Manuscript Details

Manuscript number	ANL_2018_656_R3
Title	Application of Ambulatory Phonation Monitoring (APM) in the measurement of daily speaking-time and voice intensity before and after cochlear implant in deaf adult patients
Article type	Original article

Abstract

Objective: to evaluate the changes in daily voice production, analysed through the Ambulatory Phonation Monitoring (APM), and their relationship with Quality of Life (QOL) measurements in a group of profound deaf patients treated with Cochlear Implant (CI) Methods: A total of 12 consecutive post-lingual deaf patients (8 females and 4 males) treated with CI for bilateral severe-to-profound hearing loss were enrolled. Each patient was evaluated before and after 6 months of CI use. In particular, the daily voice production evaluation was performed using the APM, while QOL information were gathered from the Italian version of the Nijmegen Cochlear Implant Questionnaire (I-NCIQ). Results: significant differences in the APM results obtained before and after CI were found. In particular, a significant decrease of the mean amplitude and a significant increase of the daily phonation time and percentage of phonation time were demonstrated after CI use in all the patients. A significant improvement in the I-NCIQ scores was demonstrated after CI use and significant correlations among I-NCIQ scores and the APM parameters were found. Conclusions: the APM could be useful in the evaluation of the benefits of cochlear implantation and may represents an indicator of deaf patient participation. In addition, the daily voice production's modifications after CI and their significant relations with the changes in QOL measurements could be useful in treatment planning as well as during pre- and post-operative counselling.

Keywords	cochlear implant; voice; QOL; APM
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Dear Editor Please find enclosed the revised version of the article ANL_2018_656

We modified the images and the abstract as requested by the reviewer and we hope you'll find the manuscript improved.

Thank you for your consideration. We are looking forward to your kind reply.

Sincerely,

Francesco Mozzanica

Response to Reviewers

Reviewer 2

Dear reviewer 2, thank you very much for your additional revision.

This paper is well revised. Correct the number of female subjects in the abstract.

Thank you for the positive comment, the number of female subjects was corrected (see the Abstract)

The revised figures are acceptable in the present form, but I am afraid that the two symbols are not distinguishable in B/W printing. The authors can use symbols with different shape.

We agree with the reviewer. The figures were consequently modified as suggested. The dots represent females, while the circles represent males.

1 Abstract

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Phonation Monitoring (APM), and their relationship with Quality of Life (QOL) measurements in a
group of profound deaf patients treated with Cochlear Implant (CI)

Methods: A total of 12 consecutive post-lingual deaf patients (8 females and 4 males) treated with CI for bilateral severe-to-profound hearing loss were enrolled. Each patient was evaluated before and after 6 months of CI use. In particular, the daily voice production evaluation was performed using the APM, while QOL information were gathered from the Italian version of the Nijmegen Cochlear Implant Questionnaire (I-NCIQ).

10 Results: significant differences in the APM results obtained before and after CI were found. In 11 particular, a significant decrease of the mean amplitude and a significant increase of the daily 12 phonation time and percentage of phonation time were demonstrated after CI use in all the patients. 13 A significant improvement in the I-NCIQ scores was demonstrated after CI use and significant 14 correlations among I-NCIQ scores and the APM parameters were found.

15 Conclusions: the APM could be useful in the evaluation of the benefits of cochlear implantation and 16 may represents an indicator of deaf patient participation. In addition, the daily voice production's 17 modifications after CI and their significant relations with the changes in QOL measurements could 18 be useful in treatment planning as well as during pre- and post-operative counselling.

19

20

21 Keywords: cochlear implant; voice; QOL; APM

1 **TEXT**

2 Introduction

3 Hearing is crucial in everyday human activities since it is involved in auditory scene analysis, noise 4 and sound source localization, speech understanding, and voice and speech production. In particular, 5 hearing provides feedback and feedforward control over voice production [1]. Feedback control 6 allows for corrections in phonation using the sensory information acquired while the task is in 7 progress. Feedforward control allows for voice production based on previously learned commands 8 without needing constant auditory feedback [1]. Thus, bilateral profound sensorineural hearing loss 9 could lead to serious health implications since it may impact not only on hearing, but indirectly also 10 on voice production [2, 3]. Bilateral profound sensorineural hearing loss, in fact, produces negative 11 effects on the production of suprasegmental aspects of speech and on the vocal parameters of deaf 12 individuals, such as deviations in fundamental frequency (F_0) , changes in formant frequencies, 13 variations in vocal intensity, and changes in resonance, length, and duration of speech [4-7]. In 14 addition, adults with untreated hearing loss are more frequently affected by sadness, depression, 15 anxiety, social isolation, insecurity and experience decreased social participation [2, 8].

16 Auditory rehabilitation can potentially reverse these adverse effects [9] and it has been found that 17 hearing restoration has positive effect on voice quality and on quality of life (QOL) [1, 10, 11]. Voice 18 changes after cochlear implantation have long been known and studied. Previous studies have 19 reported significant modification in acoustic parameters such as reduction of F₀ values in adults after 20 Cochlear Implantation (CI) [12]. More recently, it has been found a significant reduction in overall 21 severity, strain, loudness, and instability of the voice in auditory perceptual analysis in adults after CI 22 [13]. In addition, voice changes after CI have been demonstrated through longitudinal studies also in 23 children [14-17]. Although previous authors analyzed changes in voice quality in bilateral profound 24 sensorineural hearing loss treated with CI, all previous studies focused on voice production lasting 25 few seconds and no data are available on voice production during a normal day of CI patients. Yet 26 the voice production could be modified by changes in the hearing abilities and it is also possible that improvement in the ability to produce voice could play an important role in the QOL modifications
 after CI.

3 In the last years, new methods for voice production monitoring has been developed. In particular, the 4 ambulatory phonation monitoring (APM model 3200 by KayPENTAX; Lincoln Park, NJ) equipment 5 [18, 19] has been developed and commercialized to measure long-term phonation time, average and 6 mode F_0 , mean amplitude of voice production throughout a sustained period of time, such a full 7 working day [20]. The APM uses portable vocal dosimetry composed by an accelerometer placed 8 along the anterior neck which measures the vibrations from the vocal folds through the tissues of the 9 neck and converts into sound pressure levels of speech (SPL decibels). Phonation measured in this 10 way has been shown to be relatively insensitive to surrounding sounds [21]. In addition, dosimetry 11 allows quantification of all types of sound production thus recognizing volitional voice from other 12 behaviors such as throat clearing or coughing. Moreover, it records only the amount of voicing 13 produced but not the actual content of the speech, facilitating quantification without compromising 14 privacy [21].

The APM has never been applied in the evaluation of CI patients. The aim of this study is to objectively evaluate the changes in voice production using a new methodology, the APM (an accelerometer, able to collected data on phonation time, frequency and amplitude during an entire day), and to study their relationship with QOL measurements in a group of profound deaf patients treated with CI. The underlying hypothesis is that the restoration of hearing function may determine an increase of the daily phonation time and a decrease of voice amplitude.

