

Unilateral Vocal Fold Paralysis: Voice Therapy and Voice Outcomes

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The more that you read, the more things you will know. The more that you learn, the more places you'll go — **Dr Seuss**

Statement of Authorship

This thesis contains no material that has been extracted in whole or in part from a thesis that

I have submitted towards the award of any other degree or diploma in any other tertiary

institution.

No other person's work has been used without due acknowledgment in the main text of the

thesis.

All research procedures reported in the thesis received the approval of the relevant Ethics

committee.

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Date: 5th October 2018

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Abstract

Unilateral vocal fold paralysis (UVFP) is a debilitating condition arising from a recurrent laryngeal nerve injury due to iatrogenic, idiopathic or other intrinsic or extrinsic causes. The loss of voluntary vocal fold movement can result in marked changes in voice quality and performance (dysphonia) and have a significant impact on quality of life. UVFP is estimated to affect approximately 0.5% of the population - with dysphonia reported in 86.6% of all cases. Treatment for UVFP aims to improve the voice quality and restore the glottal sufficiency either through voice therapy, surgical intervention or a combination of the two. Selection of treatment type for UVFP is based on the severity of the glottal insufficiency, the associated dysphonia and the vocal requirements of the individual. However, there is currently limited evidence available to support decision making around the management of dysphonia for people with UVFP. There are a number of potential reasons for the current limitation in evidence, including: (1) inadequate development and documentation of the voice outcome measures to determine treatment effect.

The first aim of my PhD is therefore to investigate the content, timing and dosage characteristics of voice therapy provided (by speech pathologists) to patients with dysphonia due to UVFP. This has resulted in three studies in my thesis: (1) a systematic review of the current relevant literature; (2) a cross-section international survey of current practice and (3) an in-depth qualitative study of expert practice. The findings of the three studies highlighted the lack of consistency in the application of voice therapy in the literature (Study 1), and then provided key information that informed the development of a schema that outlined the key stages involved in voice therapy treatment for patients with UVFP (Study 2 and Study 3) Key elements of this schema described factors that influence decision making and goal setting for voice therapy, the timing and intensity of therapy, the measurement of therapy outcomes, and decision making for the cessation of therapy. The schema could inform both future

research into the efficacy of voice therapy in UVFP and clinical practice Together these studies will provide a triangulation of evidence to formulate a clear and prescriptive direction for voice therapy treatment for future efficacy studies, as well as for clinical practice.

The second aim of my PhD is to critically evaluate voice outcome measures that are used with patients with UVFP to determine treatment effects. There are a large number of potential voice outcomes to choose from (more than 50), across multiple dimensions of voicing (e.g. acoustic, aerodynamic, auditory-perceptual and patient self-rated measures) and therefore there is a need for clarity on the most appropriate means of detecting voice change over time. A systematic review was conducted to address the second aim. The systematic review critically evaluated the voice outcome measures used in the existing literature with respect to reliability, validity and responsiveness to change, as well as multi-dimensionality and procedural/protocol accuracy. The systematic review identified set of voice outcome measures with good psychometric properties that demonstrated their responsiveness to the treatment effect. The set of outcome measures could therefore be used for future research in UVFP.

Together the findings of this thesis provide the best evidence for the voice therapy management of UVFP and have identified several multi-dimensional voice outcome measures which are responsive to the treatment effect.

Research Output

Published peer reviewed papers as chapters of the thesis

Walton, C., Carding. P., and Flanagan, K, *Perspectives on voice treatment for unilateral vocal fold paralysis*. Current Opinion in Otolaryngology & Head and Neck Surgery, 2018. **26**(3): p. 157-161. (Chapter 3)

Walton, C., Conway, E., Blackshaw, H., and Carding, P. *Unilateral Vocal Fold Paralysis: A Systematic Review of Speech-Language Pathology Management.* J Voice, 2017. **31**(4): p. 509.e7-509.e22. (Chapter 4 - Study 1)

Walton, C., Conway, E., Carding, P., Flanagan, K. and Blackshaw, H. *Voice outcome measures for adult patients with Unilateral Vocal Fold Paralysis: A systematic review.* Laryngoscope (*In press*) (Chapter 7 - Study 4)

Submitted papers as chapters of the thesis

Walton, C., Conway, E., Carding, P., Flanagan, K. and Blackshaw, H. *Characteristics of Voice Therapy for UVFP: A survey of Speech-Language Pathologists*. (submitted to Journal of Speech, Language & Hearing Science, July 2018) (Chapter 5 - Study 2)

Walton, C., Conway, E., Carding, P., Flanagan, K., Sav, A. and Blackshaw, H. *An in-depth investigation into the Characteristics of Voice Therapy for Patients with Unilateral Vocal Fold Paralysis* (submitted to the Journal of Voice, October 2018) (Chapter 6 - Study 3)

Accepted Abstracts

Laryngology Society of Australasia- Oral Presentation (Adelaide, November 2018) - Characteristics of voice therapy for patients with UVFP – Presentation

Laryngology Society of Australasia- Oral Presentation (Adelaide, November 2018) – Voice Outcome Measures for Unilateral Vocal Fold Paralysis - Presentation

Invited Conference Presentation

Australian Voice Association Conference: Voice On! The Road to Recovery - requested topic - Voice Outcome Measures and the clinical application November 2018, Adelaide

Additional Related Publications

Blackshaw, H., et al., Does laryngeal reinnervation or type I thyroplasty give better voice results for patients with unilateral vocal fold paralysis (VOCALIST): study protocol for a feasibility randomised controlled trial. BMJ Open, 2017. **7**(9): p. e016871.

Carding, P. & Walton, C. Chapter 6 – Unilateral Vocal Fold Paralysis in *Evaluating the effectiveness of voice therapy: functional, organic and neurogenic voice disorders*. Second edition. ed. 2017: Oxford: Compton Publishing.

Carding, P., Bos-Clark, M., Fu S, Gillivan-Murphy, P., Jones, S, M., & Walton, C. *Evaluating the efficacy of voice therapy for functional, organic and neurological voice disorders.* Clinical Otolaryngology. 2017; 42(2):201-217.

Presentations

Queensland Voice Special Interest Group – July 2017 (Teleconference) - UVFP – is it as easy as 1,2,3...?

ACU Speed Session - April 2017 (Teleconference) – Unilateral Vocal Fold Paralysis... What we currently know

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List of Abbreviations

UVFP - Unilateral Vocal Fold Paralysis

SLP – Speech-Language Pathologist

RLN - Recurrent Laryngeal Nerve

SLN - Superior Laryngeal Nerve

MRI - Magnetic Resonance Imaging

CT – Computerised Tomography

LEMG – Laryngeal Electromyography

GRBAS- An auditory-perceptual voice outcome measure – G – Grade, R – Roughness, B-Breathiness, A- Asthenia & S - Strain

ENT- Ear, Nose & Throat Surgeon

RCT - Randomised Control Trial

UK - United Kingdom

QOL - Quality of Life

NHR - Noise to harmonic ratio

HNR-Harmonic to noise ratio

F0 – Fundamental Frequency

VOM - Voice outcome measure

MPT- Maximum Phonation Time

PROMS - Patient self-rated outcome measures

TA - thyroarytenoid muscle

PCA - posterior cricoarytenoid muscle

dB - decibel

Hz – Hertz

VHI-10 – Voice Handicap Index -10

"Not all those who wander are lost" J.R.R.

Tolkien

1 CHAPTER ONE: INTRODUCTION

This chapter provides an introduction to the thesis by defining Unilateral Vocal Fold Paralysis (UVFP) and reviewing the relevant laryngeal anatomy, with particular focus on the recurrent laryngeal nerve. Chapter one will also provide a detailed background of the features of UVFP with emphasis on current understandings of aetiology, incidence, diagnosis, management and measurement of the treatment effect.

1.1 Introduction

Unilateral vocal fold paralysis (UVFP) is a common voice disorder characterized by the loss of mobility to one of the vocal folds resulting in a dysphonia. A unilateral vocal fold paralysis restricts functional communication, contributes to vocal fatigue and is associated with a reduced quality of life [2, 3]. Unilateral vocal fold paralysis has a strong correlation with loss of income and reduced socialization and is estimated to affect approximately 0.41-0.51% of the population [4, 5]. Unilateral vocal fold paralysis typically requires treatment to improve voice quality either with behavioural (voice therapy) and/or surgical intervention.

1.2 Unilateral vocal fold paralysis

Unilateral vocal fold paralysis (UVFP) is a term that refers to the loss of neural innervation of the recurrent laryngeal nerve branches, which affects one side of the larynx [6]. The vocal folds are situated in the larynx and contribute to the tasks of respiration, phonation and swallowing. A

paralysis resulting from a loss of innervation to one of the vocal folds can therefore impact the ability to perform these tasks. During phonation, the immobile vocal fold affects the adduction and abduction of the vocal folds typically resulting in a perceptually weak, breathy and rough voice quality [1]. There is no clear definition of UVFP and this may lead to vague or non-specific diagnoses and terminology being used interchangeably to refer to both true UVFP and similar conditions [1, 7]. Table 1 is a list of the terminology that has been used to describe UVFP:

Table 1. Terms used to describe unilateral vocal fold paralysis

- Vocal fold/cord paresis [8, 9]
- Vocal fold/cord paralysis [10, 11]
- Paralytic dysphonia [12, 13]
- Recurrent laryngeal nerve paralysis [14-16]
- Recurrent laryngeal nerve palsy [17-19]
- Laryngeal hemiplegia [20, 21]
- Vocal fold/cord palsy [22, 23]
- Vocal fold immobility [24, 25]
- Glottal insufficiency [26, 27]
- Recurrent laryngeal nerve injury [28, 29]

These terms are not synonymous but are often used as such. This may result in considerable confusion- for example laryngeal hemiplegia may also refer to a diffuse cranial nerve lesion following a neurological event [30] and glottal insufficiency may be caused by a variety of pathologies including aging and muscle tension dysphonia [31, 32]. Therefore, for purposes of clarity, in this thesis I will use the following definition of UVFP:

Unilateral Vocal Fold Paralysis: immobility to one of the vocal folds following injury to the recurrent laryngeal nerve resulting in the loss of voluntary vocal fold movement which may result in a dysphonia.

Additionally, there are different terminologies that are used interchangeably to describe the neurological injury despite very different prognoses. Table 2 documents the terminology and definitions used in this thesis.

Table 2. Neurological terminology

Paresis- is used to refer to a weakness of the muscle, indicating that there is still some neural connection allowing for some neurotransmission to occur, this also has increased potential for recovery [10].

Palsy - is historically an older term which is used interchangeably when referring to both a paralysis or paresis when the diagnosis is uncertain [33].

Paralysis - this term indicates that the nerve is severely damaged resulting in an immobility to the damaged muscle with a poor prognosis for recovery.

1.3 **Neuroanatomy**

Peripheral Nerves – The Recurrent Laryngeal Nerve

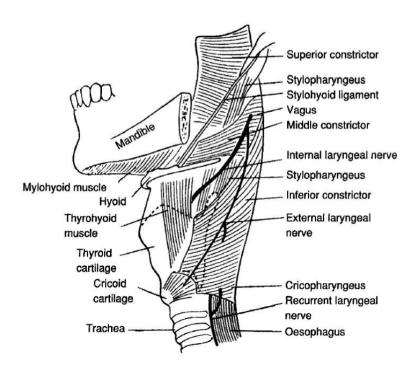
The Peripheral Nervous System (PNS) is a division of the nervous system and is considered part of the lower motor neuron making up the final common pathway for motor neurons [34]. The PNS comprises of clusters of neurones which connects the central nervous system (CNS) with the limbs and organs such as the larynx and heart [34]. The PNS includes the cranial nerves, spinal nerves, and the sympathetic and parasympathetic nervous systems. Nerves within the PNS have the ability to stretch and bend to accommodate for movements of the body and the limbs [35]. For additional protection, peripheral nerves are surrounded by a connective

tissue known as a sheath to reduce the potential for injury or trauma and support neural conduction [34].

The vagus nerve (CNX) provides the motor and sensory innervation to the larynx, via two of its branches the Recurrent Laryngeal Nerve (RLN) and the Superior Laryngeal Nerve (SLN) [36] see Figure 1. The RLN provides the primary motor innervation to the intrinsic laryngeal muscles which are responsible for the abduction and abduction of the vocal folds and also provides sensation below the vocal folds [37]. The majority of the laryngeal sensation is provided by the SLN (above the vocal folds) and which also innervates the cricothyroid muscle used for tensioning and lengthening of the vocal folds [38].

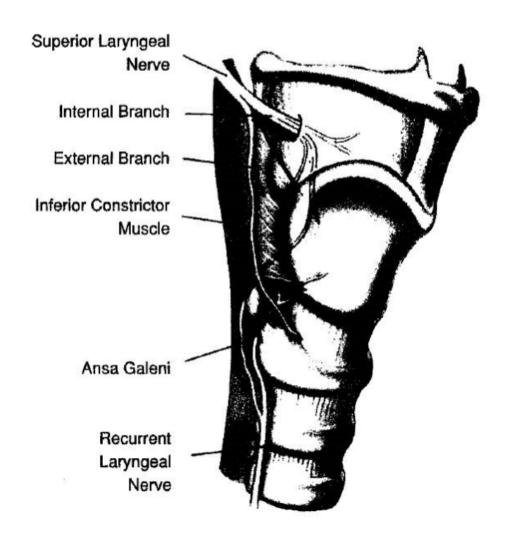
The RLN is innervated by the vagus nerve and is therefore part of the PNS. The RLN is a paired, myelinated nerve which descends into the cardiothoracic region prior to ascending to innervate the larynx [39, 40]. The pathways of the left and right RLN are different due anatomical landmarks and the positioning of the heart on the left side [37]. This difference in length and pathway means that the left RLN is almost three times more susceptible to the injuries than the right RLN [41-44].

Figure 1. Laryngeal Neuroanatomy



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Figure 2. Laryngeal Nerves



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us/Greene+and+Mathieson%27s+the+Voice+and+its+Disorders%2C+6th+Edition-p-9781861561961)

Upon entering the larynx, the left and right RLNs provide ipsilateral innervation to the three laryngeal adductors (lateral cricoarytenoid, thyroarytenoid and interarytenoid) and the one laryngeal abductor (posterior cricoarytenoid) [37] see Figure 1. The interarytenoid is unique

being the only non-paired muscle it receives bilateral innervation [34]. Effective voicing requires the coordination of several muscles innervated by the RLN specifically the thyroarytenoid and lateral cricoarytenoid for the adduction of the vocal folds, and the posterior cricoarytenoid for the abduction of the vocal folds [37].

The lateral cricoarytenoid muscle sits on either side of the larynx where it attaches from the cricoid cartilage to the vocal process of the arytenoid cartilage, almost parallel to the thyroarytenoid muscle [45]. The contraction of the lateral cricoarytenoid muscle pulls the vocal process of the arytenoid downward contributing to the adduction and lengthening of the vocal fold [37]. The thyroarytenoid muscles consists of two bellies, the internus (vocalis) and externus (thyroepiglottic) [45]. The internus muscle arises at the anterior commissure and attaches to the vocal process of the arytenoid cartilage, while the externus attaches to the lateral surface of the arytenoid cartilage [37]. The vocalis muscle is situated deep within the vocal folds, while the thyroepiglottic portion contributes to part of the aryepiglottic folds. The thyroarytenoid muscle bellies pull the arytenoid cartilage anteriorly resulting in short and relaxed vocal folds. This movement also brings the arytenoid cartilage inward and contributes to the adduction of the vocal folds [46]. This muscle is also believed to extend into the false vocal folds and contribute to ventricular phonation [47]. This interarytenoid muscle has both transverse and oblique fibres which attach to each of the arytenoid cartilages, when contracted this results in arytenoid adduction, closure of the posterior glottis and vocal fold adduction [38]. The only muscle of abduction is the posterior cricoarytenoid muscle, this arises from the posterior surface of the cricoid lamina and the muscle runs diagonally to attach to the muscular process of the arytenoid cartilage [34]. The contraction of this muscle rotates the arytenoid cartilage in the cricoarytenoid joint laterally abducting the vocal folds [45].

The superior laryngeal nerve (SLN) provides motor innervation to the cricothyroid muscle and provides sensation to the larynx above level of the vocal folds. The SLN separates from the

vagus nerve below the inferior ganglion, where it divides into two branches: the internal and external branches [37] see Figure 2. The internal branch of the SLN provides afferent signals above the glottis, then branches into three different divisions to supply the mucosa of the epiglottis, true and false vocal folds, pharyngeal walls and cricopharyngeus [34]. The external branch, innervates the ipsilateral cricothyroid muscle [38]. The cricothyroid is the antagonist to the thyroarytenoid muscle and contributes the most force for vocal fold movement [48]. Contraction of the cricothyroid muscle tilts the cricoid lamina backward at the cricothyroid joint, causing lengthening, tensing and adduction of vocal folds resulting in an increased vocal pitch [40].

1.4 Aetiology

Injuries to the peripheral nervous system can result from a range of internal and external causes. Depending on the location and the pathway of the PNS nerve, some are more susceptible to injury/ trauma than nerves within the CNS. Injury to the nerves within the PNS is typically due to one of the following: cutting, compression, transection, slicing, heat and clamping [49]. These injuries can result in sensory and/or motor deficits and vary in severity depending on the aetiology of the injury. The injured nerve may experience impeded or reduced neural firing leading to poor motor intervention to the muscles resulting in symptoms of weakness and flaccidity [1].

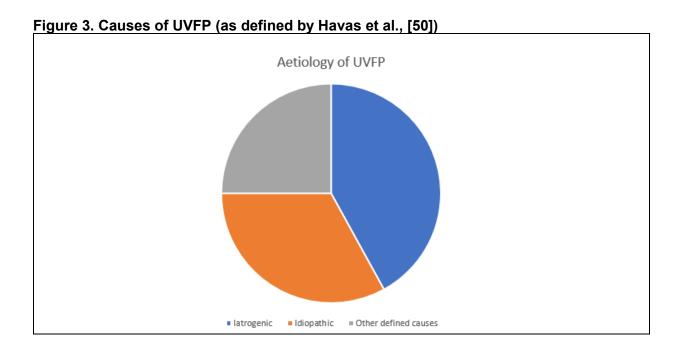
UVFP results from an injury to recurrent laryngeal nerve which provides the primary motor innervation to the larynx. The length and pathway of the recurrent laryngeal makes it more susceptible to injury leading to a potential neurogenic dysphonia [50]. The denervation or inadequate innervation of the RLN nerve affects the muscles of abduction and adduction

resulting in a loss of voluntary control of the vocal folds [44, 51]. As the RLN is a lower motor neuron, an injury to the RLN results in a flaccidity to the innervated muscles due to it being part of the lower motor neuron [52] which may lead to changes to the voice and potential aspiration [37]. Depending on the aetiology of the RLN injury, symptoms can be temporary (i.e. viral infections, inflammation to the nerve) or permanent (i.e. surgery cutting of the nerve) [1]. The location of the RLN injury can result in unilateral or bilateral injury and depending on the neural damage can lead to a paralysis or paresis of the vocal folds which is described as a neurogenic dysphonia.

It is generally considered that UVFP is a sign of an injury - not a diagnosis itself [41, 42, 53], with cases of UVFP being attributed to neoplasms, surgeries, intubation, neurological diseases, viral infections and cardiothoracic surgery [50, 54]. The three primary causes of UVFP are iatrogenic (caused by medical intervention), idiopathic (unknown or temporary cause), or other defined causes [50]. Figure 3 is pie chart displaying the different causes of UVFP as described by Havas et al. [50].

1.4.1 Difference between SLN and RLN symptoms

Damage to the SLN typically affects the tension of the cricothyroid muscle resulting in difficulty with pitch, poor transition between notes and trouble shifting between speaking and singing voices. It is noted that following SLN injury a speaking voice is typically unaffected. This is likely due to the residual innervation by the RLN leading to unaffected function of the muscles of adduction and abduction. The diagnosis of a SLN injury can be based solely on auditory-perceptual features, as there may be limited changes detected via direct visualisation [1].



The most common aetiology is iatrogenic with approximately 41-66% cases being attributed to head, neck and chest surgeries as seen in Figure 3. [41, 50, 54-56]. Of the iatrogenic causes, thyroid surgery is the most common cause of UVFP making up approximately 49% of iatrogenic cases [56, 57]. Dysphonia due to RLN injury is reported to occur in approximately 33% of thyroid surgery cases however this number is potentially underrated with other studies reporting up to 68% of voice changes following surgical interventions [39]. Iatrogenic injuries may result in ipsilateral vocal fold paralysis due to either manipulation or transection injury to the nerve. It has been proposed that there are several factors contributing to RLN injury resulting in UVFP due to iatrogenic intervention; including a lack of nerve identification, type of surgery, the experience of the surgeon, the use of nerve monitoring, extent of the surgery and the side of the surgery [1, 39].

Other defined causes of UVFP as seen in Figure 3. are attributed to 25% of UVFP cases which are most commonly associated with trauma, neoplasms, inflammation and radiation. These causes are more likely to compress the nerve, which typically resolves following the removal of the cause (e.g. neoplasm) [58]. The final cause of UVFP, idiopathic cases are reported to occur 33% of the time (Figure 3.), these are typically unknown causes of UVFP which occasionally are masking underlying causes such as undetected malignancies or neurological diseases [41, 59].

1.5 Diagnosis

The diagnosis of a PNS injury is key to determining the optimal treatment and management. The diagnosis is typically guided by the presenting symptoms and management of UVFP requires a multidisciplinary team primarily consisting of an Ear Nose and Throat surgeon (ENT) and speech-language pathologist [60]. Additionally, team members may include diagnostic specialists such as radiologists. Despite there being no current protocol for the diagnosis of UVFP [1] there are currently a range of assessments that are used [61, 62]. Table 3 lists the common assessment used to aid the diagnosis of UVFP.

Table 3. Current assessment used for diagnosis of a UVFP

- case history [1, 39]
- direct visualization [7, 63]
- perceptual and acoustic assessments [64, 65]
- laryngeal electromyography (LEMG) [62, 66]
- Medical imaging of the head and neck region (e.g. MRI and CT) [67, 68]
- Instrumental swallow assessment (Videofluroscopy or Fibreoptic Endoscopic

A case history should review current concerns, voice status, presence of dysphagia and onset to determine potential aetiology to inform the diagnosis [55]. Symptoms reported during the case history such as voice changes and dysphagia can indicate the nerves that may have been injured [52, 71]. When both dysphagia and dysphonia are reported this may indicate a brain stem injury involving several cranial nerves [37]. Cases with the dysphonia without dysphagia could indicate RLN injury due to difficulties with the abduction and adduction of the vocal folds [37, 72]. Based on the reported concerns, a patient may be referred for further assessment with medical imaging, e.g. CT, Videofluroscopic swallow study and cervical ultrasound [44], to aid the diagnosis.

In addition to a thorough case history, a direct visualisation of the larynx by an ENT surgeon, is the primary diagnostic tool used to diagnose a UVFP due to the cost and availability [7]. Direct visualization of the larynx is the 'gold standard' for the diagnoses of voice disorders [73] typically consisting of a direct visualization of the larynx using a flexible or rigid laryngoscope and/or videostroboscopy [74]. The use of direct visualisation allows for observation of the laryngeal anatomy at rest and during connected speech and has been described as the preferred instrument for assessing neurological conditions of the larynx [72]. The additional use of videostroboscopy is also recommended as it allows for observation of the cycles of vocal fold vibration and can guide treatment planning [11]. Features of UVFP typically seen during a direct visualization of the larynx one immobile vocal fold in either the median, paramedian intermediate or cadaveric positions, with additional features listed in Table 4.

Due to the similarity of features between different diagnoses it is key that clinicians distinguish between conditions before diagnosing UVFP. Similar conditions to UVFP can include: vocal fold paresis, presbyphonia, paradoxical vocal fold movement, muscle tension dysphonia and superior laryngeal nerve paralysis. Therefore, in addition to a comprehensive case history it is critical that vocalisation tasks are conducted during a direct visualisation to inform the differential diagnosis (See Table 4).

Depending on the time since injury, the immobile vocal fold may demonstrate some atrophy often characterised by "bowing" of the vocal fold [76]. Bowing is the result of prolonged loss of innervation leading to reduced tone and tension of the vocal fold. Once the symptoms and features of UVFP have been identified the patient can be referred for appropriate treatment to manage their presenting concerns.

Table 4. Features of UVFP seen by direct visualisation

- laryngeal asymmetry [37]
- incomplete glottic closure [75]
- residual movement of the injured vocal fold due to synkinesis or bilateral
- interarytenoid adduction [63]
- bowing [76]
- Differing length, height and tension of the two vocal folds [37]

To diagnose a UVFP via direct visualization, the ENT would conduct a range of tasks both at rest and during voicing. There is currently no established ENT protocol to determine the tasks used during visualization to diagnose UVFP [1], and so it is likely that the selection of

visualisation tasks would be influenced by the experience of the ENT surgeon. Phonation tasks may include: "ee-sniff", sigh, hum and sustained phonation [11]. ENT surgeons may also classify the position of the injured vocal fold at rest, using a tool such as Negus' (1947) 6 positions i.e. median, paramedian, cadaveric) [77]. Classifying the position using Negus' descriptive terms allows the ENT surgeon to establish the current positioning of the UVFP and measure any changes to the glottal gap over time [75]. Finally, laryngeal EMG is starting to be used in research to aid predictions of prognosis of UVFP and diagnosis of paralysis vs, paresis, as it helps to determine the nerve functioning and potential for recovery [66, 78]. Specifically, when conducting laryngeal EMG, the thyroarytenoid is used for assessing the potential of the RLN, while cricothyroid is used for SLN. The presence of voluntary action potentials indicates a favourable prognosis. EMG findings have been used to predict spontaneous recovery of the thyroarytenoid muscle innervation in 85% of patients following initial injury [2]. EMG is generally accurate in detecting the prognosis of nerve recovery with studies reporting between 86 - 88% accuracy of prognosis [3, 4]. Despite the features of EMG in aiding diagnosis and prognosis there are several limitations including: there is no current consensus on protocol for conducting and interpreting laryngeal EMG, it may be difficult to isolate specific laryngeal muscles when using EMG, and there are individual variations in muscle movement and clinician variances that need to be considered in the interpretation of the EMG data (Ludlow et al. 1994).

1.6 Incidence & Prevalence

There are presently limited studies which attempt to establish the incidence and prevalence of UVFP. However, from the information that is available, UVFP is approximated to affect between 0.41-0.51% of the population [4, 5, 42]. There also appears to be a higher incidence of UVFP in females than males- approximately 4: 1 [4]. UVFP results in dysphonia in as high as 83.6% of

cases while other conditions due to UVFP may include dysphagia in 9.09% patients and breathing difficulties 21.81 % [42].

There is reported to be a higher incidence of left sided UVFP compared to right sided, with approximately 66% of cases being left sided UVFP [39, 56]. This is most easily explained by the extended and tortuous route of the left RLN into the thoracic cavity prior to ascending to innervate the larynx.

1.7 Prognosis of UVFP

The prognosis of UVFP depends on the type of injury, location of the injury, resulting nerve damage and potential of nerve recovery [80]. Injuries to nerves are typically classified based on the severity and prognosis for neural recovery [81]. Table 5 is a summary of the different nerve injuries.

Table 5. Classification of nerve injuries (As defined by Seddon. [82])

Neuropraxia - results from a temporary block of conduction of nerve pulses resulting in a paresis. The recovery is quick once the blockage is cleared and typically occurs within in 6 – 8 weeks.

Axonotmesis - is a more severe type of nerve injury usually resulting from a disruption or cutting to the neuronal axon, but the sheath is typically maintained. Axonotmesis damage to the nerve will typically cause paralysis to the motor and sensory systems. There is potential for neuroregeneration and nerve recovery with this injury however it may take up to a year.

Neurotmesis - is the most severe type of nerve lesion, this is a result of damage to both the axon and connective tissue. Damage of this severity results in a complete loss of motor, sensory and automatic function, partial recovery may occur due to some reinnervation, but complete recovery is impossible. Partial recovery can occur up to two years post injury.

The prognosis of RLN injury depends on several key factors including the severity of the nerve injury seen in Table 5. As discussed in section 1.3 the PNS is part of the final common pathway so once a peripheral nerve has been injured there is a denervation of the once innervated muscle, leading to a weakness or a flaccidity to the muscle [39]. When a peripheral neve has been injured it will attempt to repair itself slowly, growing at a rate of approximately one inch per month [83]. As the nerve attempts to regenerate, the new nerve fibres may incorrectly reattach (re-anastomosis), this can lead to incomplete or disorganised innervation to the RLN resulting in an ongoing paralysis or paresis to the once innervated muscle [39]. Synkinesis presents as involuntary muscle movements can be observed due to incorrect nerve re-anastomosis following nerve injury. Synkinesis following nerve damage to the RLN can result in ineffective abduction and adduction of the vocal folds [51].

Spontaneous recovery can occur in some cases of UVFP however the incidence of recovery depends on the aetiology and time since onset. Spontaneous recovery is not typically described in iatrogenic and other causes due to the nature and likely severity of the RLN injury [39]. Idiopathic UVFP cases are most commonly experience spontaneous recovery where it is reported to occur in approximately one-third of cases [1]. The timing of the recovery was found to improve longitudinally with recovery reported at 86% after 6 months and 96% after 9 months [39].

Consequently, the type of nerve injury influences the potential recovery and prognosis for voice (and swallowing) recovery [84]. Typically, if dysphagia is present in addition to a dysphonia, the management of the dysphonia is likely sidelined, and treatment of the dysphagia is the main priority [1]. For patients with an idiopathic UVFP, this can be challenging as typically determining nerve potential depends on the underlying cause [59]. The prognosis of UVFP is typically determined by factors such as case history, direct visualization findings and severity of nerve injury. Depending on the aetiology of the injury and knowledge of the nerve injury planning of treatment can be determined. If there is knowledge that the nerve is not completely cut (i.e. neuropraxia) then treatment such as voice therapy and injections may be considered to allow up to 12 months for potential recovery [10]. If laryngeal EMG findings or case history reveal that the nerve was transected (i.e. axonotmesis and neurotmesis) the prognosis for voice recovery is poor and permanent treatment options such as laryngeal framework surgeries or reinnervation may be commenced at approximately two months after onset of symptoms [84, 85].

1.8 Symptoms and features of UVFP

The symptoms of UVFP can vary depending on the aetiology of the UVFP and resulting glottal insufficiency. Typically, a patient with a UVFP may report symptoms of hoarseness with potential breathing and/or swallowing difficulties [38]. In many cases (depending on the aetiology) vocal changes may be the first sign of a UVFP. Auditory perceptual signs of UVFP can vary depending on the type of nerve injury and resulting position of the paralysed vocal fold. Features can include a breathy, aphonic, weak voice with potential diplophonia, roughness due

to increased aperiodicity and reduced vocal intensity [43, 86]. In addition to the perceptual features, other symptoms of dysphonia due to UVFP include reduced vocal projection, shortness of breath, vocal fatigue and increased effort used to produce a voice [55, 86, 87]. This dysphonia can have a negative impact on the activity and participation of individuals resulting in a reduced quality of life [88]. The World Health Organisation (WHO) International Classification of functioning and disability (ICF) model considers activity limitation, participation restriction, personal and environmental factors and the impact these have on an individual's life. This is key for the treatment planning for patients with UVFP, as UVFP has been associated with an inability to work, social isolation and has a high correlation with stress and depression [89, 90] which can be explored through the application of the ICF model. Table 6. Outlines some of the symptoms of UVFP.

Table 6. Symptoms of UVFP

- A weak and rough voice [60]
- Vocal fatigue [60]
- Reduced ability to project the voice [91]
- Increased potential for depression [3]
- Reduced socialisation and ability to work [89]

1.9 Treatment

Peripheral nerve injuries are unique in aetiology, severity and presentation therefore the selection of management needs to reflect this. This means that treatment is necessarily

heterogeneous in order to manage the presenting injury and symptoms, the prognosis and the patient expectations. In order to select appropriate treatment options, clinicians need to be familiar with PNS anatomy and function, the different types of injuries, application of diagnostics, and understanding of prognosis and treatment options.

Treatment for UVFP aims to restore the glottal insufficiency typically through behavioural treatment e.g. voice therapy, surgical intervention, or a combination of the two treatments. Selection of treatment is based on severity of glottal insufficiency, severity of laryngeal injury and other patient related factors [60]. However, there is a lack of literature to support the different treatment options for the management of UVFP and some of these issues are central to this thesis (see Chapters 2, 5 and 6).

1.9.1 Voice Therapy

Voice therapy is a behavioural treatment provided by speech-language pathologists which is designed to reduce the severity of a dysphonia and improve functional voicing. Speech-language pathologists are trained to provide voice therapy to people with a dysphonia, having a strong knowledge of vocal anatomy and function. When providing voice therapy, a speech-language pathologist uses their knowledge of the vocal subsystems (respiratory, laryngeal and resonatory), and presenting dysphonia to improve the vocal quality and target the presenting perceptual, acoustic, aerodynamic and/or functional deficits. Voice therapy comprises of specific characteristics: content (type of behavioural treatment either direct and/or indirect), dosage (the number of treatment hours), intensity (the frequency of sessions e.g. daily, weekly, fortnightly) and duration (number of weeks/ months/ years that therapy goes for). The selection of the voice therapy characteristics should be considered within the context of the evidence base, clinician

factors, patient factors and clinic factors (EBP 4 model) [5]. The content of voice therapy can include a direct approach focusing on improving vocal function, and quality of the voice through by targeting the strength, flexibility, endurance and coordination of the laryngeal subsystems. The indirect component of voice therapy typically is provided through vocal hygiene. Vocal Hygiene refers to the effective habits of 'good' voicing, the implementation of these vocal habits have been supported in improving the overall vocal quality in patients with a dysphonia or hoarseness [6]. Direct voice therapy is an intervention that directly targets the different subsystems of voicing to achieve a good voice. Early approaches to voice therapy for patients with UVFP have focused on targeting glottal closure through forceful tasks such as pushing and pulling, more recently these tasks have been avoided due to the potential to develop secondary muscle tension, so it is key to review the current clinical voice therapy approaches [1].

