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Personality and Treatment Compliance:

Do certain personality traits influence patient compliance with voice rest?

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Abstract

Background/Purpose

Despite its widespread use, limited research exists exploring compliance with prescribed voice rest. The current study explored the relationship between personality and level of patient compliance with voice rest. We hypothesized that Extraversion and Neuroticism has a negative relationship with compliance to voice rest, and that Conscientiousness has a positive relationship with compliance to voice rest.

Method

Case study of seven patients (mean age of 42; 5 males, 2 females) undergoing surgical excision of benign vocal fold lesions prescribed up to 7 days of voice rest following surgical intervention. Participants completed the following self-report instruments: NEO-FFI-3, pre-surgical questionnaire, post-surgical questionnaire, and the VHI.

Results

Descriptive analysis revealed that similar to medication adherence, Conscientiousness and Neuroticism seem to play at least a partial role in compliance with voice rest, a treatment that requires behavioral adherence. Less clear is the relationship between Extraversion and adherent behavior, leaving us unable to provide support in favor of or against Roy and Bless' (2000) hypothesis.

Discussion

Further understanding of the role that personality plays in compliance may lead to the development of more evidence-based and individualized protocols for voice rest and foster increased success with this treatment.

Introduction

Voice rest is commonly prescribed to patients after the excision of benign vocal fold pathology to facilitate recovery from microlaryngoscopic surgery (Behrman & Sulica, 2003; Koufman & Blalock, 2009). Voice rest is thought to optimize the eventual outcome of phonosurgery by assisting mucosal healing and reducing the risk of post-surgical scarring (Behrman & Sulica, 2003; Ishikawa & Thibeault, 2008). Despite its widespread use, very few studies have actually explored the efficacy of voice rest on postoperative tissue repair (Behrman & Sulica, 2003; Koufman & Blalock, 2009). Furthermore, there is currently no gold standard protocol for voice rest treatment duration (Behrman & Sulica, 2003; Koufman & Blalock, 2009). Even fewer studies have explored patient compliance with prescribed voice rest, and those that have reveal low adherent behavior. For example, in a recent study of 84 patients on voice rest, Rousseau et al. (2011) found that only 34.5% of patients were compliant with treatment. Limited efficacy data coupled with reportedly low levels of patient compliance begs the question as to whether voice rest is even an *appropriate* treatment option for most patients. Exploring the relationship between personality and compliance behavior may emerge as a starting point in answering this question.

Personality is a construct that is easily recognized and often talked about in conversation. Interestingly, despite such familiarity, many people have a hard time providing a concrete definition for “personality” (Piedmont, 1998). Much of this difficulty stems from the fact that personality often means something a little bit different from each person to the next. This same difficulty is paralleled in personality literature, in which the exact definition of personality is dependent upon the theoretical model on which it is built (Rhodewalt, 2008). In recent decades, the five-factor model, based on trait theory, has emerged as a prominent taxonomy for describing

normal personality (Axelsson et al., 2009; Christensen and Smith, 1995; Jerant et al., 2011). The five factors in this model - Neuroticism, Extraversion, Agreeableness, Conscientiousness, and Openness - “are empirically derived clusters of dispositional tendencies that parsimoniously capture the major psychological and behavioral variation in humans” (Jerant et al, 2011, p. 2). According to this model, as well as other trait theories, personality is largely biologically driven with environment only playing a minimal role in the shaping process (Dumont, 2010; Jerant et al., 2011; Rhodewalt, 2008; Piedmont, 1998). Highlighting these points, Piedmont (1998) suggests that personality is the “intrinsic organization of an individual’s mental world that is stable over time and consistent over situations” (Piedmont, 1998, p. 2-3).

The role of personality in the development and maintenance of voice disorders may emerge as a potential explanation of patient noncompliance to voice rest (Roy & Bless, 2000; Roy, Bless, & Heisey, 2000). However, research exploring the role of personality in the development of voice disorders is still in its infancy. Currently, two sets of models exist to explain the directionality of influences between personality and voice disorders: a predisposition model and the disability “scar” hypothesis. A predisposition model asserts that personality plays a role in causing or modifying the expression of a disorder or illness, whereas the disability “scar” hypothesis proposes that having an illness or disorder causes changes in personality (Roy & Bless, 2000). In alignment with the theoretical framework of trait theories of personality, continued research using taxonomies have revealed evidence in favor of predisposition models (Roy & Bless, 2000; Christensen and Smith, 1995).

Consistent with the tenets of a predisposition model, Roy and Bless (2000) propose that certain personality dimensions lead to the development and maintenance of voice disorders. Specifically, Roy and Bless (2000) assert that the propensity towards the development of vocal

fold nodules may be a characteristic of the “impulsive behavior of neurotic extraverts” (p. 744). According to Eysenck’s Personality system, which is a three-factor model of personality, “extraverts tend to be dominant, social, and active” (Roy & Bless, 2000, p. 742; Dumont, 2010). On the other hand, Neuroticism is characterized by anxiousness, high reactivity and serves to amplify response tendencies (Roy & Bless, 2000; Roy, Bless & Heisey, 2000). Therefore, when Extraversion is paired with Neuroticism, the individual’s extraverted response tendencies are magnified leading to greater impulsive behavior. In other words, neurotic extraverts “tend to be more extraverted [and impulsive], when compared to stable counterparts” (Roy & Bless, 2000, pg. 743). Thus, despite having knowledge of the harmful effects of vocal abuse, neurotic extraverts are “unable to engage in [vocal restriction] ... in the presence of salient social rewards” (Roy & Bless, 2000, pg. 744)).

Currently, research has shown partial support for Roy and Bless’ (2000) theory. In Roy et al. (2000), the majority of patients with vocal fold nodules were classified as “low N-high E” or “high N—high E”, where “N” stands for Neuroticism and “E” stands for Extraversion (pg. 758). These findings were consistent with Roy and Bless’ (2000) hypothesis that patients with vocal nodules exhibit higher levels of Extraversion, but only partial support for their hypothesis that patients with vocal nodules exhibit higher levels of Neuroticism. Also consistent with Roy and Bless’ (2000) theory, patients with vocal fold nodules had elevated scores on the Psychoticism scale, which indicates low constraint and high impulsivity (Roy, Bless, Heisey, 2000).

Based on the Roy et al. (2000) findings, it seems possible that patients with certain combinations of elevated Extraversion and Neuroticism are less able to comply with “voice treatment techniques that require inhibition of vocal behavior” (p. 765). In other words, the same personality dimensions that presumably lead to the pre-treatment development of vocal nodules,

may also relate to the maintenance of vocal nodules post-treatment due to a lack of patient compliance to treatment (Roy & Bless, 2000; Roy, Bless & Heisey, 2000). In such cases, it may be more advantageous to suggest alternative or modified voice treatments, rather than complete voice rest. However, there is no empirical research to date that has explored the association between personality and the maintenance of voice disorders or the relationship between personality and compliance with treatment.

Research investigations have explored the relationship between personality and adherent behavior for health conditions, such as acquired immune deficiency syndrome (AIDS), cancer, asthma, multiple sclerosis, and renal failure (Axelsson et al., 2011; Bruce et al., 2009; Christensen and Smith, 1995; Jerant et al., 2011; Sundberg et al., 2010). Throughout this literature, Conscientiousness and Neuroticism consistently arise as personality factors related to adherent behavior. Studies have shown Conscientiousness to have a positive relationship with medication adherence for renal dialysis, AIDS treatment, cholesterol treatment, asthma treatment, and multiple sclerosis treatment (Axelsson et al., 2011; Bruce et al., 2009; Christensen and Smith, 1995). On the other hand, research has revealed a negative relationship between Neuroticism and medication adherence for asthma treatment, and multiple sclerosis treatment, and dementia prevention in older adults (Axelsson et al., 2011; Bruce et al., 2009; Jerant et al., 2011).

Less clear is the relationship between Extraversion and adherent behavior. Cohen et al. (2004) found a negative relationship between Extraversion and compliance with antidepressant treatment suggesting that extraverted individuals may be “‘too busy’ or too engaged to remember or prioritize taking medications” (Cohen et al., 2004, p.111). On the other hand, Courneya et al. (2002) found a positive relationship between Extraversion and exercise adherence. All of these

findings lend support to our hypothesis that a relationship exists between personality and adherence to voice treatment. Additionally, these data illustrate how these relationships may change as a function of the particular treatment in question, for example medication adherence vs. exercise adherence or treatment of one disease process over another. Thus, research specific to compliance with commonly prescribed voice treatments, such as voice rest, are needed and would allow us to gain a better understanding of the relationship between personality and compliance with treatment.

In the present study, we explored the relationship between personality and level of patient compliance with voice rest. Given the exploratory nature of this study, the main focus was to investigate whether personality-specific trends exist in relation to compliance. In other words, whether individuals who display similar personality profiles on a personality inventory, such as the NEO-Five Factor Inventory-3 (NEO-FFI-3), respond to prescribed voice rest with similar patterns of voice use. Additionally, with the Roy and Bless (2000) theory in mind, we also investigated the following exploratory hypotheses: 1) The more extraverted a person, the less compliant he or she will be with voice rest, and 2) The more neurotic a person, the less compliant he or she will be with voice rest.

Methods:

Participants

Seven individuals (mean age of 42; 5 males, 2 females) served as participants. All participants were patients at the Vanderbilt Voice Center who were prescribed voice rest for up to seven days following surgical intervention. Additional factors that might potentially influence adherent behavior, such as demographic information, singing status, occupation, and level of

education were also collected. The following inclusion and exclusion criteria were used during participant selection:

Inclusion Criteria:

- 18 years of age or older
- Patient undergoing surgical excision of benign vocal fold lesions
- Physician prescription of up to 7 days of voice rest following surgical intervention

Exclusion Criteria:

- Younger than 18 years of age
- Patient unwilling to participate

Procedures and Description of Self-Report Instruments

Prior to involvement in the study, all participants completed a document of informed consent (Appendix A). After consenting to participate in the study, each participant completed the following self-report instruments:

1. NEO-Five Factor Inventory-3 (NEO-FFI-3; McCrae and Costa, 2010; Appendix B)

The NEO-FFI-3, which is the shorter 60-item version of the NEO-Personality Inventory-3, was completed at the time of the consent (McCrae and Costa, 2010). All of the NEO inventories are considered *genotypic* measures of personality and therefore, are designed to uncover the “basic psychological strata of person,” rather than those behaviors prone to changes (Piedmont, 1988, p. 2). The 60-item questionnaire contains five 12-item scales to identify the five broad personality dimensions of Neuroticism (N), Extraversion (E), Openness (O), Agreeableness (A), and Conscientiousness (C) (McCrae and Costa, 2010). Participant responses are measured on a 5-point Likert scale with the following five response options: strongly disagree (0), disagree, neutral, agree, and strongly agree (4; McCrae and Costa, 2010). Extraversion and Neuroticism were of primary interest; however, given the exploratory nature of the study, data were collected for all personality factors, including Openness, Agreeableness, and Conscientiousness. At the end of the inventory, three yes-or-no questions served as a

validity checks to determine if the participant had responded to all questions, entered responses across the rows, and responded accurately and honestly (McCrae and Costa, 2010).

When scoring the NEO-FFI-3, each participant received a raw score for each personality domain that was later matched with a T score. Based on published norms in personality research, the NEO-FFI-3 provides different scales to convert raw scores to T scores according to gender and age (McCrae and Costa, 2010). For example, separate norms are often used for men and women, “so that a T score of 50 represents average *for a man or for a woman*” (McCrae and Costa, 2010, p.18). Additionally, adolescent norms are used to interpret scores of individuals between 12 and 20 years old (McCrae and Costa, 2010). As all of the participants in this study were over the age of 20 years old, T scores were calculated using the adult norms of the appropriate gender of the participant. T scores are qualitatively interpreted according to the following five levels: *very high* (T score of 66 or greater), *high* (T score of 56 to 65), *average* (T score of 45 to 55 greater), *low* (T score of 35 to 44), and *very low* (T score of 34 or lower) (McCrae and Costa, 2010). When interpreting each participant’s score, it is very important to keep in mind that the NEO-FFI-3 was designed to “measure traits that approximate a normal, bell-shaped distribution; [thus,] it is expected that most individuals will obtain scores near the average [for each] scale, with [only] a small percentage scoring at either end” (McCrae and Costa, 2010, p. 17).

2. Voice Handicap Index (VHI; Jacobson et al.1997; Appendix C)

The VHI was completed at the time of consent to assess how an individual’s voice problem impacted various aspects of their everyday lives. The VHI is a 30-item self-report questionnaire used to measure the handicapping effects of voice disorders (Jacobson et al.,

1997). The index is divided into three 10-item subscales: an emotional subscale, a functional subscale, and a physical subscale, with each item being measured by a yes or no response.

3. Pre-surgical questionnaire (Appendix D)

Prior to vocal fold surgery, participants received two questionnaire packets, the pre-surgical questionnaire and post-surgical questionnaire, at time of consent. It was the patient's responsibility to hold onto the post-surgical questionnaire until after surgical intervention to complete the questions while on voice rest. The pre-surgical questionnaire was used to gather demographic information, as well as *baseline* information regarding duration of voice use, intensity of voice use, and alternative methods of communication used during treatment.

The cover sheet of the packet requested demographic data from each participant such as age, gender, occupation, level of education, and number of individuals in the household. These demographic factors were selected a priori to control for confounding variables that might potentially influence compliance. For example, studies have shown that age has a positive relationship with adherent behavior (Christensen and Smith, 1995). Additionally, Rousseau et al. (2010) found that women were more compliant than men with regard to voice rest treatment. Sundberg et al. (2010) discovered a similar gender effect in patient compliance to asthma treatment.

The remainder of the participant packet included daily questionnaires that were filled out for seven days prior to vocal fold surgery. Each day, the participant was asked to record whether they worked/went to school, as well as to self-report their estimated duration of voice use, maximum intensity of voice use and alternative methods of communication used during treatment.

Duration of voice use was measured using a 100-mm visual analog scale (VAS) anchored by *not at all* and *very much* at 0 and 100 mm respectively to the question “How much did you use your voice today (including whispering)” and with the following prompt: “I used my voice...”. VAS scores were obtained by measuring with a ruler where each participant placed a mark on the scale; this length provided the VAS score. For example, if a participant placed a mark at 64 mm, their VAS score was 64.

Intensity of voice use was measured in response to the question “Circle the number that best describes the maximum loudness of your voice use today?” A 5-point Likert scale provided the following five response options to this question: 1 corresponding to *I did not use my voice*, 2 corresponding to *whisper*, 3 corresponding to *conversational level*, 4 corresponding to *talking loudly*, and 5 corresponding to *yelling*.