The relevance of this study lies in the fact that, by objectively analyse the daily voice production modification after CI, the clinicians could provide additional support on the efficacy of the CI in the treatment of deafness and further evaluate the impact of CI on daily communication and voice. Data on phonation time, in fact, could represent an indirect measure of participation in communication, while the modifications of voice amplitude after CI could inform about the changes in vocal attitude

- 1 of deaf patients. Besides, the knowledge of the modification of voice production after CI and its
- 2 relationship with QOL measurements might help clinicians in pre-operative counselling.

1 Materials and methods

In this single-case experimental study a group of post-lingual deaf patients was evaluated. The study
was carried out according to the Declaration of Helsinki and it was previously approved by the
Institutional Review Board of our hospital.

5

6 *Population*

7 Clinical data were obtained from 12 consecutive post-lingual deaf patients (8 females and 4 males) 8 treated with CI for bilateral severe-to-profound hearing loss by the same surgeon in our centre. The 9 most frequent aetiology of deafness was meningitis followed by deafness of unknown origin. Mean 10 length of hearing impairment was 8.3 ± 3.2 years (range 6-11 years). The average age at CI surgery 11 was 47.3 ± 13.7 years (range 34-74 years). All the patients received unilateral CI, none of them used 12 combined electric-acoustic stimulation in the implanted ear and none of them continued to wear a 13 hearing aid on the ear contralateral to the CI ear. Each patient enrolled in the study gave his/her 14 written informed consent. All the patients underwent auditory rehabilitation after CI. Exclusion 15 criteria were: reading limitations of any origin, speech disorders due to malformation, acquired 16 damages to the speech organ, motor speech disorders, voice disorders of any origin besides deafness, 17 intraoperative complications, difficulty in CI fitting, associated disability.

18

19 *Outcome measures*

Voice production evaluation: the ambulatory phonation monitoring (APM model 3200 by KayPENTAX; Lincoln Park, NJ) equipment [18, 19] was used to measure voice production before and after 6 months of CI use. Each patient was asked to identify a "typical" day on which the measurements could be performed. Before starting each new recording, a sound pressure level (SPL) calibration was performed using a microphone positioned 15 cm from the subject's mouth. The acquired data included:

1	•	Phonation time (in minutes): express the time during which the vocal folds have been in	
2		phonatory vibration.	

- Percentage of phonation time: expresses the percentage of the recording time during which
 the vocal folds have been in phonatory vibration.
- Average F_0 (in Hertz): expresses the mean frequency at which the vocal folds vibrate.
- Mode F₀ (in Hertz): expresses the value of F₀ at which most phonation occurs during the
 recording.
- Average amplitude (in SPL dB): expresses the mean value of the amount of energy of the
 voice sound wave [20, 22].

10 Speech perception test: for the speech perception assessment of CI patients the Italian version of 11 disyllabic testing without lip-reading and without masking [23, 24] were assessed. Speech perception 12 was scored in best-aided conditions in quiet [25]. In this group of patients, the best-aided condition 13 reflected the patient's daily listening condition, defined as cochlear implant alone, since in no cases 14 a contralateral hearing aid was used. Measurements were assessed in a sound-treated room using 15 recorded materials presented at 70 dB sound pressure level from a loud-speaker placed at 0° azimuth. 16 Test materials consisted of lists of 10 open-set disyllabic words [23, 24] and responses were scored 17 as the percentage of words correctly identified.

18 Self-assessment of QOL: as far as the QOL assessment is concerned, each of the enrolled patients 19 managed to complete autonomously the Italian version of the Nijmegen Cochlear Implant 20 Questionnaire (I-NCIQ) [26, 27] immediately before the APM evaluation (before the implantation 21 surgery and after 6 months of CI use). The I-NCIQ is a self-assessment questionnaire composed by 22 six different sub-domains: basic sound perception, advanced sound perception, speech production, 23 self-esteem, activity limitations and social interactions. The answers to the questionnaire are provided 24 on a 5-point Likert scale, with scores ranging from 0 to 100 for each of the sub-domain. Higher scores 25 mean better QOL.

1 Statistical Analysis

Statistical tests were performed using SPSS 23.0 statistical software (SPSS, Inc., Chicago, IL). The differences in APM results, speech perception test and NCIQ scores before and after CI were assessed using Wilcoxon signed rank test. The Spearman correlation test was used to analyse the correlation between the APM and I-NCIQ scores. Correlation strength was considered high for values greater than 0.7, moderate for values ranging between 0.5 and 0.7 and low for values less than 0.5 [28]. In addition, scatter plots displaying the correlation between the I-NCIQ total score and the parameters of APM were included.

1 **Results**

After CI, all the patients had auditory thresholds of 40 dBHL or better for all speech frequencies on sound field audiometry. No substantial changes in the medical conditions of the CI users that could possibly modify the QOL or the phonatory behaviour of the patients (such as stroke, traumatic injuries, surgical complications, metabolic or cardiologic diseases) were reported during the second evaluation. The time required to calibrate the APM and to fulfil the I-NCIQ questionnaire never exceeded 5 and 10 minutes respectively.

As far as the voice production evaluation is concerned, all the patients well tolerated the APM device. The mean duration of data sampling used for the phonation monitoring, excluding sleeping time, was 12.8 ± 3.1 hours (range 10-15 hours) during the first assessment and 11.9 ± 3.9 (range 9-14) during the second assessment. No difference in the mean duration of data sampling before and after 6 months of CI use were demonstrated on Wilcoxon signed rank test (p = 0.358).

The APM results obtained before and after 6 months CI use are reported in Table 1 and 2. A significant increase of the phonation time and percentage of phonation time were demonstrated after CI use in all the patients (p = 0.012 and p = 0.011 respectively on Wilcoxon signed rank test). On the other hand, a significant decrease of the amplitude average was demonstrated after CI use in all the patients (p = 0.033 on Wilcoxon signed rank test). Finally, after CI use the F₀ mode significantly decreases in males and females (p = 0.012 and p = 0.002 respectively on Wilcoxon signed rank test) while the F₀ average significantly increases in females (p = 0.026 on Wilcoxon signed rank test).

As far as the speech perception test is concerned, the percentage of words correctly identified in the pre-treatment condition was 13.75%. After 6 months of CI this percentage increased to 86.25%. This difference was found significant on Wilcoxon signed rank test (p = 0.001). The results obtained in the I-NICQ before and after CI use are reported in Table 3. A significant improvement in the scores of each of the 6 subscales and of the total score of the questionnaire was demonstrated on Wilcoxon signed rank test.