One key aim of the thesis is to investigate the characteristics of voice therapy management for patients with UVFP with a clear understanding of the evidence base that underpins clinical practice. The theoretical underpinning of voice therapy and the role of voice therapy in the management of voice disorders and management of neurological dysphonia will be discussed in Chapter 2. The specifics of voice therapy for the management of UVFP will be discussed further in Section 2. Chapter 4 contains a systematic review which reviews the current characteristics of voice therapy provided to patients with UVFP within the published literature. This is followed by Chapters 5 and 6 which address the current clinical perspectives of speech-language pathologists of the characteristics of voice therapy through the use of a cross-sectional survey and semi-structured in-depth interview respectively.

1.9.2 Surgical Treatment

Surgical treatment performed by an ENT surgeon is designed to improve the medialisation of the paralysed vocal fold with the unaffected side [92]. Surgical treatment can be temporary or permanent and can include: injections, medialisation or reinnervation [93].

As surgical treatment is not the focus of this thesis there is limited depth provided into the different surgical approaches for the management of UVFP. Further information to be provided in chapter 2 about current surgical approaches used to treat UVFP.

1.10 Voice Outcomes

Outcome measures are tools used to help clinicians in determining the treatment effect and are key in the reporting of clinical research. Outcome measures are required to be valid, reliable, practical (utility) and responsive to the treatment effect in order to report the effects of the intervention [94-96]. Therefore the second main aim of this thesis was to explore and evaluate the voice outcome measures used in the published literature by speech-language pathologists and ENT surgeons to assess the treatment effect for patients with UVFP. This would inform future clinical research and determine if the outcomes measures used were consistent with the findings of Aim 1 and practice regarding voice outcome measures that may be useful in determining a treatment effect. This aim is addressed in section 3 of the thesis. I have conducted a systematic review evaluating the voice outcome measures reported by the literature in detecting the treatment effect for patients with UVFP, which is reported in Chapter 7.

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2 CHAPTER TWO: PERSPECTIVES ON VOICE THERAPY FOR UNILATERAL VOCAL FOLD PARALYSIS

As discussed in Chapter 1, Unilateral Vocal Fold Paralysis (UVFP) arises from an injury to the Recurrent Laryngeal Nerve (RLN) resulting in a dysphonia which warrants treatment. Due to the nature of the nerve injury, and the resulting Peripheral Nervous System (PNS) deficit, the paralysed vocal fold presents as flaccid, typically leading to reduced glottal sufficiency, and both perceptual and functional changes to voicing. Treatment, either voice therapy and / or surgical intervention, is commonly provided to improve the presenting glottal insufficiency and dysphonia.

Chapter two provides an outline of the current perspectives for the management of UVFP, specifically exploring the aims of the treatments, and the current evidence for the different treatment approaches. Chapter two will also discuss the outcome measures currently used by clinicians to report and detect the treatment effect.

This chapter is a published manuscript:

Perspectives on voice treatment for unilateral vocal fold paralysis. Walton, C., Carding. P., and Flanagan, K, <u>Current Opinion in Otolaryngology & Head and Neck Surgery</u>, 2018. 26(3): p. 157-161.



Perspectives on voice treatment for unilateral vocal fold paralysis

Chloe Walton, Paul Carding, and Kieran Flanagan

Purpose of review

Unilateral vocal fold paralysis (UVFP) is a common cause of neurogenic dysphonia resulting in glottal insufficiency. To restore glottal sufficiency and reduce the presenting dysphonia, treatment involving either surgical intervention, voice therapy or a combination of the two is typically provided. Currently, there is no consensus for the most effective voice treatment for UVFP. This results in an inability to compare current studies, and a lack of treatment effectiveness for the management of UVFP. This study aims to review the most recent literature for the management of dysphonia due to UVFP to establish the current evidence base for voice treatment options.

Recent findings

There was found to be a lack of consistency in the rationale, selection and timing of the surgical intervention and/or voice therapy being provided for patients with UVFP.

Summary

Further consensus is required for the rationale and selection of voice treatment prescriptions for the management of UVFP in order to improve treatment effectiveness and voice outcomes in patients with UVFP.

Keywords

surgery, treatment, unilateral vocal fold paralysis, voice therapy

INTRODUCTION

Dysphonia due to unilateral vocal fold paralysis (UVFP) results from a neurological injury, leading to glottal insufficiency and potential dysphagia and breathing difficulties (The most common neurological injury is iatrogenic, resulting from induced injury to the recurrent laryngeal nerve typically following surgery to the head and neck region. The second most common cause is noninduced to the recurrent laryngeal nerve such as neoplasms, traumatic injuries and neurological diseases and idiopathic cause is when the cause of the UVFP is unable to be determined.) [1,2] The vocal folds, which are housed in the larynx, contribute to the tasks of swallowing, respiration and phonation. The larynx is innervated by the vagus nerve (CNX); two of its branches the recurrent laryngeal nerve (RLN) and the superior laryngeal nerve (SLN) provide sensory and motor innervation to the larynx. The RLN provides the primary innervation to the intrinsic laryngeal muscles responsible for the abduction and abduction of the vocal folds and sensation below the vocal folds. The SLN provides sensory innervation to the majority of the larynx (above the vocal folds) and innervates the cricothyroid muscle used for lengthening and tensing the vocal folds to adjust the pitch of the voice [3]. UVFP results from an injury to RLN, which leads to the loss of mobility to one of the vocal folds. As the RLN is a lower motor neuron [4], the injury results in the flaccidity to the innervated ipsilateral muscles of abduction and adduction, which typically leads to a dysphonia due to a glottal gap and occasionally breathing and swallowing difficulties [1,5,6].

UVFP is estimated to affect approximately 0.41–0.51% of the population [7,8] with dysphonia reported in 83.6% of cases [9]. People with UVFP typically exhibit dysphonia due to an immobile vocal fold that causes air escape during voicing and disrupts the mucosal wave contributing to a perceptually rough and breathy voice [10,11]. Dysphonia due to UVFP is associated with vocal fatigue

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KEY POINTS

- Currently, there is no consensus for the definition or diagnosis of UVFP.
- Lack of a clear rationale for treatment and justification of voice treatment selection.
- No consistent treatment approach for the management of dysphonia due to UVFP.
- A combination of voice therapy and surgical intervention will likely contribute to improved patient outcomes.
- Careful selection of multidimensional voice outcome measures is required to accurately detect the treatment effect.

and reduced vocal efficiency, which impacts on the quality of life of patients and has a strong correlation with loss of income and reduced socialization [12-14].

Currently, there is no clear consensus for the definition or diagnosis of UVFP [15,16]. The nomenclature in recent studies includes palsy, hemiplegia and paresis, which are poorly defined and are used interchangeably to refer to both true UVFP and related conditions [17,18,19*,20]. This lack of diagnostic clarity is then directly reflected in the lack of consensus of treatment approaches and the consequential limited evidence base for the effectiveness of treatment of patients with UVFP. This review will therefore focus on the current situation with regard to the rationale and selection of treatment, surgical treatment approaches, behavioural voice therapy approaches, combination approaches and detecting change following treatment.

The selection and rationale for treatment choice

Treatment of UVFP aims to reduce the glottal insufficiency and improve voicing through surgical treatment, behavioural voice therapy exercises or a combination of the two. Effective management of UVFP requires accurate diagnostic and prognostic information in order to construct a clear treatment rationale. This treatment rationale should align with the concerns and needs of the patient(s) and the stated aims of intervention. A number of factors are likely to influence the selection of treatment, including onset of injury, cause, degree of glottal insufficiency, severity of dysphonia and prognosis [15,21]. Additional factors that may impact treatment selection include patient concerns, age, comorbidities, treatment facility, clinician experience/skills

and equipment availability [15,22*]. Despite the increasing number of studies reporting the effectiveness of treatments for UVFP, for example [10,23*,24*,25], most studies do not provide a clear clinical rationale for the selection of the treatment programme [15,21,26].

The establishment of a UVFP definition and diagnostic protocol would enable the development of clear treatment rationales that would, in turn, guide treatment selection for any individual patient. This approach has been recently articulated by Munin et al. [27"] and Pardo-Maza et al. [28"] who report on laryngeal electromyography (LEMG) as clinical tool in determining accurate diagnosis and prognosis of UVFP [27**,29,30]. The use of LEMG allows for classification of nerve injuries using the Seddon [31] or Sunderland [32] classification systems by identifying features such as fibrillation and nerve conduction distal to the lesion [33]. The adoption of such prognostic tools enables the formulation of a treatment plan based on knowledge of severity of nerve injury (e.g. neuropraxia vs. neurotmesis) and timing considerations (i.e. prognosis) for planning intervention.

Randolph [22"] suggests that there are several different treatment options for patients who present with temporary vocal fold paralysis (e.g. neuropraxia or axtonotomesis) or a small glottal gap (<1-3 mm)[34]. In cases wherein there is a small glottal gap, behavioural voice therapy is commonly used as an initial treatment option for managing the dysphonia [5,10]. The implied rationale is that voice therapy aims to improve vocal fold adduction (by targeting the nonparalysed vocal fold) and prevents potential compensatory vocal hyperfunction [15]. In addition, the commencement of early intervention aims to apply principles of neuroplasticity (e.g. use it or lose it) and delay the onset of atrophy the paralysed muscles [35,36]. Similarly, the early use of temporary injection laryngoplasty aims to improve the vocal quality by reducing glottal insufficiency and preempts the likelihood of developing vocal hyperfunction and in some cases may reduce the requirement for more permanent surgical interventions [37–40,41**]. However, studies that report on the effectiveness of voice therapy [23,42,43] and injection laryngoplasty [24,25] rarely articulate the rationale behind the treatment selection (e.g. size of glottal gap and prognosis) and there is an assumption that all patients in the studies require the same treatment approach.

Permanent surgical interventions are more likely to be indicated in cases of UVFP wherein there is significant glottal insufficiency, poor overall prognosis of recovery due to suspected axonotomesis or neurotomesis, severe persistent dysphonia, aspiration and/or poor response to initial intervention (e.g. behavioural and/or temporary injection) [15,22*]. Despite this common practice, there are very few published studies that clearly articulate the rationale to justify these surgical treatment choices [10,44*]. A large number of surgical intervention studies describe the surgical techniques but do not articulate the rationale for treatment selection or the pathway of patients entering the study (e.g. no spontaneous recovery, previous ineffective voice therapy, temporary injection laryngoplasty or use of LEMG for prognosis) [44*,45].

Current surgical treatment approaches

There are a number of surgical procedures described in the literature that fall into two main categories: medialisation and reinnervation. Medialisation procedures aim to medialize the paralysed vocal fold to facilitate better approximation with the unaffected side during tasks such as phonation and can involve the injection of one of a number of substances (e.g. hyaluronic acid and fat) [22,26,46] and a number of laryngeal framework techniques, including medialisation thyroplasty (implant), arytenoid repositioning (arytenoid adduction) and cricothyroid repositioning [15,44,47]. The vocal fold injection approaches can be further divided into temporary vs. more permanent interventions depending on the substance used [48,49] and the effect of the injection laryngoplasty can last for several years depending on the substance [34]. Thyroplasty Type 1 (medialisation) is the most common laryngeal framework surgery for UVFP and involves a synthetic implant to bulk up the paralysed vocal fold and move it to a more medialized position for voicing and is used for patients with a larger glottal gap nearly 2–3 mm [45,50,51]. However, several authors suggest that despite the immediate improvement in glottal closure following medialization, overtime the deinnervated muscles continue to atrophy contributing to changes in vocal quality and requirement of revision surgery [35,52]. Reinnervation surgery is a more recent surgical procedure for UVFP that restores innervation to the RLN through the use of a donor nerve (typically the ansa cervicalis) to allow for nerve regeneration and restoration of muscle bulk [8,53]. Reinnervation is associated with delayed restoration of the voice, which may take from several months to 2 years [54,55] and therefore sometimes paired with temporary injection laryngoplasty to restore glottal closure [45]. Despite both medialization and reinnervation procedures reporting outcome efficacy, there is no current surgical treatment that completely restores function of the paralysed vocal fold or laryngeal symmetry [44*,51].

Similar to the behavioural and injection laryngoplasty interventions described above, there is currently a lack of knowledge about which patients will most benefit from which surgical approach. Despite the variety of surgical procedures reported in the literature, there are no well designed comparative studies of any two (or more) techniques [26,44*]. Furthermore, there is limited research comparing the long-term voice outcomes following surgical intervention for patients with UVFP [44*]. There is also emerging evidence that suggests that factors such as age or comorbidity may impact on treatment outcomes [10,55]. Therefore, further research is required to determine the optimal factors for selection of surgical treatment for improved voice outcomes in patients with UVFP.

Current behavioural voice therapy approaches

Voice therapy is a behavioural treatment designed to reduce the severity of a dysphonia and improve functional voicing. The characteristics of the voice therapy are typically a combination of both direct (behavioural techniques focused on the different subsystems of voicing) and indirect (advice and guidance for managing external and personal factors contributing to a voice disorder) treatments. Despite voice therapy being a common treatment for patients with UVFP [7], there is limited evidence of effectiveness and limited detail of the characteristics of a successful treatment programme [6,40,56,57]. There is no current consensus as to the content, timing, duration and frequency of the voice therapy provided as reported for the treatment of other types of voice disorders, for example muscle tension dysphonia [58]. Consequently, there is still great variability in the characteristics of the voice therapy making it difficult to determine the optimal treatment programme for patients. Several recent studies of voice therapy for patients with UVFP have demonstrated improved research methodology through the implementation of a treatment protocol and a prospective methodological design [23",43,59"]. Future research should focus on developing and devising a voice therapy treatment protocol, which is as evidence based as possible, contains specific exercises (That are replicable) with clearly articulated goals, is based on the patient's diagnosis and presenting concerns and needs and contains information about timing, frequency and duration of treatment.

Combination treatment approaches

In many clinical settings, a combination of both voice therapy and surgical treatment is used to treat UVFP. Voice therapy may be used presurgery to minimize concomitant vocal hyperfunction and postsurgery to maximising habitual phonatory

function [15]. Despite this current practice, again there is no clear consensus of the voice therapy content in these circumstances. There are no published studies that have compared the additional benefits of a combined approach to a surgical (or behavioural) treatment alone [44*]. Whilst there is a growing body of evidence of the benefits of various treatments for patients with UVFP, there is no clarity of many aspects of practical patient management, including knowledge of which patients benefit from which treatments; the characteristics of the treatment (e.g. voice therapy, surgery or a combination of the two); the timing and sequence of the intervention and the long-term effects and maintenance of the treatment effect.

Detecting change following treatment

Outcome measures are tools used by health professionals to determine the treatment effect and therefore must be valid, reliable, responsive to change in order to report the success of the intervention [60]. Studies that utilize surgical and/or voice therapy intervention for the management of UVFP show significant variability in the selection of voice outcome measures to determine treatment effect [61]. There are a number of voice outcome measures with established good psychometric properties (e.g. validity, reliability and responsiveness to change) in detecting the treatment effect, for example GRBAS [62], maximum phonation time [63] and Voice Handicap Index [63,64]. Despite this evidence, there still appears to be a lack of rationale in the selection of the voice outcome measures and reporting of their validity, reliability and responsiveness to change for patients with UVFP. The variability in the selection and rationale of voice outcome measures limits the potential to compare studies and overall treatment effect, but primarily demonstrates a lack of consensus of the most appropriate voice outcome measures that can be used to determine the treatment effect for people with UVFP [26,51,61]. Several recent studies have utilized a multidimensional approach that includes visuo-perceptual, acoustic, aerodynamic, auditory-perceptual and patient self-rated measures [10,25,42,43]. Future studies must ensure the selection of a multidimensional voice outcome measures ensuring the selected measures have published validity, published reliability and internal reliability and a responsiveness to change.

CONCLUSION

The study aimed to review the current literature for the management dysphonia resulting from UVFP, it did not address treatment for other conditions that may

arise from UVFP, for example airway protection, airway clearance and effort closure, these would require a future publication. Currently, there is no consistent approach to the voice treatment for patients with UVFP and the evidence base is consequentially weak and inconclusive. Despite the improvements in recent studies, many studies lack a rationale for the selection and design of the voice treatment. Surgical techniques (including both temporary and permanent procedures) are well described and replicable. In contrast, voice therapy techniques are poorly described with respect to content, timing, duration and frequency. Voice treatment efficacy for all interventions is severely limited by a variable and nontransparent (unjustified) choice of outcome measures, which are commonly not overtly linked with the goals of treatment. Therefore, considerable preliminary work is required in the design and execution of voice treatment comparison studies that will ultimately provide the evidence base for best patient-centred practice for people with dysphonia due to UVFP.

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Conflicts of interest

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3 CHAPTER THREE: RATIONALE FOR STUDY METHODOLOGIES

This thesis aims to address the gaps in the current literature relating to treatment selection and outcome measurement in the management of dysphonia for people with UVFP. As identified in Chapters one and two, the thesis aims to:

- 1) Investigate the characteristics voice therapy provided to patients with UVFP. To establish the evidence base with regards to the content, timing, duration and frequency of the voice therapy provided.
- 2) Critically evaluate voice outcome measures that are used for patients with UVFP. This includes the explanation of the rationale for choice of the voice outcome measures, the reliability and validity and the responsiveness to change of the measures in detecting the treatment effect.

In order to meet these aims, four studies will be conducted. Chapter three details the rationale for the methodologies used within the four included studies and outlines how each will address the specific aim.

3.1 Introduction

This thesis sought to bridge the gap in the knowledge and understanding of the voice therapy provided to patients with UVFP and the voice outcome measures used to measure the treatment effect. In particular the focus of the thesis is the exploration of clinical voice therapy as provided by speech-language pathologists; and the voice outcome measures used to detect the treatment effect. In order gain a comprehensive understanding of the voice therapy and voice outcome measures a multiple methods approach was used. This resulted in the development of four inter-related studies of varying research methodologies including: qualitative and quantitative methods to address the research aims.

3.2 AIM 1: To investigate the content, timing and dosage characteristics of voice therapy provided (by speech-language pathologists) to patients with dysphonia due to UVFP.

To address Aim one of this thesis, a triangulated approach was selected to investigate the evidence from a range of data sources via three different study methodologies. Three different types of evidence would be explored to provide a comprehensive understanding of research evidence, as well as clinical approaches to voice therapy provided by clinicians.

3.2.1 STUDY 1: Unilateral Vocal Fold Paralysis: A Systematic Review of Speech-Language Pathology Management

To address Aim one, study one systematically reviewed published literature for the effectiveness of speech-language pathology intervention for the management of UVFP and explored the characteristics of the voice therapy provided. This approach was taken to establish the research evidence as no previous systematic summary the speech pathology literature for the management of UVFP has been published. The use of a systematic review to summarise the external evidence in a clear and logical manner allows for the

establishment of a clear understanding of the current evidence. The results of the systematic review revealed that there is no consensus for the characteristics of the voice therapy provided to patients with UVFP within the published literature. The findings of the systematic review were used to help inform the methods for two subsequent studies which further investigated the content, timing and dosage characteristics of voice therapy provided to patients with UVFP.

3.2.2 STUDY 2: Characteristics of Voice Therapy for UVFP: A survey of Speech-Language Pathologists

It was found in study one that there was a lack of consistency in the research evidence for the voice therapy characteristics, specifically content, timing, and dosage used to manage patients with UVFP. To investigate the voice therapy characteristics provided clinically by speech-language pathologists to patients with dysphonia due to UVFP a cross-sectional survey was selected. The cross-sectional survey approach was selected as it allowed for both a large sampling of the target population and establishment of the current voice therapy characteristics used by speech-language pathologists. The results of the cross-sectional survey revealed that there were several factors which influenced the selection of the treatment – suggesting a further in-depth perspective of the speech–language pathologists were required to explore these features.

3.2.3 STUDY 3: The Characteristics of Voice Therapy for Patients with Unilateral Vocal Fold Paralysis: Semi-structured Interviews

The final study developed to address Aim one and explore the characteristics of voice therapy provided to patients with UVFP was via semi-structured in-depth interviews. In-depth interviews allow for the collection of experiences and perspectives, in this case of several speech–language pathologists in the provision of voice therapy to patients with UVFP, and an exploration of the themes and factors identified in the cross-sectional survey. A qualitative

framework was used to identity the themes of the responses in addition to the voice therapy schema developed in Study two. The results of the in-depth interviews revealed several key findings from the expert's clinical experience that should be used in the selection and use of voice therapy for patients with UVFP.

3.3 AIM 2: To critically evaluate and explore the voice outcome measures that are used for patients with UVFP.

Aim two of the thesis involves exploring and appraising the voice outcome measures used by speech-language pathologists and ENT surgeons to detect the treatment effect for patients with UVFP and establishing the rationale for selection, validity, reliability and responsiveness to change to detect the treatment effect. Both speech-language pathologists and ENT surgeons were included within this aim as these specialties both provide treatment to improve the voice quality in patients with UVFP. This information can be used to inform the identification of most appropriate outcome measures for clinicians and researchers to detect the treatment effect for voice therapy for patients with UVFP.

3.3.1 STUDY 4: Voice outcome measures for adult patients with Unilateral Vocal Fold Paralysis: A systematic review.

To address Aim two, study four a systematic review was selected to appraise the voice outcome measures literature for UVFP since 2003 [1]. This methodology was selected to determine the voice outcome measures currently used by speech-language pathologists and ENT surgeons to determine the treatment effect and to appraise studies for multidimensionality, timing, selection rationale, validity, reliability and responsiveness to change of the voice outcome measures. In order to explore, the current voice outcome measures used in the UVFP treatment literature a systematic review methodology was selected to explore and appraise the current state of the evidence [2]. The findings revealed a lack of consensus for voice outcome measures used to measure the treatment effect.

However, the review identified several voice outcome measures that should be considered by future studies.

3.4 References

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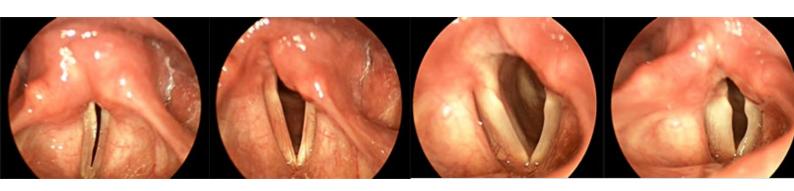
Section 2 – Voice Therapy for Unilateral Vocal Fold Paralysis

Section Two comprises Chapters 4 - 6, and will report on the following studies, which address Aim one of the thesis:

Chapter 4: Study 1 - Unilateral Vocal Fold Paralysis: A Systematic Review of Speech-Language Pathology Management.

Chapter 5 Study 2: Characteristics of Voice Therapy for UVFP: A survey of Speech-Language Pathologists.

Chapter 6 Study 3: An in-depth investigation into the Characteristics of Voice Therapy for Patients with Unilateral Vocal Fold Paralysis



4 CHAPTER FOUR: Unilateral Vocal Fold Paralysis: A Systematic Review of Speech-Language Pathology Management

As discussed in section 1, there is current uncertainty related to the available evidence for the treatment of Unilateral Vocal Fold Paralysis (UVFP), specifically with respect to the behavioural voice therapy treatment provided by a speech-language pathologist.

Study 1, described in the current chapter, aims to establish the current state of the evidence for the speech pathology management of UVFP through the means of a systematic review. The systematic review methodology allows for an objective appraisal of the current research literature and summarises the current characteristics of the voice therapy provided to patients with dysphonia due to UVFP, specifically the content, timing and dosage of the treatment.

The findings of the systematic review are anticipated to inform an evidence-based guide for the speech pathology treatment of UVFP that may be utilised in future research and clinical practice.

This chapter is a published manuscript:

Unilateral Vocal Fold Paralysis: A Systematic Review of Speech-Language Pathology Management. Walton, C., Conway, E., Blackshaw, H., and Carding, P. <u>Journal of Voice</u>, 2017. 31(4): p. 509.e7-509.e22.

Unilateral Vocal Fold Paralysis: A Systematic Review of Speech-Language Pathology Management

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Summary: Objectives. Dysphonia due to unilateral vocal fold paralysis (UVFP) can be characterized by hoarseness and weakness, resulting in a significant impact on patients' activity and participation. Voice therapy provided by a speech-language pathologist is designed to maximize vocal function and improve quality of life. The purpose of this paper is to systematically review literature surrounding the effectiveness of speech-language pathology intervention for the management of UVFP in adults.

Study Design. This is a systematic review.

Methods. Electronic databases were searched using a range of key terms including dysphonia, vocal fold paralysis, and speech-language pathology. Eligible articles were extracted and reviewed by the authors for risk of bias, methodology, treatment efficacy, and clinical outcomes.

Results. Of the 3311 articles identified, 12 met the inclusion criteria: seven case series and five comparative studies. All 12 studies subjectively reported positive effects following the implementation of voice therapy for UVFP; however, the heterogeneity of participant characteristics, voice therapy, and voice outcome resulted in a low level of evidence. **Conclusions.** There is presently a lack of methodological rigor and clinical efficacy in the speech-language pathology management of dysphonia arising from UVFP in adults. Reasons for this reduced efficacy can be attributed to the following: (1) no standardized speech-language pathology intervention; (2) no consistency of assessment battery; (3) the variable etiology and clinical presentation of UVFP; and (4) inconsistent timing, frequency, and intensity of treatment. Further research is required to develop the evidence for the management of UVFP incorporating controlled treatment protocols and more rigorous clinical methodology.

Key Words: Unilateral vocal fold paralysis–Voice therapy–Speech pathology.

INTRODUCTION

Unilateral vocal fold paralysis (UVFP) arises from a loss of innervation to one of the branches in the recurrent laryngeal nerve (RLN) and results typically in a dysphonia and occasionally dysphagia. Dysphonia can have a significant impact on patients' everyday communication demands and typically requires behavioral and/or surgical management. The RLN innervates all of the intrinsic muscles of the larynx, with the exception of the cricothyroid muscle. Given its recurrent nature and length, the left branch of the RLN is more susceptible to injury, which may be owing to neoplasms, traumatic injury, neurologic diseases, iatrogenic, or idiopathic causes. The severity of these injuries varies depending on etiology and can be classified into three types: neuropraxia, axonotmesis, or neurotmesis.² Neuropraxia is a temporary block of nerve impulses as seen in local anesthetics. Axonotmesis is more severe, usually a disruption or cutting of the axon, leading to paralysis in the motor and sensory systems.³ There is potential for recovery with axonotmesis if the trigger causing the nerve damage is removed, with a prolonged recovery potentially months or years. Finally, neurotmesis is the most severe nerve damage where the entire nerve fiber is cut or damaged, resulting in a complete loss of motor, sensory, and automatic function, with a potential for only partial recovery.⁴

Description of interventionThe aim of treatment for UVFP

ated stress and depression.14

The aim of treatment for UVFP is to restore functional voicing and improve glottal insufficiency.⁵ Current management of UVFP is either through (1) surgical intervention, (2) speech therapy (voice) exercises, or (3) observation.³ Typically, the management of UVFP is influenced by factors such as presence of aspiration, nerve injury, nasoendoscopic findings, vocal demands, comorbidities, electromyography findings, and patient concerns.^{15,16} Depending on the above factors, people with UVFP may receive one or a combination of management options.

UVFP results in immobility to one of the vocal folds, causing glottal incompetence because of poor vocal fold adduction.^{5,6} In

comparison, vocal fold "paresis" is described as a muscular weakness, whereas vocal fold "palsy" is a term that includes

both paralysis and paresis.8 The prevalence of voice disorders

in the general population is 6.6%, and the incidence of UVFP among those with voice disorders has been calculated at 1.2%. 10

ing, swallowing, and body stabilization difficulties. 11,12 Dysphonia

due to UVFP can have a significant impact on the quality of life

and participation of patients, impacting on them functionally, physiologically, and emotionally, ¹³ which may lead to associ-

People with UVFP typically experience perceptually hoarse, weak voices with associated vocal fatigue and potentially breath-

There are a number of systematic reviews of the clinical efficacy of surgical interventions for UVFP^{17–19} and of speech-language pathology intervention for the management of other types of dysphonia.^{20–24} However, to date, there are no systematic reviews of speech-language pathology voice treatment for adults with UVFP. It is important to undertake a review of the

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@ 2017 The Voice Foundation. Published by Elsevier Inc. All rights reserved. http://dx.doi.org/10.1016/j.jvoice.2016.11.002 literature to determine current treatment trends used with this population and to assist with the planning and implementing of future research in this clinical area. The prevalence of UVFP and the significant burden it places on functional communication and the quality of life of patients require strong clinical evidence to ensure effective and timely treatment.

Aim

The aim of this literature review is therefore to critically evaluate the literature to determine the evidence base for the effectiveness of speech-language pathology voice treatment for the management of dysphonia arising from UVFP. The evaluation of the literature pertaining to the effectiveness of this intervention approach will be conducted through the rating of studies according to the National Health and Medical Research Council (NHMRC) levels of evidence (Intervention), ²⁵ risk of bias assessment (where appropriate), and detailed critical appraisal.

METHOD

Search strategy

Seven electronic databases were searched, including PubMed, Embase, CINAHL, Web of Science, Scopus, CENTRAL, and Medline on January 23, 2016. Table 1 lists the search terms (both as keywords and as Medical Subject Headings terms) that were used to identify potentially relevant studies in the seven databases. The search was limited to human studies, but no language or time restrictions were applied. Additionally, the reference lists of the selected papers were searched for additional literature.

Identification of studies

Studies sourced from the electronic database search (January 23, 2016) were imported into *EndNote*, where duplicates were excluded. The remaining studies were imported into *Covidence* for electronic management and review by the authors. The review process was conducted in three stages; first, two review authors

TABLE 1. Search Terms	
Population	Intervention
1. Dysphon* 2. "Recurrent laryn*" 3. "Unilateral vocal fold" 4. "Vocal fold par*" 5. "Unilateral vocal cord" 6. "Vocal cord par*" 7. "Unilateral recurrent	14. "Voice therap*" 15. "Voice exercise" 16. Therapy 17. "Speech pathology" 18. "Speech therapy" 19. Treatment 20. Management
laryn*" 8. "Laryn* palsy" 9. "Laryn* hemipleg*"	21. Rehabilitation 22. "Behavio* management"
10. "Glott* incompetence"11. "Vocal fold immobility"12. "Voice disorder"	23. Intervention24. "Voice training"
13. Combine 1–12 using "OR" Combine 13 + 25 using the ter	25. Combine 14–24 using "OR" m "AND"

(CW and EC) independently screened titles and abstracts obtained from the database searches to assess inclusion or exclusion. Articles in the search were assessed based on the following inclusion criteria: adult participants between the ages of 18 and 70 years, confirmed diagnosis of UVFP, presence of dysphonia, intervention provided by a speech-language pathologist, and studies with pre-post outcome data. Articles were excluded if they were editorials and review articles (ie, no intervention outcome data).

Any conflicts were resolved by discussion with the fourth author (PC). Following title and abstract screening, full-text articles were sourced for review. The same review authors (CW and EC) independently reviewed the full-text identified studies against the predefined inclusion and exclusion criteria. Again, any conflicts were resolved by consulting with the fourth review author (PC). Finally, the reference lists of the identified articles and gray literature were also scrutinized.

For each study, the following data were extracted to contribute to the critical appraisal (if available):

- 1. *Study:* publication year, study design, study location, mean age of study population, gender, number of participants;
- 2. *Cases:* type of UVFP, severity of paralysis and dysphonia, and time since onset
- 3. *Treatment:* type of voice treatment received, duration of treatment, frequency of treatment, home program or homework expectations
- 4. *Controls or groups:* controls used, other treatment allocation, randomization
- 5. Outcomes: reported results and tools for measurement

Study classification

Two tools were used to classify the current evidence for speech-language pathology management of UVFP in adults. First, the NHMRC levels of evidence²⁵ were used to provide a framework for determining the level of evidence (Table 2). Included studies were reviewed by the authors and allocated to one of the NHMRC levels of evidence based on their methodology.

Risk of bias assessment was conducted using the A Cochrane Risk Of Bias Assessment Tool: for Non-Randomized Studies of Interventions (ARCROBAT-NRSI)²⁶ on all comparative study designs to determine the rigor of intervention for nonrandomized studies. Risk of bias assessment provides scaffolding for an evaluation of study validity and assists with the establishment of a rigorous evidence base.²⁷ The authors provided consensus judgments on ACROBAT-NRSI²⁸ parameters and ranked them according to "high," "low," and "unclear" risk of bias.

RESULTS

Using our search strategy, we identified 3311 studies; 2310 were excluded after review of title or abstracts and 98 studies were excluded after full-text review. Fifteen full-text articles from the abstract screen were unable to be sourced for full-text review despite a conscious effort. Figure 1 illustrates the flow of data extraction from the seven databases to the final 12 papers for detailed critical appraisal.

A summary of each of the 12 studies included for critical appraisal are listed in Table 3.