Data on alternative methods of communication were gathered by checking all that apply to the question, “How did you communicate today?” The options provided were *voice*, *whisper*, *gesture*, *mouthed words*, *writing*, *text/email*, *other* with a line for an explanation.

The participant held onto this pre-surgical questionnaire packet and turned it in with the post-surgical questionnaire at the time of the follow-up appointment.

4. Post-surgical questionnaire (Appendix E)

As explained above, prior to vocal fold surgery, participants received two questionnaire packets, the pre-surgical questionnaire and post-surgical questionnaire, at time of consent. The post-surgical questionnaire was used to gather information regarding the patient’s duration of voice use, maximum intensity of voice use, and alternative methods of communication throughout the voice rest treatment period. The post-surgical questionnaire was filled out daily for the seven days following vocal fold surgery. The measures of duration of voice use, intensity

of voice use and alternative methods of communication were identical in both pre- and post-surgical questionnaires. Along with pre-surgical questionnaire, the post-surgical questionnaire was returned at the time of the follow-up appointment.

Study Design

The study explored two variables: personality and compliance. Personality served as an independent variable, and compliance served as a dependent variable. Personality was operationalized by NEO-FFI-3 personality factors. Compliance was explored in two ways: *absolute* compliance and *relative* compliance. Absolute compliance was operationalized by VAS score, such that VAS scores of 0 indicated complete compliance with voice rest and VAS scores greater than 0 failed to indicate complete compliance with voice rest. Relative compliance was operationalized by comparison of pre-surgical and post-surgical duration of voice use, such that decreasing percentages of voice use from pre-surgery to post-surgery indicated increasing levels of compliance with treatment.

Descriptive analyses were used to explore broadly whether individuals with certain personality factors responded to voice rest in similar ways, and more specifically whether relationships emerged between certain personality factors and compliance. The personality factors of interest in this study included Extraversion, Neuroticism, and Conscientiousness. As previously indicated, we hypothesized that Neuroticism and Extraversion would have a negative relationship with voice rest compliance. Further, we made a decision to explore the relationship between Conscientiousness and compliance post-hoc to further explicate the potential relationship between these two variables. In concurrence with research in other medical fields, we hypothesized that Conscientiousness has a strong positive relationship with voice rest compliance (Axelsson et al., 2011; Bruce et al., 2009; Christensen and Smith, 1995).

The extremely small sample size of this study was both a limitation and significant strength, allowing for in-depth analyses to be performed of individual participant data. The duration of daily voice use for each participant was plotted out pre-surgically and post-surgically using VAS scores. This visual representation provided a general description of individual patterns of voice use and how they might relate to intrinsic factors such as personality and demographic data. Additionally, these analyses allowed us to not only gauge whether individuals with those intrinsic factors displayed higher or lower levels of duration of voice use, but also how the length of prescribed voice rest might play a role in compliance to treatment.

Results

High Extraversion (H-E), Low Neuroticism (L-N), High Conscientiousness (H-C)

Four of the participants in this study – CR, PA, OT, and PM – achieved high scores in Extraversion, low scores in Neuroticism, and high scores in Conscientiousness on the NEO-FFI-3. The following paragraphs explicate individual trends for each of these participants followed by a group analysis of how this personality profile of H-E, L-N and H-C fits with the predicted hypotheses outlined in the introduction to our manuscript.

CR

CR is a 43-year-old male who reportedly lives alone. He listed his occupation as a builder, and does not consider himself a singer. He listed high school as the highest level of education completed. Information gathered from the pre-surgical questionnaire suggested that CR used various methods of communication daily at baseline. For example, he reported that he communicated by using his voice, whispering, text/email, gesture and writing in the seven days prior to surgery and voice rest. He attended work daily for the seven days prior to surgery; however, took off work for the six days that he was on voice rest following surgery. CR's

follow-up appointment was on the 7th day following surgery; therefore, only six days of voice rest data were obtained.

NEO-FFI-3 Scores and Profile

Table 1: CR's NEO-FFI-3 Raw Score, T Score, and Description

Scale	Raw Score	T Score	Description
Extraversion	32	58	High
Neuroticism	7	33	Very Low
Conscientiousness	44	77	Very High

CR completed the NEO-FFI-3 at time of consent. His scores on the NEO-FFI-3 revealed *very high* levels of Conscientiousness, *high* levels of Extraversion, and *very low* levels of Neuroticism. As high levels of Conscientiousness and low levels of Neuroticism have been linked with increased compliance in past research, one would have predicted that CR would strongly comply with voice rest restrictions. On the other hand, one might predict that CR's high level of Extraversion alone would lead to lower levels of compliance with voice rest restrictions based on Roy and Bless' (2000) theory. However, it is worth noting that Extraversion alone, without the amplifying effects of Neuroticism (e.g. H-N and H-E), may not be enough to predict noncompliance based on Roy and Bless' (2000) theory which emphasizes the combination of H-N paired with H-E.

Duration of Voice Use

Table 2: CR's Daily Pre- and Post-surgical VAS scores (mm) and Mean VAS scores (mm)

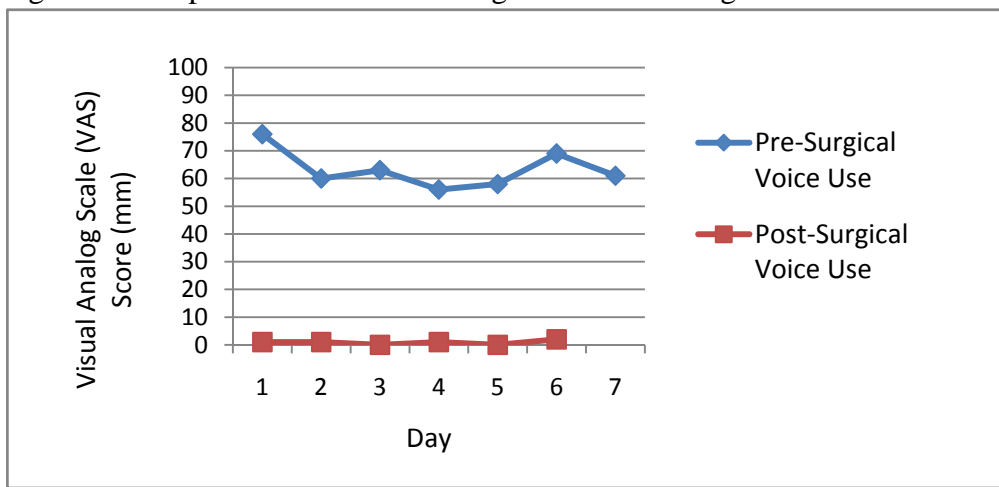
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Mean VAS
Pre-Surgical VAS	76	60	63	56	58	69	61	63
Post-Surgical VAS	1	1	0	1	0	2	n/a	.83
Pre-surgical – Post-surgical	75	59	63	55	58	67	n/a	62.17
% Decrease in VAS	98.69	98.33	100	98.21	100	97.10	n/a	98.68

CR's pre-surgical and post-surgical VAS scores, differences in VAS score, and mean VAS are displayed in Table 2. As can be observed in table 2, CR's pre-surgical VAS ranged from 61 to 76 with a mean VAS of 63, suggesting that CR used his voice regularly, but not necessarily every time he communicated. This may suggest that even *prior* to surgery and voice rest treatment, CR restricted his level of voice use. Potential explanations for such self-control may be linked to physical discomfort secondary to dysphonia, and/or hyper-vigilance in not wanting to further engage in vocal abuse. If the latter is true, it may be possible that such vigilance is related to CR's high levels of Conscientiousness.

CR's post-surgical VAS ranged from 0 to 2 with a mean VAS of .83, suggesting very minimal, if any, voice use while on voice rest. However, it should be noted that CR was not completely compliant with voice rest, as he reported VAS scores greater than 0 on four of the six days of prescribed voice rest. This raises the question: How much compliance is necessary for voice rest treatment to be successful? It should be noted that this fundamental question has never been addressed systematically. We anticipate that the results of our current line of scientific inquiry will provide further justification for exploring the above question and related essential questions surrounding this treatment modality. It should be noted that anecdotally, the above question has been posed to several of our laryngology colleagues, who generally define compliance as "not uttering a single word" and "not whispering" while on voice rest. Others argue that given a patient that "talks all of the time" when not on voice rest, even a modest reduction in voice use should be considered a success and is better than "no reduction in voice use at all" while on voice rest. Thus, these data and the research that results from systematic scientific inquiry on personality and compliance with voice rest treatment may ultimately shape and influence clinical decision-making regarding management.

As can be observed in figure 1, comparison of pre-surgical and post-surgical duration of voice use revealed a noticeable decline in voice use while CR was on voice rest. Such a sharp decline in voice use suggests that CR exhibited an extremely high level of relative compliance with voice rest restrictions. CR’s percent decrease in VAS ranged from 97.10% to 100%, further supporting CR’s relative compliance with voice rest. Such compliance is not surprising given CR’s high levels of Conscientiousness and low levels of Neuroticism.

Figure 1: Comparison of CR’s Pre-surgical and Post-surgical Duration of Voice Use



Maximum Intensity of Voice Use

Table 3: CR’s Daily Pre- and Post-surgical Level of Maximum Intensity

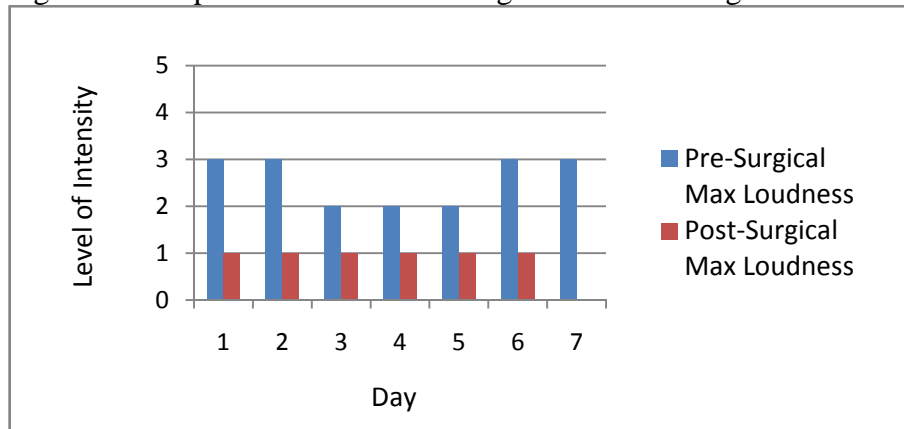
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pre-Surgical Max Intensity	3	3	2	2	2	3	3
Post-Surgical Max Intensity	1	1	1	1	1	1	n/a

* 1=I did not use my voice, 2=Whisper, 3=Conversational level, 4=Talking Loudly, 5=Yelling

As can be observed in Table 3, prior to surgery, CR’s maximum level of voice use was at the conversational level for four out of seven days, and at the whisper level for the remaining three days. Prior to surgery, CR reduced his maximum intensity level to a whisper on Day 4 and Day 5. Interestingly, these days coincided with the lowest VAS scores (e.g. 56 and 58 respectively). This reduction in maximum intensity level appears to provide further support for

the hypothesis that CR was exhibiting vocal self-control prior to surgery and the prescription of voice rest. Following surgery, CR reported that he did not use his voice for all six days of prescribed voice rest, which is unlikely given his VAS scores of greater than 0. A graphical comparison of pre- to post-surgical maximum intensity of voice use is shown in Figure 2. When reviewing the chart, recall that 1 corresponds to *I did not use my voice*, 2 corresponds to *whisper*, 3 corresponds to *conversational level*, 4 corresponds to *talking loudly*, and 5 corresponds to *yelling*.

Figure 2: Comparison of CR's Pre-surgical and Post-surgical Maximum Vocal Intensity



Alternative Methods of Communication

As mentioned above, pre-surgical data suggested that CR used various methods of communication at baseline. During the seven days prior to surgery, CR reported that he communicated by voice, whispering, and text/email daily. For five out of the seven days prior to surgery, he also reported using gestures and writing to communicate. Following surgery, CR reported using gesture, writing, and email/text as a way to communicate daily. This suggests that CR may have increased his use of gesture and writing while on voice rest; however, he did not introduce any new methods of communication while on voice rest. On his last day of voice rest, Day 6, CR reported that he used voice and whisper to communicate as well, which further confirms that CR failed to achieve complete compliance with voice rest. This may additionally

suggest a potential duration effect related to the length of voice rest, as CR did not report using his voice or whispering to communicate on any other day. The latter (e.g. duration effect) has strong implications for voice rest treatment, as Rousseau et al. (2011) found that duration of voice rest treatment ranges from 3 to 28 days, with 15% of surveyed otolaryngologists unlikely to recommend any type of voice rest (Behrman and Sulica, 2003).

Voice Handicap Index

Table 4: CR's VHI Score and Severity Rating

Scale	Score	Severity Rating
Physical	26	Severe
Functional	19	Severe
Emotional	5	Mild
Total	50	Moderate

CR completed the VHI at the time of consent. CR's scores suggested that his dysphonia had the greatest impact on his physical and functional well-being. His extremely high score on the physical scale may provide evidence that supports our predictions regarding the relationship between pre-surgical voice use self-control and physical discomfort. For example, CR indicated that the sound of his voice *almost always* varies throughout the day, that he *almost always* feels as though he has to strain to produce voice, and that he *almost always* uses a great deal of effort to speak. With such physical manifestations on his voice, it appears that CR may have exercised vocal inhibition with respect to duration and intensity of voice use even prior to surgery. Additionally, it may further explain CR's high relative compliance with voice rest treatment.

Other Factors to Consider

Other factors, such as number of household members and taking time off work may influence compliance with voice rest treatment. Thus, these "other factors" were also considered in our study. For example, CR reported living alone and taking time off from work while on

voice rest. Eliminating the demands of the work environment coupled with living alone may provide an alternative explanation for CR's extremely high level of compliance with voice rest.

PA

PA is a 40-year-old male who lives with one child at home. PA works as a financial advisor, and reported a Master's degree as his highest level of education completed. Data collected from the pre-surgical questionnaire suggested that PA used various methods of communication daily at baseline. For example, he reported communicating using voice, writing, and text/emails during the seven days prior to surgery and voice rest. PA went to work daily for the seven days prior to surgery. Unlike many of the other participants in this study, PA also attended work for four out of the seven days of prescribed voice rest.

