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International consensus

International consensus (ICON) on basic voice assessment for unilateral vocal fold paralysis

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ABSTRACT

There is a growing need for evaluation tools allowing the quantification of the outcome after voice surgeries. Since the end of the 1990s, multiple unfruitful attempts have been made to reach a consensus, including the Dejonckere protocol for the European Laryngological Society in 2001. This suggested to perform objective and quantifiable measures in the following domains: perception, acoustic, aerodynamic, self-evaluation by the patient and videolaryngostroboscopy. But in a PubMed® search with the keywords "Voice Assessment" and "Voice Outcome" since 2001 retrieving 452 articles, only 33 of them were using methods taking into account the first four dimensions proposed by Dejonckere. To elaborate a new and simpler protocol, we chose to focus on unilateral vocal fold paralyses (UVFP), which represents a homogeneous disease in terms of physiology. This protocol was elaborated on the basis of a review of the literature and of the database and experience of the IFOS panel members. In summary, our group recommends the use and implementation of the ELS "basic protocol" with some minor modifications. Voice audio recordings are an indispensable prerequisite, and may even have medico-legal implications. We recommend the systematic use of the Voice Handicap Index (VHI). Perceptual analysis must be performed by using Hirano's GRB scale and voice breathiness has to be prioritized. Currently, acoustic analysis remains optional given the lack of data to support clinical usefulness. Aerodynamic studies should include at a minimum an evaluation of the Maximum Phonation Time, calculated in seconds following multiple trials in order to obtain a recording representing the patient's best possible glottis closure.

1. Introduction

The growing need for evaluation tools allowing for the quantification of the outcome after voice surgeries is pushing clinicians to adopt new instruments proposed by researchers. However, interpretation of these results remains difficult, due in part to deficient clinician experience but also to the often-lacking scientific foundation on which these tools were created. Since the end of the 1990s, multiple unfruitful attempts have been made to reach a consensus [Denver consensus organized by Titze [1]; Dejonckere protocol for the European Laryngological Society [2], multi-parametric protocol presented by Giovanni [3]. Currently, two relevant groups exist: the Special Interest for Voice and Voice Disorders group of the American Speech-Language-Hearing Association (ASHA) [4] and the Speech-Language-Pathology committee of the European Laryngological Association.

In parallel, the Working Group of Clinical Voice Assessment was founded in 2007 by the ASHA's executive committee, under the

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chairmanship of Robert Hillman. This group's work was reported in 2009 in the American Journal of Speech Language Pathology [5]. It consisted of a meta-analysis reviewing 1077 articles published since 1930, with only 100 articles deemed adequate based on clarity and pertinence of the methodology employed. Amongst the selected papers, only 18 were dedicated to the evaluation of the severity of the vocal disorder. All papers relied on the analysis of acoustic measures (18/18), with a majority also evaluating perceptual measures (13/18).

Despite these efforts, no universal consensus exists today regarding the appropriate methodology for voice analysis, rendering the realization of a meta-analysis grouping multiple papers on laryngology and speech language pathology subjects difficult. For this reason, the IFOS board has asked us to organize a round table to address this topic during the 2017 IFOS World ENT congress. We focused our efforts on reviewing existing protocols and reflecting on, in our opinion, their insufficient utilization.

2. The European Laryngological Society (ELS) guideline (Dejonckere protocol)

A few basic principles were followed:

- given that voice is a multidimensional phenomenon [6], it is recommended to perform multiple types of measurements, which each having its specific purpose. Indeed, for some patients results can vary from one dimension to the other [7]. Therefore, results of combined scores or pooled results should be interpreted with caution;
- if perceptual measures must be published, the authors of the guideline recommend the presence of blinded jurors and the use of averaged results;
- a vocal audio recording is an indispensable prerequisite. The authors recommend a sampling frequency of at least 20 kHz, a fixed mouth-microphone distance of 10 cm and, if possible, with the microphone placed away from the mouth's axis in order to avoid interfering aerodynamic noise [1,8]. It was recommended to record a sustained/a/sound at a comfortable intensity level, followed by a slightly louder/a/sound, then a short text or sentence, and finally a sentence without voiced breaks and therefore without fricative sounds;
- in terms of "common" dysphonias, in other words excluding neurological causes or substitution voicing, it was suggested to perform objective and quantifiable measures in the following domains: perception, videolaryngostroboscopy, acoustic, aerodynamic and self-evaluation by the patient;
- in clinical practice, this is therefore the suggested protocol:
  - perceptual testing: G, R, B from Hirano's scale,
  - videolaryngostroboscopy,
  - aerodynamic studies: phonation quotient and maximum phonation time,
  - acoustic analysis: jitter (%), shimmer (%), vocal range (semitone), minimal intensity at 30 cm,
  - subjective evaluation by the patient using a double Visual Analog Scale (voice quality, social impact).

We wanted to know if the "basic protocol for functional assessment of voice pathology" [2] was used in clinical practice. To this end we performed a PubMed search with the keywords "Voice Assessment" and "Voice Outcome" since 2001. We retrieved 452 articles that fulfilled these criteria. If we disregard laryngostroboscopy which is not the goal of our present work, 33 articles were using methods taking into account the 4 dimensions proposed by Dejonckere, with 3 articles ranked as grade A and 16 as grade B. These articles are described in Table 1 [9–27].

However, heterogeneity becomes apparent when examining the details of the proposed protocol. We therefore believed that it is sound to question the pertinence of this protocol.

3. Unilateral vocal fold paralysis as our choice for patient population

Unilateral vocal fold paralyses (UVFP) represent an ideal patient population to validate a protocol of measures aiming to assess voice outcomes following a therapeutic intervention. Indeed, UVFP is a uniquely homogeneous disease in terms its physiology and biomechanics. Furthermore, multiple competing treatment modalities exist with lacking comparative studies in the literature. It is for this patient population that Philippe Dejonckere regretted most not having an established universal protocol. The group chose to initially focus their attention on this particular clinical scenario in order to delineate markers of voice evolution both before and after treatment.

Dysphonia secondary to a UVFP is due to a lack of vocal fold tension and an insufficient glottis closure during phonation (glottic gap) that can be more or less pronounced (Fig. 1). It is therefore logical to expect a significant dysphonia corresponding to glottic air leakage during phonation, in conjunction with vibratory instability secondary to asymmetric vocal fold tension. Vibratory anomalies can be highlighted by variations in frequency or amplitude by using various methods (jitter, shimmer, non-linear methods), while the breathy nature of the voice will be better underscored with spectral analyses, in particular the signal-to-noise ratio. Direct measurement of the amount of glottis air leakage can be done by computing buccal airflow during phonation, or it can be approximated by measuring the maximum phonation time, even though this test can be influenced by respiratory function. These tests are described in detail in two reference articles [28,29]. In general the voice

Table 1
Articles ranked as grade A or B using the various dimensions of the ELS protocol.

	[9]	[10]	[11]	[12]	[13]	[14]	[15]	[16]	[17]	[18]	[19]	[20]	[21]	[22]	[23]	[24]	[25]	[26]	[27]
Recommendation grade	A	A	A	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
Videolaryngostroboscopy	x	x		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Perceptual																			
G	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
RB	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Aerodynamic																			
MPT	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
PQ			x	x															
Acoustic																			
Jitter	x	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x
Shimmer	x	x	x	x	x		x	x	x	x	x	x	x	x		x	x	x	x
Range	x	x	x		x	x		x	x				x	x	x	x			
Intensity		x	x			x		x	x	x		x	x	x		x			
Self-evaluation	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x