Level	Intervention
I	A systematic review of level II studies
II	A randomized controlled trial
III-1	A pseudo-randomized controlled trial (ie, alternate allocation or some other method)
III-2	A comparative study with concurrent controls:
	■ Nonrandomized, experimental trial
	■ Cohort study
	■ Case-control study
	■ Interrupted time series with a control group
III-3	A comparative study without concurrent controls:
	■ Historical control study
	■ Two or more single-arm study
IV	Case series with either posttest or pretest-posttest outcomes

Risk of bias

Risk of bias assessment was conducted on the five level III²⁵ studies that used comparative groups. Figure 2 provides a summary of the risk of bias assessment results. A detailed documentation of the risk of bias assessment is included in the Appendix.

All studies demonstrated a high level of bias with respect to selection bias (random sequence and allocation concealment) and performance bias (blinding). Only two studies (Colton et al³⁵ and El-Banna and Youssef³⁷) had a low risk of detection bias (blinding of outcome assessment), and only one study (Busto-

Crespo et al⁴⁰) had low attrition bias (selective reporting). The majority of studies (McFarlane et al,²⁹ El-Banna and Youssef,³⁷ and Busto-Crespo et al⁴⁰) demonstrated a low risk of reporting bias (incomplete outcome data).

Critical appraisal of the identified studies Study design

The 12 included studies varied in both study design and level of evidence: seven case series (level IV),^{30–33,36,38,39} four comparative studies with no control (level III-3),^{29,34,35,40} and one comparative study with control (level III-2).³⁷

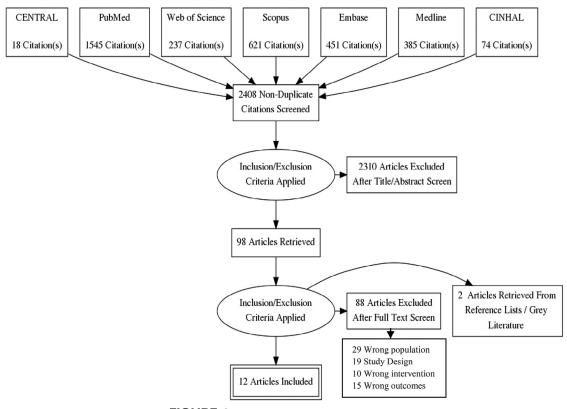
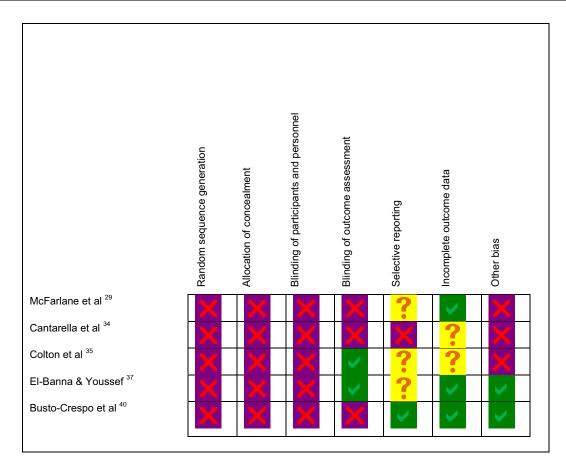


FIGURE 1. Flow diagram of data extraction.

Reference	Year	Type of Study	Level of Evidence ²⁵	n	Main Findings
McFarlane et al ²⁹	1991	Prospective	Comparative study with no controls III-3	16	Voice therapy can be used for managing some patients with UVFP
Kelchner et al ³⁰	1999	Retrospective	Case series—pre or post test IV	117	Voice therapy assists with reducing symptoms of UVFP
Khidr ³¹	2003	Prospective	Case series—pre or post test IV	3	Smith Accent Method can improve auditory-perceptual and functional outcomes
D'Alatri et al ³²	2008	Prospective	Case series—pre or post test IV	91	Voice therapy can produce significant outcomes when introduced <6 weeks post onset of UVFP
Schindler et al ³³	2008	Retrospective	Case series—pre or post test IV	40	Voice therapy can significantly improve perceptual quality and QOL of patients with UVFP
Cantarella et al ³⁴	2010	Prospective	Comparative study with no controls III-3	30	Voice therapy can be effective when commenced >3 month post onset of UVFP
Colton et al ³⁵	2011	Prospective	Comparative study with no controls III-3	26	Reduced severity of UVFP following treatment and acoustic measures can be effective to measure treatment changes
Mattioli et al ³⁶	2011	Prospective	Case series—pre or post test IV	74	Early voice therapy <4 weeks post onset can be effective for the management of UVFP
El-Banna and Youssef ³⁷	2014	Prospective	Comparative study with control III-2	42	Early voice therapy <6 months may improve outcomes for participants with UVFP
Garcia Perez et al ³⁸	2014	Prospective	Case series—pre or post test IV	10	Electrical stimulation can be effective for the management of UVFP with short-term outcomes
Mattioli et al ³⁹	2015	Retrospective	Case series—pre or post test IV	171	Early voice therapy up to 8 weeks post onset may be effective for the management of UVFP
Busto-Crespo et al ⁴⁰	2015	Prospective	Comparative study with no controls III-3	70	Voice therapy can be effective for UVFP with changes maintaining up to 1 year post treatment



Key: green (✓) = low risk of bias; yellow (?) =unclear risk of bias & red (X) = high risk of bias

FIGURE 2. Summary of risk of bias judgment of the 12 included studies.

Participant characteristics

There is considerable heterogeneity in the studies with respect to participant characteristics (Table 4). Two studies (Busto-Crespo et al⁴⁰ and Colton et al³⁵) did not report the participant age range. Six studies also included participants younger than 18 years^{29–31,33,34,36}; these were included in this review (despite the stated exclusion criteria) because the data reported included participants in our stated age range and the studies reported important data on the management of UVFP.

Diagnosis of UVFP was confirmed by videostroboscopy in only three of the five level III studies 34,37,40 and the diagnostic process was not described in other two studies. 29,35 A total of four level III studies documented etiological information 34,35,37,40: two studies reported on patients with iatrogenic paralysis only 34,37 and two studies documented a wide variation of etiologies. 35,40 All seven level IV studies reported etiology of the paralysis, and similar to the level III studies, the most common etiology of the UVFP was iatrogenic. Only two level IV studies reported the side of the paralysis. 30,31 The incidence of side of paralysis (ie, left vs right) was reported only for three level III studies. 29,34,37 The position of the UVFP (ie, paramedian vs median) was documented in the two most recent studies 37,40; no other study reported these findings.

The lack of participant information limited comparison between studies and resulted in an inability to determine the potential influence of these factors on treatment outcomes. Interestingly, the majority of the level IV case series studies had higher participant numbers than the level III group studies, with a total of 506 participants and a range of 3–171 participants within studies. The age range of the level IV studies was 12–91 years, with a distribution of 34% males to 66% females. In total, there were 664 participants included across both level III and IV studies. Of the total participants, 561 received voice therapy with treatment outcomes reported for 71% of these participants, whereas the remaining 103 (15.5%) received either surgical treatment, no intervention, or were normal participants without UVFP.

Voice therapy interventions

The published studies showed considerable variability in therapy content, timing of intervention, and therapy duration (Table 5).

Therapy content

The therapy techniques used within the level III and IV studies varied greatly and involved a wide range of direct and indirect treatments. Only one study used a treatment protocol,⁴⁰ which is of note, as the establishment of evidence-based practice (EBP) supports the implementation of such tools to ensure the variable of treatment is controlled.⁴¹ In the Busto-Crespo et al⁴⁰ study, therapy consisted of three treatment phases, each focusing on different subsystems of voicing: (1) positioning and respiration; (2) voicing through vocal exercises, humming, compression, and

TAE	BLE 4.	
Par	ticipant Charac	teristics

Reference	Number of Participants	Age Range	Male:Female	Etiology	Diagnostic Method	Side of Paralysis
Level III studies (compara	ative group studies)					
McFarlane et al ²⁹	16 (N) 6 (n, n*)	16–64	7:9	ND	ND	L: 4; R: 12 (n* L: 2; R: 4)
Cantarella et al ³⁴	30 (N, n, n*)	15–80	16:14	latrogenic	Videostrobe	L: 21; R: 9
Colton et al ³⁵	26 (N) 13 (n, n*)	ND	10:16	latrogenic Idiopathic Other	ND	ND
El-Banna and Youssef ³⁷	42 (N, n, n*)	22-52	17: 25	latrogenic	Videostrobe	ND
Busto-Crespo et al ⁴⁰	70 (N, n, n*) 1 year follow-up 32 (n)	ND	25:45	latrogenic Idiopathic Other	Videostrobe	ND
Level IV studies (case ser	ies)					
Kelchner et al ³⁰	117 (N) 25 (n) 6 (n*) 5 (n*) and medical intervention	16–91	66:52	latrogenic Idiopathic Other	Mirror or Videostrobe	L: 81; R: 36
Khidr ³¹	3 (N, n, n*)	12–79	3:0	latrogenic Other	Videostrobe	L: 3; R: 0
D'Alatri et al ³²	91 (N, n*) 30 (n)	31–68 (n)	ND	latrogenic (n) Idiopathic (n)	Videostrobe	ND
Schindler et al ³³	40 (N, n, n*)	12–82	14:26	latrogenic Idiopathic Other	Videolaryngoscope	ND
Mattioli et al ³⁶	74 (N, n*) 23 (n)	14–86	25:49	latrogenic Idiopathic Other	Videostrobe	ND
Garcia Perez et al ³⁸	10 (N, n, n*)	21-49	3:7	latrogenic	Videostrobe, EMG	ND
Mattioli et al ³⁹	171 (N, n*) 106 (n)	19–82	55:116	latrogenic Idiopathic Other	Videostrobe	ND

Note: Data included for all participants irrespective of treatment modality.

Abbreviations: EMG, electromyography; L, left vocal fold paralysis; N, total number of participants; n, number of participants with pre or post outcome data; n*, number of participants who received speech pathology intervention; ND, not described; R, right vocal fold paralysis.

TABLE 5. Summary of Therapy

Reference	Allocation or Determining of Treatment	Voice Therapy Content	Timing of Intervention	Intensity	Duration of Therapy
l evel III studies (c	comparative group studies)	•		•	. ,
McFarlane et al ²⁹		Head turning, half-swallow boom with phonation, and lateral digital manipulation	ND	ND	3–24 hours
Cantarella et al ³⁴	All received voice therapy	Relaxation, abdominal breathing with sounds on exhalation, massage, digital manipulation, sonority, glottal attacks, and resonant voice	2 treatment groups: Early: <3 months Late: >3 months	Depending on severity	10–40 sessions Homework 2–3 time a day for 10–15 min
Colton et al ³⁵	Clinical factors or patient preference—either voice therapy or surgery	Phonatory maneuvers to encourage glottal closure	ND	ND	4–6 sessions
EI-Banna and Youssef ³⁷	All received voice therapy	Pushing exercises and Smith Accent Method	2 treatment groups: Early: 2–4 weeks post onset Late: >6 months	Two 20 min sessions/wk	Early voice therapy: 16 sessions. ND for late treatment group
Busto-Crespo et al ⁴⁰	All received voice therapy	3-phase protocol: 1. Positioning and respiration 2. Voice exercises, manipulations, cough attack digital compression, and resonant voice 3. Vocal and singing exercises, auditory masking and vocal throwing, and posture	2 treatment groups: Early: <12 months Late: >12 months	Two 30 min sessions/wk	15 sessions
Level IV studies (d	case series)				
Kelchner et al ³⁰	Allocation of treatment ND. Combination of voice therapy, surgery (thyroplasty), and Gelfoam injections and surgery with voice therapy	ND	1–60 weeks post onset	ND	1–13 sessions
Khidr ³¹	All received voice therapy	Smith Accent Method	1–13 years post onset	Two 60 min sessions/wk for 8 weeks	16 sessions
D'Alatri et al ³²	All received voice therapy	Vocal hygiene, respiration, vocal exercises, half-swallow boom, falsetto, trills, speaking on inhalation, and twang	2–6 weeks post onset	Two 30 min sessions/wk	8–35 sessions
Schindler et al ³³	All received voice therapy	Respiration, vocal exercises, resonant voice, hard glottal attacks, pushing, and half-swallow boom	20–30 days post onset	Two sessions/wk	6–20 sessions
Mattioli et al ³⁶	All received voice therapy	phases: Cough attack, cough with vowels, vocal function exercises, pushing, forcible exercise with manipulation, and maneuvers Optimizing vocal parameters and motility recovery	2–4 weeks post onset	Two sessions/wk	14–20 sessions and daily homework
Garcia Perez et al ³⁸	All received voice treatment	Electrical stimulation with sustained phonation	10-24 months post onset	One 30 min session/wk	10 sessions
Mattioli et al ³⁹	All received voice therapy	phases: Cough attack, cough with vowels, vocal function exercises, pushing, forcible exercise with manipulation, and maneuvers Optimizing vocal parameters and motility recovery	3 treatment groups: Within 4 weeks 4–8 weeks >8 weeks post onset	Two sessions/wk	12–18 sessions and daily homework

cough attack; and (3) voice projection, singing, and biofeedback. The authors reported that individual variations were applied during these phases and that participants were continually monitored to ensure maintenance of previously taught phases. 40 Mattioli et al^{36,39} described two phases of treatment: (1) focus on vocal fold movement and (2) focus on voice quality. These studies used a combination of voice therapy techniques including coughing with voicing, vocal function exercises and laryngeal manipulation, and other maneuvers to achieve glottal closure and encourage functional voicing. 36,39 The remaining studies used individualized treatment approaches with various combinations of direct therapy techniques focusing on respiratory, laryngeal, and resonatory subsystems. 29,32-35 Treatment techniques included halfswallow boom, Smith Accent Method, pushing exercises, and glottal attack. 29,34,35,37 Two studies on treatment effectiveness did not provide any description of the therapy received by patients. 30,35 Theoretically, the major value of level III and IV studies is to focus on clear and detailed intervention approaches that can be tested more formally in controlled designs. 41 The current review of the therapy content suggests a lack of homogeneity between the studies conducted to date. Therefore, further research is required to focus on specific therapy techniques to develop the understanding of optimal voice therapy management of UVFP.

Therapy timing and duration

The timing of voice treatment (ie, length of time post diagnosis) was used as a comparator in several studies that investigated the impact of early intervention post diagnosis compared with later intervention. 30,34,37,39,40 However, the definition of "early" voice therapy ranged from "within 4 weeks post diagnosis" 37,39 to "less than 1 year post onset." Similarly, there was inconsistency in defining "late therapy," ranging from "more than 3 months" to "greater than 12 months post onset." There were numerous studies that described the range of time post onset when therapy was commenced; however, we did not use this variable. 30–33,36,38 Two studies did not report or examine time post onset of UVFP at commencement of voice treatment. 29,35

Duration of treatment differed between participants within each study and across studies. Therapy duration appeared to be determined by participant severity and clinical judgment. Only one level III study controlled this variable, with all participants receiving 15 sessions of treatment, 30 minutes twice weekly. 40 One level IV study also controlled treatment duration, reporting all participants received 10 sessions of electrical stimulation.³⁸ El-Banna and Youssef³⁷ reported using Smith Accent Method for 16 sessions, 30 minutes twice weekly; however, the authors also report the use of additional therapy techniques, without further information regarding duration, and so total treatment duration is unclear. Overall, the number of total therapy sessions used across the level III and IV studies varied from 1 to 40, with severity of UVFP noted as a factor in clinical decision making for studies without prescriptive treatment protocols. Three studies reported the use of home practice for participants as part of their treatment, with Cantarella et al³⁴ providing a clear explanation of tasks completed, as well as the frequency and intensity of this practice, whereas Mattioli et al^{36,39} made no comment regarding specific home practice guidelines.

The intensity of treatment also varied between studies, with nine studies reporting on intensity. The intensity ranged from weekly to twice weekly across the nine studies, with the majority of studies reporting a twice weekly treatment regime. ^{31–33,37,39} Three studies made no reference to the intensity of treatment provided. ^{29,30,35}

Voice outcome measurement

A range of speech-language pathology outcome measures was used across the 12 studies. These have been outlined in Table 6.

A total of nine studies used a multidimensional approach to outcome measurements. 31–34,36–40 Multidimensional voice assessment is defined in the current review as the assessment of two or more of the following areas that can be impacted by UVFP: visuo-perceptual assessment of physiological changes, auditory-perceptual assessment of impairment, aerodynamic assessment of airflow and pressure in relation to voicing, and quality of life outcome measures. A multidimensional assessment provides a holistic measure of treatment outcomes across the range of relevant factors.

All nine studies with multidimensional outcomes included the assessment of physiological outcomes using visuo-perceptual ratings of an endoscopic examination. Specifically, glottal closure was assessed by an ear nose throat (ENT) doctor, typically using videostroboscopy (eight multidimensional studies, one unidimensional study), before and after treatment. Only two studies reported the inclusion of ratings from more than one ENT assessor for the endoscopic findings; Busto-Crespo et al⁴⁰ described the use of two independent ENT raters, who provided consensus ratings on the positioning of the paralyzed vocal fold and completeness of glottal closure pre and post treatment. The authors reported good interrater reliability between the raters; El-Banna and Youssef³⁷ presented three blinded ENT assessors with randomized video recordings of paired pre- and post-endoscopic assessments and asked them to categorize the findings into one of three categories (reduced glottal gap, no change, or increased glottal gap). Although multiple assessors were used, this study did not describe inter-rater reliability between raters. The remaining seven studies reported descriptive features or results from unpublished ENT scales to describe change from pre to post treatment.

Auditory-perceptual rating of voice quality was another feature of the multidimensional outcome measurement commonly used in the included studies; grade, roughness, breathiness, asthenia, and strain scale^{31,34,37,42} and grade, instability, roughness, breathiness, asthenia, and strain scale^{33,42,43} were the most commonly used assessment methods for voice quality. Statistical analysis of auditory-perceptual pre- to posttreatment outcomes were reported in five of the studies, 32-34,37,40 where only Cantarella et al³⁴ reported inter-rater reliability for the grade, instability, roughness, breathiness, asthenia, and strain measures. Despite the report of low inter-rater reliability, the study states that the four judges listened to each sample several times to achieve consensus, which was used for statistical analysis.³⁴ Studies assessing auditory-perceptual features appeared to predominately use several judges; however, without the use of inter-rater reliability data, the results should be interpreted with caution as there is a significant potential for outcome measurement bias.

	Outcome		
Reference	Measurement(s)	Assessment	Results
Level III studies	(comparative group	studies)	
McFarlane et al ²⁹	Unidimensional	Unpublished 10-point perceptual rating scale	No statistics reported
Cantarella	Multidimensional	Videostrobe (observation)	No statistics reported
et al ³⁴		MPT, GRBAS, VHI	Both treatment groups statistically significan improvement (<i>P</i> < 0.05)
		MDVP (Jitter, vFo, Shimmer, vAm, NHR, and DUV)	Early treatment group statistically significant improvement ($P < 0.05$) on all MDVP variables; late treatment group statistically significant improvement ($P < 0.05$) on Jitte
			vFo, and NHR
Colton et al ³⁵	Unidimensional	Unpublished 10-point severity of dysphonia scale	Statistically significant improvement ($P < 0.09$
El-Banna and	Multidimensional	Videostrobe (unpublished scale)	No statistics reported
Youssef ³⁷		GRBAS and DSI	Early treatment group statistically significant improvement (<i>P</i> < 0.05)
		VPSS	Both treatment groups statistically significant improvement (<i>P</i> < 0.05)
Busto-Crespo V et al ⁴⁰	Multidimensional	Videostrobe	Early treatment group statistically significant improvement (<i>P</i> < 0.05)
		MPT	Early treatment group not significant (<i>P</i> = 0.303); Late treatment group no statist reported
		Spectographic and VHI-10	Both treatment groups statistically significan improvement (<i>P</i> < 0.05)
		Jitter	Early treatment group statistically significant improvement ($P < 0.05$); late treatment gro (female participants) ($P < 0.05$)
		Shimmer, NHR, F0	Both treatment groups not significant
_evel IV studies	s (case series)	, ,	
Kelchner	Unidimensional	Videostrobe or Mirror (observation)	No statistics reported
et al ³⁰		Unpublished 7-point perceptual rating scale	Voice therapy and surgery group statistically significant improvement ($P < 0.05$)
Chidr ³¹	Multidimensional	Videostrobe (unpublished scale and descriptive features)	No statistics reported
		MPT, GRBAS, VHI	No statistics reported
D'Alatri et al ³²	Multidimensional	Videostrobe, MPT, jitter, shimmer, NHR, GRBAS, and VHI	Statistically significant improvement ($P < 0.0$
		F0	No statistics reported
Schindler et al ³³	Multidimensional	Videolaryngoscope (descriptive comment)	No statistics reported
		MPT, GRIBAS, shimmer, VHI, jitter, NHR, and Spectographic	Statistically significant improvement ($P < 0.0$
		F0	Not significant ($P = 0.25$)
Mattioli et al ³⁶	Multidimensional	Videostrobe (descriptive comment)	No statistics reported
		MPT, F0, shimmer, jitter, and NHR	Statistically significant improvement (P < 0.0
Garcia Perez	Multidimensional	Videostrobe (descriptive comment)	No statistics reported
et al ³⁸	BA Ist II	MPT, jitter, shimmer, NHR and NNE	Statistically significant improvement (P < 0.0
Mattioli et al ³⁹	Multidimensional	Videostrobe (descriptive comment) MPT, F0, jitter, and NHR	No statistics reported Both treatment groups statistically significan
		Shimmer	improvement ($P < 0.05$) Groups 1 and 2 statistically significant improvement ($P < 0.05$); Group 3 not significant ($P = 0.064$)

Abbreviations: DSI, Dysphonia Severity Index; DUV, degree of unsounded voice; F0, fundamental frequency; GRBAS, perceptual rating scale (grade, roughness, breathiness, asthenia, strain); GRIBAS, perceptual rating scale (grade, roughness, irregularity, breathiness, asthenia, strain); jitter, cycle-to-cycle variations of fundamental frequency (Hz); MPT, maximum phonation time; NHR, noise-to-harmonic ratio; NNE, normalized noise energy; shimmer, cycle-to-cycle variations of amplitude (dB); vAm, variation's coefficient of amplitude; VHI, Voice Handicap Index; VHI-10, Voice Handicap Index 10; VPSS, Voice Problem Self-Assessment Scale.

significant (P = 0.064)

Overall, visuo-perceptual and audio-perceptual ratings were limited by the lack of inter- and intra-rater reliability data. Without the use of inter-rater reliability data, the results should be interpreted with caution as there is significant potential for outcome measurement bias.

Aerodynamic outcome measures were reported in eight studies, all using maximum phonation time as a simple measure of airflow. Overall, seven of the studies reported statistically significant improvements following treatment, ^{32–34,36,38–40} suggesting the importance of aerodynamic measures with this population.

Assessment of the impact of UVFP on patients' quality of life was conducted in six of the multidimensional studies using patient-reported questionnaires: the Voice Handicap Index, 31-34 the Voice Handicap Index-10, 31,40 and the Voice Problem Self-Assessment Scale. 37 Five of these studies reported statistical analysis with significant improvement in patients' quality of life. Patient self-reports of vocal handicap are considered highly valid voice outcome measures and contribute significant impact to the documentation of treatment benefit. 44

The other three studies used unidimensional assessment of treatment outcomes, concentrating on only one outcome being auditory-perceptual.^{29,30,35}

Summary of voice therapy treatment results

All 12 studies subjectively reported positive effects following the implementation of voice therapy for UVFP, with nine using a multidimensional approach to measure their treatment effects. A majority (n = 10) of the included studies used statistical analysis for all or some of the outcome measures. This provided methodological strength to the evidence of treatment efficacy. However, in general, as previously mentioned, visuo-perceptual and audio-perceptual ratings were limited by the lack of interand intra-rater reliability data. Without the use of inter-rater reliability data, the results should be interpreted with caution as there is significant potential for outcome measurement bias. 46

Overall, the outcomes of the 12 included studies provide preliminary evidence that is supportive of the implementation of voice therapy for UVFP. A key objective of level III and IV studies is the establishment of treatment protocols and reliable outcome measures that can be used in more advanced research designs.⁴¹ However, future research should be conducted to improve the current methodological limitations of research by (1) ensuring that a research uses a multidimensional approach for the assessment of intervention, (2) incorporating statistical analysis to allow for an objective assessment of research outcomes, and (3) limiting the current omissions seen in the currently available level III and IV studies. Once these features have been refined, it is anticipated that this will allow for improved assessment of treatment effect, assisting with the establishment of not only improved quality of research within studies (statistical significance) but eventually allowing for clinical trials and in turn clinical significance.

DISCUSSION

This is the first systematic review to evaluate the current evidence for speech-language pathology or voice therapy for patients with UVFP. The search of seven electronic databases using clear

search terms, specified inclusion criteria, and independent reviewing produced a total of 12 suitable studies. In general, the studies demonstrate positive effects and report improvements across several voice outcome measures. This was best evidenced in two recent studies^{37,40} that provided evidence of treatment benefit with relatively low risk of bias and robust methodology. Furthermore, these studies demonstrated that additional parameters such as therapy timing and frequency may contribute to the overall success of treatment. However, the current level of evidence is limited, and further research is required to establish treatment efficacy for speech-language pathology management of UVFP.

Using the NHMRC levels of evidence²⁵ classification, the 12 included studies of voice therapy for UVFP were identified as being level III. Pring⁴⁷ suggests that it can be challenging for behavioral research to achieve a high level of evidence status compared with medical and pharmacological research. Behavioral treatment such as voice therapy is typically individual based on diagnosis and requires a pragmatic approach that can hinder blinding. Therefore, the interpretation of speech-language pathology studies using the NHMRC classification can dismiss the significance of this early-stage research in attempting to establish the "therapeutic effect." Alternatively, Robey⁴¹ describes a five-phase model of research development that acknowledges that evidence of treatment effectiveness requires a development through a series of hierarchical stages. Phase one focuses on determining the therapeutic effect of a treatment using either individual case studies or case series. This phase may provide "proof of concept" that the implementation of a therapeutic technique appears to provide beneficial clinical change. Phase two allows refinement of the clinical research question and develops the methodology through the examination of patient characteristics, treatment protocols, and the selection of appropriate (valid and reliable) assessments to measure the treatment effect. Phase three involves testing the efficacy and internal validity of the clinical question through clinical trials involving larger numbers of participants and multiple groups, including a control group. Phase four addresses the external validity of studies, focusing on the use of large-scale effectiveness studies to determine whether the treatment effects observed in efficacy studies also translate into the clinical environment. The final stage, phase five, investigates the feasibility of treatment and patient and provider satisfaction within the models of health care.

A majority of the studies discussed in this systematic review can be classified within phase one of the Robey⁴¹ model. The studies are generally case series and lack a nontreatment comparator. Although these case series designs are at high risk of bias, they focus on determining the therapeutic effect of voice therapy and provide preliminary evidence of the therapeutic effect through the use of pre- or posttreatment measurements. Several of the identified studies may be considered to be entering phase two of the Robey model.^{34,37,39,40} These studies show evidence of the development of inclusion and exclusion criteria, refinement of participant characteristics, and the commencement of using therapy protocols.^{37,40} Further progress through phase two and into clinical trials of treatment efficacy (ie, Robey phase three⁴¹) requires additional refinement of several key

components: participant characteristics, voice therapy interventions (including content and dosage), and voice outcome measurement. These are discussed in detail below.

Participant characteristics

As evidenced from the critical appraisal, there is currently a significant variability in recruitment numbers, age ranges, gender, side of lesion, and etiology. The lack of specificity in inclusion and exclusion criteria emphasizes that many current studies remain in phase one of Robey's⁴¹ model. The control of participant variables is usually achieved by specifying inclusion and exclusion to ensure that all patients share certain characteristics. The controlling of participant characteristics allows for accurate comparison between participants and, in turn, their treatment outcomes. The current studies indicate that key characteristics used to measure treatment outcomes have yet to be established for this population and, in turn, the variables to control. One recent study reported on patient homogeneity between patient groups in relation to age range and gender, all having a clinical diagnosis of UVFP arising from iatrogenic etiology.³⁷ Uniformity of participant characteristics and subsequent ability to compare the impact of treatment would be further enhanced by reporting and controlling for variables such as side of paralysis (and hence likelihood of comorbidity) and positioning and severity of the UVFP. In contrast, Busto-Crespo et al⁴⁰ did not report the age of participants who received intervention and included a broad range of etiologies of UVFP. A failure to control these variables results in a lack of clarity as to which types of patients may most benefit from voice therapy intervention.

Voice therapy interventions

High-quality evaluation of treatment efficacy requires a clear definition and understanding of the nature of the treatment in terms of both content and duration. Case series are often highly valuable to help determine intervention details; however, this was not generally the case with the studies identified in the current systematic review. Overall the included studies lacked content and specific description of the therapy approaches, limiting their usefulness of what Robey⁴¹ suggests is typically undertaken in phase one of research.

There were a number of studies that reported on "phases of treatment"36,37,39 and a number that described the use of one or a combination of voice therapy techniques in an "individualized approach." The reporting of an individualized approach indicates that the approach to voice therapy varies for each participant rather than general to the condition, that is, UVFP. The advantage of an individual approach is that it matches the variability of the participants, whereas its weakness is that it cannot compare outcomes across (or even within) studies. To increase the treatment fidelity, recent study has moved toward using a protocol approach to provide a more structured framework for the treatment program similar to other areas of voice therapy intervention. 40 Busto-Crespo et al 40 described a clinical hierarchical approach to the implementation of voice therapy across participants and used treatment techniques that are well supported in other areas of voice research. This allows for individualized levels of treatment while at the same time ensuring consistency.⁴⁰ The current evidence available does not allow for a summary of specific therapy techniques for the management of UVFP. It is unlikely that specific treatment for UVFP will ever achieve consistency for this condition because of the sheer number of potential variables.

The use of protocol-driven therapy also gives rise to recommendations of duration and intensity of treatment. These features are closely controlled in other areas of speech-language pathology and, more recently, in voice therapy (ie, Lee Silverman Voice Treatment - LOUD (LSVT-LOUD)⁴⁸) considering the focus on such factors as neuroplasticity and principles motor learning. Presently, literature for the management of functional dysphonia is working to refine these features. ^{49,50} Three studies ^{37,38,40} attempted to control therapeutic intensity and duration when treating patients with UVFP; however, the lack of reporting specifics limits the applicability of this. De Bodt et al⁵¹ encourage the establishment of a potential framework; however, further research is required to refine these for the UVFP population.

However, timing of treatment implementation post diagnosis was unclear owing to either no reporting or a considerable variance in the definition of what constituted "early" or "late" intervention. It is also unclear how these timings relate to principles of motor learning and neuroplasticity in a UVFP context. Future phase two studies of treatment efficacy for patients with UVFP require the employment of both a clear treatment protocol and an agreement about treatment dosage and timing to establish the foundation for more advanced clinical trials.

Voice outcome measurement

The human voice is a complex instrument, with multiple factors influencing the presenting vocal quality and functioning of the voice. 52 Voice disorders such as UVFP can have a significant impact across many vocal features and in an individual's quality of life. Therefore, a multidimensional approach to assessment is required to holistically measure the impact of treatment and allow for comparison between studies.⁴⁵ Studies that reported unidimensional measurements of voice outcomes provide very limited valid evidence of vocal change over time. According to Robey, 41 treatment outcomes should consist of examining change in two or more of the following areas: physiological features, impairment level outcomes, and quality of life. For patients with UVFP, the utilization of multidimensional measures would improve sensitivity and validity in detecting the nature and magnitude of the treatment effect. This in turn would contribute to the establishment of treatment efficacy of voice therapy for patients with UVFP.

Although a number of the identified studies in this systematic review used multidimensional voice outcomes, there were limitations in the application and administration of these assessments compared with other areas of voice therapy effectiveness research. Ten out of the 12 studies used videostroboscopy to report a change in vocal fold closure patterns post therapy, but none used a published visuo-perceptual stroboscopic evaluation protocol and rarely were the descriptive terms defined. The implementation of such tools would minimize potential of bias, allow for comparison between studies, and improve quality of evidence for treatment of UVFP.

The use of both visuo- and auditory-perceptual ratings is common in the reported studies and in voice literature more

generally as part of a multidimensional assessment. Standard practice for visuo- or auditory-perceptual ratings requires more than one rater with a report of inter- and intra-rater reliability.⁴⁵

This practice was found in only one paper⁴⁰ where intrarater reliability was reported for positioning of the paralyzed vocal fold and completeness of glottal closure pre- and post treatment. It is unclear why the literature in treatment efficacy of voice therapy for UVFP has not adopted the voice outcome measurement practices that are well documented in other related areas such as functional voice disorders^{20,24,53} and neurologic voice disorders,⁵⁴ but their adoption in voice therapy for UVFP could only improve the quality of evidence for UVFP treatment.

CONCLUSION

Research into speech-language pathology management of UVFP is only now coming into phase two of the Robey model, as seen

in the methodology of studies such as that of Busto-Crespo et al⁴⁰ and El-Banna and Youssef.³⁷ These two recently published studies have worked to refine the clinical question and establish more rigorous methodologies to determine the efficacy of voice therapy for UVFP. However, in accordance with Robey's model,⁴¹ further research is required to establish the appropriate or required outcome measures, participant features, and treatment protocol for this area before moving into phase three research, that is, controlled clinical trials investigating efficacy.

Voice therapy for UVFP needs to develop studies that are randomized, have a clear protocol, and use experimental designs. This will allow improved clinical decision making for voice clinicians and improve efficacy and effectiveness of research. The inclusion of such factors and implementation of an objective methodology would improve treatment outcomes and the evidence base for this population.