Neo-FFI-3 Scores and Profile

Table 5: PA's NEO-FFI-3 Raw Score, T Score, and Description

Scale	Raw Score	T Score	Description
Extraversion	42	74	Very High
Neuroticism	8	34	Very Low
Conscientiousness	37	58	High

PA completed the NEO-FFI-3 at the time of consent. His scores on the NEO-FFI-3 revealed *very high* levels of Extraversion, *high* levels of Conscientiousness, and *very low* levels of Neuroticism. Given CR's compliant behavior and similar personality profile, one might predict that PA would strongly comply with voice rest restrictions. However, it may be the case that PA's *very high* levels of Extraversion would result in lower levels of compliance with voice rest when compared to CR, who exhibited *very high* levels of Conscientiousness. Again, it is worth noting that Extraversion alone, without the amplifying effects of Neuroticism (e.g. H-N and H-E), may not be enough to predict noncompliance based on Roy and Bless' (2000) theory which emphasizes the *combination* of H-N paired with H-E.

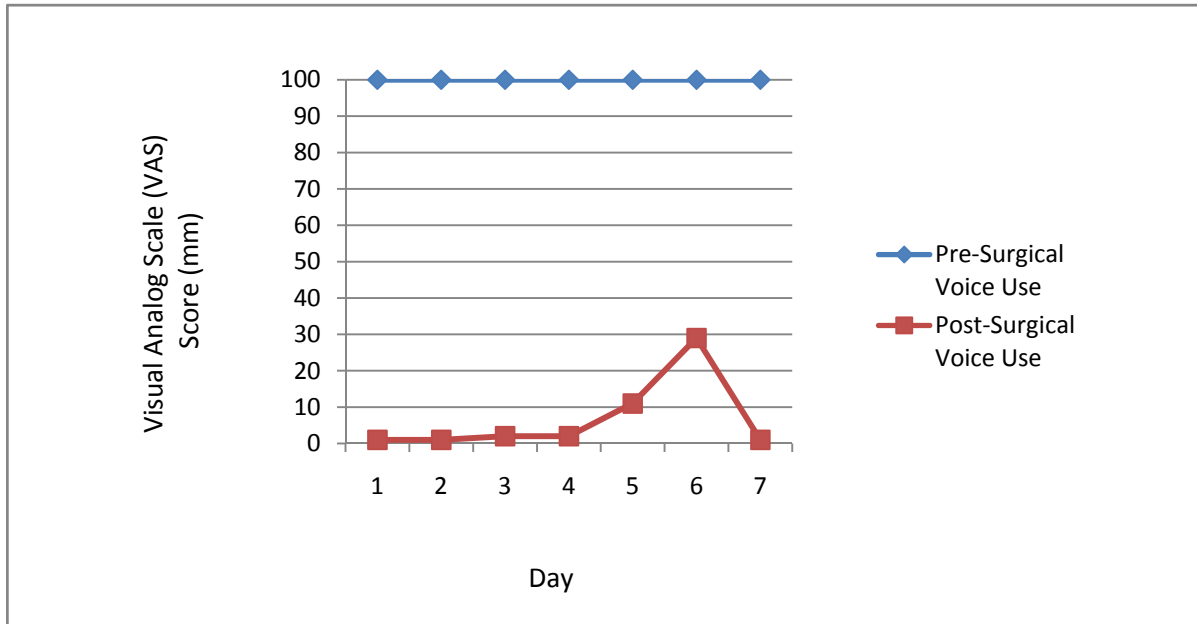
Duration of Voice Use

Table 6: PA's Daily Pre- and Post-surgical VAS scores (mm) and Mean VAS scores (mm)

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Mean VAS
Pre-Surgical VAS	100	100	100	100	100	100	100	100
Post-Surgical VAS	1	1	2	2	11	29	1	6.71
Pre-surgical – Post-surgical	99	99	98	98	89	71	99	88.57
% Decrease in VAS	99	99	98	98	89	71	99	88.57

PA's pre-surgical and post-surgical VAS scores, differences in VAS score, and mean VAS are displayed in Table 6. As can be observed in Table 6, PA's pre-surgical VAS remained constant at 100, suggesting that PA used his voice every time that he wanted to communicate all seven days prior to surgery. PA's post-surgical VAS ranged from 1 to 29 with a mean VAS of 6.71, suggesting that he used his voice at least once daily while on voice rest. Such behavior indicated that PA, similar to CR did not comply completely with voice rest. However, as can be seen in Figure 3, comparison of pre-surgical and post-surgical duration of voice use revealed a noticeable decline in voice use while PA was on voice rest, particularly during Days 1-4 and Day 7. Such an observation appears to again suggest a duration effect, as there was an increase in PA's voice use during the latter days of voice rest treatment. However, increased VAS scores may also be associated with increased demands of the work environment as PA went to work for the full day on Day 5 and Day 6 of the voice rest treatment period. PA's percent decrease in VAS ranged from 71% - 99%, which indicates a high level of relative compliance with voice rest treatment.

Figure 3: Comparison of PA’s Pre-surgical and Post-surgical Duration of Voice Use



Maximum Intensity of Voice Use

Table 7: PA’s Pre- and Post-surgical Level of Maximum Intensity

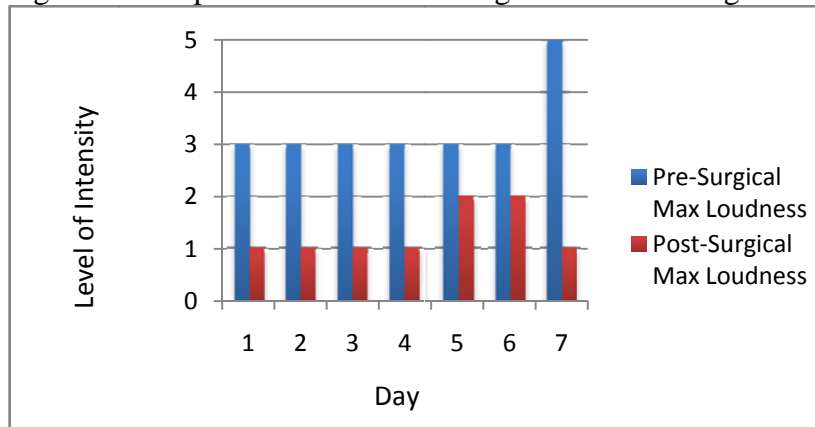
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pre-Surgical Max Intensity*	3	3	3	3	3	3	5
Post-Surgical Max Intensity	1	1	1	1	2	2	1

* 1=I did not use my voice, 2=Whisper, 3=Conversational level, 4=Talking Loudly, 5=Yelling

As can be observed in Table 7, prior to surgery, PA’s maximum intensity of voice use was at a conversational level for six out of seven days, and yelling for the last day prior to surgery. Following surgery, PA reported that he did not use his voice for five out of six days of prescribed voice rest, which may not be accurate as PA did not report a VAS score of 0 on those days. On Day 5 and Day 6, PA reported whispering as his maximum intensity level. As PA went to work on Day 5 and Day 6, it is unclear whether such increases in PA’s intensity level near the end of the voice rest treatment period is related to a duration effect vs. increased demands of the work environment.

Although PA did not exhibit complete compliance with voice rest treatment, it is clear that he made efforts to comply with voice rest not only by decreasing his daily duration of voice use, but also by reducing the level of intensity during episodes of voice use. Figure 4 displays a graphical comparison of pre- to post-surgical maximum intensity of voice use. When reviewing the figure, recall that 1 corresponds to *I did not use my voice*, 2 corresponds to *whisper*, 3 corresponds to *conversational level*, 4 corresponds to *talking loudly*, and 5 corresponds to *yelling*.

Figure 4: Comparison of PA's Pre-surgical and Post-surgical Maximum Vocal Intensity



Alternative Methods of Communication

As mentioned above, PA's pre-surgical data suggested that he used various methods of communication at baseline. During the seven days prior to surgery, PA reported that he communicated using voice, writing, and text/email daily. Following surgery, PA reported using gesture, writing, and text/email to communicate daily. He additionally reported whispering for two out of the seven days of voice rest, and mouthing words and using his voice for one out of the seven days of voice rest. PA's increased use of alternative methods of communication towards the end of the prescribed voice rest treatment period may be an indication that it became increasingly difficult for PA to meet the demands of voice rest as the week progressed.

Voice Handicap Index

Table 8: PA’s VHI Score and Severity Rating

Scale	Score	Severity Rating
Physical	31	Severe
Functional	10	Mild
Emotional	6	Mild
Total	47	Moderate - Severe

PA completed the VHI at the time of consent. His pre-treatment scores suggested that PA’s dysphonia had the greatest impact on his physical well-being. He reported that the clarity of his voice was *always* unpredictable and that he *always* feels that he had to strain his voice to speak. PA’s dysphonia appears to have had a lesser functional and emotional impact as he reported that he *never* avoided groups because of his voice and that he was *never* emotionally upset because of his voice problem. Interestingly, PA did report *sometimes* feeling handicapped by his voice problem.

Other Factors to Consider

PA reported living at home with one child and attending work while on voice rest. The increased demands of household members, as well as the work environment may provide a potential explanation for PA’s decreased compliance with voice rest when compared to CR who lived alone and did not attend work while on voice rest. For example, the days when PA went into work for a full day, Day 4 and Day 5, corresponded with the highest VAS scores for voice use, greater maximum intensity level, and an increased number of alternative methods of communication. Although PA exhibited lower levels of relative compliance with voice rest than CR, it should be emphasized that PA still exhibited high levels of relative compliance for the majority of days that he was on voice rest.

OT

OT is a 59-year-old male who reportedly lives at home with one other adult. He worked as a VP of Finance at a University. He reported a post graduate degree as his highest level of education completed. Data collected from the pre-surgical questionnaire suggested that OT used various methods of communication daily at baseline. For example, he reported communicating using his voice and text/email for all seven days prior to surgery and additionally using gesture for two of the seven days prior to surgery. OT reported working for five of the seven days prior to surgery and reported “n/a” for the remaining two days. Following surgery, OT took off from work for five of the seven days of voice rest, and reported “n/a” for the remaining two days. Although it is unclear what OT meant by his response of “n/a,” it may be the case that these days were weekend days in which OT was not expected to work.

Neo-FFI-3 Scores and Profile

Table 9: OT’s NEO-FFI-3 Raw Score, T Score, and Description

Scale	Raw Score	T Score	Description
Extraversion	44	>/=75	Very High
Neuroticism	10	37	Low
Conscientiousness	38	60	High

OT completed the NEO-FFI-3 at the time of consent. His scores on the NEO-FFI-3 revealed *very high* levels of Extraversion, *high* levels of Conscientiousness, and *low* levels of Neuroticism. Given the similarity of OT’s personality profile to previous participants, one might have predicted OT to strongly comply with voice rest restrictions as well. However, it may be the case that OT’s *very high* levels of Extraversion would result in lower levels of compliance with voice rest when compared to CR, who exhibited *very high* levels of Conscientiousness. Again, it is worth noting that Extraversion alone, without the amplifying effects of Neuroticism (e.g. H-N

and H-E), may not be enough to predict noncompliance based on Roy and Bless’ (2000) theory which emphasizes the combination of H-N paired with H-E.

Duration of Voice Use

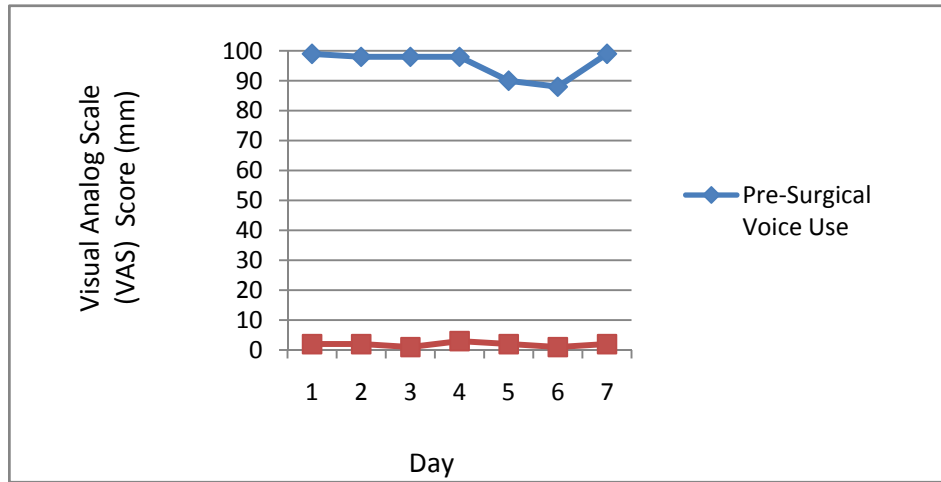
Table 10: OT’s Daily Pre- and Post-surgical VAS scores (mm) and Mean VAS scores (mm)

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Mean VAS
Pre-Surgical VAS	99	98	98	98	90	88	99	95.71
Post-Surgical VAS	2	2	1	3	2	1	2	1.86
Pre-surgical – Post-surgical	97	96	97	95	88	87	97	93.85
% Decrease in VAS	97.98	97.96	98.98	96.94	97.78	98.86	97.98	98.06

OT’s pre-surgical and post-surgical VAS scores, differences in VAS score, and mean VAS are displayed in Table 10. As can be observed in Table 10, OT’s pre-surgical VAS ranged from 88-99 with a mean VAS of 95.71 suggesting that OT used his voice nearly every time that he wanted to communicate for at least five of the seven days prior to surgery. Interestingly, OT’s lowest VAS scores corresponded to Days 5 and Day 6 in which he indicated “n/a” in response to whether he worked or took the day off. These data appear to suggest that greater demands are placed on OT’s voice in the work environment than on days in which he does not go to work.

OT’s post-surgical VAS ranged from 1 to 3 with a mean VAS of 1.86, suggesting that he used his voice at least once daily while on voice rest. These data indicate that OT did not comply with the physician’s order of complete voice rest. However, as can be observed in Figure 5, comparison of pre-surgical and post-surgical duration of voice use revealed a noticeable decline in voice use while OT was on voice rest. Similar to CR, OT’s mean percent decrease in VAS was 98.06, which indicated a high level of relative compliance with voice rest restrictions.