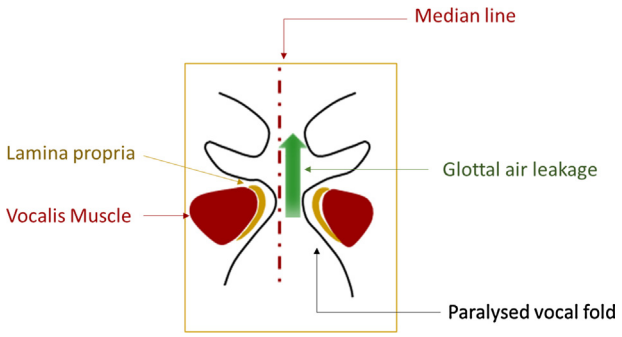

Fig. 1. Dysphonia secondary to a UVFP is due in part to insufficient glottic closure that can be more or less pronounced.

is found to be of weak intensity. Interestingly, quantification of the amount of air leakage during laryngostroboscopy seemed not reliable [30–32]. Regardless, laryngoscopy remains an important evaluation tool recommended by both the ELS protocol and the American Academy of Otolaryngology, and its realization should not be challenged [33].

4. Our study

We hereby present the results extracted from the analysis of the database belonging to one of the groups of the panel (A Giovanni, A Mattei and M Roux). From January 2013 to Mai 2016, we collected data from 153 patients (75 men and 78 women) followed for a UVFP not previously treated. The etiologies were grossly as follows: 30% idiopathic, 32% post-thyroid surgery and 30% post-thoracic surgery. Exclusion criteria included patients with an underlying neurological or medical etiology.

Perceptual analysis was performed by 3 experienced speech-language pathologists with over 5 years of experience in our department. The G, R and B items of Hirano's scale were analyzed on a scale ranging from 0 to 3. Each speech-language pathologist interpreted the audio recordings separately. The audio recordings used for perceptual analysis were taped with the following material:

- AKG C4000 B Microphone (Germany);
- numeric-analog convertor RME Fireface UC (Germany);
- analysis software and signal edition: Praat;
- focal XS Book Music System speakers (France) situated at 50 cm from the auditor in a quiet room.

Table 2
Data from the perceptual analysis. For each grade G, R and B, patients are distributed from 0 to 3 according to the severity of their dysphonia for each parameter. In parenthesis in the 2nd column is the number of patients prior to the application of exclusion criteria, with the G grading being performed during the initial consultation.

	G	R	B
0	0 (0)	2	6
1	15 (39)	26	23
2	38 (75)	33	31
3	26 (39)	17	18
Not analyzed	–	–	1
Total analyzed	79 (153)	79	78

We excluded recordings that had incoherent grade G and B assessments from the various members of the jury. In fact, our goal was to obtain sufficiently proto-typical voices in order to render future comparison with objective measures useful. We retained a total of 78 recordings from those collected, the findings of which are outlined in Table 2. Of note, none of the patients were graded as G0. The fact that the examiners were aware of the diagnosis and the objective of our study is a potential bias and limitation of our project.

The comparative analysis of G, R and B results is illustrated in Fig. 2 and demonstrates that the G grade is not an independent criterion from B and R. It seems that G grading is strongly linked to elevated B and R scores. In other words, a patient classified as B3R2 and a patient classified as B2R3 will both end up being classified as G3. For this reason, we will favor the B grade for the remainder of our study and for the final proposed protocol.

Objective acoustic and aerodymanic measures were recorded with the EVA apparatus EVA [34]. We describe in Table 3 the results of these measures in correlation with the perceptual B grade.

We also analyzed Voice Handicap Index (VHI) data as it relates to G grading. Indeed, we decided to compare a global subjective evaluation (VHI) with a global perceptual evaluation by using the

