Chapter 6) shows poorer MPT results in female patients. Localization of the cartilage fenestration, the angle between the implant free edge and the middle plate, and the implant length are possible factors influencing results in females. Design of study 5 supports the implication of prosthesis angulation.

This discrepancy of outcome in disfavor of females exists since the initial article written on MTIS by W. Montgomery. Their argument for this finding is that normal MTP values are lower in women.

Unfortunately, very few studies comparing pre- and post-operative results after MT by another technique or implant stratify their results by gender. A comparison with other MT techniques is therefore impossible.

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

Study 6 demonstrates a difference in the results for female patients as well. In this case, the VHI-30 difference was significantly poorer.

Study 6 shows variability in the realization of cartilage fenestration during MTIS. This variability had very limited effect on results of the whole cohort. A careful examination of these, however, asserts that the best vocal results are obtained when the implant is placed the most anterior and inferior on the thyroid ala. Again, there is a gender difference in results. None of the patients implanted antero-inferiorly were female.

As a matter of fact, length of the prosthesis and cartilage fenestration location, represent collinear factors as they both may influence the implant versus arytenoid interaction.

It is important to note that these results relate to separate cohorts of a limited number of patients ($n = 20$ for study 5 and $n = 28$ for study 6). Multi-centric studies will need to verify these findings.

TAKEHOME MESSAGE 3:

MTIS provides excellent results for male individuals. Female patients have a lower benefit after MTIS. The depth of the implant, as well as cartilage fenestration location, are factors influencing this gender discrepancy.

General conclusions of the thesis.

From studies 2 and 3, it can be deduced that the outcome indicators used in studies 4 to 7 are adequate. Moreover, a specific indicator, the mean airflow, seems of particular interest and at present is underused.

The MTIS was confirmed to be highly effective in the very long term and its high performance can even be considered to be permanent.

Besides for MTIS, no other preliminary studies on thyroplasty have shown slightly poorer vocal results in female patients compared to those found in male patients. Although in the majority of laryngology studies, the question of statistical power remains, these findings are nonetheless challenging and deserve further research.

In view of the results of studies 6 and 7, this difference in results could possibly be reduced by modifying both the shape of the endo-laryngeal portion of the implant (allowing a better α -ratio) and the size of its anchoring base (allowing maximum anterolateral cartilage fenestration for anchoring).

In any case, the MTIS is a valid technique that should benefit from these research data to improve its qualification of vocal results from good to excellent for both genders.

Perspectives

One of my mentors, Professor Yves Guerrier, from the University of Montpellier in France, once said to me that good research led to more questions than answers. This is certainly the case at the end of this thesis.

Regarding the VOIs

The conclusions of this work (Chapter 2 & 3) served as a basis for the discussion of the establishment of an International Consensus on Basic Voice Assessment for UVFP [10]. New studies will focus on the creation and validation of a French and Dutch version of MeAF in the all-voiced sentence.

A correlation study of MeAF and Phonatory Quotient before and after MTIS is also planned.

Regarding the Larynx Ruler

A team of engineers from the Université Libre de Bruxelles (ULB) led by Mr B. Mertens is working on the production of LR fiberscopes and their EU certification. Once this is obtained, a clinical study comparing the results provided by the LR with the results obtained by MIMICS processed CT imagery will be launched. This will make it possible to carry out other prospective studies concerning the treatment of posterior glottic leaks.

Concerning the improvement of MTIS results in women

A preliminary study of 3D printed template for cartilage fenestration localization is ongoing.

Fully customized 3D printed implants study based on pre-operative planning imagery will have to be done subsequently. Depending on the outcome of this study it will be necessary to decide on a switch to a custom-made 3D printing model or the development of different sizes of a new female prosthesis.

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