Figure 5: Comparison of OT’s Pre-surgical and Post-surgical Duration of Voice Use



Maximum Intensity of Voice Use

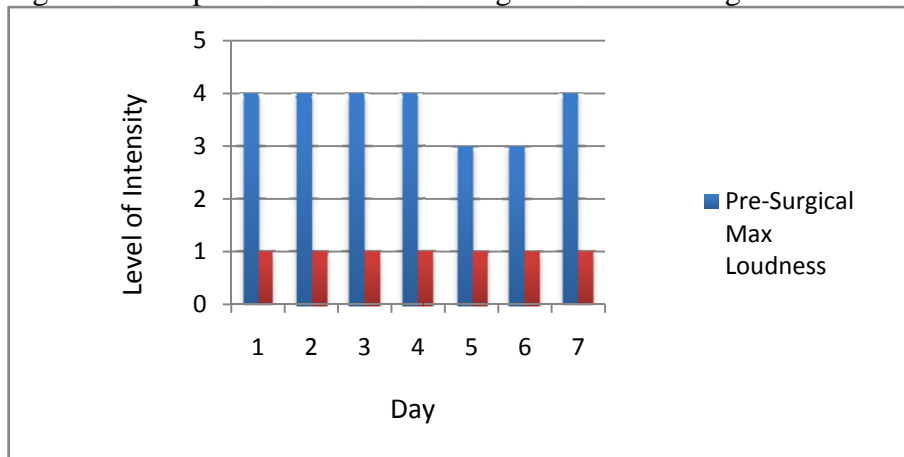
Table 11: OT’s Pre- and Post-surgical Level of Maximum Intensity

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pre-Surgical Max Intensity*	4	4	4	4	3	3	4
Post-Surgical Max Intensity	1	1	1	1	1	1	1

* 1=I did not use my voice, 2=Whisper, 3=Conversational level, 4=Talking Loudly, 5=Yelling

As can be observed in Table 11, prior to surgery, OT’s maximum level of voice use was talking loudly for five out of seven days, and at the conversational level for two out of seven days (e.g. Day 5 and 6). Recall that Day 5 and Day 6 also corresponded to the days with lower VAS scores in which OT reported “n/a” in response to whether he went to work or took the day off. OT’s reduced intensity level on these days further supports the hypothesis that demands on his voice are less when OT is not in the work environment. Following surgery, OT reported that he did not use his voice for all seven days of prescribed voice rest; however, this does not coincide with his reported VAS score of greater than 0 on these days. Figure 6 below is a graphical comparison of pre- to post-surgical maximum intensity of voice use. Recall that 1 corresponds to *I did not use my voice*, 2 corresponds to *whisper*, 3 corresponds to *conversational level*, 4 corresponds to *talking loudly*, and 5 corresponds to *yelling*.

Figure 6: Comparison of OT’s Pre-surgical and Post-surgical Maximum Intensity



Alternative Methods of Communication

As mentioned above, pre-surgical data suggested that OT used various methods of communication at baseline. During the seven days prior to surgery, OT reported that he communicated by voice and text/email daily. Additionally, for two out of the seven days prior to surgery, he also reported using gesture to communicate. Following surgery, OT reported using gesture, mouthed words, writing, and email/text as a way to communicate daily. This suggests that OT introduced new methods to communicate while on voice rest.

Voice Handicap Index

Table 12: OT’s VHI Score and Severity Rating

Scale	Score	Severity Rating
Physical	28	Severe
Functional	21	Severe
Emotional	22	Severe
Total	71	Severe

OT completed the VHI at the time of consent. These scores indicate that OT’s dysphonia had an equally significant impact on his physical, emotional, and functional well-being. For example OT indicated that his voice problem *almost always* upsets him and that he *almost always* has to repeat himself when speaking face-to-face. Additionally he *almost always* feels

that he uses a great deal of effort to speak and that his voice difficulties *almost always* restrict his personal and social life. The severity of OT's dysphonia prior to surgical intervention may provide an alternative explanation for OT's strong relative compliance with voice rest.

Other Factors to Consider

OT reported that he lived with one other adult. Constantly having another person around may make it more difficult to comply with voice rest; however, this did not seem to be the case for OT who had extremely low VAS scores while on voice rest. Similar to the majority of the participants in this study, OT also took time off from work while on voice rest. Eliminating the demands of the work environment may help to explain his compliant behavior especially when considering the increased vocal demands OT's work environment appeared to place at baseline.

PM

PM is a 36-year-old male who reportedly lives with one other adult and five children. He works as a teacher and basketball coach. He reported a Bachelor's of Science as his highest level of education completed. Data collected from the pre-surgical questionnaire suggested that PM used various methods of communication daily at baseline. For example, he reported communicating using his voice, whisper, gesture, mouthed words, writing, and text/email during all seven days prior to surgery and voice rest. PM reported working for five of the seven days prior to surgery and reported "n/a" for the remaining two days. Similar to our speculations with OT, we suspect that "n/a" is related to a weekend day in which PM was not expected to go into work. PM took the day off from work for six of the seven days on voice rest, and reported attending work on the last day of voice rest.

Neo-FFI-3 Scores and Profile

Table 13: PM's NEO-FFI-3 Raw Score, T Score, and Description

Scale	Raw Score	T Score	Description
Extraversion	36	64	High
Neuroticism	13	41	Low
Conscientiousness	46	73	Very High

PM completed the NEO-FFI-3 at the time of consent. His scores on the NEO-FFI-3 revealed *very high* levels of Conscientiousness, *high* levels of Extraversion, and *low* levels of Neuroticism. Given his similarity in personality profile to previous participants, it seemed likely that OT would strongly comply with voice rest restrictions. However, it may be the case that OT's *high* levels of Extraversion result in lower levels of compliance based on Roy and Bless' (2000) theory. Again, it is worth noting that Extraversion alone, without the amplifying effects of Neuroticism (e.g. H-N and H-E), may not be enough to predict noncompliance as Roy and Bless (2000) emphasize the combination of H-N paired with H-E.

Duration of Voice Use

Table 14: PM's Daily Pre- and Post-surgical VAS scores (mm) and Mean VAS scores (mm)

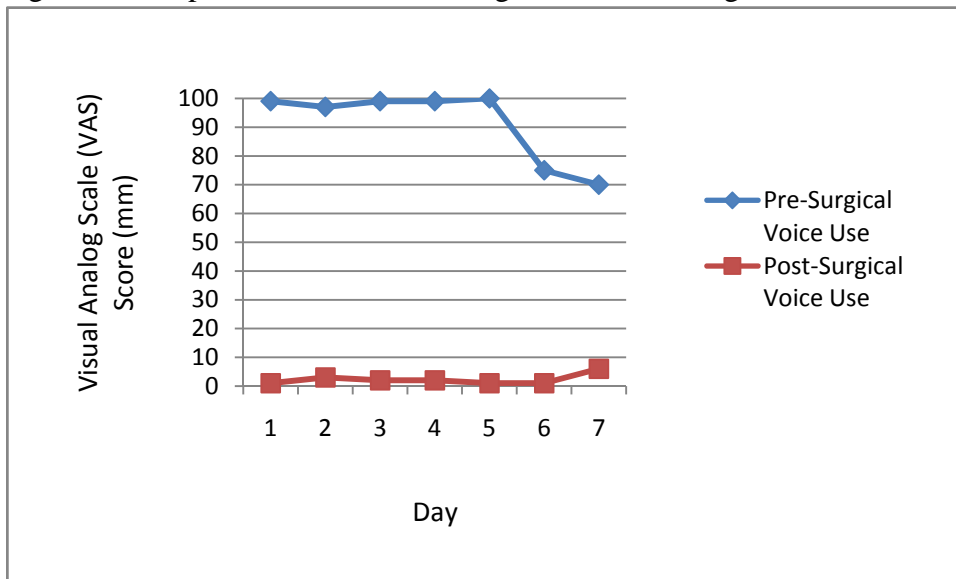
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Mean VAS
Pre-Surgical VAS	99	97	99	99	100	75	70	91.29
Post-Surgical VAS	1	3	2	2	1	1	6	2.29
Pre-surgical – Post-surgical	98	94	97	97	99	74	64	89
% Decrease in VAS	98.99	96.91	97.98	97.98	99	98.67	91.43	97.49

PM's pre-surgical and post-surgical VAS scores, differences in VAS score, and mean VAS are displayed in Table 14. As can be seen above, PM's pre-surgical VAS ranged from 70-100 with a mean VAS of 91.29 suggesting that PM used his voice nearly every time that he wanted to communicate for at least five of the seven days prior to surgery. Similar to OT, PM's

lowest VAS scores corresponded to days (e.g. Day 6 and Day 7) in which he specified “n/a” in response to whether he worked or took the day off. We interpreted this as suggestive that PM may have greater vocal demands in the work environment, which is further supported by PM’s reports of using his voice to coach games on four of the five days in which he went to work prior to surgery.

PM’s post-surgical VAS ranged from 1 to 6 with a mean VAS of 2.29, suggesting that he used his voice at least once daily while on voice rest. These data indicate that PM did not comply with the physician’s order of complete voice rest. However, as can be observed in Figure 7, comparison of pre-surgical and post-surgical duration of voice use revealed a noticeable decline in voice use while PM was on voice rest. PM’s mean percent decrease in VAS was 97.49, which indicates a high level of relative compliance with voice rest restrictions. As PM scored high in Conscientiousness and low in Neuroticism, such compliance is not surprising.

Figure 7: Comparison of PM’s Pre-surgical and Post-surgical Duration of Voice Use



Maximum Intensity of Voice Use

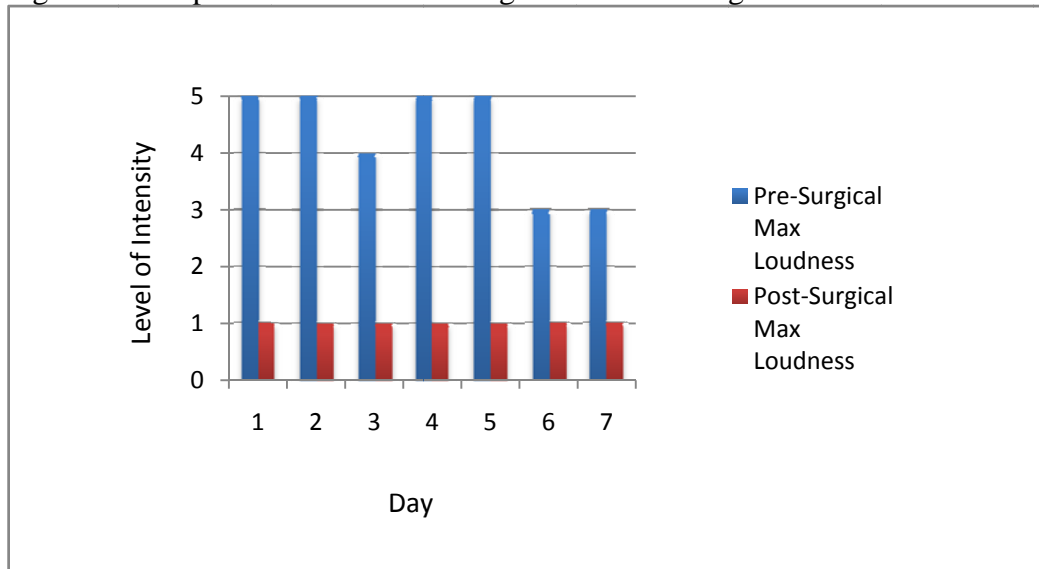
Table 15: PM’s Pre- and Post-surgical Level of Maximum Intensity

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pre-Surgical Max Intensity*	5	5	4	5	5	3	3
Post-Surgical Max Intensity	1	1	1	1	1	1	1

* 1=I did not use my voice, 2=Whisper, 3=Conversational level, 4=Talking Loudly, 5=Yelling

As can be observed in Table 15, prior to surgery, PM’s maximum level of voice use was yelling for four out of seven days, conversational for two out of seven days, and talking loudly for one out of seven days. Following surgery, PM reported not using his voice for all seven days of prescribed voice rest, which differed from his VAS scores of greater than 0 on each day of voice rest. Figure 8 shows a graphical comparison of pre- to post-surgical maximum intensity of voice use. When reviewing the figure, recall that 1 corresponds to *I did not use my voice*, 2 corresponds to *whisper*, 3 corresponds to *conversational level*, 4 corresponds to *talking loudly*, and 5 corresponds to *yelling*.

Figure 8: Comparison of PM’s Pre-surgical and Post-surgical Maximum Vocal Intensity



Alternative Methods of Communication

As mentioned above, pre-surgical data suggested that PM used various methods of communication at baseline. During the seven days prior to surgery, PM reported that he communicated by using his voice, whisper, gesture, mouthed words, writing, and text/email. Following surgery, PM reported using gesture, mouthed words, writing, and email/text to communicate for six out of seven days, and only writing and email for one out of seven days. Comparison of pre- and post-surgical methods of communication revealed that PM essentially used the same methods of communication prior to and during voice rest.

Voice Handicap Index

Table 16: PM's VHI Score and Severity Rating

Scale	Score	Severity Rating
Physical	14	Mild
Functional	8	Mild
Emotional	8	Mild
Total	30	Mild

The VHI was completed by PM at the time of consent. These scores suggested that PM's dysphonia had only a mild impact on his physical, functional, and emotional well-being. PM reported that he *never* felt incompetent because of his voice problem and *never* felt that his voice problem restricted his personal or social life. He did report that *sometimes* he had to strain to produce voice and that *sometimes* his voice would give out on him while he was speaking.

Other Factors to Consider

PM reported living with one other adult and five children. It is suspected that living in larger households places increased vocal demands on members living in the household. Interestingly, despite having the largest household in the study PM demonstrated high levels of relative compliance with voice rest. Similar to most of the participants in the study, PM also took

time off from work while on voice rest. Eliminating the demands of the work environment may help to explain his generally compliant behavior.

Personality – Compliance Hypothesis: H-E, L-N, H-C

The compliance data gathered from CP, PA, OT, and PM seems to fit in nicely with their personality profiles in the domains of Neuroticism and Conscientiousness. As mentioned in the introduction, high levels of Conscientiousness and low levels of Neuroticism have consistently been linked with higher levels of medication adherence with many types of disease processes. The data gathered from this cluster of participants suggest that Conscientiousness and Neuroticism are not only related to medication compliance, but potentially behavioral compliance as well. Contrary to Roy and Bless' (2000) hypothesis, the compliant behavior exhibited by this cluster does not lend support in favor of a negative relationship between Extraversion and compliance to voice rest. It may be the case; however, that in some cases (e.g CR) extremely high levels of Conscientiousness outweighed his high levels of Extraversion, tipping his behavior in favor of compliance. Additionally, it may be the case that only high levels of Extraversion *paired* with high levels of Neuroticism negatively impact compliance with voice rest, which is a personality combination that was not found by any of the participants in this data set.

High Extraversion (H-E), Low Neuroticism (L-N), Average Conscientiousness (A-C)

Only one participant in this study – SM – achieved a high score in Extraversion, low score in Neuroticism, and average score in Conscientiousness on the NEO-FFI-3. Thus, a group analysis was not feasible and the following paragraphs are dedicated to solely exploring individual trends for SM.

