Diplomarbeit

EXTERNAL VOCAL FOLD MEDIALIZATION
thyroplasty with titanium vocal fold medialization implant (TVFMI) - long-term results of voice and life quality

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Graz, am 28.April 2017

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Graz, am 28.April 2017 *David Hortobagyi eh*

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Zusammenfassung

Einleitung

Die Stimmlippen sind im Wesentlichen für die Stimmbildung verantwortlich. Durch den Strom der Ausatemluft werden sie in Schwingung versetzt und bilden einen Ton. Infolge einer einseitigen Stimmlippenlähmung ist die Schwingungsfähigkeit der gelähmten Stimmlippe eingeschränkt und es strömt zu viel Luft durch die Stimmritze, was eine heisere Stimme zur Folge hat. Dies führt zu einer Beeinträchtigung der verbalen Kommunikation und in weiterer Folge auch zu einer Verschlechterung der Lebensqualität. Es gibt jedoch unterschiedliche Möglichkeiten, um die Stimmbildung in solchen Fällen zu verbessern. Diese Arbeit behandelt eine von G. Friedrich entwickelte Technik, bei der das gelähmte Stimmband mittels eines Titanimplantates nach medial gedrängt um die Stimmritze bei der Phonation wieder zu verengen. Es sollen die Unterschiede vor und nach Einsetzen des Implantates aufgezeigt werden.

Material und Methoden

116 PatientInnen aus dem Patienteninformationssystem MEDOCS erfüllten die Einschlusskriterien, wobei sich zwei jeweils zweimal einer Titanimplantation unterziehen mussten. Von diesen wurden - sofern vorhanden - retrospektiv jeweils prä- und postoperativ die Parameter SSI, Jitter, Shimmer, MPT, DI, DSI und F0 zur Beurteilung der Stimme erhoben und mithilfe des Statistikprogrammes SPSS die Unterschiede ausgewertet. Alle Parameter bis auf den DI waren sowohl vor als auch nach der Operation normalverteilt.

Ergebnisse

SSI ($p < .000$), MPT ($p < .000$) und DI ($p < .000$) verbesserten sich signifikant nach der Operation. Auch die restlichen Parameter verbesserten sich häufig nach der Titanimplantation, jedoch waren die Unterschiede nicht signifikant: Jitter ($p = .144$), Shimmer ($p = .749$), F0 ($p = .864$) und DSI ($p = .079$).

Diskussion

Obwohl nicht in allen Parametern eine signifikante Verbesserung nachgewiesen werden konnte, zeigten vor allem diejenigen, die die Selbsteinschätzung der Patienten in Betracht zogen (SSI), eine signifikante Verbesserung. Letztendlich ist das subjektive Gefühl des Patienten entscheidend. Darüber hinaus haben das Material und die Operationstechnik wesentliche Vorteile. All diese Tatsachen bekräftigen die Behauptung, dass das Einsetzen des Titanimplantates eine hervorragende Methode ist, die Lebensqualität von Menschen mit einseitiger Stimmbandlähmung zu verbessern.

Abstract

Introduction

The vocal folds (VF) are basically responsible for phonation. According to the myoelastic theory, the flow of the exhaled air induces oscillation of the VF and thereby producing the primary sound. Due to unilateral VF palsy, too much air can pass through the glottic gap. The result is hoarseness and dyspnea. This impairs the oral communication and further deteriorates quality of life. Various possibilities to improve the phonation in these cases are available in clinical routine. This paper covers a technique developed by Friedrich, in which an inserted titanium implant shifts the paralysed VF into a median position, thus narrowing the glottic gap while the patient phonates. The aim is to reveal differences between the voice before and after the surgery.

Material and Methods

116 patients from the communication and information system MEDOCS fulfilled the inclusion criteria, two of them even had to undergo the surgery twice. The parameters SSI, Jitter, MPT, DI, DSI and F0 were ascertained pre- and postoperatively and assessed with the aid of SPSS. All parameters, except for the DI, were distributed normally before as well as after the surgery.

Results

SSI ($p < .000$), MPT ($p < .000$) and DI ($p < .000$) improved significantly after the surgery. The other parameters improved too, however the differences were not significant: Jitter ($p = .144$), Shimmer ($p = .749$), F0 ($p = .864$) und DSI ($p = .079$).

Discussion

Even though not all parameters improved significantly, particularly the subjective ones did. Eventually, the patients' self-assessment is the key factor. Furthermore, the material and the technique itself have essential advantages. All these facts confirm that TVFMI-thyroplasty is an outstanding procedure to treat patients with dysphonia due to a unilateral VF paralyses.

Index

Abbreviations

DI……..……Dysphonia index
DSI……..…Dysphonia Severity index
F0……..…….Pitch of the sound
MPT…….……..Mean phonation time
SSI……..……Stimmstörungsindex
TVFMI……..….Titanium vocal fold medialization
VHI……..……..Voice handicap index
VF……..……Vocal fold
VFP……..……Vocal fold paralysis
UVFP…….……..Unilateral vocal fold paralysis

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Introduction

For a successful ventilation and phonation of both vocal folds (VF), an immaculate movement is essential. We distinguish between unilateral and bilateral VF paralysis. In the latter, problems with ventilation come to the fore whereas in the former phonation is primarily impaired.(1)

The reason of VF palsy is often a damage of the recurrent laryngeal nerve, which innervates the majority of the larynx muscles. There are different ways of how the nerve could be injured. The most frequent are iatrogenic, as a consequence of surgery, associations with neoplastic diseases and idiopathic, where the cause is unknown.

Patients with unilateral paralysis of the VF usually present themselves in hospital with dysphonia, thus hoarseness, decreased vocal resilience and aspiration. Further, examinations show an impaired motility of the VFs and an incomplete glottic closure. These symptoms may have huge influence on the quality of life. Therefore it is important to diagnose and treat unilateral VF palsy as early as possible.

There are basically two possibilities how the phonation of these patients can be enhanced. First of all there is the conservative voice therapy, which in some patients though does not achieve a satisfying improvement. For these patients we have diverse surgical options, for example medialization thyroplasty, arytenoid adduction, injection laryngoplasty and laryngeal reinnervation.

All of these invasive procedures as well as the non-invasive ones have the restoration of the laryngeal function, by approaching the VFs to each other and consequently reducing the glottis closure in common. (2)(3)(4)(5)

Anatomy and Physiology

The Larynx is the source of voice and is located between the trachea and the hyoid bone on a level with the fifth and sixth cervical vertebra. However, there is a great variability concerning the laryngeal anatomy like gender-related dimorphism and age specific differences amongst others, but I will not go into this in detail.(6)

The laryngeal skeleton consists of nine cartilages, three single, thyroid (cartilago thyroidea), cricoid (cartilago cricoidea), Epiglottis, and three in pair, two arytenoid (cartilago arytaenoidea), two cornicula laryngis (cartilago corniculata) and two cuneiform (cartilago cuneiformis). These are flexibly linked to each other by various ligaments so that movement among themselves is possible.(7)(8)(9)

Basically one can divide the cavity of the Larynx into three parts:(7)

- Vestibulum laryngis (cavitas laryngis superior) extends from the aditus laryngis, which is bounded by the epiglottis, plicae aryepiglotticae and incissura interarytaenoidae, to the false vocal cords (plicae vestibulares).
- Cavitas laryngis intermedia is between plicae vestibulares and true vocal cords / vocal folds (plicae vocales). It reaches laterally the ventriculus laryngis.
- Cavitas infraglottica is located between plicae vocales and the lower border of the cricoid cartilage, where it merges downwards into the trachea.