APPENDIX. SUMMARY OF FINDINGS TABLE

McFarlane et al²⁹

Methods	Prospective, concurr	ent control, not randomized		
Participants	Sixteen patients with UVFP, 6 (3 female, 3 male) received voice therapy, whereas other groups consisted of Teflon injection (4), reinnervation (6), normal speakers (6)			
Interventions	Participants received treatment from the same clinician, hours of voice therapy ranged from 3 to 24 hours. Techniques included head turning, lateral digital manipulation and half-swallow boom			
Outcomes	Three listener groups consisting (n = 27) of 9 ENT, 9 speech therapy (SPs), 9 lay listeners rated the voices blindly. They rated voices perceptually on 6 parameters: pitch, loudness, hoarseness, roughness, breathiness, and quality using a 10-point scale.			
Notes	Nil severity of participants with UVFP reported, nil cause of UVFP reported, nil reason for allocation to treatment group, and nil functional and instrumental outcome measures used.			
NHMRC level of evidence Risk of bias	III-3			
Bias	Authors' judgment	Support for judgment		
Random sequence generation (selection bias)	High risk	Nil reporting of randomization or allocation		
Allocation concealment (selection bias)	High risk	Nil reporting of allocation concealment or how participants were allocated to their treatment group		
Blinding of participants and personnel	High risk	Nil blinding of participants to treatment		
(performance bias)—all outcomes		Judges blinded to treatment		
		Use of random samples		
Blinding of outcome assessment (detection bias)—all outcomes	High risk	Not consistent pre or post assessment		
Selective reporting (reporting bias)	Unclear risk	Different voice therapy used Varied severity between groups		
Incomplete outcome data (attrition bias)—all outcomes	Low risk	Nil attrition		
Other bias	High risk	Poor content Nil inclusion and exclusion criteria		

Cantarella et al³⁴

Cantarella et al ³⁴			
Methods Participants	Prospective—Quasi-experimental design, not randomized Thirty adults all had a confirmed diagnosis of UVFP iatrogenic (16 males, 14 females), 2 groups created based on time since onset. Early group: 14 participants (mean time 1.79 months); late group: 16 participants (mean time		
Interventions	29.81 months) All participants received voice therapy, total sessions 10–40, and frequency of treatment depended on severity, daily homework prescribed, treatment programs tailored to participant needs, which included relaxation, abdominal breathing with sounds on exhalation, massage, digital manipulation, sonority,		
Outcomes	glottal attacks, and resonant voice. Treatment outcomes focused on improved loudness, steadiness, and reduced vocal effort. Outcomes seen to improve for both treatment groups across perceptual and function outcomes with some significant results. Treatment UVFP is still effective even if delayed in initiation.		
Notes	Treated at an otolaryngology unit in Milan		
NHMRC level of evidence	III-3	3,	
Risk of bias	0		
Bias	Authors' judgment	Support for judgment	
Random sequence generation (selection bias)	High risk	Nil randomization	
Allocation concealment (selection bias)	High risk	Nil concealment	
Blinding of participants and personnel (performance bias)—all outcomes	High risk	Nil blinding—? who provided treatment Participants all received different treatments	
Blinding of outcome assessment (detection bias)—all outcomes	High risk	Nil reporting of judges being blinded	
Selective reporting (reporting bias)	High risk	Not all data presented—only for 12 MDVP	
Incomplete outcome data (attrition bias)—all outcomes	Unclear risk	Nil attrition reported	
Other bias	High risk	Variability of treatment Nil documentation of dysphonia severity Compliance with treatment	
Colton et al ³⁵		compliance with treatment	
Methods	Prospective—Quasi-expe	erimental design, not randomized	
Participants	Twenty-six participants all had a confirmed diagnosis of UVFP (16 females, 10 males). Varied etiology discussed. Thirteen participants received surgery (thyroplasty), 13 received voice therapy.		

Methous	Frospective—Quasi-experimental design, not randomized			
Participants		s all had a confirmed diagnosis of UVFP (16 females, 10 ogy discussed. Thirteen participants received surgery		
	(thyroplasty), 13 rec	eived voice therapy.		
Interventions	Voice therapy consistent of 4–6 sessions devised by the speech-language pathologist			
Outcomes	Treatment outcomes focused on acoustic changes between the two treatment groups, severity of dysphonia decreased for both treatment groups			
Notes	Nil initial level of severity rated, limited quantitative data, nil documenting of hov participants were recruited for study.			
NHMRC level of evidence	III-3	,		
Risk of bias				
Bias	Authors' judgment	Support for judgment		
Random sequence generation (selection bias)	High risk	Nil randomization		
Allocation concealment (selection bias)	High risk	Treatment or group allocation determined by clinical factors and patient choice		
Blinding of participants and personnel (performance bias)—all outcomes	High risk	Nil blinding of participants		
Blinding of outcome assessment (detection bias)—all outcomes	Low risk	Apparent blinding of assessors		
Selective reporting (reporting bias)	Unclear risk	Only acoustic assessed Rating scale used not references		
Incomplete outcome data (attrition bias)—all outcomes	Unclear risk	Nil attrition reported		
Other bias	High risk	Timing of outcomes assessments varied between groups Nil voice therapy specifics—? direct or indirect treatment Overall severity of participants		

Timing since onset

El-Banna and Youssef³⁷

Methods	Prospective—Quasi-	experimental design, not randomized			
Participants	Forty-two participants all diagnosed with UVFP (17 males, 25 females). Divided into 3 groups: early voice therapy (22 participants), 2–4 weeks after onset; no voice therapy (12 participants); and late voice therapy, 6–14 months after onset				
Interventions	One clinician provided all of the treatment, individualized based on level of glottal incompetence and compensatory behaviors used. Treatment includes pushing exercised with hard glottal attack and Smith Accent Method				
Outcomes	This study aimed to assess the efficacy of early voice therapy. Reported better outcomes for early-intervention group compared with no therapy or late-therapy groups				
Notes	Used inclusion criter	ia, study conducted in Egypt			
NHMRC level of evidence	III-2				
Risk of bias					
Bias	Authors' judgment	Support for judgment			
Random sequence generation (selection bias)	High risk	Nil randomization Patient preference			
Allocation concealment (selection bias)	High risk	Allocated based on patient preference			
Blinding of participants and personnel (performance bias)—all outcomes	High risk Late-group participants convinced about the importan of voice therapy				
Blinding of outcome assessment (detection bias)—all outcomes	Low risk Three judges blinded to assessing glottal gap and GR				
Selective reporting (reporting bias)	Unclear risk	Documentation of treatment between groups not consistent			
Incomplete outcome data (attrition bias)—all outcomes	Low risk Nil attrition				
Other bias	Low risk	Inclusion and exclusion criteria Groups not equal numbers			

Busto-Crespo et al⁴⁰

Methods	Prospective—Quasi-experimental design, not randomized					
Participants	Seventy participants all with a diagnosis of UVFP (initially 105; however, data excluded from study) (25 males, 45 female). Divided into 2 groups depending on time of initiating therapy: group 1, 47 participants, <1 year since onset; and group 2, 23 participants, >1 year since onset.					
Interventions	Treatment protocol for participants developed, 3 stages—fifteen 30 min sessions conducted twice a week by a speech-language pathologist targeting pulmonary function, voice source, vocal tract, articulation, and cerebral integration.					
Outcomes	Effects of voice therapy protocol on participants with UVFP with varied timing of onset for UVFP. Better outcomes reported for early referral treatment group; however, both groups reported gains and retention of skills up to a year post treatment.					
Notes	Voice pathology unit					
NHMRC level of evidence	III-3					
Risk of bias						
Bias	Authors' judgment	Support for judgment				
Random sequence generation (selection bias)	High risk	Nil randomization				
Allocation concealment (selection bias)	High risk	Based on timing of diagnosis and commencement of voice therapy				
Blinding of participants and personnel (performance bias)—all outcomes	el High risk Nil blinding					
Blinding of outcome assessment (detection bias)—all outcomes	High risk Two ENT judges, no reports of being blinded					
Selective reporting (reporting bias)	Low risk	Protocol used				
Incomplete outcome data (attrition bias)—all outcomes	Low risk Attrition participants excluded from all data analysis					
Other bias	Low risk Longitudinal data reported Consistent voice therapy provided					

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4.10 Addendum

Since the publication of the systematic review in the Journal of Voice, there have been four published treatment studies related to the voice therapy management of UVFP [1-4] that would have met the inclusion criteria for the systematic review [5]. Firstly, Barcelos et al. [1] provided individualised voice therapy to 61 patients comprising of education, pushing and pulling and forced adduction, twice weekly with an average treatment duration of 12 sessions (SD= 6) to patients with UVFP resulting from treatment for cancerous lesions. Secondly, Kao et al. [3] reported on a randomised control trial which provided early intervention to 19 patients with U(adductor)VFP, specifically providing a 16-session protocolled weekly treatment which included hard glottal attack, vocal function exercises and resonant voice therapy. Thirdly, the study by Ras et al. (2017) was a randomised control trial with 29 patients which compared conventional voice therapy to electrical stimulation supported voice therapy. Therapy was provided in 12 sessions twice weekly, with voicing tasks including coughing and vowel productions [4]. Finally, the study by Vij, Gupta and Vir. [2] was a randomised control trial involving patients with injuries to the Recurrent Laryngeal Nerve or Superior Laryngeal Nerve, who received a combination of voice therapy and surgery or voice therapy in isolation. The voice therapy was individualised to the patients and comprised of pushing and pulling, head tilt, digital manipulation and half swallow boom. This therapy was provided twice weekly and then reduced after one month.

The inclusion of these four studies into the findings of the systematic review would not change the conclusions of the systematic review [5]. Despite the improvement in some of the aspects of methodological quality, including the use of randomised control trial design in three of the studies, and one using a treatment protocol, the studies continued to demonstrate (1) variability in the treatment approaches investigated, with limited rationale for their selection, (2) variability in the assessment battery used to measure outcomes; variability in the aetiology and clinical characteristics of the studied populations and (4)

variability in the timing, frequency and intensity of the treatment provided. These four factors were highlighted by the systematic review as characteristic of the current literature, and possible explanations for the lack of clear efficacy data relating to speech pathology treatment for people with UVFP. Further research is therefore required to build the evidence base.

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5 CHAPTER FIVE: CHARACTERISTICS OF VOICE THERAPY FOR UNILATERAL VOCAL FOLD PARALYSIS: A SURVEY OF SPEECH-LANGUAGE PATHOLOGISTS

The systematic review described in Chapter four revealed that there is limited published evidence for the speech pathology management of Unilateral Vocal Fold Paralysis (UVFP), and that of the evidence that is available there is limited consensus for the characteristics of the voice therapy being provided. In order to better understand the characteristics of voice therapy being used to treat patients with UVFP and add to the evidence base, the clinical perspectives of speech pathologists was sought to help understand the clinical characteristics of the voice therapy provided to patients with UVFP. Therefore, Chapter five reports on a study that aims to establish the current clinical perspectives of speech-language pathologists who provided voice therapy to patients via the means of a cross-sectional survey.

This study is currently under review by a Journal and we anticipate publication soon:

Characteristics of Voice Therapy for UVFP: A survey of Speech-Language Pathologists.

Walton, C., Conway, E., Carding, P., Flanagan, K. and Blackshaw, H. (submitted to Journal of Speech, Language & Hearing Research, July 2018)

5.1 Abstract

Purpose: Unilateral vocal fold paralysis (UVFP) results in a debilitating dysphonia which typically warrants treatment. Speech-language pathologists select and provide behavioural treatment for patients with UVFP with the aim to restore glottal closure and improve vocal quality and endurance. However, there is currently no consistent approach for the content, timing and dosage of the voice therapy provided. This is the second study in a series of three integrated projects that are designed to explore this subject in detail. To investigate the content, timing and dosage characteristics of voice therapy provided by speech-language pathologists to patients with dysphonia due to unilateral vocal fold paralysis.

Method: This is a cross-sectional survey study. A questionnaire (18 questions) was designed using the findings of a systematic review and disseminated electronically to speech-language pathology professional groups and voice experts. Participants were asked to respond to a range of open and closed questions about their perspectives on the characteristics of voice therapy for patients with unilateral vocal fold paralysis.

Results: A total of 110 participants responded to the questionnaire in full. Respondents reported variability in the content, timing and dosage of voice therapy provided to patients with unilateral vocal fold paralysis. Despite the variability, there was found to be several consistent factors and themes used by respondents to guide their selection of voice therapy characteristics.

Conclusion: This study identified variability in the current selection and use of voice therapy characteristics provided to patients with unilateral vocal fold paralysis. Common factors and themes which guide treatment selection were identified. However, these features warrant further study with in-depth structured interviews and thematic analysis which will enable further examination of key components of voice therapy used for patients with this voice disorder.

Keywords: Unilateral Vocal Fold Paralysis, Voice Therapy, Speech Pathology, Treatment

5.2 Introduction

Background

Voice therapy is a behavioural treatment designed and implemented by speech-language pathologists to treat dysphonia. In general, voice therapy is provided as either a) a means of preventing dysphonia [1], b) the primary treatment for the presenting condition – for example: muscle tension dysphonia [1, 2], or c) an adjunct to surgical intervention - for example: unilateral vocal fold paralysis [3]. There are a number of examples of prescriptive voice therapy protocols in the literature for specific voice disorders (e.g. [4, 5]). These protocols have emerged from treatment efficacy studies which require methodological control of the independent variable. However, clinical practice may follow a less protocol driven hierarchy here it would be rare for a speech-language pathologist to use a single type of voice therapy or the same treatment dosage for all patients (e.g. [6, 7]). Speech-language pathologists select and design the therapy content, timing and dosage based on their clinical knowledge and on what is best suited to the patient, their presenting dysphonia and the clinical setting [8-12]. For these reasons the details relating to the content, timing and dosage of voice therapy in clinical practice are sparse for most voice disorders [1, 4, 13-15].

Patients with a Unilateral Vocal Fold Paralysis (UVFP) typically experience a dysphonia that is perceptually breathy, rough and weak voice and associated with reduced quality of life [16-18]. Voice therapy is commonly the primary treatment option for dysphonia due to UVFP when (a) there is a small glottal gap (usually < 2 mm) and (b) there are no concomitant breathing and swallowing issues [19]. In this context, voice therapy aims to restore glottal closure and improve voice quality and durability. Voice therapy is also minimally invasive, allows time for any spontaneous recovery and prevents the development of maladaptive compensatory habits [20]. A recent systematic review found 12 studies which reported on the outcome of voice therapy for patients with UVFP [3]. The review concluded that there

was a lack of consensus for the content, timing and dosage of voice therapy provided, even though studies reported good treatment effects [3].

Several previous studies have used qualitative methods to understand the current practices of clinicians for the management of voice disorders. When current treatment approaches are unclear a qualitative systematic approach can be useful to identify underlying theoretical principles of practice [21]. Survey-based tools and questionnaires allow researchers to potentially recruit large numbers of participants and establish themes and theories that can be further explored by other qualitative methods (for example in-depth structured interviews [21]). Responses from questionnaire based surveys have been used to describe general voice therapy approaches general [9] and specifically for functional dysphonia [11]. However, to date, no study has attempted to identify the characteristics of voice therapy provided by speech-language pathologists to patients with UVFP using a cross-sectional survey-based methodology.

The present study is one in a series of three studies that aims to identify and explore voice therapy characteristics for patients with UVFP. The first study was a systematic review of the published literature 2000-2016 about the characteristics and effectiveness of voice therapy for the management of patients with UVFP [3]. The 12 studies that met the inclusion criteria for the systematic review were found to be low levels of evidence using the NHMRC scale [22]. The findings of the systematic reviews revealed that there was no standardized intervention, inconsistent use of voice outcome measures and variable treatment dosage. The authors concluded that published evidence of voice therapy management for patients with UVFP was at "establishing proof of concept" phase [23]. Therefore, a second study was undertaken to characterize the clinical expertise of clinicians who regularly provide voice therapy provided to patients with UVFP. This is the subject of this paper.

The findings from the recent systematic review [3] also formed the basis of the content of the questionnaire used in the cross-sectional survey as described below. A third study is planned to explore the key components using in-depth structured interviews and thematic analysis. Therefore, the aim of this study was to use a questionnaire to conduct a cross section survey to explore the characteristics of voice therapy for patients with UVFP.

Specifically, we aim to answer three primary questions:

- 1) What are the typical components of voice therapy provided to patients with UVFP?
- 2) Which factors impact the selection of the voice therapy characteristics?
- 3) Is there clinical consensus with the current research evidence for the voice therapy characteristics?

5.3 Methods

This project was approved by the Australian Catholic University Human Research Ethics Committee – Project register number: 2016-242E (20th December 2016).

The methodology falls into two main components: questionnaire development (rationale and content development) and survey procedure (participant recruitment and dissemination procedure)

Questionnaire Development

A questionnaire format was chosen because it was the most effective way to answer the aims of the study as described above. The combination of questions allowed the collation of a representative overview of the current characteristics of voice therapy for patients with UVFP [21]. The questionnaire was developed by the five authors who comprised of experienced voice researchers, methodologists and research practitioners. Qualtrics© software was used to provide an electronic platform for the questionnaire to enable a wide dissemination as reported in other studies [24-26]. The questionnaire comprised of 18

questions which were based on the findings of a recent systematic review [3] and was comprised of closed, multiple choice and free-text questions. The questionnaire content focused on different areas of clinical management including assessment, outcome measurement and treatment decision making (See appendix 5.7). The opening questions focused on the demographics of the respondents and was followed by a section requiring respondents to select the relevant types of voice outcome measures used (using multiplechoice options) and name the specific voice-outcome measure/s with free-text (e.g. Q 8.). The third section included a combination of qualitative and quantitative questions to determine the content, timing and dosage of the voice therapy for patients with UVFP. Several questions (e.g. Q 9) used a Likert scale to quantify certain aspects of content and frequency of the voice therapy. The listed voice therapy options were based on the findings of a recent systematic review [3] and published case studies [27-29]. There were also opportunities for clinicians to respond by free-text response in order to elaborate where appropriate. The final section focused on the factors which influence the selection of the voice therapy characteristics as well as professional development undertaken by respondents. A Likert scale was also used (Q 16) to quantify the relative importance of factors which may influence the characteristics of voice therapy as per previous literature [8] and [30]. The questionnaire was piloted with a convenience sample of three experienced speech-language pathologists to determine the utility. Based on this feedback, questions were modified and revised which resulted in the final version used for the current study. It was estimated that the questionnaire would take 15 minutes to complete. All returned questionnaires were anonymous. A copy of the questionnaire is in included in Appendix 5.7.

Survey procedure

The questionnaires were disseminated electronically in June 2017 to databases of speechlanguage pathologists from voice special interest groups, social networks and professional associations. A follow up reminder email was sent six weeks later to encourage further responses. Recipients were also encouraged to disseminate the questionnaire to other speech-language pathology colleagues to enable maximal snowball sampling. To be included in data analysis, participants needed to have provide consent (sought at the start of the questionnaire), were required to have had experience in treating patients with UVFP and to have completed the questionnaire in full. Respondents received no incentives to complete the questionnaire. Once the results were collated, the quantitative data was analysed using Qualtrics © (e.g. percentages and frequency distribution) and thematic analysis of the descriptive data was conducted.

5.4 Results

Respondent demographics

A total of 154 respondents commenced the questionnaire and 110 questionnaires were completed and subsequently included in the analysis. Due to the snowball style of recruitment, the authors are unable to quantify the total number of speech-language pathologists who received the questionnaire. It is unclear why some respondents did not fully complete the questionnaire, but it is hypothesised that some did not meet the inclusion criteria and that time and workload commitments were potential barriers to completion.

Respondents were from a number of countries including USA, UK, Canada, Australia, Ireland and Switzerland. Table 1. provides a summary of the respondent demographics including workplace setting and clinical experience.

Table 1. Demographic information of questionnaire respondents (Total n = 110)

Years of experience as a SLP	Percentage of respondents (%)	Current Workplace Setting	Percentage of respondents (%)	
0 - 5 years	23	Hospital Inpatient	32	
5 - 10 years	23	Hospital Outpatient	37	
10 - 15 years	16	Private Practice	15	
15 - 20 years	10	Community	8	
> 20 years	28	University	5	
		Other settings	3	

Percentage of caseload voice disorders Percentage of respondents (%)		Number of UVFP seen within the past 12 months	Percentage of respondents (%)	
None	10	None	6	
1-25%	39	1- 9	51	
26 – 50%	13	10 - 19	13	
51 – 75%	10	20 - 29	11	
76- 100%	28	30 - 39	5	
		40 – 49	7	
		50 +	7	

It is clear that a majority of respondents worked in a hospital setting and that they represented a wide range of clinical experience.

Voice Outcome Measures

Table 2. contains a list of the most commonly used voice outcome measures reported by the respondents to detect the treatment effect for patients with UVFP. There was no reported difference in the selection of pre and post voice therapy voice outcome measures. The responses were collated one of five different voice outcome measure categories as previously described [3, 13, 31]. The most commonly used voice outcome measures reported by the respondents were Maximum Phonation Time [39] and S/Z ratio [32] (35% of respondents), the Voice Handicap Index- 10 (VHI-10) [33] (31% of respondents) and the GRBAS [34] (29% of respondents). A smaller number of respondents (15%) reported to use other non-voice outcome measures examples including: AusTOMS [35], Leicester Cough Questionnaire [36], Vocal Tract Discomfort Scale [37] and the Evaluation of the Ability to Sing Easily (EASE) [38].

Table 2. Hierarchy of voice outcome measures

Tubic E. Incluiding	or voice outcome measures			
Types of Voice Outcome	Percentage of Respondents (%)	Examples of voice outcome measures used by		
Measures	who used each VOM type	respondents		
Auditory-Perceptual	73%	GRBAS [34], CAPE-V [39] & Perceptual Voice Profile [40]		

Aerodynamic measures	65%	MPT [41] & S/Z [32], mean flow rate, sub glottic pressure
Patient self-rated assessments	64%	VHI [41], VHI-10 [33], VoiSS [42] & VOS [43]
Visuo-perceptual measures	60%	Videostroboscopy, Laryngoscopy (flexible or rigid)
Acoustic features	34%	Jitter, Shimmer, NHR, F0, pitch range

Key: VOM – Voice Outcome Measure, *GRBAS* – perceptual rating scale (Grade, roughness, breathiness, asthenia, strain), CAPE-V - Consensus Auditory-Perceptual Evaluation of Voice, MPT – Maximum Phonation Time, S/Z ratio – assesses for glottal insufficiency (voiceless / voiced), VHI – Voice Handicap Index (30 Questions), VHI-10 – Voice Handicap Index (10 Questions), VoiSS- Voice Symptom Scale, VOS – Voice Outcome Survey, Jitter - cycle-to-cycle variations of fundamental frequency (Hz), Shimmer - cycle-to-cycle variations of amplitude (dB), NHR- Noise to harmonic ratio, F0 - fundamental frequency.

Characteristics of voice therapy

Content of therapy

Figure 1 shows the frequency of the type of voice therapy used with UVFP patients. Indirect voice therapy i.e. vocal hygiene was used by 80% of respondents to patients with UVFP. Direct techniques including: respiration/ breathing, Vocal Function Exercises [7] and Resonant Voice [4] were used by 50% or more respondents. The least frequently used treatments were LSVT® 12.4% [29] and electrical stimulation 6.7% [27]. A number of techniques were reported to be "used occasionally" by some respondents (i.e. digital manipulation, pushing exercises) but it is unclear in what circumstances these were applied. Respondents were asked to list other types of voice therapy that they used with UVFP that were not included as options in the questionnaire. These additional techniques included: trills [6], tubing therapy/ LaxVOX [44], straw therapy [45], counselling, swallow-sigh, forced plosives [46, 47], head turn & lift, adduction exercises and singing exercises.

^{*} Percentages do not total 100 as they are based on responses to separate questions.

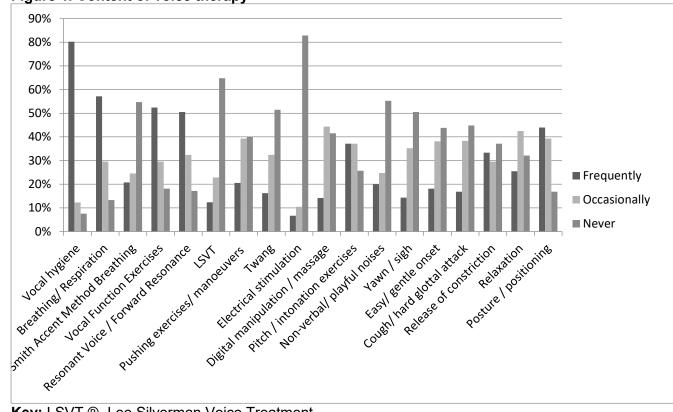


Figure 1. Content of voice therapy

Key: LSVT ®- Lee Silverman Voice Treatment

The results in Figure 1 highlight the considerable variability between respondents in the types voice therapy used to treat patients with UVFP. Apart from the general consensus for the use of vocal hygiene, the respondents did not agree on a typical type of voice therapy for patients with UVFP and it could be hypothesised that there is an individuality to the voice therapy selected. For example, the "release of constriction" exercises were reported to be used frequently by 34% of respondents, but also reported to never be used by 37% of respondents when treating patients with UVFP. Similar variability was seen with the selection of pitch / intonation exercises (37% frequently vs. 25% never) and relaxation (25% frequency vs. 32% never).

Justification for voice therapy

Table 3 lists a series of factors provided by the respondents for the types of patients they considered 'ideal' or typical patients for voice therapy treatment, along with rationales considered for those that do not receive voice therapy treatment. The most commonly reported treatment approach for patients with UVFP was a combination of surgical intervention and voice therapy. However, it is clear from the respondents that some patients with UVFP did not receive voice therapy at all. The stated rationale for not providing voice therapy was predominantly related to patient factors that impacted on their appropriateness for voice therapy. These factors included the presence of a large glottal gap, airway compromise, dysphagia and other concomitant medical conditions. Interestingly, limited or inconsistent access to ENT services appeared to be a major determinant for both providing and not providing voice therapy.

Table 3. Justification for voice therapy

Often provide voice therapy	Sometimes provide voice therapy	Rarely provide voice therapy
All patients except those who are end	Depends on ENT e.g. Priority for surgery	Large glottic gap
of life		
Education/ indirect therapy about the	Cause of the UVFP	No access to ENT
voice and how it works even if surgery		
follows		
Except if there are airway issues or	If the patient declines surgery or patients	Treatment for other conditions –
dysphagia	level of concern	voice less priority e.g. radiation/
		cancer
Limited access to ENT	To facilitate optimal voicing	Dysphagia
While awaiting ENT review or surgery	Depends on the position of the VFs	Airway compromise
Dependent on glottal gap	Limited ENT support	
	Minimal aspiration risk	
	Awaiting spontaneous	
	recovery	

Key: ENT – Ear Nose & Throat Surgeon, UVFP – Unilateral Vocal Fold Paralysis; VFs – Vocal Folds;

Timing of intervention

To further understand the role of the speech–language pathologist in the management of UVFP, respondents were asked to identify when voice therapy was commenced in a typical patient's journey. The majority of respondents reported that voice therapy (direct and/or indirect) was commenced at a "pre-surgical" stage (73% of cases) and then also following surgical intervention (61% of cases). Less commonly, voice therapy was provided at only the post-surgical intervention stage in 18% of cases. In the small number of cases (9%) where no surgical intervention was offered, the timing of voice therapy was influenced by service factors such as waiting lists and caseload availability (i.e. not based on a clinical rationale).

Dosage

Duration of therapy

The majority of respondents reported that they provided 10 or fewer sessions of voice therapy to patients with UVFP. A total of 43% of respondents reported that they provide 1 - 5 sessions of voice therapy, while 39% provided 6 - 10 sessions of voice therapy. Only 6% of respondents reported to provide more than 10 sessions of voice therapy. The remaining 12% of respondents were unable to quantify the number of voice therapy sessions and suggested that it was dependent on a number of factors such as patient diagnoses and clinical experience.

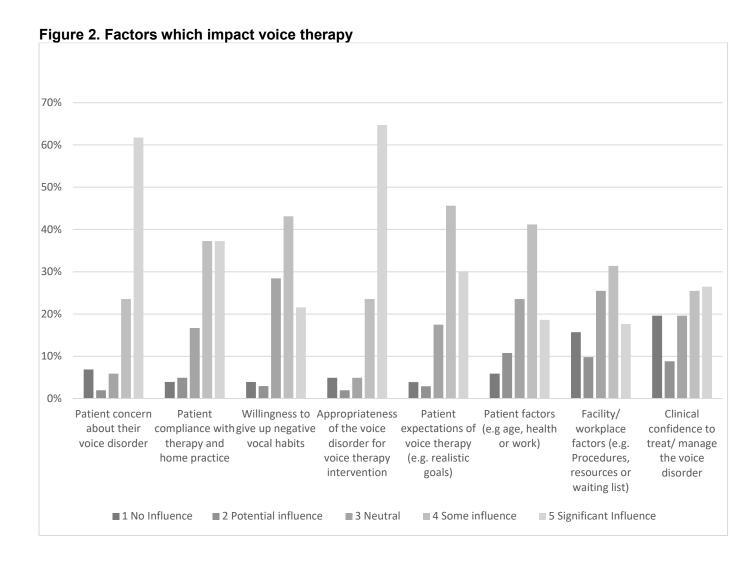
Frequency of therapy

The most commonly reported frequency of therapy provided was weekly voice therapy for UVFP patients (42%), whilst others reported a fortnightly provision (20%). More intensive therapy was less common (twice weekly = 16%, daily = 6%). It was unclear from the

questionnaire why more intensive types of voice therapy frequency were less common and only provided to certain patients. A total of 16% of respondents reported variable frequency of voice therapy which was dependent on patient factors e.g. availably to attend voice therapy and treatment success. Respondents also described a reduction in the frequency of sessions over time (e.g. weekly to fortnightly and then monthly) in a presumed stepped-withdrawal approach.

Factors which impact delivery of voice therapy

Figure 2 shows the factors identified by the respondents that were likely to impact the delivery and provision of voice therapy to patients with UVFP. The factor reported to have a more significant impact were "appropriateness of the voice disorder" and "patient concern". The two factors that were most frequently reported to have little impact on the provision of voice therapy were "facility and work place settings" and "clinical confidence of the speech-language pathologist".



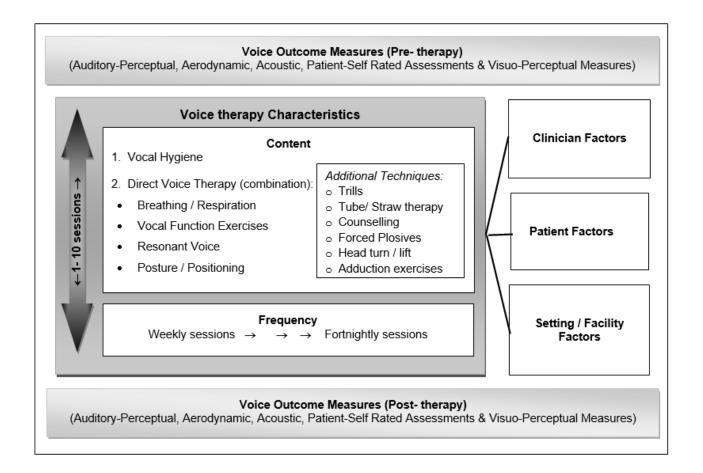
Further training

Most respondents (77%) reported to have participated in professional development to enhance their knowledge of voice and guide treatment selection for UVFP. Respondents identified examples of their professional development including: training provided by national speech pathology organisations, voice conferences, voice courses presented by developers of techniques e.g. Voicecraft ® [48] and the undertaking of post-graduate study.

Summary of voice therapy characteristics (as reported by respondents)

Respondents who completed the questionnaire identified the characteristics of the voice therapy that they provide to patients with UVFP. Figure 3 is a summary of the typical characteristics (as identified by the majority of the participants) and treatment journey for patients with UVFP. The typical respondent was characterised as follows: (a) working as a speech-language pathologist for less than 15 years, (b) has been treating voice patients for less than 10 years and (c) works in a hospital setting where (d) they see less than 25 patients with UVFP per year. The typical respondent has also sought professional development to develop their voice skills which help guide their selection of the voice therapy characteristics.

Figure 3. Typical voice therapy process as reported by a majority of questionnaire respondents



5.5 Discussion

This is the first study to report on the content, timing and dosage characteristics of voice therapy provided to patients with UVFP by speech-language pathologists in clinical practice. An electronic questionnaire format was used to collect a range of data from 110 speech-language pathologists across a number of countries and with a variety of levels of experience. The findings of the questionnaire reveals variability in the characteristics of the voice therapy currently provided by speech-language pathologists and helps to identify the factors which influence the design and delivery of the therapy programme.

Previous studies

To date no studies have specifically investigated the characteristics of the voice therapy provided to patients with UVFP using a cross-sectional survey design. Previous studies have used a survey-based approach to investigate the characteristics of treatment for various

other voice disorders [9, 11]. These studies have found that clinicians utilised a range of treatment techniques and that clinical experience is an important factor in clinical decision making. In addition, Sellars et al. [49] reported on the treatment approaches used by speech-language pathologists working in the United Kingdom in the management of non-organic 'hoarseness' and also identified a number of patient-centred factors that guide treatment selection.

Walton et al.'s recent systematic review [3] revealed that there was a disparity in the published literature regarding the content, timing and dosage of the voice therapy provided to patients with UVFP. The cross-sectional survey data reported above serves as further confirmation of these findings. The systematic review [3] also highlighted the poor quality of the existing studies and recommended the development of treatment protocols in order to formally control the independent variable to test intervention efficacy. Several recent studies have described a voice therapy treatment protocol for patients with UVFP [27, 50, 51]. However, these treatment protocols were not based on current practitioner consensus of content, timing and dosage of the voice therapy provided to UVFP patients. Despite there being no current consensus for the characteristics of voice therapy provided to UVFP patients, recent papers note that there are likely to be a number of factors that may contribute to the success of voice therapy [2, 3, 27, 28]. The data from our current cross section survey provides valuable insight into clinical practice as currently performed by a wide variety of experienced clinicians. This data may therefore provide a basis by which more standard treatment protocols can be realistically developed.