SM

SM is a 25-year-old female who reportedly lives with one other adult. She works in the food service industry, and also reported that she is a singer. She listed a GED as her highest level of education completed. Data collected from the pre-surgical questionnaire suggested that SM used various methods of communication daily at baseline. For example, she reported communicating using her voice, gesturing, mouthing words, and using text/email during the seven days prior to surgery and voice rest. SM reported working daily for the seven days prior to surgery; however, she took time off from work during the voice rest period. SM's post-operative appointment was on the sixth day following surgery; therefore, only five days of voice rest data were obtained.

Neo-FFI-3 Scores and Profile

Table 17: SM's NEO-FFI-3 Raw Score, T Score, and Description

Scale	Raw Score	T Score	Description
Extraversion	35	60	High
Neuroticism	14	40	Low
Conscientiousness	34	52	Average

SM completed the NEO-FFI-3 at the time of consent. Her scores on the NEO-FFI-3 revealed *high* levels of Extraversion, *average* levels of Conscientiousness, and *low* levels of Neuroticism. As low levels of Neuroticism have been linked with increased compliance in previous research, one might predict high levels of compliance with voice rest. On the other hand, SM's high levels of Extraversion might also suggest lower levels of compliance based on Roy and Bless' (2000) theory. It is worth noting that Extraversion alone, without the amplifying effects of Neuroticism (e.g. H-N and H-E), may not be enough to predict noncompliance based on Roy and Bless' (2000) theory which emphasizes the combination of H-N paired with H-E. As the NEO-FFI-3 "measures traits that approximate a normal, bell-shaped distribution," it is

expected that most people will score in the average range for each scale (McRae and Costa, 2010, p. 17). As SM scored in the average range on the Conscientiousness scale, it was not considered to be a factor of extreme significance in her personality profile.

Duration of Voice Use

Table 18: SM’s Daily Pre- and Post-surgical VAS scores (mm) and Mean VAS scores (mm)

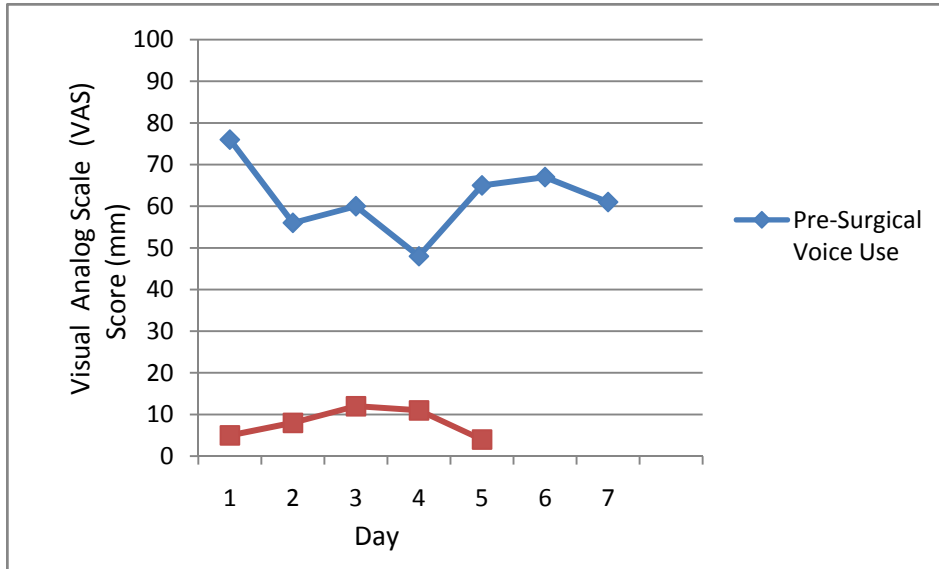
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Mean VAS
Pre-Surgical VAS	76	56	60	48	65	67	61	61.78
Post-Surgical VAS	5	8	12	11	4	n/a	n/a	8
Pre-surgical – Post-surgical	71	48	48	37	61	n/a	n/a	54
% Decrease in VAS	93.42	85.71	80	77.08	93.85	n/a	n/a	86.01

SM’s pre-surgical and post-surgical VAS scores, differences in VAS score, and mean VAS are displayed in Table 18. As can be seen above, SM’s pre-surgical VAS ranged from 48 to 76 with a mean VAS of 62, suggesting that SM used her voice regularly; however, not every time that she wanted to communicate. Given the rapid shifts in VAS scores from day to day, it does not appear as if SM was intentionally engaging in vocal restraint prior to voice rest. SM’s post-surgical VAS ranged from 4 to 12 with a mean VAS of 8, suggesting that she used her voice at least once daily while on voice rest and did not comply completely with voice rest.

As can be observed in Figure 9, comparison of pre-surgical and post-surgical duration of voice use revealed a noticeable decline in voice use while SM was on voice rest though not as steep as other participants. SM’s percent decrease ranged from 77% - 93% confirming lower levels of relative compliance when compared to the first cluster of participants. Her *only* average levels of Conscientiousness and high levels of Extraversion may help explain her lower levels of compliance when compared to participants with higher levels of Conscientiousness. Although at

a lower level than other individuals in the study, it should be noted that SM still demonstrated relative compliance with voice rest restrictions.

Figure 9: Comparison of SM’s Pre-surgical and Post-surgical Duration of Voice Use



Maximum Intensity of Voice Use

Table 19: SM’s Pre- and Post-surgical Level of Maximum Intensity

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pre-Surgical Max Intensity*	3	4	4	3	4	4	4
Post-Surgical Max Intensity	2	2	2	2	2	n/a	n/a

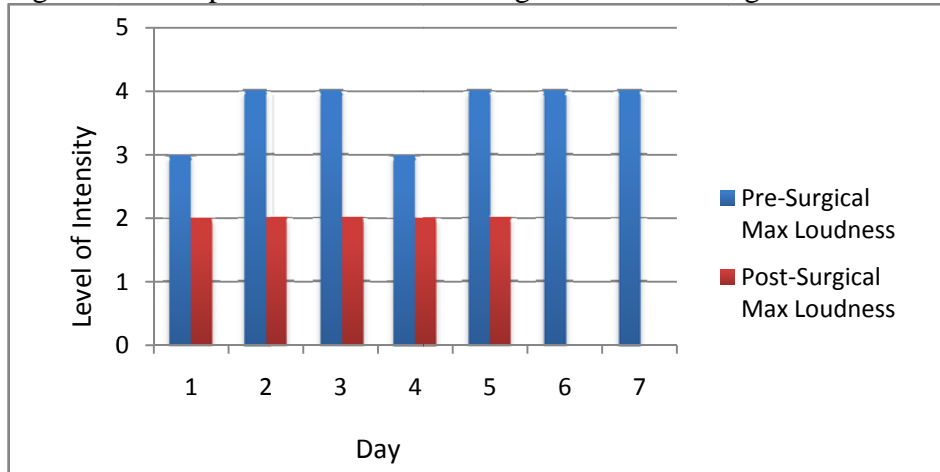
* 1=I did not use my voice, 2=Whisper, 3=Conversational level, 4=Talking Loudly, 5=Yelling

As can be observed in Table 19, prior to surgery, SM’s maximum level of voice use was talking loudly for five out of seven days, and conversational for two out of the seven days.

Following surgery, SM reported whispering as her maximum intensity of voice use for all six days of prescribed voice rest, which provides further support that SM used her voice at least once daily while on voice rest. However, she did appear to make efforts to at least partially comply with voice rest, not only by decreasing her duration of voice use, but also by reducing the level of intensity during episodes of voice use. Figure 10 shows a graphical comparison of pre- to post-surgical maximum intensity of voice use. When reviewing the figure, recall that 1

corresponds to *I did not use my voice*, 2 corresponds to *whisper*, 3 corresponds to *conversational level*, 4 corresponds to *talking loudly*, and 5 corresponds to *yelling*.

Figure 10: Comparison of SM’s Pre-surgical and Post-surgical Maximum Vocal Intensity



Alternative Methods of Communication

As mentioned above, pre-surgical data suggested that SM used various methods of communication at baseline. During the seven days prior to surgery, SM reported that she communicated using her voice, mouthed words, and used text/email daily. For five out of the seven days prior to surgery, she also reported the use of gestures to communicate. Following surgery, SM reported only using writing and email to communicate daily. Contrary to the information she provided on the duration of voice use and maximum intensity of voice use, she did not report using her voice or whispering to communicate at all during the five-day period of voice rest. Despite this inconsistency, it remains likely that SM used her voice or whispered on at least one occasion daily while on voice rest.

Voice Handicap Index

Table 20: SM's VHI Score and Severity Rating

Scale	Score	Severity Rating
Physical	12	Moderate
Functional	24	Severe
Emotional	21	Severe
Total	57	Moderate to Severe

SM completed the VHI at the time of consent. These scores suggested that SM's dysphonia impacted her the greatest emotionally and functionally. SM reported that she *almost never* felt physically affected by her voice. As a result, SM may have had less incentive to comply with voice rest recommendations, which may help explain her lower levels of relative compliance with voice rest when compared to other participants.

Other Factors to Consider

Other factors, such as the number of household members and taking time off from work may also influence compliance with voice rest. SM reported that she lived with one other adult. Constantly having another person around may make it more difficult to comply with voice rest, and might explain her relatively lower levels of compliance. SM also took time off from work while on voice rest. Eliminating the demands of the work environment may help to explain her generally compliant behavior.

Personality – Compliance Hypothesis: SM

SM's relative compliance with voice rest seems to fit in best when considering the Neuroticism domain of her personality profile. Low levels of Neuroticism have consistently been linked with higher levels of medication adherence with many types of disease processes; thus, it is likely that low levels of Neuroticism may be associated with more compliant behavior to voice rest. Interestingly, although SM scored similarly in Extraversion and Neuroticism to the first group of participants, she displayed lower levels of relative compliance when compared to the

first cluster of participants. A possible explanation for this may be the fact that Conscientiousness was not a defining personality factor for SM, but was a defining factor for CR, PA, OT, and PM.

High Extraversion (H-E), Average Neuroticism (A-N), High Conscientiousness (H-C)

Only one participant in this study – PD– achieved a high score in Extraversion, average score in Neuroticism, and high score in Conscientiousness on the NEO-FFI-3. Thus, a group analysis was not feasible and the following paragraphs are dedicated to solely exploring individual trends for PD.

PD

PD is a 43-year-old male who reportedly lives with one other adult and two children. He listed his occupation as a coal miner, and does not consider himself a singer. He listed 11th grade as his highest level of education completed. Information gathered from the pre-surgical questionnaire suggested that PD *did not* use alternative methods of communication daily at baseline; he reported only using his voice. He attended work for five of the six days prior to surgery; however, took off work for the six days of prescribed voice rest following surgery. PD’s follow-up appointment was on the 7th day following surgery; therefore, only six days of voice rest data were obtained.

Neo-FFI-3 Scores and Profile

Table 21: PD’s NEO-FFI-3 Raw Score, T Score, and Description

Scale	Raw Score	T Score	Description
Extraversion	33	60	High
Neuroticism	20	51	Average
Conscientiousness	42	66	Very High

PD completed the NEO-FFI-3 at time of consent. His scores on the NEO-FFI-3 revealed *very high* levels of Conscientiousness, *high* levels of Extraversion, and *average* levels of Neuroticism. When considering PD’s high levels of Conscientiousness, one might predict high levels of compliance with voice rest. On the other hand, when considering PD’s high levels of Extraversion, one might predict lower levels of compliance with voice rest based on Roy and Bless’ (2000) theory though it is worth noting that Extraversion alone, without the amplifying effects of Neuroticism (e.g. H-N and H-E), may not be enough to predict noncompliance. The NEO-FFI-3 was designed with the assumption that most people will score in the average range for each scale (McRae and Costa, 2010, p. 17). As PD scored in the average range on the Neuroticism scale, it was not considered to be a prominent aspect of his personality profile.

Duration of Voice Use

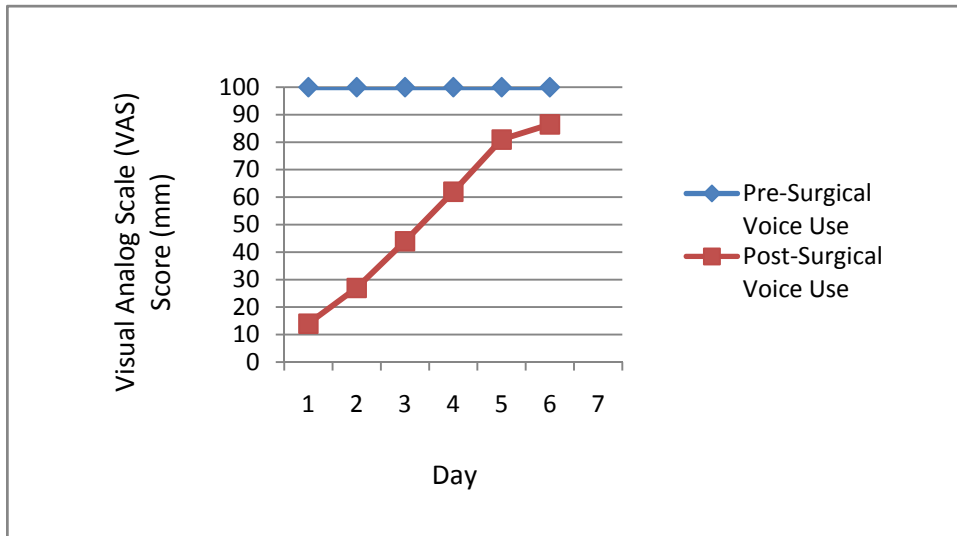
Table 22: PD’s Daily Pre- and Post-surgical VAS scores (mm) and Mean VAS scores (mm)

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Mean VAS
Pre-Surgical VAS	100	100	100	100	100	100	100	100
Post-Surgical VAS	14	27	44	62	81	86.5	n/a	52.42
Pre-surgical – Post-surgical	86	73	56	38	19	13.5	n/a	47.58
% Decrease in VAS	86	73	56	38	19	13.5	n/a	47.58

PD’s pre-surgical and post-surgical VAS scores, differences in VAS score, and mean VAS are displayed in Table 22. As can be observed in Table 22, PD’s pre-surgical VAS remained constant at 100, suggesting that PD used his voice every time that he wanted to communicate for all seven days prior to surgery. PD’s post-surgical VAS ranged from 14 to 86.5 with a mean VAS of 52.42, suggesting that he used his voice at least once though most likely more than once daily while on voice rest. These data indicated that PD, similar to the other participants did not comply with his physician’s order of complete voice rest.