Plica vocalis or true VF is named after its function, which is producing voice. It is subdivided into two parts, a posterior intercartilaginous part, which consists of the vocal process (processus vocales) of the arytaenoid cartilage, and an anterior interligamentous one, which is formed by the ligamentum vocale stretched between the vocal process and the ala of thyroid cartilage. These are covered by an epithelium, which is loosely attached to the tissue beneath. Between the plicae vocales there is a fissure, called rima glottidis. During ventilation it is widened at its maximum, so that the air encounters less resistance. (7)(10)

While people are talking, rima glottidis is narrowed. The air increases the pressure below the closed vocal cords. Once exceeding the pressure above it, the air displaces the loosely attached epithelium and passes the VF. But only a little amount of it can do so, because according to the myoelastic-aerodynamic theory of voice production, rima glottidis closes immediately again. This has two reasons. Firstly the elastic components of the VF tissue. Thereby it tends to regain its initial, closed position. Secondly the fast airflow causes a suction effect (Bernoulli's principle), which re-

stores the VF to its closed position as well. This process is repeated frequently and leads to periodic compression of the air, which is perceived as sound.(10)(1)(11)

A perfect phonation requires a coordinated interaction between the laryngeal muscles and their nerves.(12)

It is possible to divide these muscles into two groups: (7)(8)(9)

Muscles, which are responsible for the degree of tension of the VF:

- Musculus cricothyroideus ("Anticus") arises from the anterior part of the arch of the cricoid and inserts into the lower border of the thyroid with its pars recta and into the lower border of the cornu inferius with its pars obliqua. It approximates the cricoid to the thyroid and simultaneously enlarges the distance between the thyroid and the arytaenoid cartilage, thus tenses the VF *(Fig. 1,2,3)*.
- Musculus vocalis has the same pathway as the vocal ligament from the vocal process to the thyroid and regulates the tension of VF by relaxing it *(Fig.1,2,3).*
- Musculus thyroarytaenoideus lies parallel with the musculus vocalis, also relaxing the VF. Furthermore it has also an outer portion, which supports the rotation of the vocal processes of arytaenoid cartilage inwardly, thus narrows the rima glottidis *(Fig. 1,2,3).*

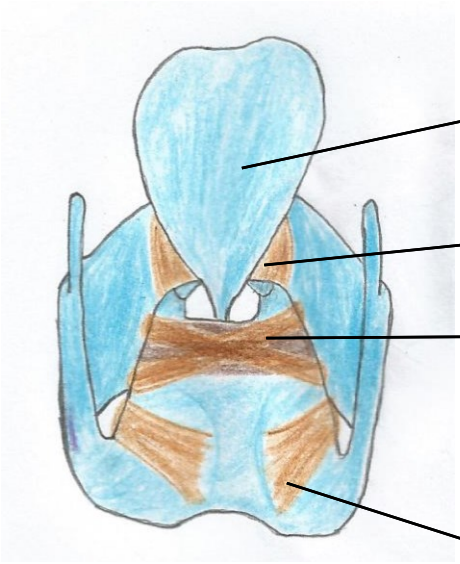
Muscles, which open or close the rima glottidis:

- Musculus cricoarytaenoideus posterior ("Posticus") arises from the posterior surface of the lamina cartilaginis cricoidei and inserts into the lateral part of the muscular process (processus muscularis) of the arytaenoid cartilage. It is the only muscle that enlarges the rima glottidis *(Fig.1,2,3).*
- Musculus cricothyroideus lateralis ("Lateralis") is attached between the upper border of the lateral part of the cricoid and the muscular process of the arytaenoid cartilage. By rotating the vocal process inwards, it closes the rima glottidis *(Fig.1,2,3)*.
- The musculi arytaenoidei (obliquus and transversus) arise on one arytaenoid cartilage and insert into the opposite one. Their function is to approximate both cartilages to each other, thereby narrowing the rima glottidis *(Fig.1,2,3).*

Basically the innervation of the larynx is effected by the tenth cranial nerve (nervus vagus), or to be precise by two of its branches: 1. The superior laryngeal nerve (nervus laryngeus superior), which descends by the side of the internal carotid and divides into two branches; the external laryngeal branch innervates the cricothyroid muscle, inferior constrictor of the pharynx and with some filaments the thyroid gland;

the internal laryngeal branch passes through the thyrohyoid membrane and, reaching the inner surface of the larynx, supplies the mucous membrane above the VF.

2. The recurrent laryngeal nerve, named after its reflected course: On the right side it turns backwards around the subclavian artery and on the left side around the ligamentum arteriosum, which is a remain of the ductus arteriosus. The nerve ascends on both sides between the trachea and oesophagus until reaching the larynx. There it gives off, amongst other, the inferior laryngeal nerve (Nervus laryngeus inferior). This supplies all of the previously mentioned laryngeal muscles, except the musculus cricthyroideus, and further the mucous membrane beneath the vocal cords. The left recurrent laryngeal nerve is, because of its extended course, more vulnerable than the right one. (7)