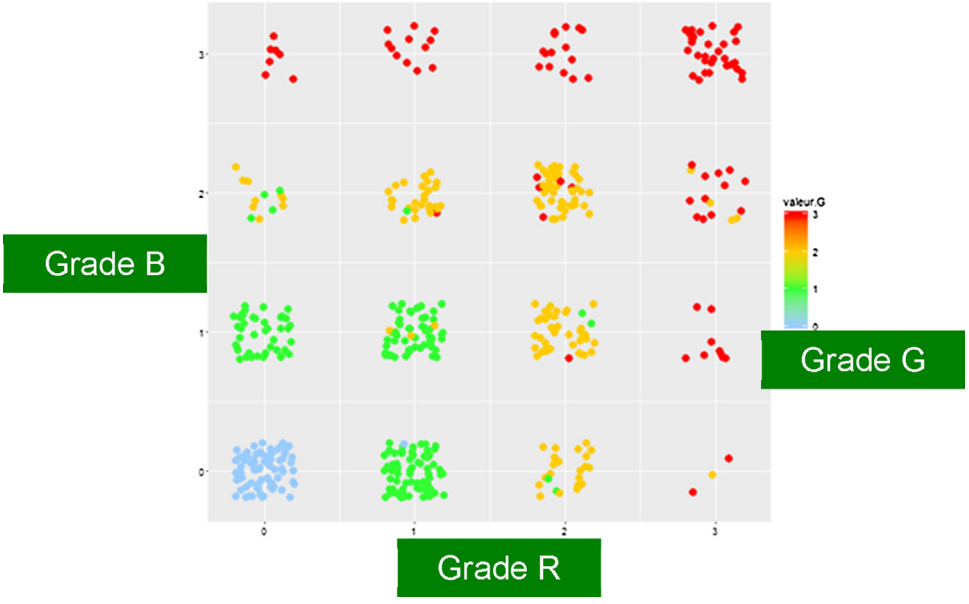

Fig. 2. Distribution of patients according to G, R and B grades. One point represents 1 patient. The axis of abscissas shows the grade R from 0 to 3. On the Y-axis, the grade B from 0 to 3. One color is assigned to each patient according to the grade G: blue for 0, green for 1, yellow for 2, red for 3.

Table 3
Data from objective analysis: comparison of various acoustic parameters between grades B0, B1, B2 and B3.

	B0	B1	*P*	B2	*P*	B3
BA	148 (88)	226 (72)	0.01	263 (201)	0.04	496 (241)
MPT	10.7 (5.1)	9.5 (4.6)	0.01	5.9 (3.3)	0.05	3.6 (3.2)
Jitter	0.38 (0.16)	0.81 (0.76)	<0.01	1.5 (1.1)	0.15 (NS)	1.9 (0.95)
SNR > 1 kHz	76 (10)	64 (21)	<0.01	48 (24)	0.01	30 (14)

BA: buccal airflow; MPT: maximum phonation time; SNR: signal to noise ratio > 1 kH. Statistical significance defined as $P < 0.05$. Because of the small number of B0 cases it was judged meaningless to compare B0 vs. B1.

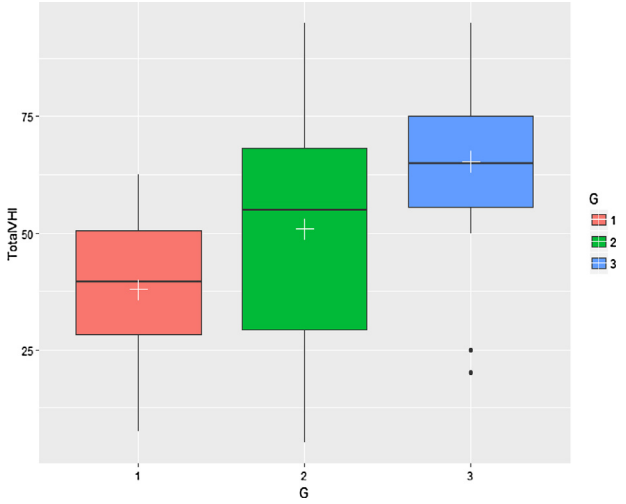

Fig. 3. Correlation between VHI and G grade. The axis of abscissas shows grade G (G1, G2, G3 from left to right). On the Y-axis, the VHI (Voice Handicap Index).

Table 4
Data from the perceptual and objective analyses of a series of 75 patients operated in Marseille for Montgomery Implant placement.