Comparison of pre-surgical and post-surgical duration of voice use revealed a visible decline during the initial four days of voice rest with a significant spike in voice use on Day 6 and Day 7. Such a trend is suggestive of a duration effect, as PD’s VAS scores appeared to steadily increase with each day of voice rest. PD’s percent decrease in VAS ranged from 13.5% - 86%, which indicated fluctuating levels of relative compliance with voice rest restrictions. Given his *very high* levels of Conscientiousness, PD’s lower level of compliance is a bit surprising. It may be the case that PD’s high level of extraversion overpowered the role of Conscientiousness in adherent behavior. It may also be the case that only high levels of Conscientiousness paired with low levels of Neuroticism are related with the highest levels of compliance.

Figure 11: Comparison of PD’s Pre-surgical and Post-surgical Duration of Voice Use



Maximum Intensity of Voice Use

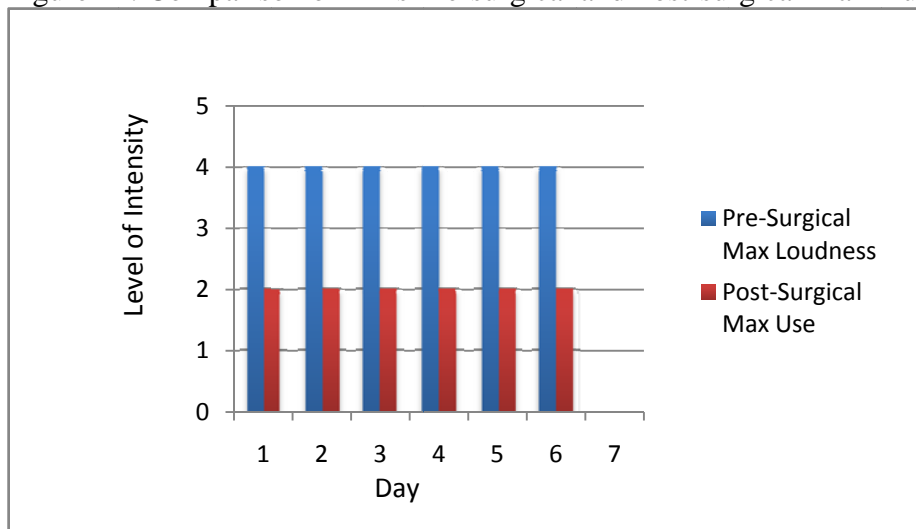
Table 23: PD’s Pre- and Post-surgical Level of Maximum Intensity

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pre-Surgical Max Intensity*	4	4	4	4	4	4	4
Post-Surgical Max Intensity	2	2	2	2	2	2	n/a

* 1=I did not use my voice, 2=Whisper, 3=Conversational level, 4=Talking Loudly, 5=Yelling

As can be seen in Table 23, prior to surgery, PD’s maximum level of voice use was talking loudly for all of the seven days prior to voice rest. Following surgery, PD reported that he whispered each of the six days that he was on prescribed voice rest, which is consistent with the assumption that he used his voice at least once everyday while on voice rest. Interestingly, even on the post-surgical days with higher VAS scores, PD’s maximum level of vocal intensity remained at a whisper level. This suggested that even on his most loquacious days while on voice rest, PD attempted to demonstrate compliance by keeping his maximum intensity level at a whisper during these episodes of voice use. Figure 12 shows a graphical comparison of pre- to post-surgical maximum intensity of voice use. When reviewing figure 12, recall that 1 corresponds to *I did not use my voice*, 2 corresponds to *whisper*, 3 corresponds to *conversational level*, 4 corresponds to *talking loudly*, and 5 corresponds to *yelling*.

Figure 12: Comparison of PD’s Pre-surgical and Post-surgical Maximum Vocal Intensity



Alternative Methods of Communication

As mentioned above, pre-surgical data suggested that PD *did not* use various methods of communication at baseline. During the seven days prior to surgery, PD only reported communicating by using his voice. Following surgery, PD reported using whisper for six out of

six days, gesture for four out of six days, mouthing words for three out of six days, writing for two out of six days, and text/email for one out of six days. Although PD initially increased his methods of communication, throughout the course of the voice rest period, his use of alternative methods to communicate steadily decreased.

Voice Handicap Index

Table 24: PD’s VHI Score and Severity Rating

Scale	Score	Severity Rating
Physical	29	Severe
Functional	21	Moderate - Severe
Emotional	19	Moderate - Severe
Total	69	Severe

PD completed the VHI at the time of consent. These scores suggested that PD’s dysphonia had the greatest impact on his physical well-being. However, it should be noted that his voice seemed to also significantly impact his functional and emotional well-being. We would have expected higher levels of compliance given the overall severity in which PD reported that dysphonia affected his life.

Other Factors to Consider

Other factors, such as the number of household members and taking time off from work may also influence compliance with voice rest. PD reported living with one other adult and two children, which is the second largest household reported in this study. Such a large household may help explain why PD used greater durations of voice use while on voice rest compared to the other participants.

Personality – Compliance Hypothesis: PD

PD’s level of compliance was not as easily predicted by his personality profile. Given the significant role that Conscientiousness has been shown to play in adherent behavior, it was

expected that PD would have exhibited a much higher level of compliance with voice rest. Instead PD emerged as the least compliant participant in this study. Additionally, PD is also the first participant in which Neuroticism did not emerge as a prominent component of a participant's personality profile. It may be the case that without the mediating effects of *low levels* of Neuroticism, PD's high levels of Extraversion outweighed the role of Conscientiousness and had a negative impact on compliance. This may lend some support to Roy and Bless' (2000) theory that high levels of extraversion are related to lower levels of compliance with voice rest.

Average Extraversion (A-E), Average Neuroticism (A-N), High Conscientiousness (H-C)

Only one participant in this study – MS – achieved an average score in Extraversion, average score in Neuroticism, and high score in Conscientiousness on the NEO-FFI-3. Thus, a group analysis was not feasible and the following paragraphs are dedicated to solely exploring individual trends for PD.

MS

Participant MS is a 48-year-old female who reportedly lives with one other adult. She works as an assistant automotive service manager. She listed high school as her highest level of education completed. Data collected from the pre-surgical questionnaire suggested that MS used various methods of communication daily at baseline. For example, she reported communicating using her voice and text/email during the seven days prior to surgery and voice rest. MS reported taking time off from work for six of the seven days prior to surgery and reported “n/a” for the last day. Similar to pre-surgical work attendance, MS also took time off from work three of the

four days on voice rest, and reported “n/a” for the last day. MS’s post-operative appointment was on the 5th day following surgery; therefore, only four days of voice rest data were obtained.

Neo-FFI-3 Scores and Profile

Table 25: MS’s NEO-FFI-3 Raw Score, T Score, and Description

Scale	Raw Score	T Score	Description
Extraversion	31	53	Average
Neuroticism	18	45	Average
Conscientiousness	43	66	Very High

MS completed the NEO-FFI-3 at the time of consent. Her scores on the NEO-FFI-3 revealed *very high* levels of Conscientiousness, *average* levels of Extraversion, and *average* levels of Neuroticism. When considering MS’s extremely high levels of Conscientiousness, one might predict high levels of compliance with voice rest. Recall that the NEO-FFI-3 was designed to “measure traits that approximate a normal, bell-shaped distribution;” therefore, it is expected that most people will score in the average range for each scale (McRae and Costa, 2010, p. 17). As MS scored in the average range on both the Extraversion and Neuroticism scale, neither factor was considered to be dominant aspects of her personality profile.

Duration of Voice Use

Table 26: MS’s Daily Pre- and Post-surgical VAS scores (mm) and Mean VAS scores (mm)

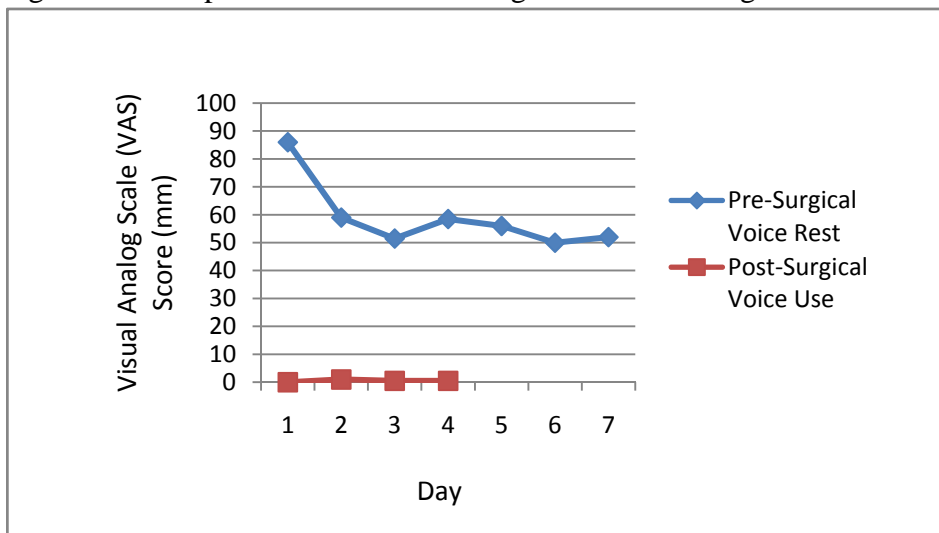
	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Mean VAS
Pre-Surgical VAS	86	59	51.5	58.5	56	50	52	59
Post-Surgical VAS	0	1	.5	.5	n/a	n/a	n/a	.5
Pre-surgical – Post-surgical	86	58	51	58	n/a	n/a	n/a	63.25
% Decrease in VAS	100	98.31	99.03	99.15	n/a	n/a	n/a	99.12

MS’s pre-surgical and post-surgical VAS scores, differences in VAS score, and mean VAS are displayed in Table 26. As can be seen above, MS’s pre-surgical VAS ranged from 50 to

86 with a mean VAS of 59, suggesting that MS used her voice regularly, but not nearly every time that she wanted to communicate. This may suggest that even *prior* to surgery and voice rest treatment, MS was restricting his level of voice use. Potential reasons for such restraint may be linked to physical discomfort secondary to dysphonia, and/or hyper-vigilance in not wanting to further engage in vocal abuse. If the latter is true, it may be possible that such vigilance is related to her extremely high levels of Conscientiousness. Additionally, it may help explain why MS took six days off from work prior to surgery. MS’s post-surgical VAS ranged from 0 to 1 with a mean VAS of .5, suggesting very minimal, if any, voice use while on voice rest.

As can be seen in the figure below, comparison of pre-surgical and post-surgical duration of voice use revealed a visible decline in voice use while MS was on voice rest. Such a steep decline suggests that MS exhibited an extremely high level of compliance with voice rest restrictions, which is further supported by her 99.12% decrease in VAS score from pre-to post-surgery.

Figure 13: Comparison of MS’s Pre-surgical and Post-surgical Duration of Voice Use



Maximum Intensity of Voice Use

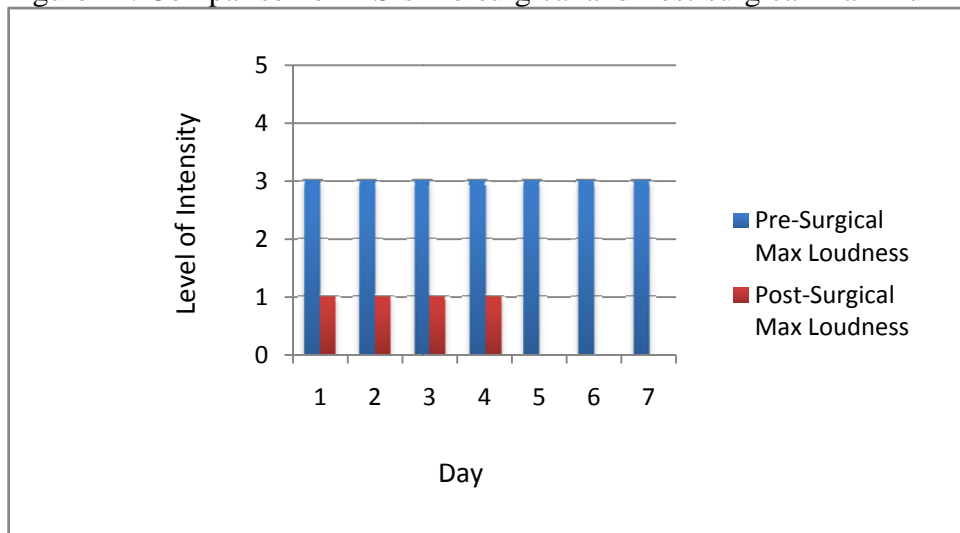
Table 27: MS’s Pre- and Post-surgical Level of Maximum Intensity

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Pre-Surgical Max Intensity*	3	3	3	3	3	3	3
Post-Surgical Max Intensity	1	1	1	1	n/a	n/a	n/a

* 1=I did not use my voice, 2=Whisper, 3=Conversational level, 4=Talking Loudly, 5=Yelling

As can be observed in Table 27, prior to surgery, MS’s maximum level of voice use was at the conversational level for all of the seven days prior to surgery. Following surgery, MS reported that she did not use her voice for all four days of prescribed voice rest. These data are largely consistent with her VAS scores, which indicated minimal if any voice use daily. A graphical comparison of pre- to post-surgical maximum intensity of voice use is shown in Figure 14. When reviewing the figure, recall that 1 corresponds to *I did not use my voice*, 2 corresponds to *whisper*, 3 corresponds to *conversational level*, 4 corresponds to *talking loudly*, and 5 corresponds to *yelling*.

Figure 14: Comparison of MS’s Pre-surgical and Post-surgical Maximum Vocal Intensity



Alternative Methods of Communication

As mentioned above, pre-surgical data suggested that MS communicated using her voice and text/email prior to surgery. Following surgery, MS increased her use of alternative methods of communication, as she reported using gesture (4/4 days) and writing (1/4 days), in addition to text/email to communicate while on voice rest. This suggests that MS introduced new alternative methods of communication (e.g. gesture and writing) while on voice rest. MS did not report using voice or whisper to communicate any day while on voice rest. Although this is largely true, MS’s VAS scores did suggest at least one instance of voice use on at least three of the days while on voice rest.

Voice Handicap Index

Table 28: MS’s VHI Score and Severity Rating

Scale	Score	Severity Rating
Physical	36	Severe
Functional	38	Severe
Emotional	40	Severe
Total	114	Severe

MS completed the VHI at the time of consent. These scores suggest that MS’s dysphonia had an equally significant impact on her physical, functional, and emotional well-being. MS responded *always* to 28 out of the 30 questions on the VHI. As MS’s dysphonia had such a negative impact at baseline, the idea of MS restricting her voice use prior to surgery appears to be consistent with someone displaying high levels of conscientiousness. Additionally, it may further explain MS’s extremely high compliance with voice rest.