Epiglottis

M. thyroarytaenoideus

Mm. arytaenoideus obliquus et transver-

M. cricoarytaenoideus lat.

M. cricoarytaenoideus post.

Fig.1:Larynx from behind

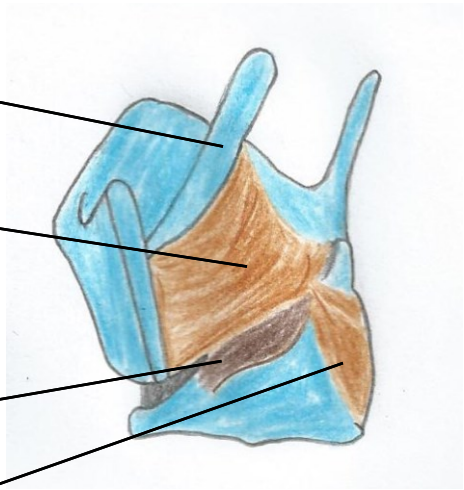


Fig. 2:Larynx from lateral

M. cricothyroideus

M. vocalis

M. cricoarytaenoideus lat.

M. thyroarytaenoideus

M. arytaenoideus transversus

M. cricoarytaenoideus post.

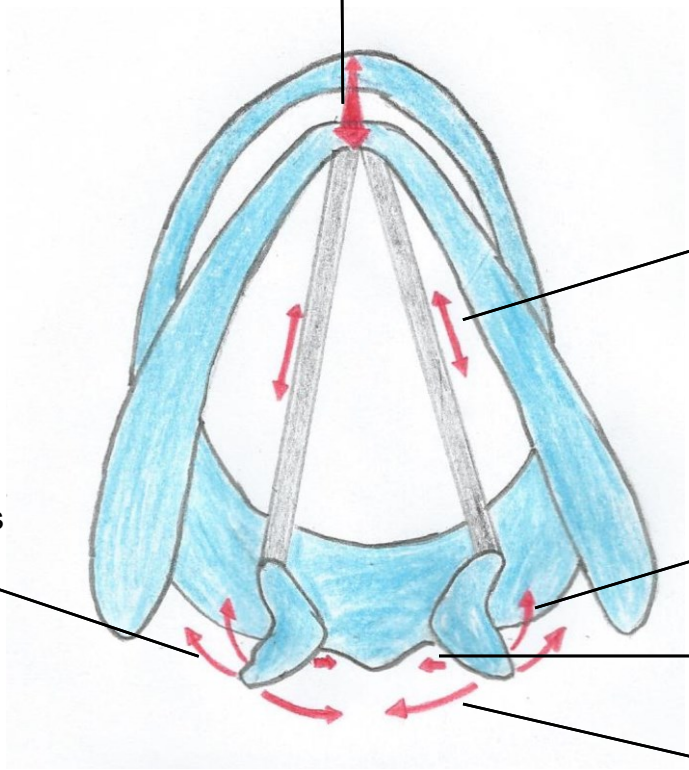


Fig. 3: Overview of muscle function

Aetiology

Vocal fold paralysis (VFP) is the inability of moving the VF, which can be caused by an ankylosis of the cricoarytaenoid joint, a tumour that fixes the VFs mechanically, posterior glottis scar formation or an injury of the vagal nerve. The latter in turn, may be affected anywhere along its course by malignancy, the therapy of a malignant tumour, neck trauma or various surgeries particularly thyroidectomy. Furthermore, there are cases where the underlying aetiology of the VF palsy is unknown, so called idiopathic VFP. Due to enhanced diagnostic methods, the group of patients with idiopathic VFP has decreased.(13)(14)

Although it is difficult to graduate these causes referred to their frequency, since they alter over the course of time as well as from country to country, one of the most frequent ones is a damage of the vagal nerve, more precisely, of the recurrent laryngeal nerve. Either the nerve is affected on both sides or only on one side, thus bilateral or unilateral. Amongst these in turn a unilateral injury is more likely than bilateral and, as mentioned previously, the left side is more injury-prone than the right. (13)(15)

The prevalent symptoms at the bilateral VFP are difficulties in breathing, as a consequence of a narrowed rima glottidis.(16)

At the unilateral VFP (UVFP) however, ventilation is spared but phonation is compromised because of an incomplete glottal closure *(Fig.4,5,6)*, hence the oscillation of the VFs is deteriorated and the voice becomes hoarse. Moreover, dysphagia can occur due to pharyngeal weakness and an impaired sensation.(17)(1)