1 The results of the correlation analysis between APM results and I-NICQ scores are reported in Table 2 4, while the results of the correlation analysis between APM results and those obtained in the speech 3 perception test are reported in Table 5. Significant correlations were demonstrated among I-NCIQ 4 sub-domains and total scores and all of the APM parameters with the only exception of F₀ average. 5 This latter, in fact, appear not significantly correlated with I-NICQ results. A significant moderate 6 positive correlation was found between I-NCIQ total score and Phonation time; while a significant 7 moderate negative correlation was demonstrated between I-NCIQ total score and Mode F_0 and 8 between I-NCIQ total and Average amplitude. No significant correlation was demonstrated between 9 I-NCIQ total and Average F₀ (see Table 4 and Figure 1-4). Significant correlations were also found among APM parameters and the results of the speech perception test. In particular, the higher 10 11 correlation was found with the parameter Average amplitude of the APM (see Table 5).

1 **Discussion**

In the present study, the daily voice production analysed through APM and its relationship with QOL measurements in a group of profound deaf patients treated with CI were analysed for the first time. Specific findings related to APM results are noteworthy. In particular, all the enrolled patients tolerated well the phonation monitoring since all of them wear the device all day long twice (before CI and after 6 months of CI use). In addition, the time required to calibrate the APM never exceeded minutes, suggesting that the phonation monitoring using APM is not a time-consuming procedure and could be performed during routine ambulatory examinations.

9 Significant differences between the APM results obtained before and after CI use were found. In 10 particular, both the phonation time and the percentage of phonation time increased after CI, while the 11 mean amplitude decreased. In addition, a significant decrease of the F_0 mode in both males and 12 females and a significant increase of F₀ average in females were also found. To the best of our 13 knowledge no data are available in the international literature on this subject and consequently it 14 appears very difficult to compare these results. However, it could be speculated that the restoration 15 of hearing function, obtained through CI, influenced the voice production of our patients. This datum 16 is not surprising as it is well known that ascending auditory pathway feeds back onto the primary 17 vocal motor network [29] thus suggesting that better hearing function could lead to improvement in audio-vocal feedback. 18

19

20 *Phonation time*

To the best of our knowledge, phonation time and percentage of phonation time during a full typical day have never been studied before; both these parameters represent the time in a day when focal folds are vibrating compared to non-vibrating time and could represent and indicator of oral communication participation, as it has been postulated in other areas [30]. Increase in phonation time in a deaf patient has two possible explanations: 1. a substitution of non-oral communication with oral communication; 2. an increased number of daily activities in which patients were speaking, possibly

1 because they were confident during conversations and consequently more inclined to speak. Further 2 studies are necessary to better define this point. However, it must be noted that the phonation time 3 and the percentage of phonation time after CI use appear still lower than those reported in previous 4 studies analysing normal hearing subjects. Misono et al [31] who studied 11 patients treated for 5 larvngeal pathologies reported a percentage of phonation time of 19.4%. Buckley et al [32] who 6 analysed the speech behaviour in a group of healthy sports coaches reported a phonation time of 13.4 7 minutes and a percentage of phonation time of 19.2%. Szabo Portela et al [33] who studied the speech 8 behaviour in a group of twelve vocally healthy female preschool teachers reported a percentage of 9 phonation time of 12% during working hours and of 5.5% during leisure time. Mozzanica et al [22] 10 who used the APM in order to evaluate the vocal demands in a group of speech and language 11 pathologists reported a percentage of phonation time of 27.3% during working hours. On the contrary, 12 Cantarella et al [20] reported a percentage of phonation time of 7.1% in a group of 92 call center 13 operators. It is possible that these diverging results could be related to differences in the studied 14 population and in the amount of phonation monitoring performed. For example, in Cantarella et al 15 study [20] the subjects wore the APM all day long, while in Buckey et al study [32] the coaches wore 16 the APM only for a typical training session.

17

18 Average amplitude

19 Phonation amplitude significantly decreased after CI. The reduction of the amplitude average 20 obtained after CI might be related to restoration in hearing feedback thus allowing patients to better 21 control their phonation using the sensory information acquired while the task is in progress. It is well 22 known that reduced auditory feedback leads ton increased voice amplitude [34]; it seems therefore 23 intuitive that with a better auditory feedback voice intensity is reduced. This hypothesis is supported 24 by the findings of Leder et al [35] who reported that profound deafness was associated with a 25 significantly increased voice intensity level. In addition, the results of amplitude average after CI 26 appear quite similar to those found in previous studies that analyzed the speech production in healthy

subjects. In particular, Cantarella et al [20] who studied the phonatory production in a sample of 92
healthy call center operators reported an amplitude average of 70.5 dB SPL. Also, Franca et al [36]
who studied the vocal demands in 8 student singers reported an amplitude average of 69.6 dB SPL.
Data on amplitude before and after CI showed that standard deviation was much higher before CI
than after CI; this datum possibly suggests that CI reduced amplitude variability among patients.

6

7 Fundamental frequency

8 F₀ mode decreased after CI in all patients. It is possible that the reduction of the F₀ mode after CI use 9 might be related to the reduction of the voice mean amplitude since intensity and pitch of the normal 10 speaking voice are known to be to some degree connected to each other [37]. Besides, reduction of 11 F_0 mode may indicate a reduction in vocal fatigue, as previous studies showed that normal hearing 12 teachers after a working day increase their F₀ and their sound pressure level of phonation due to vocal 13 fatigue [38]. Audio vocal feedback is a well-known area of study; increased F₀ in hearing impaired 14 patients has been reported by previous authors [39, 40] and previous studies also showed reduction 15 in F₀ after CI [41], however, those studies analyzed vocal production of few seconds and cannot be 16 directly compared to the data reported in the present study.

While F_0 mode decreased after CI in both male and female patients, an increase in F_0 average after CI in female patients only was found. This datum seems contro-intuitive. While F_0 mode represents the F_0 most produced, F_0 average includes also extremes, that is high and low F_0 productions during the day. Therefore, it is possible that after CI, patients produced more extremes than before the CI and that only female patients reached a statistical significance as their F_0 is higher than males. Unfortunately, the APM systems does not allow to analyze the distribution of F_0 production and we could not further support this speculation.

Contrary to data on amplitude, data on F_0 standard deviation did not show major differences before and after CI. This datum suggests larger variability among patients and differs from previous literature on F0 using APM [20]. A possible explanation is that although CI seems to improve audio
 vocal control, a variability among patients still exist after CI.

3

4 Correlation between APM, I-NCIQ scores and perception tests

5 Significant correlations among the I-NCIQ total score and some of the APM parameters were found, 6 suggesting that the modifications of vocal production were related with the modification of the OOL 7 in CI patients. In particular, a significant negative correlation was found between I-NCIQ total score 8 and average amplitude, while the higher positive correlation was found between I-NCIQ total score 9 and phonation time. It is possible to speculate that hearing restoration plays a positive role on both 10 QOL and voice production independently. Another possible explanation is that the restoration of 11 hearing function improved the voice production and this might affect the way the patient perceives 12 his disease. The latter hypothesis seems in accordance with the findings of Brandenburg et al [30] 13 who studied the talk time of 12 people with post-stroke, non-fluent aphasia and concluded that the 14 talk time could be an indicator of both communication-related and general participation. Significant 15 correlations were found among the APM parameters and the score obtained in the speech perception 16 test. Even if in none of the previous study such correlation was analysed, the presence of a positive 17 relationship between vocal production and auditory perception in CI users has been already 18 demonstrated [42]. Thus, it is not surprising that also in this study significant correlations between 19 the results of the speech perception test and the APM parameters (that measure the voice production) 20 were found.