Other Factors to Consider

Other factors, such as number of household members and taking time off from work may also influence compliance with voice rest. MS reported living with one other adult; however, this

did not appear to have a detrimental effect on her ability to comply with voice rest. MS reported taking time off from work while on voice rest, which may have also played a role in MS's compliant behavior.

Personality – Compliance Hypothesis: MS

MS's compliance with voice rest seems to be consistent with what one would expect given her extremely high levels of Conscientiousness. MS emerges as the most compliant participant in the study suggesting that high levels of Conscientiousness when uninfluenced by the effects of Extraversion and Neuroticism may relate to the highest levels of compliant behavior. However, when Extraversion or Neuroticism do make up a prominent role in one's personality, higher levels of compliance result when high Conscientiousness is paired with low Neuroticism. As Extraversion and Neuroticism were not prominent factors in MS's personality profile, Roy and Bless' (2000) hypothesis was not applicable to MS. It is important to note that even the most compliant participant in the study was unable to achieve complete compliance with voice rest.

Discussion

The present study emerged as an initial attempt to elucidate the relationship between personality and compliance specific to voice rest. Despite the *personality* component in this question, the data collected from this study have revealed *general* compliance trends separate from the trends regarding the *relationship* between compliance and personality. In fact the most prominent finding of the study was that none of the seven participants, regardless of personality, were able to achieve completed compliance with voice rest. Even the most compliant participants in the study used their voice in some manner on at least one occasion throughout the prescribed voice rest period. This begs the question as to whether complete compliance with

voice rest is a feasible treatment option for most individuals. Additionally, this finding highlights the need for further systematic scientific inquiry in answering the following fundamental question: How much compliance is necessary for voice rest treatment to be successful? Given the paucity of research exploring the efficacy of voice rest, the answer to this question is currently dependent on anecdotal evidence and clinical expertise, which varies from each prescribing clinician to the next. Continued research on compliance with voice rest treatment may ultimately shape and influence clinical decision-making regarding management.

The results of this study indicate that in addition to the *type* of prescribed voice rest (complete vs. modified), the *length* of prescribed voice rest also influences compliance behavior. Three of the seven participants appeared to fall prey to a duration effect, reporting increases in duration voice use as they progressed throughout the voice rest period. This suggests that some individuals lose resolve as the voice rest period increases resulting in decreasing compliance during the latter period of voice rest. As there is currently no standard protocol for voice rest treatment, participants may be prescribed voice rest for periods as short as 4 days, while other may be prescribed voice rest for as long as 28 days. As some patients will not be able to comply with longer periods of voice rest treatment, further research is needed to discover which length of voice rest treatment corresponds with greatest prognostic outcomes. Results from such systematic research will undoubtedly influence clinical decision-making when prescribing voice rest.

Specific to personality, the results of this study descriptively revealed that similar to medication adherence, the personality factors of Conscientiousness and Neuroticism may play an important role in areas of behavioral adherence to treatments such as voice rest (Axelsson et al., 2011; Bruce et al., 2009; Christensen and Smith, 1995, Jerant et al., 2011). The most compliant

participant in this feasibility study displayed extremely high levels of Conscientiousness with average levels of Neuroticism and Extraversion. This suggests that high levels of Conscientiousness when uninfluenced by the effects of Extraversion and Neuroticism may relate to the highest levels of compliant behavior. However, if a participant scored below or above average on the Neuroticism scale, higher levels of compliance appeared to result when high levels of Conscientiousness were paired with low levels of Neuroticism. Thus, it may be the case that the *combination* of high levels of Conscientiousness with low levels of Neuroticism is the best predictor of compliant behavior when both personality factors receive a prominent role in an individual's profile.

In regards to Roy and Bless' (2000) hypothesis, there were no participants in our pilot study with the *combination* of high levels of Neuroticism and high levels of Extraversion, yielding insufficient information to provide strong support in favor or against the role that this combination may play in the compliance question. Thus, we were unable to answer whether such a combination negatively relates to compliance with voice rest.

Interestingly, these data do suggest that high levels of Extraversion alone are not *strongly* linked to noncompliance with voice rest, though a possible association between high levels of Extraversion and lower levels of compliance was identified in one participant. It may be the case that *extremely* elevated levels of Extraversion (i.e. those that fall in the *very high* rather than *high* range) plays a greater role in influencing compliance. In these instances, extraverted tendencies may overshadow the compliance effects tied to other personality factors making up an individual's personality profile. These questions await further investigation in a larger number of patients, which should provide greater access to a range of personality profiles including those combinations not seen in the present cohort.

Of the personality-compliance findings discussed above, the most notable finding is the positive relationship between Conscientiousness and compliance with voice rest. Within our pool of participants, five out of six of the participants with high levels of Conscientiousness demonstrated high levels of compliance despite each having differing levels of Extraversion and Neuroticism. Thus, future research may be best served by further exploring the role of Conscientiousness in compliance behavior, rather than focusing on the intricacies of interactions between personality factors, such as the amplification effects of Neuroticism. Simplifying our research objectives to better uncover and understand this broad trend will likely result in greater clinical utility.

Demographic factors such as occupation, household size and education level also seem to play a role in the compliance question and in some cases may outweigh the role that personality plays in influencing compliance behavior. In the current study, we found that those individuals that took off from work while on voice rest generally had higher levels of compliance when compared with those that went in to work during the prescribed voice rest period. Additionally, the vocal demands of a participant's work environment might influence an individual's response and compliance with voice rest. For example, some occupations require constant use of your voice for communication (e.g. coal miner, teacher, and coach), while others promote various types of non-vocal communication (e.g. text and email). Individuals already using these alternative methods of communication may have an easier time acclimating to solely using these forms of communication at baseline.

Interestingly, PD, the least compliant participant in this study scored extremely high on the Conscientiousness domain. This suggests that although personality may influence compliance behavior, other factors may trump these influences from time to time. PD also had

one of the largest households in this study, one of the lower education levels, and an occupation that placed significant demands on voice use. It may be the case that one or a combination of all of these factors may account for his poor compliance behavior. Further research should systematically explore these demographic factors to better understand their role in the compliance question.

Some limitations with this study include the use of self-report measures. Future studies are needed using more objective measures such as vocal ambulatory monitoring to improve the measurement accuracy of pre and post-operative voice use. In terms of addressing the personality – compliance question, it may be helpful to also have the participant complete the personality questionnaire both at the onset and completion of the study. This would provide valuable information regarding the stability of personality traits, which would lend additional support in favor or against predisposition models.

The most significant limitation of the current study was the extremely small sample size. Such a small sample size limited the possibility of performing group analyses. However, there were some benefits to such a small sample size. By taking a case study approach, we were able to examine each individual more closely and speculate the many factors that may play a role in compliance with voice rest. In addition to personality, the results of this study suggest the need for further investigation into how the duration of prescribed voice rest, VHI profiles, work absenteeism, and number of household members may impact patient compliance with voice rest treatment.

If anything, the results of this pilot study have revealed that the compliance question is anything but clear and simple. Instead, it appears that many factors, including personality, may play a role in compliance with treatment with regard to voice rest. Future studies should not only

focus on revealing *what* factors relate to compliance, but also *how much* each of these factors contributes to influencing compliance. By uncovering these *significant* relationships, clinicians may be more able to appropriately individualize treatment to their patients. This type of individualized treatment is becoming increasingly important in the age of personalized medicine.

In the current atmosphere of health care reform, there has been increasing pressure for health care providers to provide the most time and cost-effective treatments (Piedmont, 1998). In order to meet these growing demands, services rendered must not only be efficacious, but also specific for the clients to which they are offered (Piedmont, 1998). This is extremely relevant in the case of voice rest, where intrinsic factors such as personality, may play a defining role as to whether the client is able to comply with voice rest. Similar to most treatment areas, compliance with voice rest likely has a significant impact on treatment outcomes. In 2003, the World Health Organization “suggested that improved treatment adherence would have a larger impact on society and health than most therapeutic advances” (Bruce et al., 2012; WHO, 2003). Further understanding of the role that personality plays in compliance with voice rest will ultimately help clinicians establish evidence-based protocols (e.g. length of voice rest, absolute vs. modified... etc.) for voice rest that are individualized to patients and foster increased success with treatment.

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Appendix A: Informed Consent

Vanderbilt University Institutional Review Board Informed Consent Document for Research

Principal Investigator: Bernard Rousseau, Ph.D.

Revision Date: June 5, 2011*

Study Title: VoRAAC (Voice Rest Augmentative and Alternative Communication):

A Randomized Controlled trial of text-to-speech communication versus standard of care in patients on prescribed voice rest

Institution/Hospital: Vanderbilt Medical Center

This informed consent applies to Adults, age 18 and older

Name of participant: _____ **Age:** _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your health care, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study.

1. What is the purpose of this study?

You are being asked to be in this research study because you will be having surgery to remove lesions on your vocal fold. After surgery, your doctor has prescribed voice rest therapy for you. The purpose of this study is to help us learn how patients recovering from vocal fold surgery respond to voice rest restrictions. About 50 people will be enrolled in this study at Vanderbilt.

2. What will happen and how long will you be in the study?

If you agree to take part, you will be in the study for about 2 weeks (or through your post-operative visit). You will be asked to sign a separate surgical consent form for your vocal fold surgery. All of the screening and procedures that are part of your routine medical care will occur whether you are in this study or not. You will still come to your regular clinic visits and get your standard treatment for voice fold lesions. There will be no extra clinic visits just for the study.

During the study:

- You will be "randomized" to the control group or the text-to-speech group, described below. Randomization means that you are put into a group by chance, like the flip of a coin. A computer program will place you in one of the groups. Neither you nor your doctor can choose your treatment group. You will have an equal chance of being in either of the following groups:

Control Group: You will receive the standard treatment prescribed after vocal fold surgery. This is called "voice rest".

Text-to-Speech group: You will get the standard "voice rest" prescription after surgery, but will also be given a text-to-speech (TTS) device to help you communicate while on vocal rest. You will be trained to use the device by a member of the research team. The training will take about 20-30 minutes of your time. You will return the device at your post-operative clinic visit. This device is approved by the Food and Drug Administration (FDA) and often used by Amyotrophic Lateral Sclerosis Association (ALSA) patients as a way to communicate.

- We will review your medical record to gather information about your demographics, diagnosis, medical history, clinical care and outcomes, and test results including photos or voice recordings done as part of your regular care.
- We will ask you to complete 2 questionnaires the day you enroll on the study. This will take about 20 minutes of your time.

Date of IRB Approval: July 5, 2011

Date of IRB Expiration: July 4, 2012

- Page 1 of 5 -
VoRAAC IRB Consent



Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Samuel Rousseau, Ph.D.

Revision Date: June 2, 2011

Study Title: VoRAAC (Voice Res. Augmentative and Alternative Communication):

A Randomized Controlled Trial of text-to-speech communication versus standard of care in patients or post-stroke voice loss

Institution/Hospital: Vanderbilt Medical Center

- We will ask you to complete a daily questionnaire. This may start up to 7 days **before surgery and continue up to 7 days after surgery**. This can be done at home and you will have back the completed surveys at your post-operative appointment. Each questionnaire will take about 5-10 minutes of your time. On the last full day of your voice rest, you will have an expanded survey that may take about 15 minutes to complete. Your responses to the questionnaires will not be shared with your doctor or staff.
- We will ask you to return the TTS device if you were given one. Once you have completed the last survey and returned any equipment you may have been given, your participation in the study is complete.

The schedule of activities is noted below:

Procedure	Estimated Duration	Study Entry	Pre-Surgery	Post-Surgery
Recruitment/consent	10 mins.	X		
Baseline Surveys	20 mins.	X		
TTS device training (if randomized to TTS group)	20-30 mins.		X	
Daily Pre-Surgical Questionnaire	5 – 10 mins. (for up to 7 days)		X	
Daily Post-Surgical Questionnaire	5 – 10 mins. (for up to 6 days)			X
Final Post-Surgical Questionnaire	10 – 20 mins. (final day of voice rest)			X
Review of medical record	Ongoing – done by research team			

3. Costs to you if you take part in this study:

There is no cost to you for being in this study.

4. Side effects and risks that you can expect if you take part in this study:

Being in this study will not expose you to any extra medical risks. The questionnaires may cause you fatigue or irritation due to filling out a questionnaire each day. However, the daily questionnaire should take about five minutes to complete. There is a slight risk that your personal information could be given to someone not on the study by mistake. However, your survey responses will be linked to a study ID number and not with any personal identifiable information. Staff will keep all study information in a locked file. The coded data will be kept on a computer which will be protected by passwords. Only study staff would have access to these files. Every precaution will be taken to protect your information.

5. Risks that are not known:

There may be unknown risks with being in any research study. You will be told of any important findings we learn about related to this study if we think it may change your mind about being in the study.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the investigator that an injury occurred as a direct result of the random treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

**Vanderbilt University Institutional Review Board
Informed Consent Document for Research**

Principal Investigator: Bernard Rousseau, Ph.D.

Revision Date: June 9, 2011

Study Title: VoRAAC (Voice Rest, Augmentative and Alternative Communication);

A Randomized Controlled trial of text-to-speech communication versus standard of care in patients on prescribed voice rest

Institution/Hospital: Vanderbilt Medical Center

7. Good effects that might result from this study:

- a) **The benefits to science and humankind that might result from this study:** We hope to gain more knowledge about the way people respond to voice rest, as well as how voice rest and voice restorators affect people with voice problems.
- b) **The benefits you might get from being in this study:** We do not know if being in this study will affect your voice problems. There may be no direct benefit to you from taking part in this study.

8. Other treatments you could get if you decide not to be in this study:

This is not a treatment study. You can choose not to take part. Whatever you decide, it will not affect your regular medical care.

9. Payments for your time spent taking part in this study or expenses:

You will be paid \$16 by check for completing the study, which includes the study questionnaire and return of a device if you were given one. We may ask you for your Social Security number and address before you are compensated for taking part in the study.

10. Reasons why the study doctor may take you out of this study:

There is no reason the study doctor will remove you from the study.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. This will not change your regular medical care in any way.

12. Who to call for any questions or concerns, or if you are injured:

If you should have any questions about this research study or if you feel that you have been hurt by being a part of this study, please contact Kate Van Winkle, Clinical Trials Manager, at (615) 831-4636. If you cannot reach the research staff, you may call the Vanderbilt operator at 615-322-6300 and ask the operator to page the study doctor.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2916 or toll free at (866) 224-2273.