	Preoperative Mean (standard deviation)	Postoperative Mean (standard deviation)	*P*-value	*n* (/75)
G	2.5 (0.7)	1.6 (0.7)	<0.01	43
B	2.2 (0.9)	1.2 (0.9)	<0.01	43
VHI-30 (/120)	69.6 (25.2)	21.6 (22.4)	<0.01	36
Self-evaluation (Dejonckere/10)	6.7 (2.1)	3.5 (2.5)	<0.01	34
BA (cm^3/s)	605 (317)	351 (161)	<0.01	45
MPT (s)	5 (3.5)	8 (6.2)	<0.01	53
Jitter (%)	2.3 (2.3)	0.8 (0.6)	<0.01	50
SNR (dB)	10 (6.5)	14 (5.2)	<0.01	51

BA: buccal airflow; MPT: maximum phonation time; SNR: signal to noise ratio > 1 kH. Statistical significance defined as $P < 0.05$. The N column states the number of patients for which the analysis was performed. This is non-published data.

G grade. These results are illustrated in Fig. 3. Mean VHI scores were 38% for grades G1, 51% for grades G2 and 65% for grades G3.

These findings confirm the pertinence of Dejonckere's evaluation strategy. In order to validate the usefulness of the protocol in serving the Voice Outcome Index, we applied the same protocol on a series of 75 patients who had undergone surgery for Montgomery implant placement. Of note, some of these patients were also included in the initial patient database.

The results are in the following Table 4.

These results can be instructively compared to a second series from another group forming the panel (G. Desuter) (Table 5).

Table 5
Data from the perceptual and objective analyses of a series of 48 patients operated in Brussels for Montgomery Implant placement between 2003 and 2010.

	Preoperative	Postoperative	*P*-value
	Median [P_{25}–P_{75}]	Median [P_{25}–P_{75}]	
G	3 [3; 3]	1 [1; 1]	<0.001
B	3 [3; 3]	1 [1; 1]	<0.001
VHI-30 (/120)	94 [78; 103]	28 [13.2; 50]	<0.001
MPT (s)	6.5 [4.8; 8.0]	11.5 [9.5; 16.3]	<0.001
Jitter (%)	4.10 [3.10; 5.68]	1.48 [0.90; 2.38]	<0.001

MPT: maximum phonation time; SNR: signal to noise ratio > 1 kH). Statistical significance defined as $P < 0.05$. This is non-published data.

5. The final protocol

In summary, our focus group recommends the use and implementation of the "basic protocol" brought forth by the ELS with some minor modifications. We recommend the systematic use of the Voice Handicap Index (VHI) in order to better evaluate the clinical situation and the severity of the patient's voice quality of life. It is also possible to ask the patient to rate his/her voice quality by using a visual analog scale. Other questionnaires (VoSS, SF36, EASE) can be used as adjuncts.

Perceptual analysis must be performed by using Hirano's GRB scale. No definitive proof exists regarding the increased pertinence of a visual analog scale compared to the standard 0/1/2/3 scale, but both methods can be employed. Judgment regarding voice breathiness is to be prioritized. Voice audio recordings are an indispensable prerequisite, and may even have medico-legal implications. When voice is evaluated in the post-operative setting, it is preferable to have an examiner blinded to the patient's history.

Currently, acoustic analysis remains optional given the lack of data to support clinical usefulness. The examiners' report will vary based on personal experience. Regardless, acoustic analysis should not replace a voice audio recording, even when taking into account individual perceptual judgment variability. To date, no proof exists regarding the ability of acoustic analysis to adequately summarize a patient's vocal profile. Future studies examining this topic are required.

Aerodynamic studies should include at a minimum an evaluation of the Maximum Phonation Time, calculated in seconds following multiple trials in order to obtain a recording representing the patient's best possible glottis closure. Calculating buccal airflow by using an aerophonometer is an additional investigation that can be considered. However, this requires a specialized instrument not readily available in most centers. Using a spirometer to measure Vital Capacity and estimate the Phonatory Quotient is another test that can be considered.

Therefore, by using the protocol, we were able to compare two series of patients operated for Montgomery implant placement originating from two centers that participated in the round table discussion. The results were absolutely conclusive.

Disclosure of interest

The authors declare that they have no competing interest.

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