21

22 Study limitations

The main limitations of the current study are related to the limited number of enrolled patients; thus, the data here reported should be considered preliminary. Larger studies are needed to confirm generalizability. In addition, it is also not known to what extent wearing the APM device affected patient voice and speech production. It is possible that the awareness of presence of the APM could

1 potentially affect patterns of voice production, moreover it is also possible that the APM design might 2 influence the quality of data collection (related for example to dislodgment of the sensor). Moreover, 3 the uncertainty of the measurements provided by the APM device must also be taken into account as 4 previously suggested by Bottalico et al [43] who demonstrated the APM tendency of an overestimate 5 in the calculation of both average F₀ and amplitude average. Finally, the patients enrolled in the 6 present study wore the device for only 1 day before and after the cochlear implantation. Consequently, 7 no information about how patients would have responded to wearing the device for longer are 8 available. This datum is related to the limitations of the APM itself since it needs to be recalibrated 9 every day, which logistically prevented long-time measurements [22]. However, the APM recording 10 was performed in a "typical" day selected by the patient, thus suggesting that the chosen day is most 11 likely representative of the subjects' daily pattern.

1 Conclusion

In conclusion, the present article has the merit to demonstrate objectively the daily vocal changes in CI patients. These data could be useful in the clinical management of patients with CI since the increase of voicing and the decrease of its amplitude might be considered as a goal of hearing restoration. In particular, the application of daily measure of speaking time represents an innovative way to measure impact of CI on daily communication and voice.

7

1 Acknowledgement

2 We would like to thank Eng. Gianluca Terragni, Federico Ambrogi and Patrick Boyle for their help.

Disclosure statement:

2 The authors declare that they have no conflict of interest.

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1 Figure legends:

2	Figure 1: scatter plot showing the relationship between the Italian version of the Nijmegen Cochlear
3	Implant Questionnaire (I-NCIQ) total score and the Phonation time measured through the Ambulatory
4	Phonation Monitoring (APM). The dots represent females, the circles represent males.
5	Figure 2: scatter plot showing the relationship between the Italian version of the Nijmegen Cochlear
6	Implant Questionnaire (I-NCIQ) total score and the Mode F_0 measured through the Ambulatory
7	Phonation Monitoring (APM). The dots represent females, the circles represent males.
8	Figure 3: scatter plot showing the relationship between the Italian version of the Nijmegen Cochlear
9	Implant Questionnaire (I-NCIQ) total score and the Average F ₀ measured through the Ambulatory
10	Phonation Monitoring (APM). The dots represent females, the circles represent males.
11	Figure 4: scatter plot showing the relationship between the Italian version of the Nijmegen Cochlear
12	Implant Questionnaire (I-NCIQ) total score and the Average amplitude measured through the
13	Ambulatory Phonation Monitoring (APM). The dots represent females, the circles represent males.
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Application of Ambulatory Phonation Monitoring (APM) in the measurement of daily speaking-time and voice intensity before and after cochlear implant in deaf adult patients

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Objective: to evaluate the changes in daily voice production, analysed through the Ambulatory
Phonation Monitoring (APM), and their relationship with Quality of Life (QOL) measurements in a
group of profound deaf patients treated with Cochlear Implant (CI)

Methods: A total of 12 consecutive post-lingual deaf patients (8 females and 4 males) treated with
CI for bilateral severe-to-profound hearing loss were enrolled. Each patient was evaluated before and
after 6 months of CI use. In particular, the daily voice production evaluation was performed using the
APM, while QOL information were gathered from the Italian version of the Nijmegen Cochlear
Implant Questionnaire (I-NCIQ).

10 Results: significant differences in the APM results obtained before and after CI were found. In 11 particular, a significant decrease of the mean amplitude and a significant increase of the daily 12 phonation time and percentage of phonation time were demonstrated after CI use in all the patients. 13 A significant improvement in the I-NCIQ scores was demonstrated after CI use and significant 14 correlations among I-NCIQ scores and the APM parameters were found.

15 Conclusions: the APM could be useful in the evaluation of the benefits of cochlear implantation and 16 may represents an indicator of deaf patient participation. In addition, the daily voice production's 17 modifications after CI and their significant relations with the changes in QOL measurements could 18 be useful in treatment planning as well as during pre- and post-operative counselling.

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21 Keywords: cochlear implant; voice; QOL; APM

1 **TEXT**

2 Introduction

3 Hearing is crucial in everyday human activities since it is involved in auditory scene analysis, noise 4 and sound source localization, speech understanding, and voice and speech production. In particular, 5 hearing provides feedback and feedforward control over voice production [1]. Feedback control 6 allows for corrections in phonation using the sensory information acquired while the task is in 7 progress. Feedforward control allows for voice production based on previously learned commands 8 without needing constant auditory feedback [1]. Thus, bilateral profound sensorineural hearing loss 9 could lead to serious health implications since it may impact not only on hearing, but indirectly also 10 on voice production [2, 3]. Bilateral profound sensorineural hearing loss, in fact, produces negative 11 effects on the production of suprasegmental aspects of speech and on the vocal parameters of deaf 12 individuals, such as deviations in fundamental frequency (F_0) , changes in formant frequencies, 13 variations in vocal intensity, and changes in resonance, length, and duration of speech [4-7]. In 14 addition, adults with untreated hearing loss are more frequently affected by sadness, depression, 15 anxiety, social isolation, insecurity and experience decreased social participation [2, 8].

16 Auditory rehabilitation can potentially reverse these adverse effects [9] and it has been found that 17 hearing restoration has positive effect on voice quality and on quality of life (QOL) [1, 10, 11]. Voice 18 changes after cochlear implantation have long been known and studied. Previous studies have 19 reported significant modification in acoustic parameters such as reduction of F₀ values in adults after 20 Cochlear Implantation (CI) [12]. More recently, it has been found a significant reduction in overall 21 severity, strain, loudness, and instability of the voice in auditory perceptual analysis in adults after CI 22 [13]. In addition, voice changes after CI have been demonstrated through longitudinal studies also in 23 children [14-17]. Although previous authors analyzed changes in voice quality in bilateral profound 24 sensorineural hearing loss treated with CI, all previous studies focused on voice production lasting 25 few seconds and no data are available on voice production during a normal day of CI patients. Yet 26 the voice production could be modified by changes in the hearing abilities and it is also possible that improvement in the ability to produce voice could play an important role in the QOL modifications
 after CI.