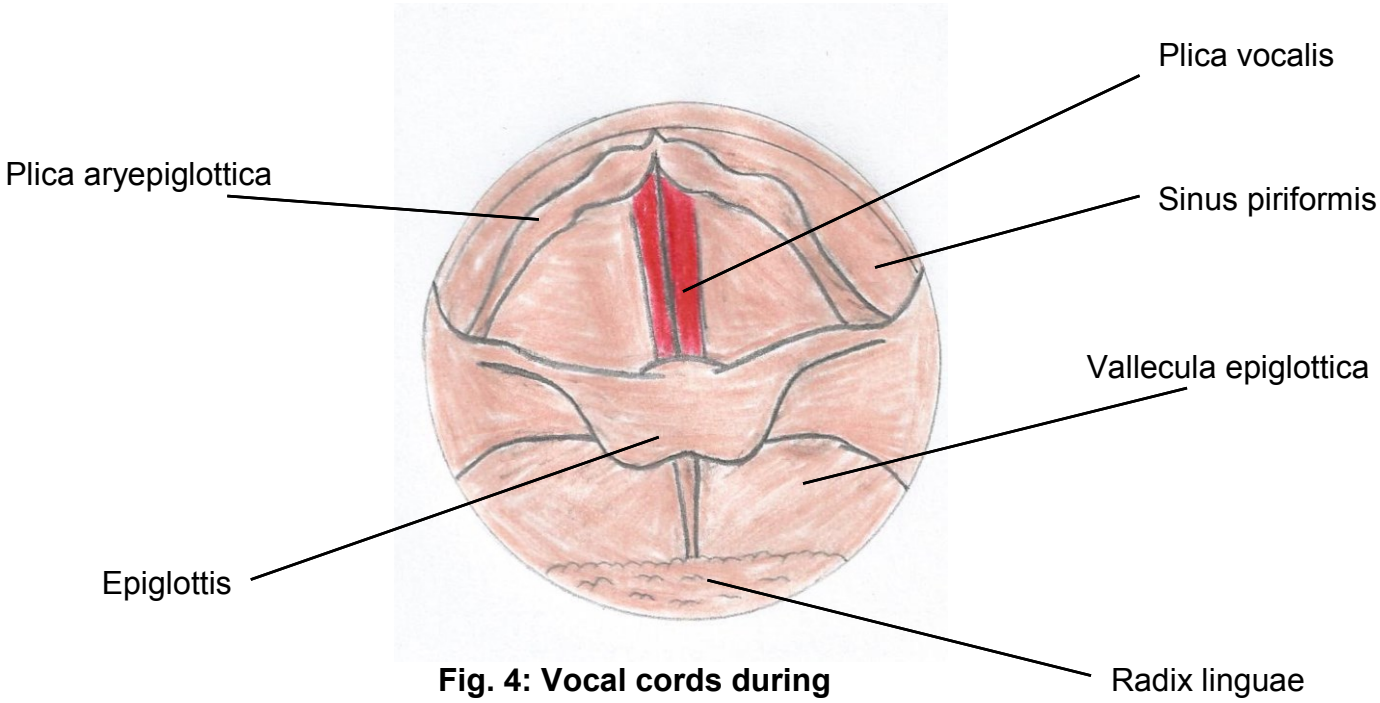


Fig. 4: Vocal cords during phonation

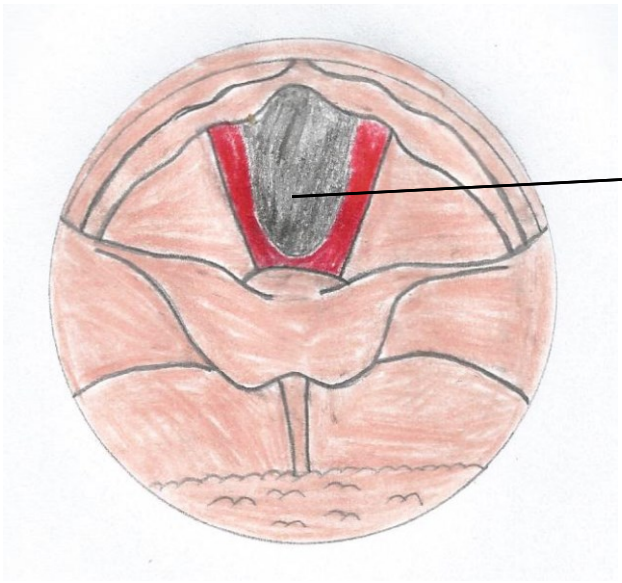


Fig. 5: VF during ventilation

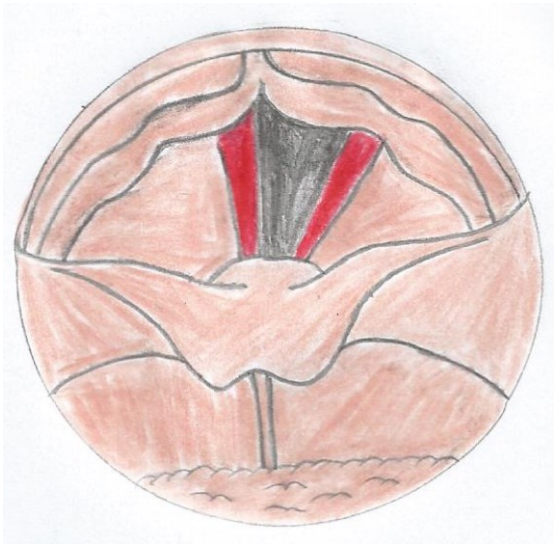


Fig. 6: Left-sided paralysed VF during phonation

Diagnostic

If a patient presents with voice disorder, such as hoarseness, it requires comprehensive diagnostic methods. It is important to find out the aetiology and to make a diagnosis, also for assessing the prognosis and the postoperative outcome. The methods should consider organic, functional, psychological and social aspects. To meet these necessary requirements, a thorough anamnesis, a precise examination of the vocal organs, an analysis of the voice itself and an assessment of the proper voice from the patient himself is indispensable.(1)

Anamnesis

Taking *patients history* is not only important for discovering the beginning of dysphonia, patients risk factors and other useful information about the disease, but also for the physician to get an idea about the patients voice, thus to assess it roughly.

Respiration

Even though good ventilation is necessary for a successful phonation, the evaluation of the *respiratory system* stands in the background of examinations.

Examination of the larynx

To *screen* the *voice organ* in the narrower sense, the larynx, two things should be considered. On the one side it is important to inspect and palpate it from the outside. On the other side, assessing the larynx from the inside is mandatory. Videostroboscopy has been established as a very good examination method to do so. Beside the appraisal of the laryngeal mucosa, it enables to see the rapid movements of the VFs by using synchronised flashes. These flashes show snapshots of different phases of consecutive VF movements and pretend to be one movement in slow motion. Of course there are also other possibilities to assess VF motility, but they could not assert themselves so far.

Examination of the voice

A speech therapist should perform a perceptual voice sound analysis with the help of the GRBAS scale or the alternative RBH scale in German speaking countries whereby roughness, breathiness and hoarseness of the *voice is assessed* according to a four-point scale (0 = normal – 3 = severe impairment). Furthermore *computer assist-*

ed measurements allow an objective evaluation of the voice by quantifying the frequency and amplitude fluctuation, jitter and shimmer respectively, and other parameters for instance normalized-noise-energy or harmonics-to-noise-ratio.

Patients self-assessment

Equally important as the methods mentioned above, is to appraise the degree of impairment of the patient in everyday life. In order to objectivise this, numerous questionnaires were created which all focus on intra-psychic, communicative and social factors. One process that has acquitted itself well is the “voice handicap index” (VHI). It contains thirty questions and the patient indicates how often he or she is affected by the given statement (0 = never – 4 = always). The disadvantage of this survey is the amount of questions. Hence Nawka has developed one, called “Stimmstörungsindex” (SSI), with only twelve questions but coming to similar results.(18) However, none of the existing questionnaires has accomplished to cover all aspects influencing the quality of life.

Indices

The single parameters of each method make it harder to assess the patient in his entirety. Therefore indices were developed. These incorporate some parameters and facilitate the holistic view. (1)(19)(20)(21)(22)(23)(24)

Therapy

As already mentioned previously, there are various causes, which can lead to UVFP. These may frequently occur together. Thereby, a multidimensional therapy and an individual adaption for each and every patient are inalienable. The two main domains are speech and language therapy and different phonosurgical methods. Besides those, in some cases psychotherapy and electromyostimulation can be required additionally. The latter is applied in early UVFPs and can support a re-innervation of the muscles.

The aim of speech therapy is not just the enhancement of the voice itself, but rather a holistic improvement of phonation by using different exercises. Consequently speech therapists intervene within the scopes, which are responsible for a perfect voice formation, thus, better self-awareness in relation to breathing, posture, phonation and articulation.(1)

According to the source-filter-theory, the VFs are the location where voice arises, but the vocal tract intensifies some frequencies and reduces others, thus lets the voice sound as it sounds. Nevertheless, *phonosurgery* pertains solely to interventions in the region of the VFs. For operations including also the vocal tract, the term *phonetosurgery* is used.(1)(25)

Phonosurgery does not mean a single operation technique, but it comprises various types of surgeries, which all have their purposes in common: recovery, improvement and maintenance of the voice.

Friedrich et al. distinguish four groups (25):

Vocal fold surgery

It involves all interventions on the vocal cords per se. Its primary goal is to preserve the capability to oscillate or to adjust the tension and position of the folds. One operation, which belongs to this category of phonosurgery and is often used in patients with UVFP, is VF augmentation by injecting various materials. The application composed of autologous fat, collagen, Calciumhydroxylapatite (CaHa), or hyaluronic is an established phonosurgical technique, which is performed also office-based without necessity of hospitalisation. Due to the injection, the VF increases and therefore the rima glottidis becomes narrower. The advantage of this procedure is its simple feasibility. But, since manipulation is directly at the VF, this can impair its structure and thereby its vibration.

Neuromuscular surgery

This type has different approaches. On the one hand it is used in patients with anomalous high tension of the vocal cords, suppressing the responsible nerves by resecting them or by injecting botulinium toxin for paralyzation may help. On the other hand, if the nerves are injured, thus the muscles immobile, as with UVFP, laryngeal re-innervation may be an option. There are diverse possibilities to reconnect the nerves, for example direct end-to-end anastomosis or nerve implantation. This method is the only one, which can possibly lead to an entire recovery of the muscular function. However, this is not very likely because a minimum amount of fibres are necessary to regain function. Another problem that can occur is that the different fibres of adductor and abductor muscles are not assorted, but spread all over the nerves. As a result of that, the adductor and abductor fibres may reconnect randomly.

Reconstructive surgery

By means of this surgery it can be able to restore the communicative abilities of the patient after the larynx was removed.

Laryngeal framework surgery

This refers to any operation on the laryngeal skeleton. The advantage of these techniques is its external access. This enables to adjust the position and tension of the VFs without injuring the VF tissue, thus without changing its ability to oscillate. They can be distinguish regarding to their functional aim:

- Approximation laryngoplasty, as its name implies, approaches the vocal cord to the median. Here in turn it is possible to differentiate arytenoid adduction and medialization thyroplasty (=Thyroplasty Type 1). Both are very important in the treatment of UVFP. In the former the distance to the median is decreased by rotating the arytenoid cartilage and thereby the processus vocalis inwards. At the medialization thyroplasty the entire VF is pushed in from lateral and hereby narrows the rima glottidis. Commonly used materials to push it in are titanium, gore-tex and silicone.
- Expansion laryngoplasty enlarges the gap between the VFs to improve the voice.
- Tensioning laryngoplasty increases the tension of the VFs, basically by extending the distance between processus vocalis and the thyroid cartilage. One technique to do so is the so-called cricothyroid approximation.
- Relaxation laryngoplasty has the converse effect to the previous by approaching the attachments to each other.