13. Confidentiality:

The data collected from you (study questionnaires) will be assigned a study ID code that contains no personal identifiable information. This study ID code and your personal identifiable information will be maintained separately on a password protected computer. Members of the research team only will have access to these files. Any original hard copy study documents will be kept in the research team locked office. Your personal information will remain confidential and will not be used if study information is published or presented at a scientific meeting.

Date of IRB Approval: July 5, 2011

- Page 3 of 5 -
VoRAAC Informed Consent

Date of IRB Expiration: J. y 4, 2012



VANDERBILT UNIVERSITY
INSTITUTIONAL REVIEW BOARD

**Vanderbilt University Institutional Review Board
Informed Consent Document for Research**

Principal Investigator: Bernard Rousseau, Ph.D.

Revision Date: June 9, 2011

Study Title: VoRAAC (Voice Res. Augmentative and Alternative Communication)

A Randomized Controlled trial of text-to-speech communication versus standard of care in patients on prescribed voice rest

Institution/Hospital: Vanderbilt Medical Center

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Rousseau and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study you are agreeing ("authorization") to the use and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Rousseau and his study team may share the results of your study and/or non-study linked questionnaire/surveys, photos or voice recordings, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board and the National Institutes of Health (NIH). Federal agency rules may not apply to these groups. They have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Bernard Rousseau in writing and let him know that you withdraw your consent. His mailing address is 1313 21st Avenue South, Room 602, Nashville, TN 37232-4400. At that time, we will stop getting any more information you. And, the health data we shared before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the study, doctor or research site holds the data. To ensure the scientific quality of this research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

(The rest of this page has been left blank on purpose.)



Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Bernard Rousseau, Ph.D.

Revision Date: June 8, 2011

Study Title: VoRAAC (Voice First Augmentative and Alternative Communication):

A Randomized Controlled Trial of Text-to-Speech Communication versus Standard of Care in Patients on
prescribed voice rest

Institution/Hospital: Vanderbilt Medical Center

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date

Signature of patient/volunteer

Consent obtained by:

Date

Signature

Printed Name and Title

Date of IRB Approval: July 6, 2011

Date of IRB Expiration: July 4, 2012

- Page 3 of 4 -
VoRAAC Adult consent



VANDERBILT UNIVERSITY
Institutional Review Board

Appendix B: NEO-Five Factor Inventory – 3

ID# _____

Name _____ Age _____ Sex _____ Today's date _____

1. I am not a worrier.
2. I like to have a lot of people around me.
3. I enjoy concentrating on a fantasy or daydream and exploring all its possibilities, letting it grow and develop.
4. I try to be courteous to everyone I meet.
5. I keep my belongings neat and clean.
6. At times I have felt bitter and resentful.
7. I laugh easily.
8. I think it's interesting to learn and develop new hobbies.
9. At times I bully or flatter people into doing what I want them to.
10. I'm pretty good about pacing myself so as to get things done on time.
11. When I'm under a great deal of stress, sometimes I feel like I'm going to pieces.
12. I prefer jobs that let me work alone without being bothered by other people.
13. I am intrigued by the patterns I find in art and nature.
14. Some people think I'm selfish and egotistical.
15. I often come into situations without being fully prepared.
16. I rarely feel lonely or blue.
17. I really enjoy talking to people.
18. I believe letting students hear controversial speakers can only confuse and mislead them.
19. If someone starts a fight, I'm ready to fight back.
20. I try to perform all the tasks assigned to me conscientiously.
21. I often feel tense and jittery.
22. I like to be where the action is.
23. Poetry has little or no effect on me.
24. I'm better than most people, and I know it.
25. I have a clear set of goals and work toward them in an orderly fashion.
26. Sometimes I feel completely worthless.
27. I shy away from crowds of people.
28. I would have difficulty just letting my mind wander without control or guidance.
29. When I've been insulted, I just try to forgive and forget.
30. I waste a lot of time before settling down to work.
31. I rarely feel fearful or anxious.
32. I often feel as if I'm bursting with energy.
33. I seldom notice the moods or feelings that different environments produce.
34. I tend to assume the best about people.
35. I work hard to accomplish my goals.
36. I often get angry at the way people treat me.
37. I am a cheerful, high-spirited person.
38. I experience a wide range of emotions or feelings.
39. Some people think of me as cold and calculating.
40. When I make a commitment, I can always be counted on to follow through.

41. Too often, when things go wrong, I get discouraged and feel like giving up.
42. I don't get much pleasure from chatting with people.
43. Sometimes when I am reading poetry or looking at a work of art, I feel a chill or wave of excitement.
44. I have no sympathy for beggars.
45. Sometimes I'm not as dependable or reliable as I should be.
46. I am seldom sad or depressed.
47. My life is fast-paced.
48. I have little interest in speculating on the nature of the universe or the human condition.
49. I generally try to be thoughtful and considerate.
50. I am a productive person who always gets the job done.
51. I often feel helpless and want someone else to solve my problems.
52. I am a very active person.
53. I have a lot of intellectual curiosity.
54. If I don't like people, I let them know it.
55. I never seem to be able to get organized.
56. At times I have been so ashamed I just wanted to hide.
57. I would rather go my own way than be a leader of others.
58. I often enjoy playing with theories or abstract ideas.
59. If necessary, I am willing to manipulate people to get what I want.
60. I strive for excellence in everything I do.

Enter your responses here—remember to enter responses ACROSS the rows.
 SD = Strongly Disagree; D = Disagree; N = Neutral; A = Agree; SA = Strongly Agree

ENTER ACROSS →	1 (SD) (D) (N) (A) (SA)	2 (SD) (D) (N) (A) (SA)	3 (SD) (D) (N) (A) (SA)	4 (SD) (D) (N) (A) (SA)	5 (SD) (D) (N) (A) (SA)
	6 (SD) (D) (N) (A) (SA)	7 (SD) (D) (N) (A) (SA)	8 (SD) (D) (N) (A) (SA)	9 (SD) (D) (N) (A) (SA)	10 (SD) (D) (N) (A) (SA)
	11 (SD) (D) (N) (A) (SA)	12 (SD) (D) (N) (A) (SA)	13 (SD) (D) (N) (A) (SA)	14 (SD) (D) (N) (A) (SA)	15 (SD) (D) (N) (A) (SA)
	16 (SD) (D) (N) (A) (SA)	17 (SD) (D) (N) (A) (SA)	18 (SD) (D) (N) (A) (SA)	19 (SD) (D) (N) (A) (SA)	20 (SD) (D) (N) (A) (SA)
	21 (SD) (D) (N) (A) (SA)	22 (SD) (D) (N) (A) (SA)	23 (SD) (D) (N) (A) (SA)	24 (SD) (D) (N) (A) (SA)	25 (SD) (D) (N) (A) (SA)
	26 (SD) (D) (N) (A) (SA)	27 (SD) (D) (N) (A) (SA)	28 (SD) (D) (N) (A) (SA)	29 (SD) (D) (N) (A) (SA)	30 (SD) (D) (N) (A) (SA)
	31 (SD) (D) (N) (A) (SA)	32 (SD) (D) (N) (A) (SA)	33 (SD) (D) (N) (A) (SA)	34 (SD) (D) (N) (A) (SA)	35 (SD) (D) (N) (A) (SA)
	36 (SD) (D) (N) (A) (SA)	37 (SD) (D) (N) (A) (SA)	38 (SD) (D) (N) (A) (SA)	39 (SD) (D) (N) (A) (SA)	40 (SD) (D) (N) (A) (SA)
	41 (SD) (D) (N) (A) (SA)	42 (SD) (D) (N) (A) (SA)	43 (SD) (D) (N) (A) (SA)	44 (SD) (D) (N) (A) (SA)	45 (SD) (D) (N) (A) (SA)
	46 (SD) (D) (N) (A) (SA)	47 (SD) (D) (N) (A) (SA)	48 (SD) (D) (N) (A) (SA)	49 (SD) (D) (N) (A) (SA)	50 (SD) (D) (N) (A) (SA)
	51 (SD) (D) (N) (A) (SA)	52 (SD) (D) (N) (A) (SA)	53 (SD) (D) (N) (A) (SA)	54 (SD) (D) (N) (A) (SA)	55 (SD) (D) (N) (A) (SA)
	56 (SD) (D) (N) (A) (SA)	57 (SD) (D) (N) (A) (SA)	58 (SD) (D) (N) (A) (SA)	59 (SD) (D) (N) (A) (SA)	60 (SD) (D) (N) (A) (SA)

Now answer the three questions labeled A, B, and C below.

- A. Have you responded to all of the statements? ___ Yes ___ No
- B. Have you entered your responses across the rows? ___ Yes ___ No
- C. Have you responded accurately and honestly? ___ Yes ___ No

Appendix C: Voice Handicap Index

Voice Handicap Index (VHI)
 (Jacobson, Johnson, Grywalski, et al., 1997)

Instructions: These are statements that many people have used to describe their voices and the effects of their voices on their lives. Make a check in the box that indicates how frequently you have the same experience. Even if it is "never" or not applicable, please choose one box per statement.
 (Never = 0 points; Almost Never = 1 point; Sometimes = 2 points; Almost Always = 3 points; Always = 4 points)

	Never	Almost Never	Sometimes	Almost Always	Always
F1. My voice makes it difficult for people to hear me.					
P2. I run out of air when I talk.					
F3. People have difficulty understanding me in a noisy room.					
P4. The sound of my voice varies throughout the day.					
F5. My family has difficulty hearing me when I call them throughout the house.					
F6. I use the phone less often than I would like.					
E7. I'm tense when talking with others because of my voice.					
F8. I tend to avoid groups of people because of my voice.					
E9. People seem irritated with my voice.					
P10. People ask, "What's wrong with your voice?"					
F11. I speak with friends, neighbors, or relatives less often because of my voice.					
F12. People ask me to repeat myself when speaking face-to-face.					
P13. My voice sounds creaky and dry.					
P14. I feel as though I have to strain to produce voice.					
E15. I find other people don't understand my voice problem.					
F16. My voice difficulties restrict my personal and social life.					
P17. The clarity of my voice is unpredictable.					
P18. I try to change my voice to sound different.					
F19. I feel left out of conversations because of my voice.					
P20. I use a great deal of effort to speak.					
P21. My voice is worse in the evening.					
F22. My voice problem causes me to lose income.					

Voice Handicap Index (VHI) (cont.)

	Never	Almost Never	Sometimes	Almost Always	Always
E23. My voice problem upsets me.					
E24. I am less out-going because of my voice problem.					
E25. My voice makes me feel handicapped.					
P26. My voice "gives out" on me in the middle of speaking.					
E27. I feel annoyed when people ask me to repeat.					
E28. I feel embarrassed when people ask me to repeat.					
E29. My voice makes me feel incompetent.					
E30. I'm ashamed of my voice problem.					

P Scale

F Scale

E Scale

Total Scale

Please circle the word that matches how severe you feel your voice problem is today.

Normal

Mild

Moderate

Severe

Appendix D: Cover Sheet for Pre-and Pos-Surgical Questionnaire

Appendix C Cover Sheet for Pre-and Post-Surgical Questionnaire

The Vanderbilt Voice Care Center is performing a study to learn more about how patients communicate before and after undergoing vocal fold surgery. Your responses to the questions below are confidential and will not be shared with your physician.

Age:

Gender: male female

Are you a singer? yes no

Name:

Date of Birth:

Occupation:

Highest level of education completed:

Do you live alone? Yes No

If no, how many OTHER adults (18 years or older) do you live with?

How many children (17 years or younger) do you live with?

Participant Code:
investigator

(this code will be filled in by the study)

Appendix E: Pre-Surgical Questionnaire

Appendix D Pre-Surgical Questionnaire – all groups

Date: _____

Pre-Surgery DAY _____

Participant Code: _____

1) Please check the appropriate response:

- I worked/went to school today.
- I took the day off from work/school today because of my voice.
- N/A

2) Make a mark on the line between 0 and 10 to answer the following statement:

How much did you use your voice today (including whispering)?
I used my voice ...

0
Not at all

10
Every time I wanted
to communicate

3) Circle the number that best describes the maximum loudness of your voice use today?

- | | | | | |
|------------------------|----------|----------------------|----------------|----------|
| 1 | 2 | 3 | 4 | 5 |
| I did not use my voice | Whisper | Conversational level | Talking Loudly | Yelling |

4) How did you communicate today? (check all that apply)

- | | | |
|----------------------------------|--|---|
| <input type="checkbox"/> Voice | <input type="checkbox"/> Mouthed words | <input type="checkbox"/> Other (explain): |
| <input type="checkbox"/> Whisper | <input type="checkbox"/> Writing | |
| <input type="checkbox"/> Gesture | <input type="checkbox"/> Text/ Email | |

Appendix F: Post-Surgical Questionnaires

Appendix E Post-Surgical Questionnaire – CON group

Date: _____

Post-Surgery DAY _____

Participant Code: _____

1) Please check the appropriate response:

I worked/went to school today.

I took the day off from work/school today because of my voice.

N/A

2) Make a mark on the line between 0 and 10 to answer the following statement:

How much did you use your voice today (including whispering)?

I used my voice ...

0
Not at all

10
Every time I wanted
to communicate

I was able to communicate effectively today without using my voice or whispering.

0
Not at all

10
Every time I wanted
to communicate

3) Circle the number that best describes the maximum loudness of your voice use today?

1
I did not
use my
voice

2
Whisper

3
Conversational level

4
Talking Loudly

5
Yelling

4) How did you communicate today? (check all that apply)

___ Voice

___ Mouthed words

___ Other (explain):

___ Whisper

___ Writing

___ Gesture

___ Text/Email

Appendix F Post-Surgical Questionnaire – TTG group

Date: _____

Post-Surgery DAY _____

Participant Code: _____

1) Please check the appropriate response:

I went to school today.

I took the day off from work/school today because of my voice.

NA

2) Make a mark on the line between 0 and 10 to answer the following statement:

How much did you use your voice today (including whispering)?

I used my voice ...

0 Not at all 10 Every time I wanted to communicate

I was able to communicate effectively today without using my voice or whispering.

0 Not at all 10 Every time I wanted to communicate

How much did you use the Lightwriter SL-40 device today instead of using your voice or whispering?

0 Not at all 10 Every time I wanted to communicate

3) Circle the number that best describes the maximum loudness of your voice use today?

1 I did not use my voice 2 Whisper 3 Conversational level 4 Talking Loudly 5 Yelling

4) How did you communicate today? (check all that apply)

Voice Mouthed words Lightwriter SL-40
 Whisper Writing Other (specify): _____
 Gesture Text/ Email _____