3 In the last years, new methods for voice production monitoring has been developed. In particular, the 4 ambulatory phonation monitoring (APM model 3200 by KayPENTAX; Lincoln Park, NJ) equipment 5 [18, 19] has been developed and commercialized to measure long-term phonation time, average and 6 mode F_0 , mean amplitude of voice production throughout a sustained period of time, such a full 7 working day [20]. The APM uses portable vocal dosimetry composed by an accelerometer placed 8 along the anterior neck which measures the vibrations from the vocal folds through the tissues of the 9 neck and converts into sound pressure levels of speech (SPL decibels). Phonation measured in this 10 way has been shown to be relatively insensitive to surrounding sounds [21]. In addition, dosimetry 11 allows quantification of all types of sound production thus recognizing volitional voice from other 12 behaviors such as throat clearing or coughing. Moreover, it records only the amount of voicing 13 produced but not the actual content of the speech, facilitating quantification without compromising 14 privacy [21].

The APM has never been applied in the evaluation of CI patients. The aim of this study is to objectively evaluate the changes in voice production using a new methodology, the APM (an accelerometer, able to collected data on phonation time, frequency and amplitude during an entire day), and to study their relationship with QOL measurements in a group of profound deaf patients treated with CI. The underlying hypothesis is that the restoration of hearing function may determine an increase of the daily phonation time and a decrease of voice amplitude.

The relevance of this study lies in the fact that, by objectively analyse the daily voice production modification after CI, the clinicians could provide additional support on the efficacy of the CI in the treatment of deafness and further evaluate the impact of CI on daily communication and voice. Data on phonation time, in fact, could represent an indirect measure of participation in communication, while the modifications of voice amplitude after CI could inform about the changes in vocal attitude

- 1 of deaf patients. Besides, the knowledge of the modification of voice production after CI and its
- 2 relationship with QOL measurements might help clinicians in pre-operative counselling.

1 Materials and methods

In this single-case experimental study a group of post-lingual deaf patients was evaluated. The study
was carried out according to the Declaration of Helsinki and it was previously approved by the
Institutional Review Board of our hospital.

5

6 *Population*

7 Clinical data were obtained from 12 consecutive post-lingual deaf patients (8 females and 4 males) 8 treated with CI for bilateral severe-to-profound hearing loss by the same surgeon in our centre. The 9 most frequent aetiology of deafness was meningitis followed by deafness of unknown origin. Mean 10 length of hearing impairment was 8.3 ± 3.2 years (range 6-11 years). The average age at CI surgery 11 was 47.3 ± 13.7 years (range 34-74 years). All the patients received unilateral CI, none of them used 12 combined electric-acoustic stimulation in the implanted ear and none of them continued to wear a 13 hearing aid on the ear contralateral to the CI ear. Each patient enrolled in the study gave his/her 14 written informed consent. All the patients underwent auditory rehabilitation after CI. Exclusion 15 criteria were: reading limitations of any origin, speech disorders due to malformation, acquired 16 damages to the speech organ, motor speech disorders, voice disorders of any origin besides deafness, 17 intraoperative complications, difficulty in CI fitting, associated disability.

18

19 *Outcome measures*

Voice production evaluation: the ambulatory phonation monitoring (APM model 3200 by KayPENTAX; Lincoln Park, NJ) equipment [18, 19] was used to measure voice production before and after 6 months of CI use. Each patient was asked to identify a "typical" day on which the measurements could be performed. Before starting each new recording, a sound pressure level (SPL) calibration was performed using a microphone positioned 15 cm from the subject's mouth. The acquired data included:

1	•	Phonation time (in minutes): express the time during which the vocal folds have been in	
2		phonatory vibration.	

- Percentage of phonation time: expresses the percentage of the recording time during which
 the vocal folds have been in phonatory vibration.
- Average F_0 (in Hertz): expresses the mean frequency at which the vocal folds vibrate.
- Mode F₀ (in Hertz): expresses the value of F₀ at which most phonation occurs during the
 recording.
- Average amplitude (in SPL dB): expresses the mean value of the amount of energy of the
 voice sound wave [20, 22].

10 Speech perception test: for the speech perception assessment of CI patients the Italian version of 11 disyllabic testing without lip-reading and without masking [23, 24] were assessed. Speech perception 12 was scored in best-aided conditions in quiet [25]. In this group of patients, the best-aided condition 13 reflected the patient's daily listening condition, defined as cochlear implant alone, since in no cases 14 a contralateral hearing aid was used. Measurements were assessed in a sound-treated room using 15 recorded materials presented at 70 dB sound pressure level from a loud-speaker placed at 0° azimuth. 16 Test materials consisted of lists of 10 open-set disyllabic words [23, 24] and responses were scored 17 as the percentage of words correctly identified.

18 Self-assessment of QOL: as far as the QOL assessment is concerned, each of the enrolled patients 19 managed to complete autonomously the Italian version of the Nijmegen Cochlear Implant 20 Questionnaire (I-NCIQ) [26, 27] immediately before the APM evaluation (before the implantation 21 surgery and after 6 months of CI use). The I-NCIQ is a self-assessment questionnaire composed by 22 six different sub-domains: basic sound perception, advanced sound perception, speech production, 23 self-esteem, activity limitations and social interactions. The answers to the questionnaire are provided 24 on a 5-point Likert scale, with scores ranging from 0 to 100 for each of the sub-domain. Higher scores 25 mean better QOL.

1 Statistical Analysis

Statistical tests were performed using SPSS 23.0 statistical software (SPSS, Inc., Chicago, IL). The differences in APM results, speech perception test and NCIQ scores before and after CI were assessed using Wilcoxon signed rank test. The Spearman correlation test was used to analyse the correlation between the APM and I-NCIQ scores. Correlation strength was considered high for values greater than 0.7, moderate for values ranging between 0.5 and 0.7 and low for values less than 0.5 [28]. In addition, scatter plots displaying the correlation between the I-NCIQ total score and the parameters of APM were included.

1 **Results**

After CI, all the patients had auditory thresholds of 40 dBHL or better for all speech frequencies on sound field audiometry. No substantial changes in the medical conditions of the CI users that could possibly modify the QOL or the phonatory behaviour of the patients (such as stroke, traumatic injuries, surgical complications, metabolic or cardiologic diseases) were reported during the second evaluation. The time required to calibrate the APM and to fulfil the I-NCIQ questionnaire never exceeded 5 and 10 minutes respectively.

As far as the voice production evaluation is concerned, all the patients well tolerated the APM device. The mean duration of data sampling used for the phonation monitoring, excluding sleeping time, was 12.8 ± 3.1 hours (range 10-15 hours) during the first assessment and 11.9 ± 3.9 (range 9-14) during the second assessment. No difference in the mean duration of data sampling before and after 6 months of CI use were demonstrated on Wilcoxon signed rank test (p = 0.358).

The APM results obtained before and after 6 months CI use are reported in Table 1 and 2. A significant increase of the phonation time and percentage of phonation time were demonstrated after CI use in all the patients (p = 0.012 and p = 0.011 respectively on Wilcoxon signed rank test). On the other hand, a significant decrease of the amplitude average was demonstrated after CI use in all the patients (p = 0.033 on Wilcoxon signed rank test). Finally, after CI use the F₀ mode significantly decreases in males and females (p = 0.012 and p = 0.002 respectively on Wilcoxon signed rank test) while the F₀ average significantly increases in females (p = 0.026 on Wilcoxon signed rank test).