These previously mentioned methods, the surgical as well as the non-operative, do not exclude each other, but may rather be combined if necessary. Phonosurgery is just one component of the holistic treatment of UVFP and is not indicated before the nonsurgical procedures are totally exhausted.(1)(25)(26)(27)(28)(2)(29)

Materials & Methods

The data were gathered with the aid of the communication and information system MEDOCS. The parameters of the patients which met inclusion criteria, were collected retrospectively and inserted into an excel document. However, the analysation of the data was performed by means of the statistic and analyse software SPSS.

Statistical analyses

Initially the parameters have been evaluated concerning their frequency. Furthermore the metrically scaled data has been reviewed whether they were normally distributed or not with the aid of a Shapiro-Wilk test. When a normal distribution was detected, a t-test for dependent samples was performed to assess if there are significant differences between the pre- and postoperative data. If it did not reveal a normal distribution, Wilcoxon-signed-rank test was used.

A statistically significant difference between the parameters prior the operation and after it is defined as a significance value p lower than .05, and consequently the null hypothesis will be rejected, whereas if $p \geq .05$ the null hypothesis will be maintained.

Inclusion criteria

I included all patients, who underwent a titanium VF medialization in the last 15 years at the ENT-Department of the Medical University of Graz and appeared hereof in MEDOCS. Patients who received a different type of phonosurgery or whose VF was medialized by another material than titanium were excluded. Moreover, the cases in which the type of operation could not be identified with the help of MEDOCS, were not taken into account neither.

Usually TVFMI is only performed in patients with unilateral VF palsy. Nevertheless, paralysis of both sides was not assessed as exclusion criteria, as long as the other inclusion criteria were met.

Furthermore one more patient was excluded from calculations because of severe intraoperative complications. As a result of that, the operation had to be abandoned. However, this case will be elucidated more precisely later.

Patients

Altogether 116 patients met the inclusion criteria. However, on two of these patients TVFMI had to be performed twice. Each of those two were considered as two different cases. As a result of that, the total amount of cases is 118.

Of these 118 cases, 69 (58,5 %) were men and 49 (41,1 %) were women *(Table 1)*. The youngest patient was 14 years old, the oldest 83. The average age amounts to 54,55 years with a standard deviation of 15,499. 117 patients had a unilateral VF paralyses, hereof 73 (61,9 %) had an impairment of the left side and 44 (37,3 %) of the right side. This frequency distribution was to be expected because, like already mentioned previously, the left recurrent laryngeal nerve is more injury-prone than the right one. Only one patient (0,8 %) had paralyses of both VFs *(Table2)*.

The causes of the VF immobility were diverse. In 64 patients (54,2 %) the nerve got injured during one of the following surgeries. 36 (30,5 %) patients underwent a strumectomy, 21 (17,8 %) an intervention on the thorax, mainly pneumectomy or lobectomy, 6 (5,1 %) persons a neurological surgery, and one (0,8 %) was operated on the aorta. In 4 patients (3,4 %) the paralyses was associated with a tumour, in one person (0,8 %) bronchitis was attributed for the palsy and in 33 cases (28,0 %) other aetiology were found such as an insult or a trauma. 14 (11,9%) patients were subsumed idiopathic, because the underlying reason could not be found. In two patients (1,7 %) there were no causes documented in MEDOCS*(Table 3)*.

On average 67 months elapsed between diagnosis and TVFMI. The minimum time that passed, until an intervention was performed, was less than a month, the maximum was 540 months. In 18 cases there was no time documented, when the diagnosis was made *(Table 4)*.

19 patients (16,1 %) underwent a type of phonosurgery already before, two of them even thyroplasty type I, according to Friedrich, whereby one of those two additionally underwent VF augmentation. The VFs of the remaining 17 persons were augmented with various materials.

Only 13 patients (11,0 %) had to undergo further operations on the VFs, after having undergone a thyroplasty type I, 104 (88,1 %) did not and in one case it was not possible to find out.

Regarding the anaesthesia, 42 (35,6 %) underwent a general anaesthesia whereas 65 (55,1 %) patients were anaesthetised locally. In 11 cases in turn, no anaesthetic method was recorded.

The paralysed vocal cords can take up various positions. 14 (11,9 %) patients had a laterally positioned VF, 31 (26,3 %) an intermediate position, 52 (44,1 %) a paramedian and 2 (1,7 %) a median one. In 19 (16,1 %) cases the position was missing in MEDOCS.

		frequency	percentage
valid	male	69	58,5
	female	49	41,5
	total	118	100,0

Table 1: Gender

		frequency	percentage
valid	left	73	61,9
	right	44	37,3
	left & right	1	,8
	total	118	100,0

Table 2: affected side

		freuquency	percentage
valid	Struma surgery	36	30,5
	Thoracic surgery	21	17,8
	Vascular surgery	1	,8
	Neurosurgery	6	5,1
	Tumour	4	3,4
	Infection	1	,8
	Idiopathic	14	11,9
	Other reasons	33	28,0
	total	116	98,3
missing	-111	2	1,7
total		118	100,0

Table 3: Aetiology

N	valid	100
	missing	18
mean		67,24
median		20,00
modus		12
range		540
minimum		0
maximum		540

Table 4: months until TPL

Surgical methods

All surgeries followed the thyroplasty type 1 according to Friedrich. Yet, some of them were added by other methods. 73 (61,9 %) got merely a TVFMI, in 11 (9,3 %) patients a strip of Gore-Tex was inserted before the titanium implant, in 7 (5,9 %) patients it was combined with an arytenoid adduction, in 19 (16,1 %) patients with a cricothyroid approximation and in 5 cases (4,2 %) TPL was joined with arytenoid adduction and cricothyroid subluxation *(Table 5)*.

The skin is incised obliquely across the thyroid cartilage on the proper side. Further the prelaryngeal muscles, which cover the thyroid cartilage, have to be thrust aside, to visualise the cartilage. Then, depending how big the cartilage is, a 6x11mm window, usually in women's cartilage, or a 6x13mm, usually in men's cartilage, is cut (*Fig.7*). Now the titanium implant can be adjusted depending on anaesthetic procedure.

In cases in which the patients were operated in local anaesthesia, the adaption could be done under acoustic control, meaning that the patient had to talk while the surgeon put the titanium implant through the window. If the patient had a total intravenous anaesthesia, the position of the VF was assessed with the help of an endoscope.

Once the implant is in an appropriate position, it can be fixed with Gore-Tex sutures.

However, if this surgery does not achieve satisfying results, it can be combined with other. If medialization of the VF by TVFMI is insufficient, a strip of Gore-Tex can be inserted before implantation through the cartilage window (*Fig.8*).

Another way to reach a better medialisation of the VFs is arytenoid adduction. At this procedure a suture is threaded through the processus muscularis of the arytenoid cartilage and fixed ventrally. Thereby the processus vocalis moves inwards and the glottis becomes narrower.