In addition to providing insights into current practice in UVFP treatment, the current study also further develops the methodological approaches used in the current literature by (a) using a survey tool with content and structure developed from the findings of a published

systematic review [3] and (b) using an electronic dissemination process that enabled access to a broad range of practicing speech-language pathologists, leading to the collection of a large sample size. Furthermore, the use of a questionnaire allowed for the collection of descriptive responses. This enabled a detailed analysis of the current clinical perspectives of speech-language pathologists who provide voice therapy for patients with UVFP.

Main Findings

The current study provides some promising information for the use of voice therapy for the management of patients with UVFP and identifies some clinical characteristics of voice therapy that can be used in future clinical trials in order to maximise transfer to practice. Respondents reported that voice therapy was offered to approximately 52% of patients with UVFP and this was slightly higher than previous reports [52]. This finding may be due to the majority of respondents reporting to working in a hospital (inpatient / outpatient) setting. Predominately, patients with UVFP received a combination of surgical intervention and voice therapy with voice therapy preceding and following the surgical intervention. The majority of respondents also reported using a combination of direct and indirect voice therapy typically for a maximum of 10 sessions provided on a weekly basis. The respondents showed variability in the content, timing and dosage of voice therapy provided to this patient group. Direct treatments commonly included respiration / breathing exercises, vocal function and coordination exercises and therapy to maximise vocal resonance. These treatment techniques and approaches have evidential support with other voice disorders (e.g. functional dysphonia [11, 49]) but have a more limited evidence base for treating patients with UVFP. Specific voice therapy techniques require further research to establish evidence of efficacy for UVFP treatment. Despite the variability, there was found to be several consistent factors and themes used by respondents to guide their selection of voice therapy characteristics.

Themes which guide voice therapy

The current study has enabled the identification of a number of themes as described by respondents. The following features may be considered when designing voice therapy for patients with UVFP in both a clinical and a research context;

- (1) Aims of voice therapy: The overall goals of voice therapy for UVFP should aim to (a) improve glottal closure, (b) eliminate any (secondary) laryngeal hyperfunction and abusive/maladaptive vocal habits (c) improve airflow efficiency for phonation and (d) improve vocal quality and durability [13, 16, 19]. As reported by the respondents, voice therapy that endangers these four main tenants of treatment for patients with UVFP would be considered contraindicated, may cause harm and may exacerbate the voice symptoms.
- (2) An individual treatment approach: The questionnaire respondents reported that the voice therapy provided is not a 'one size fits all approach'. It is clear that patients with UVFP are affected differently and a number of patient related factors (e.g. perception of disability and vocal demands) impact on treatment design. This does not preclude the use of a treatment protocol for patients with UVFP but does mean that the protocol would need to be sufficiently flexible to accommodate individual patient context.
- (3) Timing of voice therapy: It would appear that the timing of voice therapy is strongly influenced by the referral source rather than by the speech pathologist. It was not possible to explore other factors that may impact on therapy timing within the current questionnaire format. An alternative methodology such as an in-depth structured interview may provide more detailed information about the timing of voice therapy. Several recent studies have opted for early voice therapy intervention for the management of UVFP [28, 50, 51]. This approach is presumably based on principles of neuroplasticity and motor-learning [53, 54] and an aim to reduce the potential for maladaptive phonatory behaviours [16, 28, 55]. However, the evidence base for this approach is limited [16, 50]. Similarly, early voice therapy intervention as a strategy to reduce the need for surgical intervention has not yet been explored.

- (4) Content of voice therapy: There is currently no consensus for the content of voice therapy provided to patients with UVFP. However, a combination of both direct and indirect voice therapy treatments was commonly reported to address the relevant subsystems of phonation (respiration, phonation and resonance). There have been several recently published treatment protocols which use this subsystem approach [28, 56]. Despite encouraging results, further studies are required to fully evaluate the treatment efficacy of these approaches.
- (5) Voice therapy dosage (duration and frequency): The evidence base has yet to establish the optimal duration dosage of the voice therapy for patients with UVFP. Nevertheless, published studies [16, 51, 55] do appear to have an upper limit of treatment sessions and the questionnaire data indicates that a large majority of clinicians do not offer more than 10 sessions. This suggests that the choice to extend voice therapy beyond 10 sessions would require significant reflection about (a) the appropriateness of the candidate for voice therapy b) the aims of the voice therapy and (c) the possibility that the voice therapy may be contributing to or maintaining the dysphonia. Similarly, the frequency of voice therapy for patients with UVFP has not been examined in the literature. Studies from related areas (for example Functional Dysphonia [57, 58]) have compared weekly therapy to more intensive treatment and have found improved satisfaction and quality of life in patients with functional dysphonia with more intensive treatment. However, it is not clear how transferable these findings are to patients with UVFP given the theoretical principles of motor learning and neuroplasticity that are relevant to conditions of neurological impairment [53, 59].

Clinical Implications

The results of this present study and those of previous UVFP research identify that there is currently no consensus for the characteristics of voice therapy provided to patients with

UVFP. The findings of this study suggested that the lack of consensus is the result of an individualised approach to the treatment selection. This study discovered two key features for the clinical implementation of voice therapy for patients with UVFP. These were: 1) despite the variability in the voice therapy characteristics there is a typical process for the voice therapy provided to patients with UVFP as seen in Figure 3 and 2) the treatment selection is individualised as it is impacted by several factors including: clinician, patient and setting/ facility factors. The collated findings of the study shown in Figure 3 should be used as a guide by speech-language pathologists when selecting and individualised voice therapy treatment approach for patients with UVFP.

Strengths and weaknesses

A cross sectional survey was used, with a variety of question types in order to gather information to investigate the current perspectives for the characteristics of the voice therapy provided to patients with UVFP. A variety of question types were selected in order to gather information on the content, timing and dosage of the voice therapy. Furthermore, the study was able to recruit a large number of participants from a range of countries which provided a diverse perspective. However, some respondent features could be considered a limitation of the current study. For example, 10% of respondents reported that their current clinical caseload does not include voice disorders and identified both clinical rotations and management positions as contributing factors for this. Similarly, 8% of respondents reported to have not seen a patient with UVFP within the past 12 months due to a variety of reasons (including maternity leave and increased managerial responsibilities). However, the data from these participants were included because the respondents were still able to provide valuable perspectives on the subject matter. The current study specifically focused on the perspectives of the speech pathologist who provide voice therapy. However, the findings in

Table 3 suggest further exploration is required to inform the understanding of how the ENT surgeon interacts with the speech-language pathologists clinical decision making and treatment selection. We also recognise that the design of the questionnaire did not always allow the participants to provide context and rationale for some of their responses. An example of this was the dosage of voice therapy where respondents were unable to explain the rationale behind their delivery model. Additional features that were not investigated by the questionnaire included provision of homework (specifically the quantity, duration and content) and the effects of fatigue when selecting voice therapy. It is recognised that a further more detailed examination of these factors is required using a structured interview methodology with subsequent thematic analysis using a qualitative framework.

5.6 Conclusion

The findings of this cross-sectional survey study have revealed there is currently variability in the selection and use of the voice therapy techniques by clinicians who treat patients with UVFP, as well as variability in the content, timing and dosage of the voice therapy for patients with UVFP. These results concur with the findings of related literature [9, 11, 49] and a recently published systematic review pertaining to voice therapy for patients with UVFP [3]. Several factors were identified which are likely to impact and guide treatment selection and these features should be considered when designing voice therapy for patients with UVFP in both a clinical and research setting. A set of themes and characteristics have been identified to aid the design and delivery of voice therapy for patients with UVFP in both a clinical and a research context. A future study aiming to complete a detailed analysis of clinician clinical decision making using semi-structured interviews will be conducted in order to investigate these survey data further.

Acknowledgements:

Thank you to the speech-language pathologists who participated in this study. We appreciate your help in answering the questionnaire - your contribution to this study is invaluable for helping future voice research.

5.7	Appendix
Q 1.	Which country and region do you work in? (Please write below)
Q 2.	What is your current main clinical work setting?
	Hospital - inpatient Hospital - outpatient Community Private Practice University Other (please specify)
Q 3. belov	How many years of clinical (speech pathology) experience do you have? (Please write w)
	How many years of clinical experience do you have working with voice disorders? ase write below)
	Have you had clinical experience treating dysphonia due to unilateral vocal fold lysis? (Please enter your response below)
☐ ☐ (Plea	No Yes, I have treated patients with dysphonia due to unilateral vocal fold paralysis ase enter the approximate years in the box below)

	Please estimate the percentage of people with a voice disorder on your current clinical load?
	None 1-25% 26 - 50% 51-75% 76- 100%
	Please estimate number of patients with a voice disorder due to unilateral vocal fold ysis that you have seen within the past 12 months
fold p	Which outcome measure/s do you use to assess a voice disorder due to unilateral vocal paralysis? (Please select as many outcome measures as needed. If selected, please de the name of the outcome measure/s)
	Auditory perceptual voice assessment (e.g. GRBAS [34], CAPE-V [39])
imag	Visual perceptual assessment (e.g. Interpretation of videostrobe / laryngoscope es)
	Aerodynamic assessment (e.g. maximum phonation time, S/Z ratio [32])
Patie	ent self-rated assessment (e.g. VHI [60], V-RQOL [61])
	Acoustic features assessment (e.g. jitter, shimmer, harmonic-to noise ratio)
	Other
$\overline{\Box}$	None of the above

Q 9. Please indicate how often you would use each of the following types of voice therapy for treating patients with unilateral vocal fold paralysis.

(Frequently - use with > 50% of patients with UVFP)

(Occasionally - use with < 50% of patients with UVFP)

	Frequently	Occasionally	Never
Vocal hygiene			
Breathing/ Respiration			
Smith Accent Method Breathing			
[62]			
Vocal Function Exercises			
(Stemple, 2004)			
Resonant Voice / Forward			
Resonance			
LSVT [63]			
Pushing exercises/ maneuvers			
against resistance			
Twang			
Electrical stimulation			
Digital manipulation / massage			
Pitch / intonation exercises			
Non-verbal/ playful noises			
Yawn / sigh			
Easy/ gentle onset			
Cough/ hard glottal attack			
Release of constriction			
Relaxation			
Posture / positioning			

	there any other additional types of voice therapy that you would use for treating vocal fold paralysis? (If yes, please list any additional types of therapy below)
	es
☐ No	
offered as (Please s e.g. non-o	your current main clinical setting, is voice therapy (direct and/or indirect) ever as the initial mode of treatment for patients with unilateral vocal fold paralysis? elect the most appropriate response and list situations when this typically occurs dysphagic patients, limited access to ENT etc.) ways
Sc	ometimes
☐ Ne	ever
at what st	atients are selected for surgical intervention for their unilateral vocal fold paralysis, tage is voice therapy typically offered? re-surgery only pst-surgery only re-and Post-surgery to voice therapy provided w many voice therapy sessions do you typically provide to patients with unilateral
	paralysis?
☐ 6 · ☐ 11	- 5 sessions - 10 sessions I+ sessions ther
•	our typical practice, how often are voice therapy sessions offered for patients with vocal fold paralysis?
	aily wice / week eekly ortnightly ther

		1	2	3	4	5	
(1 = N	lo influence, 3 = Neu	ıtral & 5 =	= Signif	icant inf	luence))	
	planning and implement	•					ving statements influence h unilateral vocal fold
	None of the above						
Other							
	Acoustic features a	assessme	ent (e.g	. jitter, s	shimme	r, harmoı	nic-to noise ratio)
Patier	nt self-rated assessm	nent (e.g.	VHI [6	0], V-R(QOL [6 [,]	1])	
	Aerodynamic asse	ssment (e.g. ma	ximum	phonati	on time,	S/Z ratio [32])
image		1556551116	ent (e.g	. ппегр	etation	or videos	strobe / laryngoscope
□ -	Auditory perceptua						<u> </u>
	Auditory porcontus	l voice a	ccoccm	ont (o	CDR	V (1711 SV	VDE // (301)
patien		al fold pa	aralysis	? (Plea	se sele	ct as mar	cess of voice therapy for ny outcome measures as s)

Patient concern about their voice disorder								
Patient compliance with								
therapy and home								
practice								
Willingness to give up								
negative vocal habits								
Appropriateness of the								
voice disorder for voice								
therapy intervention								
Patient expectations of								
voice therapy (e.g.								
realistic goals)								
Patient factors (e.g.								
age, health or work)								
Facility/ workplace								
factors (e.g.								
Procedures, resources								
or waiting list)								
Clinical confidence to								
treat/ manage the voice								
disorder								
Q 17. Have you received f management of voice disc (If yes, please list the prof ☐ No ☐ Yes	orders?			elopme	nt in the a	assessme	ent and	
Q18. Would you like to ma for patients with unilateral or was not captured in the	vocal fol	d paraly	sis that	•	•			

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6 CHAPTER SIX: AN IN-DEPTH INVESTIGATION INTO THE CHARACTERISTICS OF VOICE THERAPY FOR PATIENTS WITH UNILATERAL VOCAL FOLD PARALYSIS

The study reported in Chapter five (Study two) explored the clinical perspectives of speech-language pathologists about the voice therapy provided to patients with Unilateral vocal fold paralysis (UVFP). The findings provided an overview of the clinical characteristics of the voice therapy provided by speech-language pathologists, and informed the development of a voice therapy schema, which outlined key factors involved in the provision of voice therapy to people with UVFP.

However, the findings highlighted further questions about the specifics of the components of management (e.g. patient, clinician and clinical setting factors) and the rationale that clinicians had for their clinical application. These questions require more in-depth exploration that was beyond the scope of a cross-sectional survey. Therefore, the study described in Chapter six (study 3) will explore these questions in further detail, using an in-depth interview methodology.

This study is a submitted manuscript:

Walton, C., Conway, E., Carding, P., Flanagan, K., Sav, A. and Blackshaw, H. *The Characteristics of Voice Therapy for Patients with Unilateral Vocal Fold Paralysis: Semi-structured Interviews* (submitted to the Journal of Voice, October 2018)

6.1 Abstract

Background: There is currently limited consensus in the unilateral vocal fold paralysis (UVFP) literature for the characteristics of voice therapy used to manage patients with dysphonia. This study is the final part of a three-part investigative study design to determine the characteristics of voice therapy provided to patients with neurogenic dysphonia due to UVFP. It aims to gain an in-depth understanding from the clinical experience of speech-language pathologists and to determine the factors and themes which impact and help guide voice therapy treatment practice.

Objective: To explore the clinical perspectives of speech-language pathologists who provide voice therapy to patients with neurogenic dysphonia due to UVFP.

Study Design: Qualitative research design, using semi-structured, in-depth interviews Methods: Seven in-depth, semi-structured interviews were conducted with experienced speech-language pathologists. The authors developed the interview guide based on the findings of two previously published studies a) a systematic review and b) a cross-sectional and the interviews were conducted via phone or skype and recorded. They were then transcribed and analysed using the Framework of Analysis technique and a previously developed components of voice therapy schema.

Results: Four themes and associated sub themes were identified from the interview data. These were 1) Context for guiding voice therapy, 2) Components of voice therapy, 3) Success and ceasing voice therapy and 4) Evidence-based practice. The results demonstrated a consensus for the components of voice therapy and the factors which influence clinical decision making.

Conclusions: The findings of the study provide a guide for the treatment of UVFP which should be applied to future UVFP research and clinical management of dysphonia arising from UVFP.

Keywords: Voice Therapy, Unilateral Vocal Fold Paralysis, Treatment, Dysphonia

6.2 Introduction

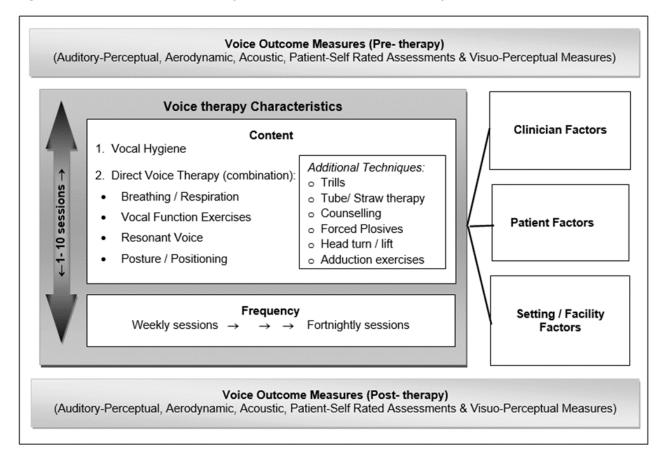
Dysphonia due to unilateral vocal fold paralysis (UVFP) is a motor disorder resulting from iatrogenic, idiopathic or other acquired injuries to the recurrent laryngeal nerve (RLN) [1, 2]. The motor deficit results in the absence of abduction and adduction to one of the vocal folds when phonating, leading to a glottal insufficiency. The paralysed vocal fold presents as flaccid with reduced muscle tone due to a loss of innervation to the intrinsic laryngeal muscles innervated by the RLN [3]. These neuromuscular deficits consequently impact upon the balance of the entire vocal mechanism, including respiratory control, voice onset timing, voice quality and resonance [3-7]. Therefore, voice therapy is a common treatment approach used to rehabilitate neurogenic dysphonia secondary to UVFP. However, the specific characteristics of optimal voice therapy for this patient group are not known [1]. The first criteria of evidence-based practice (EBP) is to determine if treatment practices are clearly described and readily replicated [8, 9]. The process of describing treatment practices is a complex one, which requires analysis of both external sources (e.g. research evidence) and internal sources (e.g. clinical expertise and practice context) [10]. To begin to address the issues of identifying and describing the characteristics of optimal voice therapy provided for the management of dysphonia in patients with UVFP. This study uses in-depth semi structured interviews with practicing speech-language pathologists to determine their current routine clinical practice for patients dysphonia resulting from UVFP.

A recent systematic review found that there was variability in the characteristics of voice therapy in the research literature, particularly regarding the content, timing and dosage of treatment [1]. One recommendation made by this systematic review was the incorporation of treatment protocols in order improve the quality of evidence for the management of UVFP [1]. Several of the more recent studies examining voice therapy treatment for UVFP have begun to demonstrate increasing methodological quality by articulating specific treatment goals, standardising the content of voice therapy (using protocols), commencing intervention

early and implementing intensive treatment approaches [7, 11, 12]. However, despite these developments, there remains ongoing variability in the literature for the voice therapy characteristics (specifically content, timing and dosage) provided to patients with UVFP. This limits the ability to establish evidence-based voice therapy and the principles of the management for these patients [1].

A recent study by the authors of this paper used a cross-sectional survey design to investigate the characteristics of the voice therapy provided to patients with UVFP by Speech Pathologists [13]. The survey responses from Speech Pathologists (n=110) revealed that the provision of voice therapy is strongly influenced by factors associated with the patient (e.g. age), the clinician (e.g. professional development) and the workplace setting (e.g. waiting lists). The study also found that the characteristics of voice therapy, specifically the content, timing and dosage of treatment, were individualized for patients, rather than directed by a protocol [13]. Figure 1 summarizes the findings of this cross-sectional survey, specifically illustrating the components of the voice therapy used for the management of patients with UVFP. Five key factors were recommended by the previous study to guide the voice therapy selection: aims of the voice therapy, individual approach, timing, content and dosage of the treatment [13]. However, given the design of the study, we were unable to collect detailed information of clinical rationale or decision-making processes of the speechlanguage pathologists with respect to the five key features. Therefore, in order to gain a deeper understanding, it is important to seek the detailed perspectives of experts within the field.

Figure 1. Cross-sectional survey components of voice therapy [13]



Aims of the current study

The current study was designed to gain an in-depth understanding of the decision-making processes and the characteristics of voice therapy used, in the management of patients with neurogenic dysphonia arising from UVFP from the perspectives of expert clinicians. To achieve this, a series of semi-structured, in-depth interviews were conducted with expert voice clinicians about their experiences in the management of UVFP. The data was analysed using a qualitative Framework of Analysis [14] approach.

6.3 Method

The current study used a qualitative phenomenological design to explore the experiences of Speech Pathologists who work with people with UVFP. The therapy schema produced by the cross-sectional survey (Figure 1) [13] was used to guide the interview guide and analysis

of the semi-structured interviews. This approach is in keeping with previous research that has aimed to gather in-depth knowledge of the treatment characteristics of voice therapy for other types of voice disorders [15-17].

The study was approved by the Australian Catholic University Human Research Ethics committee (number: 2016-242E).

Interview guide design

In-depth semi-structured interviews were conducted to allow participants to share detailed perspectives of their clinical reasoning, specifically the 'why' of decisions made relating to characteristics of voice therapy, which were not captured in previous research.

The interview guide was divided into three different sections (a) context, (b) voice therapy for UVFP and (c) factors which influence voice therapy. Questions in the context section focused on the clinical experiences of the speech-language pathologists. Questions related to voice therapy asked about the components of voice therapy used to manage patients with UVFP, and the factors section included questions about the effectiveness of voice therapy and the future directions. To ensure the developed interview guide captured the intended outcomes, the authors reviewed the interview guide with an independent expert qualitative researcher (AS) and conducted pilot interviews with two speech pathologists prior to commencing data collection. The interviews were audio recorded, and transcribed verbatim prior to analysis.

Participants

Participants were recruited from the 110 Speech-Language Pathologist (SLP) respondents to a recently conducted online cross-sectional survey on the same topic [13]. Participants who responded to the cross-sectional survey, were invited to further volunteer to participate

in the semi-structured interviews. A set of three questions were sent to the participants who volunteered to be potential interview respondents (1. How long have you been a speech pathologist?, 2. How many years have you worked assessing and treating voice disorders?, and 3. In the past 12 months, how many patients with UVFP have you seen?). Based on the responses, potential interviewees were selected if they met the criteria for being experienced clinicians in managing patients with UVFP. The inclusion criteria included: at least 1 year of clinical experience, experience managing patients with dysphonia and current or recent treatment of patients with UVFP within the past 12 months. Potential participants were then invited to take part in the interview and provided verbal informed consent prior to commencing the interview.

Interview Procedure

All interviews were conducted by the first author (CW), allowing her to have a first-hand knowledge of the data to support analysis. Interviews were conducted either via skype (6) or via the telephone (1). The interviews were recorded using electronic devices. The complete interview guide is provided in the appendix. The interviews comprised of open-ended questions, which allowed the participants to share their perspectives. All participants were asked the same questions outlined in the interview guide, while additional questions were used to further explore participant responses or gather further detail. Additionally, confirming of responses was conducted during the interview to ensure a 'circling back technique' [18] using such prompts as 'can you tell me more?'.

The interviews ranged in time from 25 - 50 minutes (Average interview length 41 minutes). After the 7^{th} interview there was adequate sampling of speech pathologists and thematic saturation of the data was achieved and no further interviews were conducted.

Analysis of Data

The data analysis was conducted over three months (March – May 2018). The data were analysed using a Framework of Analysis technique as described by Ritchie and Spencer [14]. Upon completion of the interviews, the participants were allocated a participant number based on sequential order (e.g. V001), the de-identified recordings were then transcribed verbatim by a professional transcription service. The written transcripts were sent to the respective participants for review, feedback and approval. This 'interviewee checking' process aided the quality of data collection and trustworthiness of the findings, allowing interviewees the chance to validate the content of the transcripts and ensure that the interview captured their perspectives and clinical experiences [14]. The Framework of Analysis comprises of five stages 1) familiarisation, 2) identifying thematic framework, 3) indexing, 4) charting and 5) mapping and interpretation [14]. Consequently, data analysis commenced with the familiarisation of the data via multiple readings of the transcripts. In the second phase of the analysis, the first author (CW) used the three topics from the interview guide as priori codes used for initial coding. From this analysis the following themes and sub themes were revealed: context (clinical setting, patient features, clinical background), voice therapy for UVFP, and factors which influence the treatment effect. The third phase of the data analysis involved revision and refining of the initial themes, and the identification of a new theme 'evidence- based practice', which became evident from the interview data during initial coding. In the fourth phase, the coded data were extracted from the transcripts and collated into an excel document and mapped by the themes and sub- themes identified from the interviews. The final phase was the mapping interpretation of the key characteristics within the excel document including: diagnosis, pre-voice assessments, goal setting, voice therapy components, progress & review-outcome measures and goals. This final analysis guided the development of a schematic follow chart which allowed for a clear understanding of the interview findings.

6.4 Results

Participants

Seven experienced speech-language pathologists participated in the study (mean of 18 years' experience treating voice disorders). Respondents worked in both hospital (inpatient / outpatient) (75%) and/or private practice settings (25%), with a portion of their clinical caseload including the active assessment and treatment of voice disorders including patients with UVFP. Clinical experience of the interview respondents with voice disorders ranged from two to approximately 30 years (approx. average 15.5 years.

Thematic Analysis

The data revealed four main themes with a series of sub-themes embedded within them, these are outlined in Table 1. Each theme will be described individually.

Table 1. Identified themes and sub-themes

THEME 1: Context for guiding voice therapy including:

- Diagnosis and aetiology
- Glottal insufficiency and compensation
- Patient assessment
- Patient preferences for voice therapy

THEME 2: Components of voice therapy including:

• Therapy techniques

• Timing of intervention

• Dosage (duration and frequency)

• Practice (homework)

THEME 3: Success and Ceasing of Voice Therapy:

• Outcome measurement

Success and treatment progress

• Discharge decisions and progress

THEME 4: Evidence-based practice:

Need for evidence

Future of UVFP research

THEME ONE: Context for guiding voice therapy

A series of key factors were highlighted by the participants with respect to the contextual information they use when making treatment decisions, including diagnosis and aetiology, degree of glottal insufficiency and individual patient factors.

Diagnosis and Aetiology

The speech-language pathologists acknowledged that both the aetiology and severity of RLN injury were key determiners of treatment selection (and prognosis):

"It probably would depend ... on the aetiology of the ... UVFP ... So, whether it was any iatrogenic injury, or whether it's thought to be post viral." (V006)

"If [the UVFP has] ... arisen from a medical procedure...how [has] the nerve... been affected? Has it been damaged, or stretched?... Do we expect recovery?" (V007)

However, the respondents reported that a lack of detail provided in the referrals (that they receive from other professionals) relating to the function of the vocal folds was a barrier to making treatment decisions ("Sometimes the referral [description] is not necessarily what in fact you see [during direct visualisation]." - V004). Additionally, that the use of different diagnostic terminology influenced their treatment selection ("If [the referral states] paresis...see if we can get ... [the vocal fold] ... functioning again, while if it's a paralysis, trying to get that other vocal fold to compensate" - V001).

It was agreed between the speech-language pathologist participants that being involved in the multidisciplinary voice team and being directly involved in the interpretation of diagnostic information (including attendance during the direct visualisation of the vocal folds) enhanced the ability of participants to make treatment decisions:

"Liaison with ENT... working out where the breakdown is, working out how stimulable the patient is [to voice therapy], and ...the patient's ... prognosis." (V006)

Glottal Insufficiency and Compensation

The position of the paralysed vocal fold and resulting glottal insufficiency helped to determine voice therapy goals:

"[It depends on] how big the glottic gap is ... if the [paralysed] vocal fold is sitting in the midline, then ... you can get good glottic closure. But if it's sitting in the paramedian position, it's going to be a different situation." (V005)

Furthermore, the respondents all agreed that a main goal of voice therapy for UVFP was to restore glottal sufficiency:

"Aiming to improve the closure of the vocal folds ...[and] vocal quality so that they can use their voice how they would like to day-to-day." (V001).

When asked to expand on this generic aim, the respondents reported that the restoration of glottal sufficiency referred to improving vocal fold closure ("Assist them ... to get some sound as soon as possible so that they can function". – V005) in order to achieve functional voice ("to give the patient the most functional voice for them, based on what their needs are"-V002). The importance of preventing any abnormal voicing or compensatory habits was also discussed ("not abusing their voice too much. I want them to be using their voice well even with using that functioning vocal fold well and not abusing their voice"-V004).

The observation of the laryngeal movements and the function during voicing, specifically the use of maladaptive compensatory behaviours further helped guide the selection of voice therapy:

[To] "See whether the patient has already developed any secondary behaviours, so we can do something about it in speech therapy... Is that patient getting functional voice out or not?" (V007)

Patient assessment

All respondents reported that patient performance on voice assessments helped determine the level of impact on the voicing subsystems, which guided the focus of the voice therapy for UVFP:

"The first thing we do with all patients is ... assessment of all three areas of phonation, respiration and resonance and we try to look where ... the problem is." (V003).

Specifically, the selection of treatment stemmed from the patient's presenting deficits as indicated by the results of the baseline assessments, indicating a deficiency in one or more of the voicing subsystems:

"My priority [for treatment] would be respiratory and phonatory, but I will always talk to the patients about the three subsystems and talk about trying to get balance across the three subsystems." (V002)

Patient preferences for voice therapy

All of the speech-language pathologists noted that goal setting should be patient-centered:

"It's very much a collaboration with the patient and their perception of their voice, ... one primary goal that's common to all patients would be to get the best voice possible ... As voice therapist, it's very tempting to strive for that ultimate holy grail of the perfect voice for a patient, where it might not be their goal at all." (V007)

Similarly, the respondents reported that there were several key patient factors, which impacted upon the selection of voice therapy. These included the patient's voicing requirements, level of motivation, and availability to participate in voice therapy:

Voicing requirements - "Some [patients] want to talk loud, some want to be heard in background noise, some want to sing again, the next one wants to Skype." (V003)

Motivation - "It's that ... willingness [for a patient] to ... participate in a longer type of treatment than a sort of a quick fix approach [from surgical intervention]." (V004)

"Some of them will ... just be hanging on until they can get the surgery, and I think that affects their motivation in therapy." (V007)

Availability - "Sometimes they're busy, or there's things going on that are distracting them [from undertaking voice therapy]". (V002)

Realistic goals (& prognosis)

Respondents also reported that goals of treatment needed to be realistic and that it was

important that patients were made aware that they are unlikely to achieve the pre-morbid voice quality following therapy:

"It might not be necessarily that they've got a clear voice, or a voice without any dysphonia [post voice therapy], but it ... meets their needs." - V001)

"I think it's important to have a really frank conversation with the patient about what they're likely to be able to achieve from speech pathology... [and allowing the patient] ... to make a decision about whether they want to do therapy." (V003)

THEME TWO: Components of voice therapy:

The participants identified a number of components of the voice therapy that they used to manage patients with UVFP, specifically therapy techniques, timing, dosage and home practice.

Therapy techniques

There was agreement that voice therapy techniques for the management of UVFP included both direct and indirect treatment approaches. There was also agreement that the initial voice therapy techniques focused on vocal hygiene and education to prevent any compensatory behaviours from occurring:

"First session would usually involve goal-setting, and also a discussion of vocal hygiene." (V001)

Direct voice therapy was commonly delivered using a "bottom up" approach, working systematically through the voicing subsystems or from 'simple' to more complex vocal maneuvers:

"Initially focus on trying to ...get an increased drive to the vocal folds ... using diaphragmatic abdominal breathing." (V002)

"Start with a tone that ... [the patient] can get ... [then] ...move on to combinations of vowels and consonants, move on to words, move on to sentences, paragraphs."

(V007)

Interestingly, the direct therapy techniques used for the management of UVFP relied heavily on techniques designed for other non-neurological types of voice disorders. One respondent said: ("It doesn't matter too much which type [of voice therapy technique], because you'll probably get benefit."- V006). Various voice therapy techniques included:

"Forward resonance, or resonance therapy." (V001).

"Vocal Function Exercices." (V003)

"Semi-occluded vocal tract ... straw therapy and Lax Vox." (V004)

"Voicecraft © with the release of constriction, and what we can do with the SOB [quality]...

that's very useful" (V007)

[Lip] "Trilling is a very good basic exercise ...[and] is always more difficult for somebody with a paralysed vocal fold because ...[they] can't build up the air pressure as much." (V005)

The speech-language pathologists reported that the progress through the voice therapy hierarchy was typically quicker for patients with UVFP compared to those with other types of (non-neurological) dysphonia. A reason for this was related to the typical rapid onset of UVFP, as described by V002, "To go from ...a normal voice to a really breathy, asthenic [voice]"; the voice therapy is targeting a new neurological deficit. The focus on the higher levels of the treatment hierarchy was also reported to allow for a more rapid achievement of voice therapy goals and faster functional transference ("Never ... start from scratch with every patient, because [they] ... are able to come up with solutions themselves... [this makes] ... the whole therapy process much shorter."- V003). An example of this was

provided by V003 with respect to Vocal Function Exercises "I would try to make those [four core exercises] more complex, ...more oriented at how we use [the] voice ... during talking [in connected speech]".

All of the clinicians agreed that voice therapy for the management of UVFP requires a combination of art and evidence base practice:

"There's ... an artform to doing it. So, if you're going to do resonant voice therapy or accent method, everyone's going to have their take on it, or their little quirks in how they explain it to the patient, or how they facilitate change in the patient." (V006)

This probably relates to the individual nature of the voice therapy where one approach cannot be used for all patients. It also refers to the patient factors discussed in Theme 1.