As far as the speech perception test is concerned, the percentage of words correctly identified in the pre-treatment condition was 13.75%. After 6 months of CI this percentage increased to 86.25%. This difference was found significant on Wilcoxon signed rank test (p = 0.001). The results obtained in the I-NICQ before and after CI use are reported in Table 3. A significant improvement in the scores of each of the 6 subscales and of the total score of the questionnaire was demonstrated on Wilcoxon signed rank test.

1 The results of the correlation analysis between APM results and I-NICQ scores are reported in Table 2 4, while the results of the correlation analysis between APM results and those obtained in the speech 3 perception test are reported in Table 5. Significant correlations were demonstrated among I-NCIQ 4 sub-domains and total scores and all of the APM parameters with the only exception of F₀ average. 5 This latter, in fact, appear not significantly correlated with I-NICQ results. A significant moderate 6 positive correlation was found between I-NCIQ total score and Phonation time; while a significant 7 moderate negative correlation was demonstrated between I-NCIQ total score and Mode F_0 and 8 between I-NCIQ total and Average amplitude. No significant correlation was demonstrated between 9 I-NCIQ total and Average F₀ (see Table 4 and Figure 1-4). Significant correlations were also found among APM parameters and the results of the speech perception test. In particular, the higher 10 11 correlation was found with the parameter Average amplitude of the APM (see Table 5).

1 **Discussion**

In the present study, the daily voice production analysed through APM and its relationship with QOL measurements in a group of profound deaf patients treated with CI were analysed for the first time. Specific findings related to APM results are noteworthy. In particular, all the enrolled patients tolerated well the phonation monitoring since all of them wear the device all day long twice (before CI and after 6 months of CI use). In addition, the time required to calibrate the APM never exceeded minutes, suggesting that the phonation monitoring using APM is not a time-consuming procedure and could be performed during routine ambulatory examinations.

9 Significant differences between the APM results obtained before and after CI use were found. In 10 particular, both the phonation time and the percentage of phonation time increased after CI, while the 11 mean amplitude decreased. In addition, a significant decrease of the F_0 mode in both males and 12 females and a significant increase of F₀ average in females were also found. To the best of our 13 knowledge no data are available in the international literature on this subject and consequently it 14 appears very difficult to compare these results. However, it could be speculated that the restoration 15 of hearing function, obtained through CI, influenced the voice production of our patients. This datum 16 is not surprising as it is well known that ascending auditory pathway feeds back onto the primary 17 vocal motor network [29] thus suggesting that better hearing function could lead to improvement in audio-vocal feedback. 18

19

20 *Phonation time*

To the best of our knowledge, phonation time and percentage of phonation time during a full typical day have never been studied before; both these parameters represent the time in a day when focal folds are vibrating compared to non-vibrating time and could represent and indicator of oral communication participation, as it has been postulated in other areas [30]. Increase in phonation time in a deaf patient has two possible explanations: 1. a substitution of non-oral communication with oral communication; 2. an increased number of daily activities in which patients were speaking, possibly

1 because they were confident during conversations and consequently more inclined to speak. Further 2 studies are necessary to better define this point. However, it must be noted that the phonation time 3 and the percentage of phonation time after CI use appear still lower than those reported in previous 4 studies analysing normal hearing subjects. Misono et al [31] who studied 11 patients treated for 5 larvngeal pathologies reported a percentage of phonation time of 19.4%. Buckley et al [32] who 6 analysed the speech behaviour in a group of healthy sports coaches reported a phonation time of 13.4 7 minutes and a percentage of phonation time of 19.2%. Szabo Portela et al [33] who studied the speech 8 behaviour in a group of twelve vocally healthy female preschool teachers reported a percentage of 9 phonation time of 12% during working hours and of 5.5% during leisure time. Mozzanica et al [22] 10 who used the APM in order to evaluate the vocal demands in a group of speech and language 11 pathologists reported a percentage of phonation time of 27.3% during working hours. On the contrary, 12 Cantarella et al [20] reported a percentage of phonation time of 7.1% in a group of 92 call center 13 operators. It is possible that these diverging results could be related to differences in the studied 14 population and in the amount of phonation monitoring performed. For example, in Cantarella et al 15 study [20] the subjects wore the APM all day long, while in Buckey et al study [32] the coaches wore 16 the APM only for a typical training session.

17

18 Average amplitude

19 Phonation amplitude significantly decreased after CI. The reduction of the amplitude average 20 obtained after CI might be related to restoration in hearing feedback thus allowing patients to better 21 control their phonation using the sensory information acquired while the task is in progress. It is well 22 known that reduced auditory feedback leads ton increased voice amplitude [34]; it seems therefore 23 intuitive that with a better auditory feedback voice intensity is reduced. This hypothesis is supported 24 by the findings of Leder et al [35] who reported that profound deafness was associated with a 25 significantly increased voice intensity level. In addition, the results of amplitude average after CI 26 appear quite similar to those found in previous studies that analyzed the speech production in healthy

subjects. In particular, Cantarella et al [20] who studied the phonatory production in a sample of 92
healthy call center operators reported an amplitude average of 70.5 dB SPL. Also, Franca et al [36]
who studied the vocal demands in 8 student singers reported an amplitude average of 69.6 dB SPL.
Data on amplitude before and after CI showed that standard deviation was much higher before CI
than after CI; this datum possibly suggests that CI reduced amplitude variability among patients.

6

7 Fundamental frequency

8 F₀ mode decreased after CI in all patients. It is possible that the reduction of the F₀ mode after CI use 9 might be related to the reduction of the voice mean amplitude since intensity and pitch of the normal 10 speaking voice are known to be to some degree connected to each other [37]. Besides, reduction of 11 F_0 mode may indicate a reduction in vocal fatigue, as previous studies showed that normal hearing 12 teachers after a working day increase their F₀ and their sound pressure level of phonation due to vocal 13 fatigue [38]. Audio vocal feedback is a well-known area of study; increased F₀ in hearing impaired 14 patients has been reported by previous authors [39, 40] and previous studies also showed reduction 15 in F₀ after CI [41], however, those studies analyzed vocal production of few seconds and cannot be 16 directly compared to the data reported in the present study.

While F_0 mode decreased after CI in both male and female patients, an increase in F_0 average after CI in female patients only was found. This datum seems contro-intuitive. While F_0 mode represents the F_0 most produced, F_0 average includes also extremes, that is high and low F_0 productions during the day. Therefore, it is possible that after CI, patients produced more extremes than before the CI and that only female patients reached a statistical significance as their F_0 is higher than males. Unfortunately, the APM systems does not allow to analyze the distribution of F_0 production and we could not further support this speculation.