Furthermore, to acquire a better tension of the vocal cords, there are two possibilities. On the one hand cricothyroid-approximation can be added. As its name implies, Gore-Tex sutures approach the cricoid and the thyroid cartilage to each other. On the other hand a so-called cricothyroid subluxation can be done. This procedure works similar as the prior mentioned one, but here the cornu inferius of the thyroid cartilage is sewed to the anterior-median part of the cricoid cartilage. As a result, the cricoid cartilage is pulled backwards and in further consequence the distance between the attachments of the VFs increases and tensions them.

		frequency	percentage
valid	TPL	73	61,9
	TPL + augmentation	11	9,3
	TPL + cricothyroid approximation	19	16,1
	TPL + arytenoid adduction	7	5,9
	TPL + arytenoid adduction + cricothyroid subluxation	5	4,2
	total	115	97,5
missing	-111	3	2,5
total		118	100,0

Table 5: surgical methods

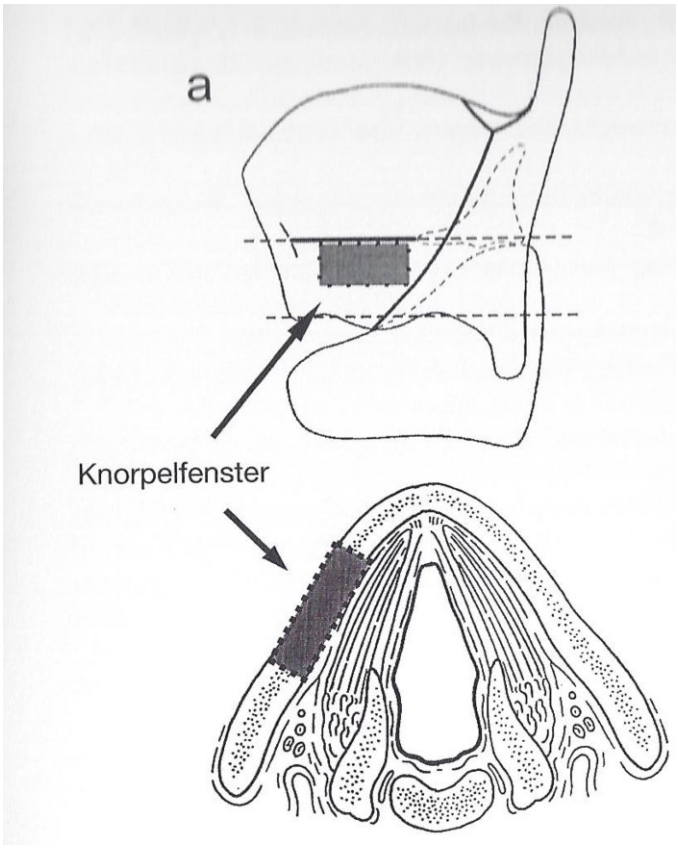


Fig. 7: Window in the thyroid cartilage

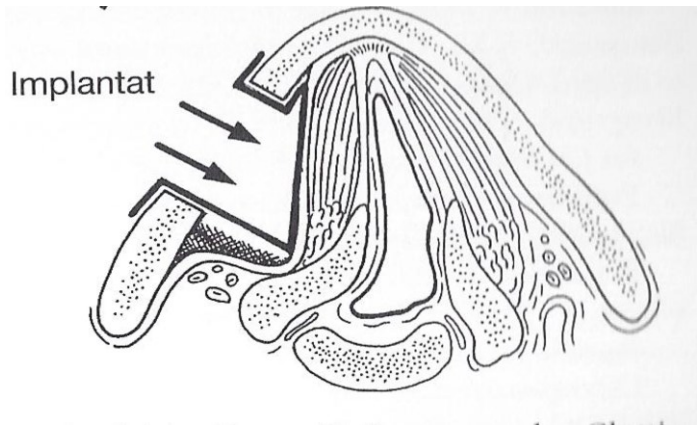


Fig. 8: Insterting the implant

Data

On one hand physicians and speech therapists examined the patients. On the other hand they had to assess their voice themselves as well by completing a questionnaire. Furthermore some of these results were summarised in one index. The parameters, which were ascertained for this work, are:

- name of the patient
- date of birth
- gender
- age at the time of the surgery
- interval between diagnosis and thyroplasty [in months]
- further VF surgeries before and after thyroplasty
- aetiology
    - thyroidectomy
    - interventions on the thorax
    - interventions on the vessels
    - neurosurgery
    - tumour
    - due to an infection
    - idiopathic
    - other reasons
- affected side
    - left
    - right
    - both-sided
- position of the affected VF
    - lateral
    - intermediate
    - paramedian
    - median
    - anaesthesia
    - general anaesthesia
    - local anaesthesia
- surgical procedure

    - TPL
    - TPL + strip of Gore-Tex
    - TPL + approximation
    - TPL + arytenoid adduction
    - TPL + arytenoid adduction + cricothyroid subluxation
- complications due to the surgery

The following parameters were all assessed pre- and postoperatively, if it was possible.

- SSI (Stimmstörungsindex)
- jitter
- shimmer
- frequency
- mean phonation time
- dysphonia index
- dysphonia severity index
- dysphagia

Results

SSI

Even though SSI is ordinally scaled, it is possible to look on it, as it was metrically scaled. Based on the fact that SSI is normally distributed in the Shapiro-Wilk test, a paired samples t-test was performed *(Table 6)*. In total the preoperative SSI of 48 (40,7 %) patients and the postoperative SSI of 47 (39,8 %) were available in MEDOCS. But there were only 33 (28 %) where the preoperative and the postoperative data were mentioned simultaneously in MEDOCS. Of these 33 patients the mean preoperative SSI came to 29,27 whereas the postoperative was 15,52. The performed paired samples t-test showed that there was a significant difference between those two ($p < .000$), consequently the null hypothesis has been rejected *(Table 7)*.

Jitter

The Shapiro-Wilk test revealed that the preoperative as well as the postoperative Jitter were normally distributed *(Table 6)*. Overall in 85 cases (72,0 %) the preoperative Jitter and in 30 (25,4 %) cases the postoperative Jitter could be ascertained. In 23 patients (19,5 %) both were documented. The preoperative mean was 4,84% and the postoperative 3,38%. So there was an improvement after the operation, but according to the dependent t-test, the improvement was not significant ($p = .144$) *(Table 7)*.

Shimmer

Also Shimmer was distributed normally. 86 times (72,8 %) preoperative Shimmer was documented and 30 times (25,4 %) the postoperative. In 23 patients (19,5 %) in turn both were mentioned in MEDOCS, with a preoperative mean of 12,02% and a postoperative of 11,11%. Due to its distribution *(Table 6)*, a paired samples t-test was performed here too, which could not prove a significant improvement between pre- and postoperative values ($p = .749$) *(Table 7).*

MPT

According to Shapiro-Wilk test, the preoperative MPT values were normally distributed, however the postoperative were not. In 106 (89,8 %) patients the MPT has been measured preoperatively, in 35 (29,7 %) postoperatively and only in 31 (26,2 %) patients both times. The preoperative mean was 6,77 seconds and the postoperative median was 11,23 seconds. Since both, the preoperative and the postoperative val-

ues were normally distributed *(Table 6)*, t-test has been performed. This showed that there was a significant increase of the MPT after surgery ($p < .000$) *(Table 7)*.