Timing of intervention

The timing of voice therapy also appeared to influence outcomes. Participants agreed that early intervention for UVFP was vital for the prevention of secondary maladaptive behaviours. However, it was noted that the application of early intervention can be impacted by external factors beyond the control of the clinician. The factors included clinical waiting lists, access to ENT services and clinical caseload demands:

"Sometimes, by the time they get in to see an ENT and then referred to us, they've got quite a well-entrenched problem". (V006)

Therapy Dosage - Duration & frequency

It was clear from the responses that the dosage of voice therapy provided, were influenced by two other factors: clinical setting and patient factors. Some speech-language pathologists, who worked in a public health care system, described workplace restrictions on the duration of the voice therapy (even allowing for the variation of individual requirements for voice therapy):

"While we are flexible, we do have an unwritten limit on probably around eight sessions." (V006)

While those in private practice noted financial limits to therapy dosage:

"People are paying for their therapy, so the ideal is to try and get them to their goal as quickly as you can... [but] ...I don't set time limits." (V005)

As patients made progress, the intensity of the voice treatment typically reduced:

"I would look at a weekly [voice therapy] treatment for the first three appointments, and then we would make it ... [every] 14 days." (V003)

"I think it's important to keep the momentum going in the beginning, to see whether we can make a change." (V007)

Respondents also agreed that intensive voice therapy was more likely to be more successful than standard (weekly) therapy, however the clinical setting was a barrier to the delivery of intensive treatment.

"Sometimes it just means you've got to cram people into really short session times, to be able to ... [provide intensive therapy]." (V006)

Practice (Homework)

To support the achievement of treatment goals, the speech-language pathologists reported the use of homework to aid learning and the functional transference of the voice therapy tasks. Daily practice and multiple short periods of practice throughout the day for their patients was recommended:

"Daily homework ... no more than fifteen minutes a day." (V001)

"Do the exercises three or four times a day ... only in short bursts." (V005)

However, it was not clear on what basis these recommendations were provided. The respondents reported the use of multiple modalities to support the successful implementation of homework tasks, including written instructions, recordings of the patient and or clinician on smart devices, and the provision of audio recording for the patients.

"Patients will get ... a handout [that] I'll type up." (V002)

"I record everything that I do. Most people use their smartphones and I record all of their exercises rather than having something written out." It often gets lost in translation so what people remember is not actually what you've done in a session."

(V005)

Some of the respondents referred to some of the principles of motor learning and neuroplasticity within the context of home practice and repetitions of treatment tasks was also discussed [19]:

"I think that we can ... go back to ... [the] ... theory on motor learning ... how do we need to change their technique so that they can get it?" (V006)

"Repetition ... is actually doing [the voice therapy exercise]. You're setting up those ... muscles ... [so] ... there's a better chance of ... [the voicing exercise] ... becoming more natural and reflexive." (V002)

[It's like the concept of] "LSVT ...giv[ing] the patient one thing [such as "think LOUD"] to think about - if they can think about that one thing, then that's going to have more benefit [for learning] than thinking about five different things." (V006)

THEME 3: Success and Ceasing of Voice Therapy

To determine the success of voice therapy and to identify when to cease treatment, a range of factors to support decision making was used, including: outcome measures, progress and criteria for discharge.

Outcome measurement

Generally, the outcome measures that respondents reported using had published validity, reliability and responsiveness to change pre and post treatment. ("I ...get other peers to do a GRBAS on ... [patient samples] for reliability and their opinion on [the perceptual voice quality]" – V004). However, one clinician reported using self-developed measures with patients to detect the treatment effect ("I use my own assessments from the Voice Clinic that we developed which involves a questionnaire" – V005). All respondents appreciated the value of a multi-dimensional approach to measurement. ("Covering every aspect [of voicing]." -V003) Participants also reported the use of outcome measures pre, post and during treatment to measure the treatment effect, and report this to their patients.

"To establish what our progress ... [has been] and then decide whether or not further therapy ... [is] warranted or whether possibly surgical intervention ...[is] required." (V005)

"It's really useful ... to say 'You were here when you first came in, and now you're here.' So, you're giving them feedback, and ... you're tracking change." (V006)

Success and treatment progress

The speech-language pathologists reported that generally there was success from voice therapy for patients:

"Most of them have usually met a lot of their goals" (V001)

"I don't think there would be too many that I've seen that wouldn't be able to converse. They might be mildly dysphonic or moderately dysphonic." (V005).

It not clear whether the clinicians kept clear pre and post multidimensional data to support their clinical practice. However, they reported that the prediction of success in voice therapy remains difficult to determine, but all agree that a trial of voice therapy is beneficial for patients with UVFP. To enhance the likely success of voice therapy, the speech-language pathologists used stimulability during the initial visual-perceptual assessment to guide the voice therapy ("try different techniques [during the direct visualization to] guide the treatment." (V001). The importance of monitoring treatment progress by conducting regular reviews of progress either at each session or after a few sessions to determine if improvement was being made, was discussed:

"I would be wanting to see improvement within a session or two, and ... [if the patient hasn't improved] ...I would want to know, is the patient not adherent? ... [Is]... the diagnosis wrong? Are they just not getting the therapy? Am I doing a bad job with the therapy?" (V006)

Participants believed that the success of voice therapy for patients with UVFP was influenced by patient factors:

"I think if you've got the right patient selection ,... if the patient has got capacity to learn, and if they are able to participate in the therapy programs. ... [But,] ... if they don't turn up, and they don't practise, I don't think ... [voice therapy is] ... going to work." (V006)

Again, this point illustrates the overlap with the findings in Theme 1. There was also agreement that success of voice therapy was difficult to determine using some of the impairment voice outcome measures as these were not as responsive to the psychosocial factors for the patient.

Discharge decisions and prognosis

Decisions related to stopping the voice therapy were typically made for each individual based on one of three reasons: a) achievement of therapy goals, b) achievement of functional voice that meets the patient's needs ("It might not be necessarily that they've got a clear voice, or a voice without any dysphonia, but it's a voice that they're happy with, and that they are happy to use" - V001) or c) failure to achieve the goals of therapy in a reasonable amount of time ("If after six sessions, the patient isn't making what I would consider significant progress, to the extent that it's making a difference for them, well then I won't continue voice therapy." - V002). This decision was not always straightforward however ("I think the difficulty comes when the patient has difficulty accepting the voice that they have achieved [from voice therapy] may not be their ideal voice" - V007).

There was an overall consensus that there is not a clear understanding of which patients will benefit from voice therapy and if patients will maintain the treatment effect, so it makes it difficult to provide clear prognostic guide for future patients, or managing patient expectations for voice therapy:

"I really would like to be able to say to patients... you will benefit from voice therapy, or you won't benefit from voice therapy at this time. I'd like us to be able to be much more definitive about what their outcome is likely to be." (V002)

THEME 4: Evidence-based practice

There was a need to improve the evidence base for the management of UVFP and several key areas from participants' clinical experience, which warrant further research.

Need for evidence

All participants noted that there is currently a lack of evidence available across the factors discussed to guide their selection of voice therapy for patients with UVFP. Due to the variable nature of UVFP ("I don't think we're dealing with a homogenous group of patients" - V006) treatment selection was not a one-size fits all approach. Presently, there is no evidence to guide the speech-language pathologists, which treatment benefits which types of patients, so they often use their previous clinical experience and trial and error, as they "haven't really seen a correlation between what [voice therapy] technique[s] and what [patient] factors tend to go together." (V006)

Similarly, the speech-language pathologists noted limited evidence to support their selection of the best voice outcome measures to use with patients who have UVFP:

"We're using the validated outcome measures as much as possible, but I think in some areas, I think we're lacking in definitive measures." (V002)

"I think we need to be using other measures [as the current measures aren't] as sensitive as we would like it to be. We're looking laryngoscopically at ... [the patients vocal folds], but let's have a look at what's happening within the muscles... perhaps using [laryngeal] electromyography." (V007)

It was mostly agreed that There is no consensus for dosage and rather clinical experience guides the drilling and homework recommendations, with one participant discussing the need to be more precise in treatment:

"[To] be much more definitive about how many trials a person should carry out in a session." (V002)

Future of UVFP research

The respondents also noted that there needed to be improvements in the evidence base for the voice therapy management of UVFP. Several considerations for future voice therapy research for UVFP and the success of patient outcomes were discussed. Firstly, the speech-language pathologists recommended a guideline for the multidisciplinary team to help inform treatment planning and when to refer to speech pathology for voice therapy:

"When ... [should the patient] ... have speech pathology? When should ... [the patient] ... have surgical treatment? If ... [the patient has] ... surgical treatment, when should they have speech pathology after that?" (V006)

Secondly, they agreed there is a need for the consensus in the diagnosis of UVFP and the application of standardised diagnostic tools and voice outcome measures with published validity and reliability and responsiveness to change, e.g. the basic protocol for functional assessment of voice pathology [20].

"Some minimum standards about assessment ... and how we describe the disorder." (V006)

Then, with respect to the treatment provided to patients with UVFP, the respondents appeared receptive to the use of a treatment guideline and protocol to help guide patient management and provide the most effective treatment:

"I think it'd be great to have a set program plan. What stage do you say therapy's not working let's ...[recommend] surgical [treatment]." (V004)

Additionally, that further research was required to guide the optimal dosage of the voice therapy for people with UVFP.

"Getting a ... timeframe ... knowing the intensity and the frequency and the valuation of what's effective and what's not." (V004)

"Timing ... That's one of the questions that I find that people do ask very often – how long will this take? How long before I get my voice back? How long before I can see a difference?" (V007)

The speech-language pathologists noted that further investigation was required about the timing of treatment and when to provide voice therapy to patients with UVFP. Despite noting that there was a lack of evidence examining early intervention in UVFP, their knowledge from other areas of voice therapy appeared to provide some guidance for their recommendation of early intervention.

The final two features that the speech-language pathologists identified, which require a stronger evidence base relate firstly to the principles of motor learning, (specifically the acquisition of a new skill by nerves innervated by the peripheral nervous system) and secondly, the impact of fatigue on the voice due to the UVFP (and the impact that treatment has on muscle fatigue):

Number of repetitions - "Be much more definitive about how many trials [per therapy target] ... we don't have that knowledge." (V002)

Fatigue - "Therapy is only going to be effective for a short time probably because of the muscle fatigue...[it]...is a major issue ... when...you're working [with patients]." (V003)

6.5 Discussion

This is the first study to conduct in-depth interviews with speech-language pathologists to explore their clinical perspectives for the management of dysphonia arising from UVFP.

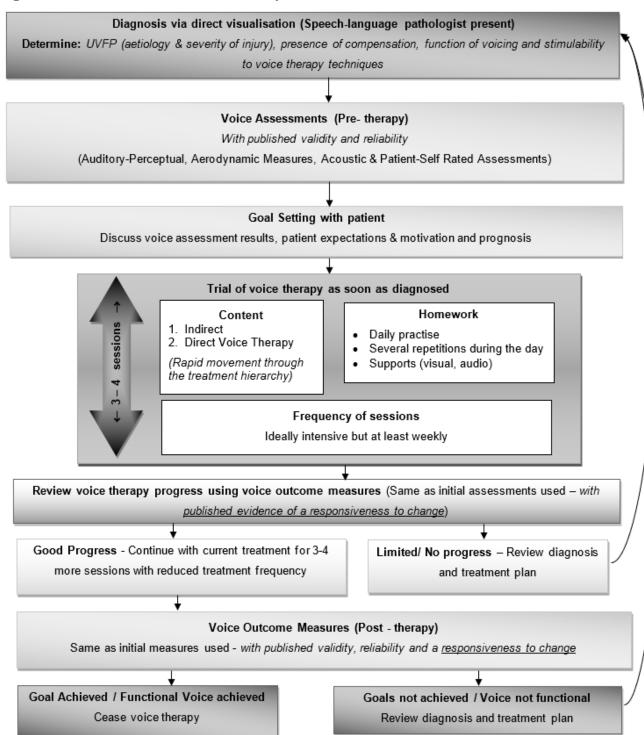
Interviews were conducted with seven speech-language pathologists to investigate their

clinical experience in the voice therapy management of patients with UVFP. The interviewees were all considered to be experienced in the management of dysphonia resulting from UVFP and came from a range of clinical settings and locations throughout the northern and southern hemispheres.

Key Findings

The findings of the in-depth interviews revealed four key themes, which illustrate the perspectives of speech-language pathologists in the management of patients with UVFP. These were 1) Context for providing voice therapy, 2) Components of voice therapy, 3) Success and ceasing therapy and 4) Evidence-based practice. Based on the findings, the previously developed 'Treatment Process Schema' (Figure 1) [13] has been revised to provide a more detailed reflection of the expert approach to speech pathology management of patients with UVFP. Figure 3. shows the current treatment schema incorporating the results from the current analysis.

Figure 3. Current treatment schema for patients with UVFP



Pre-therapy processes

Theme one highlighted the importance of the context information related to the diagnosis, aetiology severity of the nerve injury and the presenting laryngeal function to support clinical decision making. However, barriers to accessing this information have been identified both by the interviewees and the literature [21]. The findings of this study suggest that there is a lack of detail provided to speech-language pathologists in referral information relating to cases of UVFP, and that speech-language pathologists require knowledge of the type of nerve injury (i.e. axonotmesis vs. neurotmesis), to inform treatment decisions. However, it is noted in the literature that there remains a lack of clarity regarding diagnostic terminology, with multiple terms used (e.g. paralysis, paresis and palsy) and a lack of specificity in information provided surrounding the presenting severity of the UVFP and the glottal function [21]. Reaching a consensus for the diagnostic terms used for the diagnosis of RLN injuries leading to UVFP and dysphonia is important for both clinical decisions making for treatment, and support clarity in future UVFP research. To address the lack of specificity in referral information, the benefits of being included in the process of diagnosis and direct visualization of the vocal folds is necessary, something that was discussed by the participants. The attendance of the Speech-Language Pathologist at the initial diagnosis and first-hand assessment/visualization of the presenting glottal function can improve and guide the clinical decision for voice therapy provided by clinicians. The current treatment schema now reflects the first key stage for pre-therapy diagnosis and direct visualization of the vocal folds.

Baseline Voice Assessments/ Pre-treatment Voice Outcome Measures

Once the UVFP has been diagnosed, the speech-language pathologists agreed that a baseline assessment of the different laryngeal subsystems should be conducted as highlighted in Theme one. Similar to the original schema, the current analysis revealed that clinicians recommended the use of multi-dimensional assessment battery, which includes:

acoustic, aerodynamic, auditory-perceptual and patient-self rated measures (Quality of life measures). The results of these pre-treatment assessments help to provide some guidance for the focus of the voice therapy, e.g. respiratory or laryngeal focus. Previous UVFP literature has demonstrated great variability in the types of assessments used and the timing of their application [22, 23]. The findings revealed that the experts selected assessments that had published validity, reliability and a responsiveness to change. Theme 1 also illustrated that these assessments could also be used to measure the treatment effect and to determine the progress of voice therapy during treatment. The findings of the current study clearly support the need for clinical consensus for the most appropriate assessments for establishing baselines for patients with UVFP [22]. The revised schema now reflects the recommended use of voice outcome measures with published validity, reliability and a responsiveness to change furthermore. This supports the recommendations of a recently published systematic review which recommends voice outcome measures with good psychometric properties for measuring the treatment effect [22].

Goal Setting

Goal setting was not present in the original schema [13], however; theme one identified that it is a key component of the treatment process. In particular, the current findings highlighted that for the majority of the speech-language pathologists, the key goal of treatment was to improve glottal closure and achieve a functional voice. Yet, the interviews also identified a number of individual factors that were not identified in previous research [1, 13] which impact on goal setting and treatment selection. These factors were, patient motivation, patient expectations and patient preferences. Clearly, patient factors were primary influencers of the selection of the voice therapy characteristics (content, timing and dosage). The importance of an individual approach to voice therapy was identified by the previous cross-sectional survey study [13], and reflected in the original schema as "patient factors"; however, the current in-depth interviews allowed identification of the patient's individuality, which guide the

decision making. The patient is key to aiding the success of treatment by their willingness to cooperate with treatment and their expectations of the treatment outcomes. To ensure that both the speech-language pathologist and the patient jointly contribute to setting long-term patients goals based on realistic perspectives. The inclusion of goal setting in the updated schema, and the identification of individual factors that are key influences on goal setting decisions illustrates the need to reconsider previous recommendations for developing a standardized protocol, which has previously been used in the literature to treat patients with UVFP [24, 25].

Trial of voice therapy

Both the original schema and the current revision highlight the provision of voice therapy as central for individuals with UVFP. However, theme two in the current findings revealed greater detail for the components of the voice therapy [13]. The speech-language pathologists also reported on factors including timing of the voice therapy, dosage of treatment and monitor of the success, which are discussed below.

The speech-language pathologists agreed that voice therapy should be provided to patients with UVFP as soon as the diagnosis is made, and this is reflected in the current treatment schema. The timing of early treatment was noted to prevent the likely development of any compensatory habits, which may be considered maladaptive for patients with UVFP. The early treatment was also suggested to help ensure patient quality of life and maximize voicing of patients and could be provided early prior to any surgical intervention. However, the interviewees noted that this was not always possible due to setting factors such as waiting lists, delayed referrals and patient availability which was similar to previous findings in the original schema [13]. Despite there not being a clear understanding in the previous research for early intervention, more recent studies have included the provision of early

voice therapy for patients with UVFP [6, 7, 25-27]. The concept of early voice therapy warrants further investigation to compare the treatment outcomes based on the timing of intervention for patients with UVFP.

Similar to the original schema, the current findings suggest that the approach to voice therapy for people with UVFP should include a combination of both direct and indirect treatment (vocal hygiene) (Walton et al., 2018). The current findings however provided more detail regarding the details of the direct and indirect voice therapy provided. Specifically, as reflected in the updated schema, that indirect treatment should focus on the avoidance of any vocally abusive habits and compensation; and that these should be addressed in early treatment sessions. The remaining majority of treatment should focus on direct treatment or combination of treatments to address the presenting glottal insufficiency and the imbalance of the three voicing subsystems. The findings in theme two noted that the selection of the treatment content should be influenced by the findings from the initial assessment. Generally, the content of the voice therapy should target the goal of increasing glottal closure while preventing development of any compensatory behaviours. All agreed that the selected voice therapy(s) should comprise of a treatment hierarchy targeting the respiratory and/or phonatory subsystems and following practice of a single vowel tone in isolation, move from phoneme to conversational level. The content or the specific treatment technique used for UVFP remains variable in both the current and previous studies [5, 6, 13, 26, 28], however; the present study notes that the reason for the variability is related to meeting the individual needs of the patient and the characteristics of the presenting UVFP. Therefore, the included content in the schema in Figure 3 depicts the general focus of the voice therapy but encourages the clinical decision making of the speech-language pathologist to select a content type that is most appropriate for the individual patient. These findings differ from those of the previously developed schema [13] which listed a set of core voice therapy treatment types most commonly used to manage UVFP.

The interviewees agreed that the patients should be completing daily homework practice of the tasks covered in the therapy sessions to allow for functional transference. This idea has not consistently been reported in the literature and was not included in the findings of the previous study and treatment process schema [13]. The speech-language pathologists recommended that the practice of the therapy tasks should be spread out throughout the day occurring over several spaced intervals. They also recommended that the homework tasks should be supported by either written or audio recordings to guide and inform the target vocal quality. Despite limited evidence in the UVFP literature for homework, the clinicians noted to use knowledge from other areas of speech-pathology treatment and clinical experience to guide the treatment.

Dosage

Number of sessions

The interviewees noted in theme two that treatment is typically provided to patients in eight or less sessions to achieve the long-term treatment goals and achieve functional communication at conversational level. Previous research does not specify the optimal number of treatment sessions for people with UVFP, with a range of 1- 40 sessions being reported across the research literature [29], and 1-10 sessions reported by clinician respondents to the cross-sectional survey [13]. Without specific research evidence relation to the optimal number of treatment sessions, the speech-language pathologists have highlighted in theme two that monitoring progress is important in guiding the number of treatment sessions. The respondents reported that more than six- eight sessions without significant progress could be an indication that the therapy approach is not appropriate. Interestingly, the interviewees noted from their clinical experience that for patients with UVFP progress faster up the treatment hierarchy than other types of dysphonia. This may be due to the nature of UVFP (i.e. typically from an acute injury), with less likelihood of

ingrained patterns of muscle misuse and maladaptive vocal behaviours. The updated schema provides a guide for the continuing and the ceasing of the voice therapy based on the progress over the therapy sessions. The findings of theme 1 suggest that the diagnosis and presenting injury should be reviewed if there is not demonstrated success after several voice therapy sessions. Despite there being no clear duration for the voice therapy provided to patients with UVFP, the findings of the current study suggest that 'less is more' when it comes to the duration of therapy and having a treatment effect. These findings highlight the need for further investigation into the optimal duration of voice therapy to attain maximal outcome.

Frequency of sessions

The frequency for the treatment of patients was identified in theme 2 as a key factor in decision making for the management of UVFP. Similar to the original schema [13], theme 2 highlighted that the expert clinicians preferred to offer more intensive treatment at the start of therapy and then reduce the frequency as progress was made. Despite the limited literature to support this recommendation, the interviewees reported from clinical experience that this works effectively for patients with UVFP. The use of intensive treatment is seen in several types of voice therapy treatment to manage presenting dysphonia [30-32] but is yet to be examined for UVFP. The clinical rationale for recommending intensive treatment for UVFP appears to have been guided by principles of motor learning and neuroplasticity as seen in LSVT treatment [33]. Peripheral nerve injuries such as UVFP have a different prognosis and recovery to CNS deficits, treatment for UVFP likely requires a different treatment approach. The concept of neuroplasticity is a key feature in the management of a range of voice disorders. However, the respondents note the potential issues of fatigue and the impact on the frequency of the sessions. Current speech pathology treatment recommendations for CNS conditions (e.g. LSVT) are unlikely to provide a clear guide for the management of a

PNS injury and how best to address the associated fatigue. To date, understanding that UVFP is a PNS injury and how it presents to the majority of dysphonias has not been addressed in the literature or clinically tested yet.

The interviewees noted that the concept of treatment frequency should be the focus of future research, taking into consideration the principles of motor learning and skill acquisition [19] and comparing standard therapy to intensive treatment. Several of the interviewees acknowledged the principles of motor learning as a factor which guides their recommendations from homework and in session repetitions of tasks. It was agreed between the clinicians that there is presently a lack of specificity in the UVFP literature about the optimal treatment recommendations for patients with UVFP and dysphonia in general. Some noted that despite several of the treatment types having clear guides for number of repetitions per task (e.g. Vocal Function Exercise). They are cautious with the practice recommendations they provide for patients with UVFP due to the potential fatigue effects and development of maladaptive vocal compensation if undertaking too many repetitions. Despite this uncertainty, the current treatment schema outlines the interviewee's recommendations for homework. All agreed that research is required to help guide this recommendation but also the consideration of safely compensating for a paralysis and working to maximise the voice and determining the optimal dosage to acquire the goal of the treatment.

Outcome measures: Progress, therapy outcomes and discharge

The previous schema highlighted the use of multi-dimensional outcome measures to measure the treatment effect post therapy. The current results highlighted not only the need for post therapy outcome measurement, but also the importance of using the same outcome measures to track progress during therapy. The majority of interviewees reported using

measures with published validity, reliability and a responsiveness to change. This is an encouraging finding and one conclusion from a recent systematic review demonstrated that there is no consensus about the rationale for the selection of the voice outcome measures and their psychometrics [22]. The speech-language pathologists also noted the rationale for the selection and use of voice outcome measures to help detect the success of the treatment effect, reporting to use voice outcome measures which align with the patient's treatment goals and aims of the voice therapy. No detectable change following a trial of voice therapy treatment, should result in a reconsideration or re-evaluation of the diagnosis and the treatment design. This key finding differs from previous studies, in that there is a timelier expectation for a treatment effect and provides an objective means to determine treatment success and guide clinical management [13]. This finding also supports the use of measures which are valid, reliable and responsive to effectively detect the treatment effect and encourages future research to use consistent measures to help establish a consensus application. The accurate and consistent measure of the treatment effect in patients with UVFP is vital for the establishment of the evidence base.

Additionally, the interviewees recommended that patients should be reviewed after eight sessions via the same voice outcome measures that were conducted as baseline measures. They noted that the voice outcome measures do not always reflect changes following intervention, however they anticipate that patients should experience achievement of goals or functional improvements following a maximum amount of eight sessions. If this is not achieved, the speech-language pathologists agreed that a revision of the diagnosis is required to inform future management the patient would assessment and treatment planning to guide future management. The recommendation and guide for the ongoing assessment or discharge from treatment is presented in the current treatment schema in Figure 3. This provides a clear treatment guide for the management of UVFP and warrants clinical and research investigation to help establish an improved evidence base for the management of

UVFP and better treatment and voice outcomes for these patients.

Limitations / Future Directions

This study used semi-structured interviews to explore the perspectives of speech-language pathologists on the management of patients with UVFP. The seven included speech-language pathologists came from a range of settings and locations, and despite meeting criteria for expertise in the field, it is acknowledged that the clinical experience and perspectives of these speech-language pathologists may not reflect that attitudes and experiences (e.g., generalizability) of all speech-language pathologists in the field. The scope of this current paper did not allow for the inclusion of other multidisciplinary team members i.e. ENT surgeons whose diagnostics contribute to speech-language pathology clinical decision making and treatment planning. Due to the wide range of clinical settings, some of the respondents may have been more integrated into the multidisciplinary team than others and this may limit their clinical experiences and reported perspective. The recruitment of the interview participants from a previous study could be considered to have limited the sample pool and may not reflect the perspectives of the wider speech pathology community. However, that fact that the thematic saturation was met after seven interviews does suggest a considerable level of agreement in the principles of practice.

The feasibility for speech pathologists to apply some of the recommendations from the current treatment schema may be limited due to their clinical setting. The speech-language pathologists should consider what is clinically applicable within their setting and select the clinical safe vs. the clinical optimal practice until further testing of the schema is conducted.

Interestingly, none of the reported intervention to the patients with UVFP focus on the psychology or the counselling of the patients with their dysphonia. This question was not included in the interview guide, however when asked about factors which impact the success of treatment, the well-being of the patients was not discussed. This is intriguing considering the level of deficit perceived by patients with UVFP [34]to other types of dysphonia and

should be addressed by future research.

6.6 Conclusions

This study is the first study to use in-depth interviews to explore clinical perspectives of expert speech-language pathologists regarding the characteristics of voice therapy provided to patients with UVFP and the factors which impact the treatment selection. The results of this study have informed a detailed schema for the voice therapy management of people with UVFP, which could be used to both help guide clinical practice and inform future research in order to improve the state of the literature for the management of dysphonia resulting from UVFP.

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Thank you to the speech-language pathologists who participated in this study. We appreciate your help in participating in the semi-structured interviews - your contribution to this study is invaluable for helping future voice research.

6.7 Appendix

Interview Guide - Semi-structured Interviews - Voice Therapy for UVFP

Context

- 1. Can you tell me about yourself and your experiences as a speech pathologist? *E.g.* current caseload, location, experience with treating voice disorders, experience with UVFP
- 2. What is your perspective on the role of a speech pathologist in the management of voice disorders? Why this particular perspective?
- 3. Thinking about the 3 different subsystems of voicing: respiration, phonation and resonance which subsystem/s should be the primary focus of voice therapy? Why this selection?
- 4. Some people say voice therapy is more of an art than a science, what is your perspective on this?

Voice Therapy for UVFP

- 1. When planning voice therapy for UVFP, what is the primary goal/ aim of the treatment?
- 2. What knowledge/ experience helps guide your goal setting and selection of voice therapy?
- 3. Please tell me about the voice therapy you provide patients with UVFP? Describe the content of the voice therapy you provide? Are there other treatments you have thought about or would consider trying?
- 4. What are your thoughts on the use of treatment protocols e.g. *LMRVT* and hierarchies for voice disorders? Is this effective with the treatment of other dysphonias? Does this have a place in the management of UVFP?
- 5. Thinking about the timing of voice therapy, when should speech pathologists begin voice therapy with UVFP? How long is average treatment block for patients with UVFP? What factors might reduce or prolong this? Does this differ from other voice disorders? Is there a cut off for treatment that you use? (Internal or external)
- 6. Can you tell me where you think the majority of voice therapy/ treatment should be carried out? What role does homework plan in voice therapy? Is there an ideal frequency for voice therapy? How intensive should the voice therapy sessions be?

Factors which influence voice therapy

- 1. What factors impact your selection of voice therapy (Content, timing, duration and intensity) for UVFP? *E.g. Patient, Clinician, Workplace*. What are your thoughts on neuroplasticity and motor learning? Do they have a place in the planning and success of voice therapy? Why/ Why not are these factors considered?
- 2. When is voice therapy for UVFP successful? What makes it unsuccessful? How do you determine the success of voice therapy? *E.g. Voice outcome measures*. Do you go beyond treating the impairment? How frequently do you conduct these measures? What are the barriers to successful voice therapy for UVFP?
- 3. Hypothetically, if you were asked to provide a guide in a voice textbook for the tips to effectively treat patient with UVFP -what would the guide include? (E. g top five tips)
- 4. If you had a magic wand and could do anything, what do you think you would do to improve/change treatment for patients with UVFP? How can we improve the success of treatment for patients with UVFP? E.g. new or unexplored modalities of treatment/ characteristics
- 5. Do you have any additional thoughts or comments you would like to add?

6.8 References

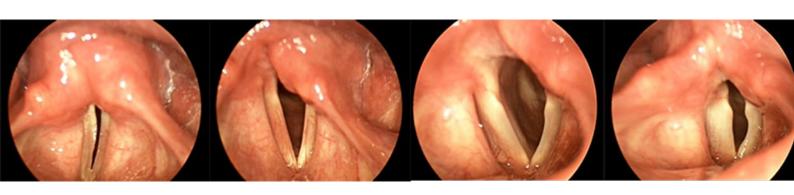
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Section 3– Voice Outcome Measures for Unilateral Vocal Fold Paralysis

Section Three comprises Chapter 7, and will report on the following study, which addresses Aim two of the thesis:

Chapter 7 Study 4: Voice outcome measures for adult patients with Unilateral Vocal Fold Paralysis: A systematic review



7 CHAPTER SEVEN: VOICE OUTCOME MEASURES FOR ADULT PATIENTS WITH UNILATERAL VOCAL FOLD PARALYSIS: A SYSTEMATIC REVIEW.

The first section of this thesis outlined the importance of voice outcome measures as clinical tools used by clinicians to report and detect a treatment effect. The findings of Chapter 2 and Chapter 4 revealed that within the current speech pathology literature and general UVFP literature that there is great variability in the types and timing of the voice outcome measures used to detect the treatment effect.

Chapters 5 & 6 revealed clinical evidence of importance of outcome measurement to clinicians...

This next study will use systematic review methodology to explore the published literature since 2003 and critically appraise the voice outcome measures used by the speech-language pathology and Ear, Nose and Throat studies to detect the treatment effect. A systematic review methodology was selected as it allowed for a critical appraisal of the current research literature.

This chapter is a published manuscript:

Voice outcome measures for adult patients with Unilateral Vocal Fold Paralysis: A systematic review. Walton, C., Carding, P., Conway, E., Flanagan, K. and Blackshaw, H. Laryngoscope (in press)

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Systematic Review

Voice Outcome Measures for Adult Patients With Unilateral Vocal Fold Paralysis: A Systematic Review

Chloe Walton : Paul Carding; Erin Conway; Kieran Flanagan; Helen Blackshaw

Objectives: Unilateral vocal fold paralysis (UVFP) typically results in marked changes in voice quality and performance and has a significant impact on quality of life. Treatment approaches generally aim to restore glottal closure for phonation and improve vocal function. There are a wide range of voice outcome measures that are available to measure the treatment effect. Careful selection of voice outcome measures is required to ensure that they are adequate for purpose and are psychometrically sound to detect the treatment effect. This article aims to critically evaluate the literature for voice outcome measures that are used for patients with UVFP.

Study Design: Systematic review.

Methods: Nine databases were searched for UVFP treatment studies published since 2003 (n = 2,484 articles). These articles and their references were screened using inclusion/exclusion criteria, including population characteristics, treatment, voice outcomes, and study findings. Data from the included articles was extracted and appraised with respect to multidimensionality, timing, selection rationale, validity, reliability, and responsiveness to change of the voice outcome measures.

Results: A total of 29 studies met the inclusion criteria for the systematic review. These studies showed considerable variability in the rationale, selection, and application of voice outcome measures for reporting the treatment effect for patients with UVFP.

Conclusion: There is currently a significant disparity in the selection and use of voice outcome measures for patients with UVFP. A set of principles around selection rationale, validity, reliability, and responsiveness to change is proposed to enhance the judicious selection of voice outcome measures for this patient group.

Key Words: Unilateral vocal fold paralysis, dysphonia, voice, outcome measure.

Laryngoscope, 00:1-11, 2018

INTRODUCTION

Unilateral vocal fold paralysis (UVFP) is the result of a recurrent laryngeal nerve injury due to iatrogenic, idiopathic, or other intrinsic or extrinsic causes. ^{1–3} The loss of voluntary vocal fold movement can result in marked changes in voice quality and performance ^{4,5} and can have a significant impact on quality of life. ^{6–8} Treatment for UVFP aims to improve the voice quality and restore the glottal sufficiency either through voice therapy, surgical intervention, or a combination of the two. ^{4,9} Selection of treatment type for UVFP is based on the severity of the glottal insufficiency, the associated dysphonia, and the vocal requirements of the individual and the clinician. ^{4,10} However, there is limited evidence on which treatment (or combination of treatments) is most

ment effectiveness is the selection and application of voice outcome measures. A previous systematic review of voice outcome measures for UVFP was conducted in 2006 and concluded that there was considerable variability in the selection and application of voice outcome measures for studies of UVFP treatment. The authors also provided a set of key recommendations for future studies. The current systematic review aims to revaluate the progress that has been made related to the recommendations since 2003.

effective. 11-15 One key component to determining treat-

There are a large number of voice outcome measures ¹⁷; therefore, there is a need for clarity of how to determine adequacy of the voice outcome measures used to detect the treatment effect. ¹⁸ Careful selection of outcome measures should be based on a sound rationale related to treatment aims and published evidence (as appropriate) of the tools' established reliability, validity, and responsiveness to change. ^{16,19} Furthermore, the complexity of the human voice means that a multidimensional approach is required to comprehensively measure vocal change over time. ^{19–21} The application of a measurement tool should follow published administration protocols (whenever possible) or be described in sufficient detail to facilitate replication. The establishment of more uniformity in the methods for determining a treatment effect would allow for greater comparison between

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studies. 19,22 The five main categories of voice outcome measures used in the literature $^{19,20,23-26}$ are listed in Table I.