Contrary to data on amplitude, data on F_0 standard deviation did not show major differences before and after CI. This datum suggests larger variability among patients and differs from previous literature on F0 using APM [20]. A possible explanation is that although CI seems to improve audio
 vocal control, a variability among patients still exist after CI.

3

4 Correlation between APM, I-NCIQ scores and perception tests

5 Significant correlations among the I-NCIQ total score and some of the APM parameters were found, 6 suggesting that the modifications of vocal production were related with the modification of the OOL 7 in CI patients. In particular, a significant negative correlation was found between I-NCIQ total score 8 and average amplitude, while the higher positive correlation was found between I-NCIQ total score 9 and phonation time. It is possible to speculate that hearing restoration plays a positive role on both 10 QOL and voice production independently. Another possible explanation is that the restoration of 11 hearing function improved the voice production and this might affect the way the patient perceives 12 his disease. The latter hypothesis seems in accordance with the findings of Brandenburg et al [30] 13 who studied the talk time of 12 people with post-stroke, non-fluent aphasia and concluded that the 14 talk time could be an indicator of both communication-related and general participation. Significant 15 correlations were found among the APM parameters and the score obtained in the speech perception 16 test. Even if in none of the previous study such correlation was analysed, the presence of a positive 17 relationship between vocal production and auditory perception in CI users has been already 18 demonstrated [42]. Thus, it is not surprising that also in this study significant correlations between 19 the results of the speech perception test and the APM parameters (that measure the voice production) 20 were found.

21

22 Study limitations

The main limitations of the current study are related to the limited number of enrolled patients; thus, the data here reported should be considered preliminary. Larger studies are needed to confirm generalizability. In addition, it is also not known to what extent wearing the APM device affected patient voice and speech production. It is possible that the awareness of presence of the APM could

1 potentially affect patterns of voice production, moreover it is also possible that the APM design might 2 influence the quality of data collection (related for example to dislodgment of the sensor). Moreover, 3 the uncertainty of the measurements provided by the APM device must also be taken into account as 4 previously suggested by Bottalico et al [43] who demonstrated the APM tendency of an overestimate 5 in the calculation of both average F₀ and amplitude average. Finally, the patients enrolled in the 6 present study wore the device for only 1 day before and after the cochlear implantation. Consequently, 7 no information about how patients would have responded to wearing the device for longer are 8 available. This datum is related to the limitations of the APM itself since it needs to be recalibrated 9 every day, which logistically prevented long-time measurements [22]. However, the APM recording 10 was performed in a "typical" day selected by the patient, thus suggesting that the chosen day is most 11 likely representative of the subjects' daily pattern.

1 Conclusion

In conclusion, the present article has the merit to demonstrate objectively the daily vocal changes in CI patients. These data could be useful in the clinical management of patients with CI since the increase of voicing and the decrease of its amplitude might be considered as a goal of hearing restoration. In particular, the application of daily measure of speaking time represents an innovative way to measure impact of CI on daily communication and voice.

7

1 Acknowledgement

2 We would like to thank Eng. Gianluca Terragni, Federico Ambrogi and Patrick Boyle for their help.

Disclosure statement:

2 The authors declare that they have no conflict of interest.

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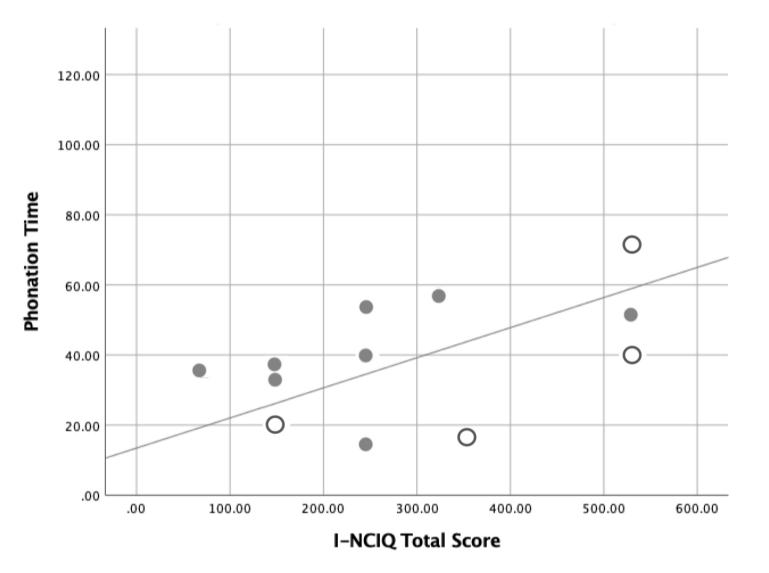
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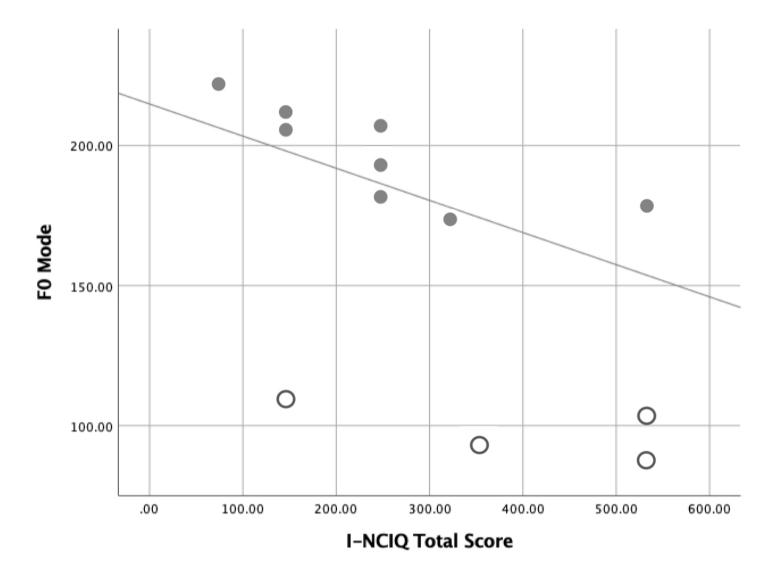
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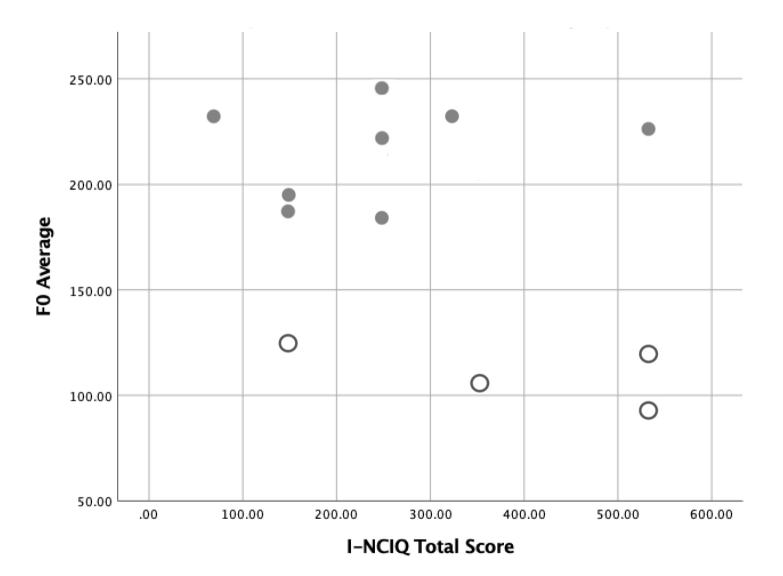
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1 Figure legends:

2	Figure 1: scatter plot showing the relationship between the Italian version of the Nijmegen Cochlear
3	Implant Questionnaire (I-NCIQ) total score and the Phonation time measured through the Ambulatory
4	Phonation Monitoring (APM). The dots represent females, the circles represent males.
5	Figure 2: scatter plot showing the relationship between the Italian version of the Nijmegen Cochlear
6	Implant Questionnaire (I-NCIQ) total score and the Mode F_0 measured through the Ambulatory
7	Phonation Monitoring (APM). The dots represent females, the circles represent males.
8	Figure 3: scatter plot showing the relationship between the Italian version of the Nijmegen Cochlear
9	Implant Questionnaire (I-NCIQ) total score and the Average F_0 measured through the Ambulatory
10	Phonation Monitoring (APM). The dots represent females, the circles represent males.
11	Figure 4: scatter plot showing the relationship between the Italian version of the Nijmegen Cochlear
12	Implant Questionnaire (I-NCIQ) total score and the Average amplitude measured through the
13	Ambulatory Phonation Monitoring (APM). The dots represent females, the circles represent males.
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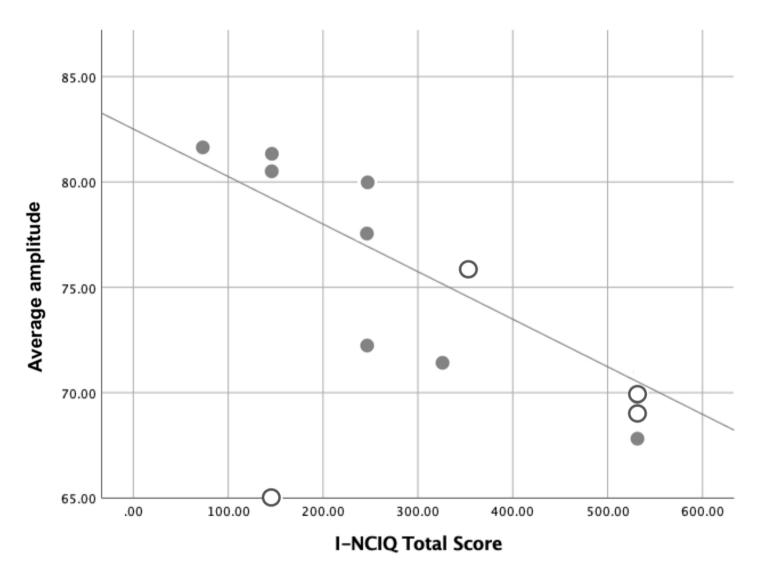


Table 1: ambulatory phonation monitoring (APM) results in the group of patients before and after 6 months of CI use. Mean \pm standard deviation and ranges (in brackets) are reported. The results of Wilcoxon signed rank test are also reported.

	Before CI	After CI	р
Phonation time (min)	23.7 ± 11.1	45.9 ± 27.1	0.012
	(3-35)	(29-115)	
Percentage of phonation time	4.5 ± 2.3	8.2 ± 3.1	0.011
(%)	(0.5-7.4)	(5.8-14.5)	
Average amplitude (dB SPL)	79.3 ± 6.1	72.8 ± 2.1	0.033
	(65-83)	(67-73)	

Table 2: ambulatory phonation monitoring (APM) results in the group of patients before and after 6 months of CI use. Mean \pm standard deviation and ranges (in brackets) are reported. The results of Wilcoxon signed rank test are also reported.

		Before CI	After CI	р
Average Fo (Hz)	Males	115 ± 45	105 ± 41	0.121
		(98-160)	(85-148)	
	Females	200 ± 58	231 ± 65	0.026
		(172-231)	(181-260)	
Mode Fo (Hz)	Males	110 ± 49	95 ± 55	0.012
		(90-145)	(87-138)	
	Females	215 ± 61	188 ± 62	0.002
		(178-243)	(162-251)	

Table 3: results of the Italian version of the Nijmegen Cochlear Implant Questionnaire (I-NCIQ) before and after CI. The total score was calculated by adding the results of each of the 6 sub-domains. The results of Wilcoxon signed rank test are also reported

I-NCIQ	Before CI	After CI	р
Basic sound perception	33.1 ± 21.5	75.5 ± 17.7	0.034
	(0-85)	(42.5-97.5)	
Advanced sound perception	37.5 ± 22.5	82.9 ± 18.9	0.025
	(0-70)	(50.5-98.5)	
Speech production	40.1 ± 23.5	74.8 ± 17.4	0.042
	(0-85)	(37.5-87.5)	
Self-esteem	43.5 ± 23.6	63.6 ± 19.2	0.049
	(7.5-85)	(17.5-80.6)	
Activity limitations	39.7 ± 23.5	$70.3 \hspace{0.2cm} \pm \hspace{0.2cm} 20.8$	0.029
	(10-85.5)	(15-97.2)	
Social interactions	46.8 ± 21.5	71.5 ± 15.6	0.038
	(7.5-80)	(37.5-82.5)	
Total score	190.1 ± 31.5	470.4 ± 40.1	0.001
	(72.5-352.5)	(244.5-532.5)	

Table 4: Correlation results between the ambulatory phonation monitoring (APM) results and theItalian version of the Nijmegen Cochlear Implant Questionnaire (I-NCIQ) scores.

	APM			
	Phonation time	Mode F ₀	Average F ₀	Average
				amplitude
I-NCIQ				
Basic Sound	0.565*	-0.665*	0.070	-0.664**
perception				
Advanced sound	0.711**	-0.498*	0.247	-0.678**
perception				
Speech production	0.476*	-0.570*	0.009	-0.613*
Self-esteem	0.531*	-0.588*	0.049	-0.603*
Activity limitations	0.467*	-0.627*	-0.070	-0.629*
Social interactions	0.488*	-0597*	0.058	-0.633*
Total score	0.553*	-0.434*	-0.95	-0.648**

* = p < 0.05; ** = p < 0.001.

Table 5: Correlation between the ambulatory phonation monitoring (APM) results and the Italian version of the bisyllable testing without lip-reading and without masking. The results of Spearman test are reported.

		Speech
		perception test
APM	Phonation time	0.321*
	Percentage of phonation time	-0.311*
	Mode F ₀	-0.362*
	Average F ₀	0.289
	Average amplitude	-0.477*
n < 0.05		

* p < 0.05