Pitch of the sound

The Shapiro-Wilk test proved a normal distribution in the preoperative as well as in the postoperative F0 *(Table 6)*. In 102 (86,4 %) cases it could be ascertained preoperatively and in 33 (28,0 %) postoperatively and in 27 (22,9 %) pre- and postoperatively coincidently. The preoperative mean came to 171,56 Hz and the postoperative to 170,67 Hz. Thereby both, pre- and postoperative, values were normally distributed t-test has been performed. This test did not show a significant difference between the pre- and postoperative mean pitches ($p = .864$) *(Table 7)*.

Dysphonia index

Neither the preoperative results nor the postoperative DI values were normally distributed *(Table 6)*. 81 (68,6 %) preoperative data, 32 (27,1 %) postoperative and 21 (17,8 %) pre- and postoperative data were available. The Wilcoxon signed-rank test displayed a significant difference between the data before and after the thyroplasty *(Table 8)*.

Dysphonia severity index

According to the Shapiro-Wilk test, the DSI prior and after thyroplasty was normally distributed *(Table 6)*. Of 75 (63,6 %) patients preoperative measured data were documented, of 28 (23,7 %) patients postoperative, and of 19 (16,1 %) patients, data were noted before and after the surgery. The preoperative midpoint was 2,16 and the postoperative median was 3,29, thus improved. However, the t-test could not show a significant improvement between these two results ($p = .079$) *(Table 7)*.

Swallowing disorders

Before the surgery swallowing disorders has been noted in 18 (15,3 %) cases, in 94 (79,7 %) no complaints were documented and in 6 (5,1 %) cases concerning this no information were available. After the operation only 2 (1,7 %) patients remained, in which dysphagia was particularly documented in MEDOCS, but even in those two patients an improvement was mentioned. In the other 16 (13,6 %) with preoperative complaints, postoperatively nothing has been noted. The patients without preoperative swallowing disorders still did not have any troubles with it.

Complications

In 111 (94,1 %) cases it was documented if there was a complication or not, 7 (5,9 %) entries to it were missing. In 90 (76,3 %) cases the operation went according to plan, whereas 21 (17,8 %) times a complication occurred.

The most frequent complication was a slight swelling in the range of the arytaenoid cartilage and the outer wound. 9 patients (7,6 %) had this complication. 5 persons (4,2 %) got merely a bruise on the skin, two (1,7 %) however had a haematoma on the VF. One (0,8 %) got suddenly dyspnoea because of a temporary lung oedema. Another patient had a laryngospasm during the operation. The remaining three (2,5 %) patients had either thrombophlebitis, alternating voice or a haematoma with slight swelling of the skin. But in all this cases the operation could be finished and the implant remained until they could leave the hospital. However, in a few cases the TVFMI might be explanted later on.

In one case the operation had to be abandoned because of complications. But this case is not included into the calculations and will be treated later.

Tests auf Normalverteilung

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	statistic	df	significance	statistic	df	significance
SSIprä	,228	5	,200*	,844	5	,177
SSIpost	,246	5	,200*	,892	5	,368
Jitterprä	,220	5	,200*	,913	5	,486
Jitterpost	,164	5	,200*	,967	5	,857
Shimmerprä	,147	5	,200*	,993	5	,990
Shimmerpost	,261	5	,200*	,883	5	,324
F0prä	,300	5	,162	,899	5	,403
F0post	,298	5	,169	,781	5	,056
MPTprä	,228	5	,200*	,936	5	,636
MPTpost	,341	5	,058	,787	5	,063
DIprä	,473	5	,001	,552	5	,000
DIpost	,473	5	,001	,552	5	,000
DSIprä	,281	5	,200*	,915	5	,499
DSIpost	,224	5	,200*	,901	5	,414

*. Lower limit of significance;

=normally distributed

a. significance correction Lilliefors

Table 6: standard distribution

Test for paired samples

		Paired differences					T	df	Sig. (2-sided)
		mean	Standard deviation	standard error of the mean	95% confidence interval of the difference lower	upper			
pair 1	SSIprä - SSIpost	13,758	11,715	2,039	9,603	17,912	6,746	32	,000
pair 2	Jitterprä - Jitter-post	1,47130	4,65864	,97139	-,54324	3,48585	1,515	22	,144
pair 3	Shimmerprä - Shimmerpost	,90870	13,42369	2,79903	-4,89614	6,71353	,325	22	,749
pair 4	F0prä - F0post	,889	26,617	5,123	-9,641	11,418	,174	26	,864
pair 5	MPTprä - MPT-post	-4,452	3,749	,673	-5,827	-3,076	-6,611	30	,000
pair 6	DSIprä - DSIpost	-1,13121	2,65133	,60826	-2,40911	,14669	-1,860	18	,079

= significant difference

Table 7: paired sample t-test

Statistic for test[a]

	DIpost - DIprä
Z	-3,699[b]
Asymptomatic significance (2-sided)	,000

a. Wilcoxon-test

b. based on positive ranks

= significant difference

Table 8: Wilcoxon-test

Discussion

Summary

The Shapiro-Wilk Test revealed that all parameters, except the Dysphonia Index (DI), were normally distributed. As a consequence only in case of the DI a Wilcoxon-Rank-Sum-test has been performed. The result of this procedure was a significant difference ($p < .000$) between the values prior and after the operation.

In all the other cases, a paired samples t-test was performed, which came to various results. Even though all the parameters improved after the operation not all of them show significance. For SSI ($p < .000$) and MPT ($p < .000$), on the one hand, significant improvements could be shown, on the other hand for Jitter ($p = .144$), Shimmer ($p = .749$), F0 ($p = .864$) and DSI ($p = .079$) no significant difference could be proven.

Limits of the report

The sample size of 118 patients would basically be enough to make a clear statement of the benefit of TVFMI. But the retrospective study also brought along some disadvantages. Only those parameters could be utilised which were available in MEDOCS, thus the validity of the results is dependent on how many parameters of each patient were documented.

The number of patients with preoperatively listed SSI was 48 (40,7 %), Jitter 85 (72,0 %), Shimmer 86 (72,9 %), F0 102 (86,4 %), MPT 106 (89,9 %), DI 81 (68,6 %) and DSI 75 (63,6 %). This may have different reasons. For one thing some parameters were not ascertained routinely. For another thing, if the voice of the patient was too poor before the operation, some parameters could not be measured. Furthermore it has to be considered that some parameters, particularly SSI, require a certain speech comprehension.

The number of patients with postoperatively documented SSI, Jitter, Shimmer, F0, MPT, DI and DSI was 47 (39,8 %), 30 (25,4 %), 30 (25,4 %), 33 (28,0 %), 35 (30,0 %), 32 (27,1 %) and 28 (23,7 %) respectively, so an even lower number of documented values than preoperatively. In addition to the previously mentioned causes other factors can be added. Firstly, the patients may be passed away in the intervening time. Secondly, the patients might be satisfied with their voice postoperatively and did as a consequence not urge to come to the follow-up examination. Due to this aspect the improvements of the voice in this study might be lower after thyroplasty than they are in actual fact.