A systematic review of treatment voice outcomes for patients with UVFP has not been published since 2006. 16 The original review (n = 92 articles published up to 2003) concluded that there was great diversity in the selection of voice outcome measures and, to improve the evidence of UVFP treatment, studies should ensure reproducibility, selection rationale of voice outcome measures, and measures with evidence of psychometrics and a responsiveness to change. 16 Our current systematic review therefore aims to retrieve articles since the last review, 16 provide a current review of the voice outcome measures used for patients with UVFP, and determine the extent of progress over the past 11 years. Using a population, intervetnion, comparison, outcome (PICO) framework, 35 we examined studies since 2003 involving adult patients with UVFP (population) who had received treatment for their resulting dysphonia (intervention) in order to determine to what extent the recommendations from the 2006 Baylor et al. 16 review have been implemented (outcome). The review will specifically consider the following aspects: 1) timing (at what time points were the measures taken); 2) selection rationale (do the selected voice outcome measures align with the treatment aims); 3) validity (do the chosen measures have established validity); 4) reliability (do the measures have established reliability and/or do the studies report their own reliability data where appropriate); and 5) responsiveness to change (do the chosen measures show change over time and report effect size).

MATERIALS AND METHODS

The systematic review was undertaken using the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines, ³⁶ and was registered with PROSPERO on December 21, 2016 (CRD42016049737). Subsequent minor changes to the original PROSPERO methodology relate to additions to the inclusion and exclusion criteria.

Voice	TABLE I. Outcome Measures
Category of Outcome Measurement	Definitions and Examples
Visuo-perceptual	Subjective rating of visual images of laryngeal anatomy and function ²⁷ e.g., videostroboscopy, laryngoscopy, stroboscopy research tool ²⁸
Auditory-perceptual	Subjective rating of the perceptual vocal quality ²⁹ e.g., GRBAS, ²⁹ CAPE-V ³⁰
Acoustic	Computerized measurements of features of the speech sound signal ³¹ e.g., jitter, shimmer, noise-to-harmonic ratio, cepstral peak prominence
Aerodynamic	Measures of respiratory components of phonation ²⁹ e.g., maximum phonation time, ³² S/Z ratio, ³³ subglottal pressure
Voice-related quality-of-life measures	Patient-rated assessment of the impact of the dysphonia ¹⁷ e.g., Vocal Handicap Index, ³² V-RQOL ³⁴

CAPE-V = Consensus Auditory-Perceptual Evaluation of Voice, GRBAS = perceptual rating scale (grade, roughness, breathiness, asthenia, strain); V-RQOL = voice-related quality of life.

Search Strategy

Identification of Studies. Nine databases were searched using a systematic approach: AHMED, Central, CINHAL, EMBASE, Medline, PubMED, Scopus, SpeechBITE, and Web of Science. The search comprised of keywords in addition to expanded searches to ensure that all possible synonyms were included (Table II). The search was limited to human studies and with no language restrictions.

Article Screening. Results from the database searches resulted in 3,352 potential studies. These were collated into End-Note, and then all duplicates (n = 868) were identified and removed. The remaining studies (n = 2,484) were then transferred to Covidence (Melbourne, Victoria, Australia), which two authors (c.w. and E.c.) used to conduct the title and abstract screening to meet the inclusion/exclusion criteria (Table III). Studies that reported on cases for which there was an unclear clinical diagnosis of UVFP (i.e., paresis or SLN palsy) were excluded. Similarly, studies were excluded if they focused on treatment of breathing difficulties or dysphagia due to UVFP because these variables may have confounded the findings of this current review. Articles were included for full-text review if the eligibility of the study could not be determined due to insufficient information supplied in the abstract or the absence of an abstract. Conflicts were arbitrated by a third author (P.C.).

The same first two authors (c.w. and E.c.) then assessed the eligibility of the full-text studies (n = 215) to further ensure that studies met the inclusion criteria of the review. Any disagreements were resolved by the third author (p.c.). The reference lists of all full-text articles were also screened by the first author (c.w.) to locate any additional articles not retrieved from the initial database searches (this resulted in the inclusion of one additional article). The PRISMA flow diagram outlining the search strategy for this systematic review is shown in Figure 1. Following this process, a final 29 studies were selected for full data extraction and analysis.

Extraction and Analysis of Data. Following the full-text review, data were extracted from the 29 studies on study design, level of evidence (National Health and Medical Research Council³⁷ definitions), participant characteristics, intervention, voice outcome measures, and timing of outcome measures. The main features of the outcome measures and the criteria for appraisal are listed in Table IV.³⁸

The above criteria in Table IV are intended to help determine study quality and to provide a means of comparison between studies. The selection rationale was based on the recommendations in a previous systematic review by Baylor et al. 16 that studies should select voice outcome measures that align with the study outcomes to accurately detect the treatment effect. Published validity and reliability of the selected voice outcome measures was also reported. 40 Published data with respect to criterion and content validity does not, of course, guarantee construct validity but was seen as the best measure for the purpose of this review. Reliability was determined by the presence of previously published reliability data and the reporting of inter- and intra-rater reliability as appropriate. Finally, we reported on voice outcome measures that indicated a responsiveness to change (P < 0.05) following intervention and on effect size when reported. 41

RESULTS

Critical Appraisal of the Identified Studies

A summary of the etiology and treatment of the UVFP in the 29 included studies are listed in Table V. For the

	TABLE II. Search Terms	
Population	Intervention (Speech-Language Pathology)	Intervention (ENT)
1. "Recurrent laryn*"	13. "Voice therap*"	28. ENT
2. "Unilateral vocal fold"	14. "Voice exercise"	29. "Ear nose throat"
3. "Vocal fold par*"	15. "Speech patholog*"	30. "Ear nose and throat"
4. "Unilateral vocal cord"	16. "Speech language patholog*"	31. Laryngolog*
5. "Vocal cord par*"	17. "Speech therap*"	32. Otolaryng*
6. "Unilateral recurrent laryn*"	18. "Voice training"	33. Combine 28–32 using "OR"
7. "Laryn* palsy"	19. Combine 13–18 using "OR"	34. Microlaryng*
8. "Laryn* hemipleg*"	20. Therap*	35. Surg*
9. "Glott* incompetence"	21. Treatment	36. Laryngo*
10. "Vocal fold immob*"	22. Management	37. Thyroplast*
11. "Vocal cord immob*"	23. Rehabilitation	38. VOX
12. Combine 1–11 using "OR"	24. "Behavio* management"	39. Mediali*
	25. Intervention	40. Augment*
	26. Combine 21–25 using "OR"	41. Inject*
	27. Combine 20 and 26 using "AND"	42. Aryten*
		43. Adduct*
		44. Montgomery
		45. Reinnervat*
		46. Implant*
		47. "Electrical stimulation"
		48. Phonosurg*
		49. Reposit*
		50. Restorat*
		51. Combine 34–50 using "OR"
		52. Combine 33 and 51 using "AND"
		53. Combine 27 and 52 using "OR"
		54. Combine 12 and 53 using "AND"

Filter = 18 years + & Humans. ENT = ear, nose, and throat. (*) - truncation symbol

purposes of this review, the etiology of the UVFP was classified using three categories: 1) iatrogenic, 2) idiopathic, and 3) other causes. Treatment modalities were categorized as either voice therapy, laryngoplasty (for the purposes of this review, no distinction was made between injectable substances or type of framework surgery), and reinnervation. Of the 23 studies reporting etiology, n=19 studies (66%) reported on patients with iatrogenic UVFP, which is reported in the literature as the most common etiology. Furthermore, of the 29 total studies, n=18 (62%) reported on

laryngoplasty (only) outcomes for the management for UVFP dysphonia. Laryngoplasty has been identified as the most common intervention for UVFP and has been described as a gold standard for the treatment of UVFP by some authors. 13,46

Type and Timing of Voice Outcome Measures

Table VI outlines the outcome measures (according to the five main categories) and the timing of the measurements in the 29 included studies. Over half of the studies, n = 18(62%), reported using four or more (i.e., multidimensional) voice outcome measures to detect a treatment effect. 21,74 However, the number of voice outcome measures varied greatly between studies, ranging from one to five voice outcome measures, with only nine studies (31%) using outcome measures from all five main categories. Some form of both acoustic and aerodynamic measures was used by 83% (n = 24) of studies. The other main categories were used less frequently: visuo-perceptual, n = 22 (76%); auditory-perceptual, n = 21 (75%); and patient self-rated, n = 17 (59%). The timing of the postintervention assessments was reported in only 55% of studies (n = 16) and ranged from 1 week to up to 24 months posttreatment.

Rationale for Voice Outcome Measures Used

Only four studies (14%) provided a clear rationale for the selection of the voice outcome measures used. 14,49,55,73 These studies provided a rationale for the selection of the voice outcome measures that aligns with the objectives and aims of the study. 16 The lack of rationale for the selection of voice outcome measures for the remaining studies may impact the quality of the results, the validity of the study conclusions, and the applicability of the findings to the clinical population. 16

Table VII provides a summary of the published validity, reliability, and responsiveness to change of the voice outcome measures.

Validity of Voice Outcome Measures Used

A total of 12 of the voice outcome measures across four of the five categories had published validity studies to support their selection. It is acknowledged that a number of voice outcome measures have incomplete or contentious validity findings. In general, the patient-self rated voice outcome measures commonly had considerable evidence of face and criterion validity data, and these measures were used across 17 studies in this review. Despite the availability of several visuo-perceptual voice outcome measures with associated validity data, none were used in the studies included in this review. Table VII summarizes the validity of the outcome measures used in the identified studies, split into the five main categories of voice outcome measures.²⁰ Note that for the purposes of this review, published validity was a yes/no question only, and there was no attempt to characterize the nature of the validity (i.e., criterion, content, or construct validity).

Inclusion and	Exclusion Criteria
Inclusion	Exclusion
Prospective study designs	Articles prior to 2003 (due to their inclusion in a previous systematic review ¹⁶
Adult participants aged 18 years+	Unilateral vocal fold paresis, bilateral paralysis, poorly described diagnose (e.g., unable to differentiate paresis and paralysis)
Diagnosed unilateral vocal fold paralysis (affecting either the L or R recurrent laryngeal nerve) diagnosed via direct visualization	Diagnosed superior laryngeal nerve paralysis or high vagal lesion
Presence of dysphonia/voice disorder warranting treatment	Presence of dysphagia (swallowing difficulties) or breathing difficulties
Intervention provided to treat the dysphonia by: 1) voice therapy (provided by a speech-language pathologist); 2) surgery (provided by an ENT); and 3) combination of surgical and voice therapy treatment	Dysarthria (motor speech deficits) or multiple cranial nerve involvement
Reported pre- and postoutcome measures both published/unpublished and report on the treatment effect following intervention	Previous vocal fold and/or head and neck surgery
Randomized control trials, pseudorandomized control trials, comparative study (with concurrent controls), comparative study (without concurrent controls),	Case study

TABLE III.

ENT = ear, nose, and throat; L = left; R = right.

and case series

Reliability of Voice Outcome Measures Used

Table VII also includes a summary of the reliability of the voice outcome measures used in the identified studies. The table both describes whether the measures have previously published reliability data to support the selection (column 4: published reliability) and lists those studies that have reported on internal reliability within their specific study, especially for interand intra-rater reliability of perceptual judgements (column 5: reported reliability).

For the purposes of this review, published reliability was a yes/no question only and there was no attempt to characterize the nature of the reliability (i.e., test-retest or internal reliability). Reporting intra- and inter-rater reliability when appropriate is seen as an indication of quality implementation of outcome measurement

Of the included voice outcome measures, a total of nine were found to have published reliability data to support their selection. Similar to validity, the reliable measures were found in four categories of voice outcome measures. A total of six studies (21%) reported internal reliability of the selected voice outcome measures used. Four of the six studies reported the reliability of unpublished outcome measures tools: one visuo-perceptual rating scale (n = 1) 47 and three auditory-perceptual rating tools. 47,54,56 Of the published outcome measures, the GRBAS was the only tool which was found to have both

published reliability and studies that reported inter/intra-rater reliability of the tool. Overall, there was limited published reliability of the voice outcome measures used in the studies and limited reporting of reliability within studies.

Responsiveness to Change for Voice Outcome Measures Used

Table VII also provides a summary of whether studies reported responsiveness to change of the outcome measures postintervention. Responsiveness to change was determined by a statistically significant difference (P=<0.05) between pre-and posttreatment measures. We recognize that responsiveness to change is more appropriately reported by including effect size rather than P values alone. However, only one study 55 reported effect size; therefore, further reporting of clinical meaningful differences was not possible.

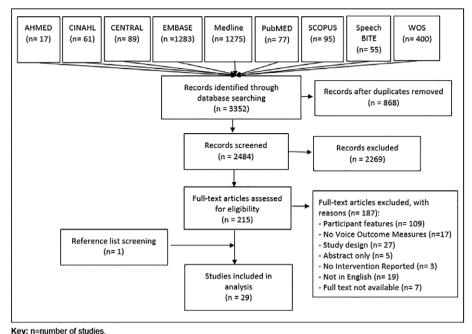
A total of 93% of the included studies demonstrated responsiveness to change on one or more voice outcome measures at a statistically significant level of P = < 0.05. Two studies did not document a responsiveness to change following intervention. All five categories of voice outcome measures appeared to demonstrate a responsiveness to change following intervention. Overall, the results indicate that a large number of voice outcome measures appear to be responsive to change following intervention for UVFP. Only one study reported a size effect to determine clinical meaningful responsiveness to change.

DISCUSSION

This systematic review evaluated 29 studies published since 2003 that used voice outcome measures to detect the treatment effect for adult patients with UVFP. The studies were appraised for their selection and use of voice outcome measures considering the following features: 1) timing, 2) selection rationale, 3) published validity, 4) published and reported reliability, and 5) responsiveness to change. The findings of this review revealed there currently is no consistent approach to the selection and use of voice outcome measures in this field. These findings are consistent with the previous review in published in 2006¹⁶ and suggest that there has been minimal uptake of the author's recommendations. In their review, Baylor et al. 16 recommended that future UVFP intervention studies should use an outcome measure protocol, provide a rationale for voice outcome measures, and promote a quality research design and methodology (to presumably enhance reliability). This current systematic review reveals there has been limited progress in adopting these recommendations over the past 12 years.

Summary of Findings

Of the studies included in this review, 93% reported a treatment effect following intervention using one or more voice outcome measure. Although the majority of studies reported positive treatment outcomes, the variability in the selection of outcome measures, as well as



Rey: n=number of studies

Fig. 1. PRISMA of search strategy for the current study.

differing features of the measures, limit the clinical impact of the findings. The accurate measurement of treatment effects requires the utilization of outcome measures that have evidence of validity, reliability, and responsiveness to change to detect the treatment effect ^{39–41,81} Without a standard adoption of these features, it is not possible to compare intervention studies or engage meta-analysis to strengthen the evidence base.

The current review identified several voice outcome measures that demonstrated acceptable levels of reliability, validity, and responsiveness to change following intervention. The GRBAS²⁹ auditory-perceptual rating, acoustic measures of jitter and shimmer, and aerodynamic measures of maximum phonation time³² demonstrated evidence of published validity, reliability, and a responsiveness to change following intervention for UVFP. In addition, three patient self-rated tools also demonstrated acceptable evidence of validity, reliability, and responsiveness to change: Voice Problem Self-Assessment Scale (VPSS-20),⁷⁸ Voice-Related Quality of Life (V-RQOL),34 and Vocal Performance Questionnaire (VPQ).80 However, there was minimal evidence provided for validity, reliability, and responsiveness to change for any of the visuo-perceptual voice outcome measures that were reported.

State of Evidence

It is clear that a critical mass of studies (n = 120 from Baylor et al. 16 study; 29 from this study) have examined the effectiveness of a variety of interventions for patients with UVFP. However, it appears that only a few very recent studies have adopted a high-quality approach to voice outcome measurement. To continue progress toward higher levels of evidence, 37 future researchers must implement improved methodological quality and

the implementation of a voice outcome measures protocol that aligns with treatment goals and incorporates measures that have demonstrated validity, reliability, and responsiveness to change. It is not clear why the UVFP research literature has not adopted these principles of voice outcome measurement. However, it is important to note that this lack of consensus and consistency of voice outcome measurement is also seen in many other areas of voice disorder treatment research, including muscle tension dysphonia, vocal fold nodules, and the management of mass lesion organic dysphonia. §2

Recommendations for Voice Outcome Measures in UVFP

Based on the findings of this systematic review, the following recommendations for selection of voice outcome measures are proposed for future UVFP intervention studies:

Features and Crit	TABLE IV. eria of the Voice Outcome Measures ^{16,39}
Feature of the outcome measure	Criteria
Selection rationale	Provides a rationale for the selection voice outcome measure that meets the objectives/aims of the study
Validity	Published evidence of the validity of the outcome measure for a dysphonic population
Reliability	Published evidence of the reliability of the outcome measures for a dysphonic population Documented inter-/intra-rater reliability of the outcome measure in the included study (where appropriate)
Responsiveness	Results of the study documenting a statistically significant change ($P < 0.05$) and effect size in the outcome measure following intervention

TABLE V. Summary of Studies

Authors	Year	NHMRC Level of Evidence ³⁷	n	Etiology	Treatment
Level II studies					
Kao et al.47	2017	II	19	Idiopathic latrogenic Other	A vs. A
Pei et al.48	2015	II	29	Idiopathic latrogenic	A vs. B
Paniello et al.14	2011	II	24	NR	B vs. C
Lau et al.49	2010	II	41	NR	B vs. B
Level III studies					
Busto-Crespo et al.50	2016	III-3	70	Idiopathic latrogenic Other	Α
Ras et al.51	2016	III-1	29	NR	Α
El-Banna et al.52	2014	III-2	42	latrogenic	Α
Lee et al. ⁵³	2014	III-3	19	latrogenic Other	С
Colton et al.54	2011	III-3	26	Idiopathic latrogenic Other	A & B
Little et al.55	2011	III-2	17	NR	В
Cantarella et al.56	2010	III-3	30	latrogenic	Α
Level IV studies					
Wong et al. ⁵⁷	2016	IV	11	Idiopathic latrogenic	В
Garcia Perez et al.58	2014	IV	10	NR	Α
Powell et al.59	2014	IV	68	Other	В
Rohde et al.60	2012	IV	9	Other	С
Stow et al. ⁶¹	2012	IV	13	Idiopathic Other	В
Cantarella et al.62	2011	IV	43	Idiopathic latrogenic Other	В
Hassan et al.63	2011	IV	13	Idiopathic latrogenic Other	С
Mattioli et al.64	2011	IV	74	Idiopathic latrogenic Other	Α
Rudolf et al.65	2011	IV	19	Idiopathic latrogenic Other	В
Bergamini et al.66	2010	IV	15	10 with latrogenic	В
Kimura et al. ⁶⁷	2010	IV	11	Idiopathic Other	В
Pratap et al. ⁶⁸	2009	IV	5	Idiopathic latrogenic Other	В
Shiotani et al.69	2009	IV	56	NR	В
D'Alatri et al.8	2008	IV	30	Some with Idiopathic latrogenic	Α
Storck et al.70	2007	IV	26	Idiopathic latrogenic Other	В
Nishiyama et al.71	2006	IV	8	latrogenic Other	В
Sittel et al.72	2006	IV	14	Idiopathic latrogenic Other	В
Lundy et al.73	2004	IV	20	Idiopathic latrogenic Other	В

A = voice therapy; B = laryngoplasty; C = reinnervation; n = number of participants; NHMRC = National Health and Medical Research Council; NR = not reported.

Multidimensional Voice Outcome Measures. The human voice is a complex phenomenon comprised of different subsystems that may change following intervention. Therefore, to accurately detect the treatment effect of UVFP, a multidimensional approach (i.e., measures of four or more voice parameters) is required. ^{19,21,39} A unidimensional approach to voice outcome measurement is unable to provide the adequate information to support treatment effectiveness and may produce false-positive results. ⁸³ Future studies that set out to measure change following treatment for UVFP should aim to use a range of measures, including visuo-perceptual, auditory-perceptual, acoustic, aerodynamic, and voice-related quality-of-life measures.

Timing of Voice Assessments. The timing of the voice outcome measurement requires careful consideration to allow for optimal detection of the treatment

effect. The variability in timing of postintervention outcome measures (1 week-24 months) makes comparison between studies and interventions problematic. Furthermore, the published studies provided limited information to determine the long-term treatment effect for patients with UVFP. It is unlikely that surgical treatment effects (e.g., laryngeal reinnervation) can be accurately detected in a timeframe of less than 12 months.84 Timing of posttreatment assessment and follow-up needs careful consideration to ensure adequate time to detect the treatment effect and to establish the longitudinal maintenance of the treatment effect. In many cases, this may result in follow-up data for up to 1-year posttreatment. It is important to note that this lack of consistency of timing of measurement is also found within other areas of voice therapy, including Parkinson disease-related voice disorder, 85,86 functional voice disorders, 87,88 and vocal fold nodules. 82,89,90

TABLE VI.
Summary of Types and Timing of Voice Outcome Measures Used

Authors	Year	Auditory-perceptual	Visuo-perceptual	Acoustic	Aerodynamic	Patient Self-rated	Timing Voice Outcome Measures (postintervention)
Kao et al.47	2017	X	X	Х	Х	X	ND
Ras et al.51	2017	X	X	Х	X	X	ND
Busto-Crespo et al. ⁵⁰	2016		X	Χ	Х	Χ	1 month and 1 year post-
Wong et al. ⁵⁷	2016	Х	X	Χ		Χ	1 week, 1 month, and 3 months post-
El-Banna et al.52	2015	X	X	Χ	X	X	ND
Pei et al. ⁴⁸	2015		X	Χ	Х	Χ	1 month, 3 months, and 6 months post-
Lee et al. ⁵³	2014		X	Χ	Х	Χ	6 months, 12 months, and 24 months post-
Garcia Perez et al.58	2014		X	Х	Х		ND
Powell et al. ⁵⁹	2014	X				X	2 weeks post-
Rohde et al.60	2012	X	X			X	ND
Stow et al.61	2012			Х	X		ND
Cantarella et al.62	2011	X	X	Х	X	X	3 months and 6 months post-
Colton et al.54	2011	X					1 month and 3 months post-
Hassan et al.63	2011	X		Х	X		1–3 months, 6–8 months, 12–14 months, and 24 months post-
Little et al.55	2011	X		Х			ND
Mattioli et al.64	2011		X	Х	X	X	ND
Paniello et al.14	2011	X	X	Х	X	X	6 months and 12 months post-
Rudolf et al. ⁶⁵	2011	X	X	Χ	Х	Χ	3 days, 6 weeks, 6 months, and 12 months post-
Bergamini et al.66	2010	X	X	Х	X	X	3 months and 6 months post-
Cantarella et al.56	2010	X	X	Х	X	X	ND
Kimura et al.67	2010	X	X	Х	X		ND
Lau et al. ⁴⁹	2010		X	Χ	Х	Χ	1–4 weeks, 3 months, and 6 months post-
Pratap et al.68	2009	X		Х	Х		ND
Shiotani et al.69	2009	X		Χ	Χ		Up to 6 months post-
D'Alatri et al.8	2008	X	X	Χ	Χ	Х	6 months post-
Storck et al.70	2007	X	X	Χ	Χ		ND
Nishiyama et al.71	2006		X		Χ		1 year post-
Sittel et al.72	2006	X	X	Х	X		ND
Lundy et al.73	2004	X	X		X		1 month post-

ND = timing of postintervention voice outcome measures not described; X = indicates the use of a measure/s within the study.

Treatment Rationale. A clear statement of the treatment aims of an intervention will inform the selection of the most appropriate outcome measures. Clear documentation of the rationale for measurement choice a priori is important to avoid potentially biased selection of post-treatment outcomes and false-positive results. We reported on only four studies that provided a clear rationale for the selection of the voice outcome measures based on the specific goals of the treatment approach. H4,49,55,73 Therefore, it is important that future studies include an articulation of the treatment aims and provide a clear rationale to support the selection and inclusion of the voice outcome measures to match the aims of intervention.

Published Validity of Outcome Measures. The accurate detection of a treatment effect also requires the use of voice outcome measures with established validity

(to ensure that the measures are measuring what they claim to be measuring).³⁹ Debate remains about the completeness of the validity studies for some voice outcome measures.¹⁹ However, the availability of some supportive validity data did not appear to influence the preference of the voice outcome measures used in most of the studies reviewed in this article. It is unclear why authors have not selected outcome measures with published validity and have, in some cases, developed their own outcome measures to detect the treatment effect. The lack of validity of the included voice outcome measures may lead to measures that are not able determine what was intended and thus may not reflect the actual treatment effect for UVFP.

Reliability of Outcome Measures. The selection of effective voice outcome measures also requires measures with established reliability to ensure consistency of findings

	Summary of Voice Outcome	TABLE VII. Summary of Voice Outcome Measures and Published Validity, Reliability, and Reported Responsiveness to Change	I. Reliability, and Reported Respon	siveness to Change	
Outcome Measures	Total Number of Papers	Published Validity	Published Reliability	Reported Reliability (embedded in the study design)	Responsiveness to Change (study with findings indicating responsiveness to change at P < 0.05 level)
Visuo-perceptual ratings Published	None	None	None	None	None
visuo-perceptual rating scales Unpulished visuo-perceptual rating scales	$n = 23^{6.14,47,48,50-53,56-58,60-62,64-67,70-73}$	None	None	n = 1 ⁴⁷	$n = 6^{8,47,49-51,53}$
Auditory perceptual ratings	98.58.66	8.56.66	N STORY		28.58.66
GRBAS ²⁹	n = 12 ^{14,51} ,52,55,57,59,60,62,63,67–69	$n = 12^{14,51,52,55,57,59,60,62,63,67-69}$	n = 12 ^{14,51} ,52,55,57,59,60,62,63,67–69	n = 2 ^{57,63}	n = 3 $n = 11^{14,51,52,55,57,59,62,63,67-69}$
RBH ⁷⁶	$n = 2^{65,70}$	None	$n = 2^{65,70}$	None	$n = 2^{65,70}$
Other*	$n = 4^{47,54,72,73}$	None	None	$n = 3^{47,54,56}$	n = 1 ⁴⁷
Acoustic measures					3
Р0	$n = 14^{8,48,50,51,56-58,61,62,64-67,70}$	None	None	NA	n = 1 ⁶⁴
Jitter	$n = 16^{8,47-53,55,56,58,62-65,68}$	None	None	NA	$n = 11^{8,47,49,51,53,55,56,58,62-64}$
Shimmer	$n = 16^{8,47-53,55,56,58,62-65,68}$	None	None	NA	$n = 13^{8,47,49,51,53,55,56,58,62-65,68}$
NHR	$n = 13^{8,47,49-51,53,55,56,58,62-64,69}$	None	None	NA	$n=12^{8,47,49,53,55,56,58,62-64,68,69}$
Other [†] vAM, vF0, DUV, VTI F low H ²	$n = 24^{8,14,47-53,55-58,61-70,72}$	None	None	ΑΝ	$n = 12^{8,14,51,55,56,58,61,65,68-70,72}$
maximum intensity, minimum intensity, pitch range, intensity range, RPDE, DFA, correlation dimension, CPPS-s, NNE, contact quotient, RAP, PPQ, sPPQ, sPPQ, APQ, sAPQ, SPI					
Aerodynamic measures MPT ³²	n – 958.14.47–53.56–58.61–73	n – 958,14,47-53,56-58,61-73	n – 958,14,47–53,56–58,61–73	4 Z	n - 918,14,47-49,51,53,56,58,61-68,70,71,73
S/Z ratio ³³	n = 1 ⁴⁸		n = 1 ⁴⁸	Z Y	None
Mean flow rate	$n = 10^{47,49,51,53,61,63,67,70,71,73}$	None	None	Ϋ́	$n = 5^{49,61,63,67,71}$
Other* PTP, PQ, glottal flow rate, vital capacity, maximum flow rate, peak air pressure, mean air pressure, mean power, mean resistance Patient self-rated	n = 9 ^{47,49,51,61,63,67,70,71,73}	None	None	⋖ 2	n = 3 ^{47,51,73}

Outcome Measures VHI32 VHI-1077 VPSS-2078	Total Number of Papers n = 118,47,49,593,56,57,80,62,64-66 n = 1 ⁵⁰ n = 2 ^{51,52}	(Continued) Published Validity n = 11 ^{8,47,49,53,56,57,60,62,64-66} n = 1 ⁵⁰ n = 2 ^{51,52}	Published Reliability None None None	Reported Reliability (embedded in the study design) NA NA	Responsiveness to Change (study with findings indicating responsiveness to change at P < 0.05 level) n = 984749.53.56.57.62.64.66 n = 150 n = 251.52
V-RQOL ³⁴	n = 1 ¹ 4	n = 1 ¹⁴	$n = 1^{14}$	Y Y	n = 11. ⁴⁴
VPQ ⁸⁰	n = 1 ⁵⁹	- E C	None	Y Y	n = 1 ⁵⁹

*Investigator-designed or single outcome measure examples of auditory-perceptual measures

*Single examples or variations of aerodynamic outcome measures

(roughness, breathiness, hoarseness); RPDE = nonlinear recurrence period APQ = amplitude perturbation quotient; CPPS-s = cepstral peak prominence speech; DFA = detrended fluctuation analysis; DUV = degree of unsounded voice; F0 = fundamental frequency; F low Hz = fun damental lowest frequency; GIRBAS = perceptual rating scale (grade, irregularity, roughness, breathiness, asthenia, strain); GRBAS = perceptual rating scale (grade, roughness, breathiness, asthenia, strain) ilter = cycle-to-cycle variations of fundamental frequency (Hz); L = left; MPT = maximum phonation time; NHR = noise-to-harmonic ratio; NNE = normalized noise energy; PPQ = pitch perturbation quotient; PTP : phonation threshold pressure; PQ = phonatory quotient; R = right; RAP = relative average perturbation; RBH = perceptual rating scale Self-Assessment Scale; V-RQOL = Voice-Related Quality of Life; VPQ = Vocal Performance Questionnaire; VTI = voice turbulence index. density entropy; sAPQ = smoothed amplitude perturbation quotient; shimmer = cycle-to-cycle variations of amplitude (dB); ion's coefficient of amplitude; vF0 = frequency variation; VHI = Voice Handicap Index (30

and accurate reporting of the treatment effect. A number of studies used the GRBAS²⁹ and RBH (roughness, breathiness, hoarseness) ⁷⁶ auditory perceptual rating scales, for which the GRBAS has extensively published reliability data. ^{91–93} However, it is methodologically sound to also report internal (inter- and intra-rater) reliability. ^{57,63} The variety of further methodological approaches that can enhance measurement reliability, including repeated measures and blinding, are commonly used in other areas of voice pathology research (e.g., ^{19,20}. The use of voice outcome measures without published reliability data and reporting of internal reliability limits the comparability within and between studies and undermines the quality of the results.

Responsiveness to Change. It is also important to ensure that the selected voice outcome measures have evidence of responsiveness to change and an effect size following intervention. The results of this review revealed that the majority of measures were responsive to change (as determined by reporting a statistically significant difference), but only one study [55] reported an effect size (to determine a clinically significant difference). However, when considering the responsiveness in the context of the other outcome features (e.g., validity, reliability, rationale), the varied degree of quality and clarity across these features may limit the confidence in conclusions regarding whether the change relates to the targeted intervention.

CONCLUSION

This systematic review demonstrates a current lack of consensus in the selection and use of voice outcome measures for detecting the treatment effect in patients with UVFP. None of the studies included in the current review (n = 29) have effectively implemented guidelines that have been developed for voice outcome measures for other voice populations. ^{19,20} Furthermore this review indicates that the recommendations from Baylor et al.'s previous review ¹⁶ have not been followed. However, several recent studies have shown considerable improvement in the methods of selection and use of voice outcome measures. ^{14,50,53,65} Future research should therefore consider the recommendations outlined above to increase the quality of research into of treatment effectiveness for patients with UVFP.