Moreover, it is to emphasize that only those values of a patient were considered in the dependent t-test or Wilcoxon-Rank sum test, which were simultaneously documented prior *and* after the operation. Even though the sample size was big, on average only for 25 people (21,1 %) the pre- and postoperative parameters were concurrently documented. These are the reasons why the results may be treated with caution.

Relevance of the results

As already mentioned previously it is inalienable that the patient assesses his voice him-/herself. Eventually it is with no importance whether Jitter, Shimmer or any other objective parameter have improved after the operation, if the patient himself does not perceive his/her own voice as better. Therefore the VHI has been created, aiding the patient when having to rate his/her own voice. This questionnaire has been translated into German from Nawka without deficiency of its validity. In further consequence he amended it insomuch that only 12 questions remained instead of the previous 30. As a result the SSI was developed, whose handling was much more convenient in the clinical daily routine. Furthermore in another report Gugatschka proved that it is possible to convert SSI score into VHI score by multiplying it with the factor 2,5. This fact enables to compare those two parameters with each other.(30)(18)

The dependent t-test showed that there was a significant difference between preoperative and postoperative measured SSI. On average the preoperative SSI was by 13,76 points higher than the value after surgery. Given the fact that a lower value of the SSI is a better score when patients assesses their voice themselves, a difference of -13,76 points is equal to an improvement.

But as a result of its subjectivity, it is difficult to evaluate if the idem difference is high or low. In the same publication in which Nawka translated the VHI, he writes that a significant alteration exists starting with a difference of 18 points or more between two scores. To receive the analogue relevant value in SSI Score, it is necessary to divide 18 by the factor 2,5, determined by Gugatschka. Doing this we reach the result of 7,2 points. Since thyroplasty exceeds this result by far in this study, it is possible to conclude that an average difference of -13,76 before and after the surgery is not only significant but also relevant.

MPT prolonged from a mean value of 4,45 seconds preoperatively to an average of 11,23 seconds as a result of the operation, being just over the pathological limit of 10 seconds.(31) Consequently TVFMI caused an essential improvement here too.

Even though both, DI as well as DSI, are indices they consist of various parameters. While DI has improved due to the operation DSI did not. Which initially sounds a little bit curious, has a simple reason. Each index includes different parameters.
At DSI the MPT, the lowest intensity, the highest frequency and Jitter are added together, whereas each of them is multiplied by a different constant factor. DI on the contrary, considers the hoarseness, the vocal range, the communicative impairment and the dynamic of the voice, thus the difference of sound intensity between the most silent and the loudest voice of the patient. (24)
Consequently DI assesses subjective parameters as opposed to DSI, which only considers objective ones. And since in this study the subjective SSI improved significantly while the most impartial parameters did not, it makes sense why DI is significantly better after surgery and DSI is not.

Excluded patient

In my report there was one patient who had to be excluded, even though she met all the criteria. The patient was a 71-year-old woman who had left-sided VF palsy after a lobectomy, in which apparently the left recurrent laryngeal nerve has been injured. The VF was in a paramedian position. The woman did not complain about dysphagia. To narrow her rima glottidis, the surgeon decided to applicate hyaloronic acid. Obviously this intervention did not lead to satisfying results. Prior the attempt of inserting titanium implants her SSI, MPT, F0 and DI amounted to 24 points, 2 seconds, 196 Hz and 1,6 points respectively. Accordingly the decision was made to additionally medialize the vocal cord with the aid of a titanium implant. But during the operation a respiratory failure occurred, thus the surgery had to be discontinued before completion. According to MEDOCS no further laryngeal surgeries for voice improvements were performed.
To sum up, the patient met the necessary requirements to be included. However she was not included because finally she did not get the titanium implant due to severe intraoperative complication.

Comparisons to other studies

Other studies showed an improvement of various voice parameters after inserting a titanium implant too. Two of them are briefly elucidated here:

- Schneider-Stickler et. al published a long-term study in February 2013 in which they examined 33 patients, who underwent a thyroplasty with TVFMI.

The screening took place at first before operation, the second time about eight weeks and the third time at least one year, with an average of 57 months, after surgery. Perceptual, acoustic, aerodynamic and laryngoscopic parameters were assessed. The majority of the parameters improved significantly at the first postoperative check-up and remained the same at the second one, with some even getting better over time. The aerodynamic tests did not show any postoperative impairment of respiration. However, this study did not consider any subjective parameters in which the patients had to rate themselves like SSI and VHI.(32)

- In another report from Schneider et. al from 2003, 28 patients were included, who were operated between 1999 and 2001. Similar examinations were performed pre- and postoperatively and reached similar results as the study previously mentioned, with the difference, that additionally dysphagia was assessed by asking the patient. 22 of them had preoperative complaints whereas postoperatively only four patients continued to express dissatisfaction about dysphagia. Furthermore the patients were asked to report if they perceived any difference related to their voice or breath after the surgery. These results improved in this study too.(28)
- Further studies were published in which the titanium implant has been compared to implants from other materials such as hydroxyapatite or silicone. The implantation of all these materials achieved improvements in various voice parameters, but in some of them, titanium has achieved even better results than the other two. However not all of these differences were significant.(33)(34)

Advantages of TVFMI

TVFMI has several advantages, not only when compared to other materials, which are used for medialization but also because of its simple and effective operation technique. Due to the fact that the implant is inserted from the outside of the larynx, thus medializing the VF from exterior, the VF tissue remains uninjured. Thereby the oscillating attitudes can be preserved and consequently the objective as well as the subjective voice parameters will be better. The possibility to anaesthetise the patient only locally enables in further consequence to assess the speaking of the patient intraoperatively. Herby the implant can be positioned optimally. Furthermore, the technique does not require any expensive tools and is timesaving. Because of the architecture of the implant, a slipping out of position is barely possible. But to be on the

safe side the implant is additionally attached by non-absorbable sutures as well.
The material has advantages as well. Titanium is an inert material; hence it does not provoke any inflammatory response. Based on its plasticity, it is able to adjust it to each and every thyroid cartilage. And even though it is almost as robust as iron, its weight amounts only half as much. Aside from that it is not ferromagnetic, consequently the implant is suitable for magnetic resonance imaging. This radiologic examination has increasingly gained importance over the last years concerning the detection and diagnoses of other diseases and is thereby of great advantage for the patient. (32)(28)(35)

Summary

In summary, all ascertained parameters in this report improved due to the titanium vocal fold medialization implant (TVFMI). However, only some of them were significantly better, with subjective parameters leading the way. As already mentioned previously, these subjective parameters are finally determined whether the patient him-/herself is content and satisfied. Moreover there are various other studies, which do not only show an improvement in objective procedures but also a slight benefit to other operation techniques and other materials. All these reasons confirm that TVFMI-Thyroplasty is an outstanding procedure to treat patients with dysphonia due to a unilateral VF paralyses.

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Fig.7: Friedrich G, Bigenzahn W, Zorowka P, Brunner E, editors. Phoniatrie und Pädaudiologie: Einführung in die medizinischen, psychologischen und linguistischen Grundlagen von Stimme, Sprache und Gehör. 3., vollst. überarb. Aufl. Bern: Huber; 2005. 490 p. (Programmbereich Gesundheit).page 127

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