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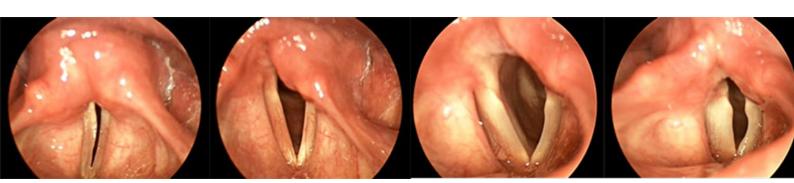
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Section 4– Summary & Conclusions

Section four comprises of Chapter 8 which provides a summary and conclusions of the thesis findings:

Chapter 8: Summary of findings & Recommendations for future studies



8 CHAPTER NINE: SUMMARY OF FINDINGS & RECOMMENDATIONS FOR FUTURE STUDIES

Through a series of four studies, this thesis aimed to investigate the characteristics of voice therapy provided to patients with Unilateral Vocal Fold Paralysis (UVFP) and to critically evaluate voice outcome measures that are used for patients with UVFP. The results of this thesis revealed a number of important findings. Firstly, there is limited published evidence for the management of UVFP and a lack of consensus for the voice therapy characteristics provided. Secondly, there are several factors which influence the clinical decision making of speech-language pathologists for the selection of the voice therapy characteristics. Thirdly, the findings of this thesis identified a treatment process schema for the speech-language pathology management of patients with UVFP. Finally, there are several voice outcome measures with good psychometric properties which have demonstrated the ability to detect the treatment effect for patients with UVFP. It was beyond the scope of this thesis to test the recommended voice therapy schema for the management of UVFP, however these findings should be considered in clinical practice and future research. The findings of this thesis have the potential to improve the voice therapy treatment for patients with UVFP and the treatment outcomes and quality of life for patients with dysphonia arising from UVFP. This chapter provides a brief review of the theoretical and clinical imperatives for the thesis (section 9.1), a synthesis of the major findings (section 9.2), an exploration of the implications of the findings for the broader literature (section 9.3) and an outline of the limitations of this thesis and suggestions for future research (section 9.4).

8.1 Theoretical and Clinical Imperatives

Unilateral vocal fold paralysis results in a voice disorder caused by a loss of innervation to one of the vocal folds leading to a glottal insufficiency. UVFP arises from an axonotmesis or neurotmesis injury to one of the RLN branches which leads to a flaccidity to the intrinsic laryngeal muscles required for voicing [1]. UVFP can have a significant impact on quality of life of patients [2-4] due to the perceptual breathy, rough and weak voice resulting from the flaccidity. In addition to the perceptual features of UVFP, patients can also develop maladaptive voicing patterns to compensate for the glottal insufficiency [5, 6]. UVFP can arise from a range of aetiologies and the prognosis depends on many factors, including aetiology, severity of the nerve injury and the size of the glottal gap. Patients with dysphonia due to UVFP typically require treatment to improve the glottal sufficiency and restore voicing through voice therapy, surgical treatment, or a combination of the two. Selection of treatment type is based on the presenting glottal insufficiency, vocal functioning, clinician factors and patient factors [7]. Voice therapy provided by speech-language pathologists is commonly considered as the initial treatment option for patients with dysphonia due to UVFP [8]. However, there is presently inadequate development and documentation of the voice therapy characteristics used to treat patients with UVFP resulting in poor treatment efficiency [9, 10]. To measure the treatment effect, clinicians use voice outcome measures that are responsive to detect the treatment effect including such features as the size of the glottal gap, the quality of the voice, the level of vocal endurance and the patient perceptions of the voice disorder [11]. Presently, there is variable and inadequate application of voice outcome measures to determine treatment effect in patients with UVFP [12]. This thesis has addressed these key gaps within the UVFP literature and helps to provide a clear guide moving forward for the evidence base and improvement of the treatment and voice outcome measures used with patients with UVFP.

8.2 Integration of results

This thesis has included multiple methodologies via a series of four studies to explore the two aims of the thesis. The first aim was to investigate the characteristics of voice therapy provided to patients with UVFP and to establish the evidence base with regards to the content, timing, and dosage of the voice therapy provided. The second aim was to critically evaluate the voice outcome measures that are used for patients with UVFP, including the explanation of the rationale for choice of the voice outcome measures, the reliability and validity and the responsiveness to change of the measures in detecting the treatment effect. Through addressing these two aims it is hoped that the research will provide a strong theoretical and evidence base for the future management of patients with UVFP. It was anticipated that through the four studies that there would be a clear guide for the characteristics of the voice therapy (specifically the content, timing and, dosage of the treatment) and a recommendation for a set of voice outcome measures which are capable for tracking voice change overtime in patients with UVFP.

8.2.1 Study 1: Unilateral Vocal Fold Paralysis: A Systematic Review of Speech-Language Pathology Management

Study 1, focused on the published evidence for the speech-language pathology management of UVFP and the effectiveness of the intervention. Twelve voice therapy studies met the inclusion criteria [13]. The findings of Study 1 revealed that there was no current consensus for the characteristics (e.g. content, timing and dosage) of the voice therapy provided in the research literature to patients with UVFP [13]. Furthermore, there was a lack of rationale and consistency of use for the voice outcome measures and variable patient features within the included studies. The findings of the systematic review, revealed that the current evidence for the voice therapy treatment is limited (e.g. at "proof of concept" level [14]) despite it being a common treatment for patients with UVFP [13]. The findings

from Study 1 provided the impetus to explore the clinical experience of speech pathologists who provide voice therapy to patients with UVFP (see Study 2).

8.2.2 Study 2: Characteristics of Voice Therapy for UVFP: A survey of Speech-Language Pathologists

Study 2 used knowledge from the systematic review in Study 1 to inform the development of a cross-sectional survey to explore the characteristics of the voice therapy provided by speech-language pathologists to patients with UVFP. The cross-sectional survey was created using Qualtrics© and was comprised of 18 open and closed questions [15]. The cross-sectional survey was disseminated using snowball sampling to voice specialists throughout Australia and the world [15]. A total of 110 questionnaires were completed by speech pathologists with a broad range of clinical experience and who worked in a range of clinical settings [15]. The findings of Study 2 revealed some consensus for the characteristics of the voice therapy provided to patients with UVFP [15]. Additionally, the cross-sectional survey respondents identified several factors (e.g. patient features, clinician training and clinic setting) which influenced the selection of the voice therapy [15]. The responses from the survey participants allowed for the establishment of a voice therapy schema which represents a typical voice therapy program for patients with UVFP [15]. However, the findings identified by the cross-sectional survey were unable to explore the clinical rationale for the voice therapy selection. These components required further investigation of the in-depth perspectives via a phenomenological design to explore the opinions of expert clinicians using semi-structured interviews (see Study 3).

8.2.3 Study 3: The Characteristics of Voice Therapy for Patients with Unilateral Vocal Fold Paralysis: Semi-structured Interviews

The final study to address Aim 1 combined knowledge from both Study 1 and 2 to devise semi-structured interviews to gain a further in-depth understanding into the factors which

guide the voice therapy selection and outcomes for patients with UVFP. Study 3 comprised of semi-structured interviews with expert speech-language pathologists until data saturation was achieved (n=7). The interviews were conducted via phone or skype and recorded and then transcribed and analysed using the Framework of Analysis [16] technique and a previously developed voice therapy schema from Study 2 [15]. Interestingly, the findings of the in-depth interviews revealed a consensus for the factors which influence the clinical decision making specifically: context (diagnosis, aetiology, glottal insufficiency, patient factors, baseline assessments, goals and, patient factors). Secondly, the respondents shared some consensus for the components of voice therapy (content, timing, dosage and homework) and the treatment progress (performance on voice outcome measures, progress and achievement of goals). The findings of Study 3 were subsequently used to further develop the treatment schema from Study 2 [15] to provide a clear guide for the planning, implementation and follow-up of the voice therapy for patients with UVFP.

Through the triangulation of the three studies, I have been able to develop a clearly documented guide for voice therapy treatment by outlining the recommendations for the content, timing and dosage and the additional factors which are likely to impact the treatment selection for patients with UVFP. Firstly, the results of the studies suggest that the content of the voice therapy should (a) use a combination of indirect and direct treatment and (b) utilise a treatment hierarchy to allow the functional transference to conversational level. The treatment content should have demonstrated evidence of stimulability during the initial diagnostics and be designed to achieve glottal closure without excessive hyperfunction. To aid the motor skill acquisition, daily homework should be completed throughout the day. Secondly, the triangulation of findings suggests that voice therapy should be timed immediately following the diagnosis (if dysphonia is the primary feature of the UVFP). Thirdly, the dosage of the treatment should be no more than six – eight sessions and begin with regular sessions (at least weekly) to maximise motor learning and skill acquisition. As

progress is made, it is likely that the intensity of treatment can be reduced. Finally, progress should be reviewed at mid-point of treatment and either continued (if progress is measured) or discontinued (if no progress is detectable). Limited or no success from voice therapy should warrant a review of diagnosis, aetiology and potential patient barriers to therapy progress. Finally, these three studies have also identified a number of key patient factors which may influence the success of the voice therapy. Specifically, these include motivation, expectations and availability to attend and participate in therapy. The three studies have achieved the objectives of Aim 1 and established the evidence base for the characteristics of voice therapy which should be explored and evaluated by future efficacy studies.

8.2.4 Study 4: Voice outcome measures for adult patients with Unilateral Vocal Fold Paralysis: A systematic review.

The second aim of this thesis was to critically evaluate the voice outcome measures that are used for patients with UVFP and to determine a set of voice outcome measures which are responsive to detecting the treatment effect. As a consequence, a study was conducted that aimed to evaluate the voice outcome measures used to determine the most appropriate measures for detecting the treatment effect in patients with UVFP. To determine the voice outcome measures currently used by clinicians in reporting the treatment effect, a systematic review of prospective UVFP treatment studies was conducted. It was hypothesized that there would be a lack of consensus between the speech-language pathology and ENT surgeon literature for the voice outcome measures used to report the treatment effect for patients with UVFP, specifically pertaining to the number of voice outcome measures used and the types of measures used by the speech-language pathologist and ENT surgeon. This systematic review examined relevant prospective studies published since 2003 and articulated the progress of the knowledge base since a previous systematic review in 2006 [12]. Twenty-nine studies met the inclusion criteria, and these were appraised for outcome measurement properties including: multidimensionality, timing (of application), selection

rationale, validity, reliability and responsiveness to change [17]. The findings of the study revealed variability in the rationale, selection and application of voice outcome measures used to measure the treatment effect in patients with UVFP [17]. Based on these findings, a set of recommendations was developed for the selection and use of voice outcome measures for future UVFP intervention studies including: multidimensional voice outcome measures (auditory-perceptual, aerodynamic, acoustic, patient self-rated and visuo-perceptual), timing of measures, rationale for selection and published validity, reliability and responsiveness to change [17]. Despite the lack of consensus for the voice outcome measures used to determine the treatment effect for patients with UVFP, the findings of Study 4 revealed several voice outcome measures which were found to have good validity, reliability and responsiveness to change. These voice outcome measures included: GRBAS, jitter, shimmer and maximum phonation time [17].

Through the final study, I was able to achieve the objective of aim two by exploring the voice outcome measures used by ENT surgeons and speech-language pathologists and critically appraising and identifying a number of voice outcome measures used by speech-language pathologist with published evidence of validity, reliability and a responsiveness to change in UVFP. This findings of the systematic review related back to those reported in the survey, interviews in Aim 1 and demonstrated that there is currently a lack of consensus for the rationale, selection and application of voice outcome measures used by speech-language pathologists and ENT surgeons. These findings support further research for the identified voice outcome measures and the clinical application of these voice outcome measures.

The results of these four studies together provide a response to the two aims of this thesis and the findings demonstrate a clear understanding of the current evidence base for two

main tenants for management of UVFP and provide a strong basis for the future management of patients with UVFP.

8.3 Comparison with pre-existing studies

This thesis aimed to explore the characteristics of the voice therapy provided to patients with UVFP, while also to determine the most responsive voice outcome measures for detecting the treatment effect for patients with UVFP. In addressing these aims, this thesis contributes to the broader literature concerning the voice therapy and voice outcome measurement for patients with UVFP. The following discussion will explore the implications of the key findings of this thesis for the research literature.

8.3.1 Voice Therapy for UVFP

Voice therapy is a core treatment for UVFP as it uses behavioural exercises to improve the function of the glottis by attempting to restore glottal sufficiency. It is typically the preferred initial treatment option for patients with dysphonia due to UVFP as it is a non-invasive treatment option compared to surgical intervention [8]. Despite the recommendation for voice therapy and the frequency of clinical application, there is limited consensus in the literature for the voice therapy provided to manage the presenting dysphonia [13, 18, 19]. Prior to this thesis, there has been no systematic review of the voice therapy literature for the management of UVFP. The majority of studies for the treatment of UVFP are retrospective case series or cohort studies and report a wide range of voice therapy characteristics in the content, timing and dosage of the treatment [2, 20, 21]. Previous studies, identified by the systematic review in Study 1, have reported a range of behavioural treatments that were specifically designed to improve glottal closure in patients with UVFP including: hard glottal attack, half-swallow boom, pushing exercises, inhalation phonation and cough attack [2, 3, 9, 22, 23]. These voice therapy exercises have more recently been identified as potentially

detrimental due to the forceful glottal closure and may contribute to the development of maladaptive voicing habits [24]. The findings of Study 1 revealed that there is currently no consensus for the key components of the voice therapy provided to patients with UVFP [13]. The characteristics of the voice therapy were found to vary greatly, and this variability within the published literature provides a limited guide for the clinic clinical management of UVFP. The findings of the cross-sectional survey and in-depth interviews focused on the clinical perspectives of speech-language pathologists and revealed an ongoing theme of variability to the components of the voice therapy provided. However, the key difference to the previously published evidence is that the speech-language pathologists acknowledged that there are several factors which influence their clinical decision making for the voice therapy provided [15]. The clinicians in both Study 2 & 3 noted that the variability of the patient factors (e.g. aetiology, time since onset, size of the glottal gap) influenced their clinical decision making. Variability in patient factors was also a common feature of the included articles in Study 1 [13] however the influence of the patient variability on the treatment effect was not acknowledged. It appears that previous treatment studies have not always considered these patient factors into their inclusion/ exclusion criteria and considered them as variables which influence treatment selection and outcomes [9, 23, 25]. This revelation of the factors used in clinical decision-making in voice therapy has two key implications. Firstly, knowledge of these factors provides a guide for future research studies, specifically in the planning of inclusion/exclusion criteria. Secondly, knowledge of these factors supports the use of an individualised approach to voice therapy, as used by previous studies, even though a rationale for this approach was not clearly provided [2, 3, 26]. Knowing the factors that guide clinical decision-making has enabled the justification of the individualisation of therapy [2, 25, 27].

Since the publication of the systematic review [13], four further papers have been published about voice therapy treatment of UVFP [28-31]. These studies demonstrated an ongoing lack of consensus for the treatment characteristics and varied patient factors which remain

as potential variables to the treatment effect. This ongoing lack of consensus within the most recently published treatment studies of the voice suggests that the current schema that was developed with knowledge from Studies 1-3 provides a relevant future guide for the management of UVFP to inform research development and clinical practice. Interestingly, the current content of UVFP voice therapy is similar to those used in the management of other types of dysphonia e.g. muscle tension dysphonia [13, 32, 33]. The recommended timing of the voice therapy for patients with UVFP is immediately following diagnosis, this theme has been utilised by several recent studies [3, 9, 25]. Despite there remaining a clear rationale for the early timing, the findings reveal early treatment is anticipated to apply principles of motor learning [34, 35], to help compensate for the glottal insufficiency, to prevent the development of maladaptive voicing habits and support the need for surgical intervention. Finally, there were differences in the recommended duration and frequency of the voice therapy. The findings of both Study 2 and 3 recommended a shorter treatment duration than previously recommended in the UVFP literature [13, 15]. The frequency of the voice therapy continues to differ between the findings of the systematic review [13] and those recommended by the clinicians and included in the voice therapy schema. The findings of the three studies outline the current evidence and provide a clear strategy via the treatment schema (developed in Study 3) to help guide the future evidence for the voice therapy for the management of UVFP.

8.3.2 Voice Outcome Measures

Voice outcome measures are a key component used by clinicians to determine the treatment effect and are key to research and clinical outcomes for the treatment of UVFP. Through the critical appraisal of the literature, this thesis suggests that there has been limited progress in the use of voice outcome measures to detect the treatment effect for patients with UVFP [17]. Prior to this thesis, a systematic review of voice outcome measure was published in 2006 [12] which identified that there was considerable disparity in the selection and use of

voice outcome measures to detect the treatment effect in patients with UVFP. Baylor [12] concluded that to improve the research evidence for UVFP, published treatment studies needed to include the following: the rationale for use of the included voice outcome measures, selection of measures with good psychometric features (e.g. validity and reliability), and improved study methodology (e.g. prospective study design). [12]. The systematic review that was conducted as part of this thesis [17] revealed that there was limited change to the voice outcome measures selected and used by clinicians in the reporting of the treatment effect [17]. Since the publication of the systematic review (in Study 4) there have been two further studies reporting on voice outcome measures for patients with UVFP post intervention. The first by Barcelos et al. [30] provided voice therapy to patients and used pre / post voice outcome measures including jitter, shimmer, noise to harmonic ration (NHR), Maximum Phonation Time (MPT), GRBASI and the Voice Handicap Index to report treatment outcomes. The other study which would have met the inclusion criteria of the systematic review was by Maccarini et al. [36] also used a set of multidimensional voice outcome measures to report the treatment effect following injection laryngoplasty, with the selected measures including visuo-perceptual, MPT, Voice Handicap Index-10 and the GRBAS. The results to the two recently published studies demonstrate that improvements have been made in the selection of the included voice outcome measures used in treatment studies and the recently included measures align with some of the recommendations of the systematic review [17]

8.4 Limitations and future directions

This thesis sought to determine the best evidence for the voice therapy characteristics used to treat patients with UVFP and to review and recommend voice outcome measures used to detect the treatment effect. This thesis did not focus on the perspectives of the ENT surgeon and their knowledge and surgical opinion which influences the assessment and treatment of UVFP, this perspective could be considered as a future direction. This thesis provides a new

insight into how speech pathologists select and use voice therapy and the application of voice outcome measures in detecting the treatment effect. A number of significant issues in the management of UVFP were raised in the studies that were beyond the scope of this thesis. These include the importance of Peripheral Nervous System (PNS) injury treatment principles and the importance of the diagnosis and aetiology of UVFP when determining a treatment plan. These factors will be discussed below and recommendations for the future direction are provided to help guide further UVFP research.

One important theme that emerged from this thesis was the potential significance of the type of injury and significance of the PNS in the management of UVFP. Further investigation of these factors was however, beyond the scope of this thesis. The treatment approaches currently reported in Studies 1, 2 and 3 do not acknowledge the types of nerve injury (e.g. neurotmesis vs. axonotmesis) and the impact of PNS injury on the treatment selection. Knowledge of the PNS and the presenting injury is key to guiding the characteristics of therapy as there is a difference between the treatment of central nervous system (CNS) versus PNS injuries [37-40]. The treatment of UVFP should also consider the concepts of motor-learning and neuroplasticity [34] and how these principles apply to the management a PNS injury. The findings of this thesis provide a clear guide for voice therapy management through the schema developed however further consideration is warranted with respect to the role of the PNS and recovery. Interestingly, the treatment schema described in this thesis may have relevance to other types of neurogenic dysphonia arising from a PNS injury (e.g. Superior Laryngeal Nerve [SLN] injury). Paresis of the SLN was not the focus of this thesis, however future studies could determine if the findings of this thesis could be applied to the management of SLN. A similar triangulated methodological approach may be used to help determine the most appropriate treatment approaches for the management of SLN UVFP.

A second theme which requires further investigation concerns the importance of accurate diagnosis of UVFP. Specifically, this refers to the use of well-defined terminology and accurate and comprehensive process of diagnosis. As discussed above, there is a lack of consistency within the neurogenic voice literature in the use of terminology (e.g. paralysis, paresis and palsy) [24, 41]. The use of different terminology may have a considerable impact on the treatment plan and treatment outcomes for these patients. A potential reason for the lack of clear terminology is the lack of consistency in the diagnostic process. Consistency and standardisation of the diagnostic process across studies would enhance patient homogeneity. Whilst endoscopic and stroboscopic visualisation may be considered essential for UVFP diagnosis, there was minimal consideration for the use of visual-perceptual assessments with published validity, reliability and a responsiveness to change (e.g. The Stroboscopy Research Instrument [42]). Application of clinical assessments with good psychometric properties will help establish a clearer understanding of the presenting glottal gap (e.g. median and paramedian) and provide a clearer guide for treatment selection. Furthermore, recent studies have reported on the value of Laryngeal Electromyography (LEMG) to help determine the severity of the nerve injury and provide a clearer insight into the prognosis which, in turn, guides treatment recommendations [43-45]. The use of improved diagnostic consistency should be a key focus for future studies to help improve the homogeneity in the management of UVFP which in turn are likely to result in improved treatment outcomes.

There were some limitations pertaining to the information of voice therapy content in studies 2 and 3. The cross-sectional survey (Study 2) data was predominantly collected from Australian clinicians. These respondents made up 59 % of the total. Whilst there were some important and detailed responses from clinicians in United Kingdom, Europe and United States of America it is difficult to know if these answers were representative of standard practice in these countries. Furthermore, the limited number of responses from these

countries from outside Australia meant that it was not possible to compare and contrast cultural and country-based findings. Future research in this area would require a larger sample size for this to provide meaningful data. As previously mentioned, neither the crosssectional study (Study 2) or the structured interviews (Study 3) provided detailed information on the psychological aspects of a voice disorder relating to UVFP. Considering that UVFP may be caused by one of a number of significant and serious medical conditions then this finding may be considered surprising. It is therefore unclear if these aspects should be incorporated into the therapy schema as described above. Study 2 identified a lack of current understanding of the role of the ENT surgeon in informing and guiding selection of voice therapy characteristics. Specifically, the role of the ENT surgeon in initially referring to speech pathology, the descriptive diagnostic features which then guide voice therapy selection and additionally the timing of voice therapy should be considered in future research. Further research is therefore required to ascertain the relative importance of these factors in the management of patients with UVFP and their subsequent influence on treatment outcome. Finally, the findings of Study 3 resulted in the development of a treatment schema, which outlines the current approaches to speech-language pathology management provided by clinicians. This schema outlines current clinical practise and is the first step in developing a treatment protocol for patients with UVFP. Further research is required within a theoretical context to appraise the schema empirically prior to clinical application.

8.5 Overall conclusions

This thesis presents the best evidence for the voice therapy management and the use of voice outcome measures for patients with UVFP as revealed by four studies. Through the findings of these studies, previous gaps within the research evidence have been addressed and the findings of this thesis present a clear direction for the improvement of treatment efficacy for patients with UFVP. The recommended characteristics of the voice therapy

though the use of a treatment schema is a valuable tool for speech pathologists to consider when treating clients with UVFP. The findings of this thesis also revealed the current evidence for the voice outcome measures used to measure the treatment effect for patients with UVFP. The recommended voice outcome measures from this thesis will provide a clear guide for clinical application and research to provide robust evidence of treatment effectiveness. It is hoped that the clinical and research application of the recommended voice therapy characteristics and voice outcome measures will improve the treatment outcomes and levels of evidence for the management of UVFP.

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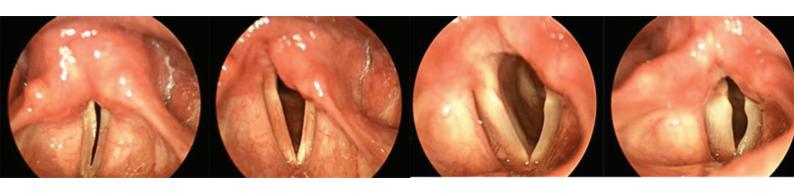
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Appendices



2016-242E Ethics application approved!

Pratigya Pozniak <Pratigya.Pozniak@acu.edu.au> on behalf of Res Ethics <Res.Ethics@acu.edu.au>

Tue 20/12/2016 2:31 PM

To: Paul Carding < Paul. Carding@acu.edu.au>; Erin Conway < Erin. Conway@acu.edu.au>;

Cc:Res Ethics < Res. Ethics@acu.edu.au>; Chloe Walton < chloe.walton@myacu.edu.au>;

Dear Applicant,

Principal Investigator: Prof Paul Carding

Co-Investigator: Dr Erin Conway, Helen Blackshaw Student Researcher: Chloe Walton (HDR Student)

Ethics Register Number: 2016-242E

Project Title: Unilateral Vocal Fold Paralysis: Voice Therapy and Voice Outcomes

Risk Level: Low Risk

Date Approved: 20/12/2016

Ethics Clearance End Date: 31/12/2018

This email is to advise that your application has been reviewed by the Australian Catholic University's Human Research Ethics Committee and confirmed as meeting the requirements of the National Statement on Ethical Conduct in Human Research

The data collection of your project has received ethical clearance but the decision and authority to commence may be dependent on factors beyond the remit of the ethics review process and approval is subject to ratification at the next available Committee meeting. The Chief Investigator is responsible for ensuring that outstanding permission letters are obtained, interview/survey questions, if relevant, and a copy forwarded to ACU HREC before any data collection can occur. Failure to provide outstanding documents to the ACU HREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research. Further, this approval is only valid as long as approved procedures are followed.

If your project is a Clinical Trial, you are required to register it in a publicly accessible trials registry prior to enrolment of the first participant (e.g. Australian New Zealand Clinical Trials Registry http://www.anzctr.org.au/) as a condition of ethics approval.

If you require a formal approval certificate, please respond via reply email and one will be issued.

Researchers who fail to submit a progress report may have their ethical clearance revoked and/or the ethical clearances of other projects suspended. When your project has been completed a progress/final report form must be submitted. The information researchers provide on the security of records, compliance with approval consent procedures and documentation and responses to special conditions is reported to the NHMRC on an annual basis. In accordance with NHMRC the ACU HREC may undertake annual audits of any projects considered to be of more than low risk.

It is the Principal Investigators / Supervisors responsibility to ensure that:

- 1. All serious and unexpected adverse events should be reported to the HREC with 72 hours.
- 2. Any changes to the protocol must be reviewed by the HREC by submitting a Modification/Change to

Protocol Form prior to the research commencing or continuing. http://research.acu.edu.au/researcher-support/integrity-and-ethics/

- 3. Progress reports are to be submitted on an annual basis. http://research.acu.edu.au/researcher-support/integrity-and-ethics/
- 4. All research participants are to be provided with a Participant Information Letter and consent form, unless otherwise agreed by the Committee.
- 5. Protocols can be extended for a maximum of five (5) years after which a new application must be submitted. (The five year limit on renewal of approvals allows the Committee to fully re-review research in an environment where legislation, guidelines and requirements are continually changing, for example, new child protection and privacy laws).

Researchers must immediately report to HREC any matter that might affect the ethical acceptability of the protocol eq: changes to protocols or unforeseen circumstances or adverse effects on participants.

Please do not hesitate to contact the office if you have any queries.

Kind regards,

Kylie Pashley on behalf of ACU HREC Chair, Dr Nadia Crittenden

Ethics Officer | Research Services Office of the Deputy Vice Chancellor (Research) Australian Catholic University

THIS IS AN AUTOMATICALLY GENERATED RESEARCHMASTER EMAIL

2016-242E Modification approved

Ms Pratigya Pozniak <pratigya.pozniak@acu.edu.au>

Tue 21/11/2017 8:33 AM

To: Prof Paul Carding <paul.carding@acu.edu.au>; Chloe Walton <chloe.walton@myacu.edu.au>;

Cc:Ms Pratigya Pozniak <pratigya.pozniak@acu.edu.au>;

Dear Paul,

Ethics Register Number: 2016-242E

Project Title: Unilateral Vocal Fold Paralysis: Voice Therapy and Voice

Outcomes

End Date: 31/12/2018

Thank you for submitting the request to modify form for the above project.

The Chair of the Human Research Ethics Committee has approved the following modification(s):

-Procedures: use of a professional transcription service to transcribe interview content

-Addition of personnel: Dr Kieran Flanagan

We wish you well in this ongoing research project.

Kind regards, Ms Pratigya Pozniak

Research Ethics Officer | Office of the Deputy Vice-Chancellor (Research) Australian Catholic University

T: 02 9739 2646 E: res.ethics@acu.edu.au

THIS IS AN AUTOMATICALLY GENERATED RESEARCHMASTER EMAIL

2016 -242E Modification approved

Ms Pratigya Pozniak <pratigya.pozniak@acu.edu.au>

Fri 17/02/2017 12:18 PM

To: Chloe Walton <chloe.walton@myacu.edu.au>;

Cc:Ms Pratigya Pozniak <pratigya.pozniak@acu.edu.au>;

Dear Chloe,

Ethics Register Number: 2016-242E

Project Title: Unilateral Vocal Fold Paralysis: Voice Therapy and Voice

Outcomes

End Date: 31/12/2018

Thank you for submitting the request to modify form for the above project.

The Chair of the Human Research Ethics Committee has approved the following modification(s):

Study 1 Questionnaire

- -Dissemination of inviation to participate in the questionnaire to a closed Face book groups of international voice experts.
- -Dissemination of invidation to participate in the questionnaire to a speech pathology Google Group "SPECS" Speech Pathology Email Chats.
- -Slight modification to the wording and ordering of several questions included in the questionnaire after a review by several expert speech pathologists and researchers.

We wish you well in this ongoing research project.

Kind regards, Ms Pratigya Pozniak

Research Ethics Officer | Office of the Deputy Vice-Chancellor (Research) Australian Catholic University

T: 02 9739 2646 F: res ethics@acu.edu.au

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RE: Request permission to republish two images in PhD

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Fri 5/31/2019 8:43 PM

To:Fussell, Luke <lfussell@wiley.com>;

Cc:Chloe Walton <Chloe.Walton@acu.edu.au>;

Hi Luke,

I have looked into this for you and our system confirms that we have all rights for the below requested title.

Good Morning Chloe,

In light of this, Permission is granted for you to use the material requested for your thesis/dissertation subject to the usual acknowledgements (author, title of material, title of book/journal, ourselves as publisher) and on the understanding that you will reapply for permission if you wish to distribute or publish your thesis/dissertation commercially.

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Should you require any further information, please do not hesitate to contact me.

Kind regards,

Paisley Chesters Permissions Co-Ordinator

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1 of 3 25/06/2019, 6:26 pm



Dear Bernadette,

I am Chloe Walton a speech pathologist and PhD student currently studying at Australian Catholic University (ACU), Australia. I am currently supervised by Professor Paul Carding, Dr Erin Conway and Dr Helen Blackshaw who are helping me to investigate voice therapy and voice outcomes for patients with UVFP. As part of my PhD, I hope to establish the current characteristics of voice therapy for patients with UVFP and determine the most appropriate voice outcome measures to detect a treatment effect.

I am writing to invite speech pathologists with experience managing voice disorders to participate in a questionnaire.

The questionnaire plans to investigate and establish the current characteristics of the voice therapy you provide for patients with unilateral vocal fold paralysis. This questionnaire is electronic and should take no longer than 10 minutes to complete.

Participation in the above task is voluntary and there is unlikely to be any direct benefit to you. Results for the above tasks will be de-identified and summarised for publication in a peer-reviewed article and published within my PhD.

Please don't hesitate to contact me if you have any questions or concerns: chloe.walton@myacu.edu.au

I have attached copies of the participant information form and link to the electronic questionnaire below.

To participate please read through the consent form and then click on the link to the questionnaire.

https://acu.qualtrics.com/SE/?SID=SV 2gEgSdpiA14udkV

Thank you for your consideration,

Chloe

Chloe Walton

Casual Academic / PhD Student Australian Catholic University 1100 Nudgee Road, Banyo QLD Australi 4014

T: +61 437481424 E: chloe.walton@acu.edu.au W: acu.edu.au



PARTICIPANT INFORMATION LETTER (Questionnaire)

Project Title:	Unilateral Vocal Fold Paralysis: Voice Therapy and Voice Outcomes
Name of Researchers:	Chloe Walton, PhD Student, Australian Catholic University
	Email: chloe.walton@myacu.edu.au
	Professor Paul Carding, Deputy Head of School, National Course
	Coordinator in Speech Pathology, Australian Catholic University
	Email: paul.carding@acu.edu.au
	Erin Conway PhD, Lecturer in Speech Pathology, Australian Catholic
	University
	Email: erin.conway@acu.edu.au
	Kieran Flanagan PhD, Lecturer in Speech Pathology, Australian
	Catholic University
	Email: kieran.flanagan@acu.edu.au
	Helen Blackshaw PhD, Programme Manager, NIHR Research
	Fellow, University College London
	Email: h.blackshaw@ucl.ac.uk

Invitation to participate in the study:

- You are invited to participate in this research study described below
- Please take your time to read this form carefully to understand the aim of the project and what it will involve.

The aims of this project:

- This project is looking at how speech pathologists provide treatment to people with voice disorders, specifically unilateral vocal fold paralysis (UVFP)
- This project aims to find out the characteristics of voice therapy for people with unilateral vocal fold paralysis, in particular the content, timing, duration and frequency of the voice therapy.
- The results of the project aim to provide recommendations for future voice therapy for patients with unilateral vocal fold paralysis.

Team undertaking the project:

- This project is being conducted by PhD student Chloe Walton and this will contribute to her Doctor of Philosophy degree at Australian Catholic University (ACU). Chloe is a speech pathologist that has clinical experience and research interest in the treatment of voice disorders.
- This project is supervised by Professor Paul Carding (Principal Investigator), Dr Erin Conway and Helen Blackshaw PhD, all experienced researchers within the field of speech pathology and research development and methodology.

What will I be asked to do?

- Complete an electronic questionnaire about your clinical experience in providing voice therapy for patients with unilateral vocal fold paralysis.
- It is anticipated that the questionnaire will take no longer than 15 minutes to complete.

What are the benefits of this project?

- Your participation in this project may not directly benefit you, but the results may help us to better understand how to improve the way we treat unilateral vocal fold paralysis.
- There are no risks associated with taking part in the project.

Can I withdraw from the project?

- Taking part in this project is completely voluntary.
- You will not be paid any money for taking part in the project.
- By clicking on the button below you are consenting to participate in this project.
- You are free to stop taking part in the project at any time prior to submitting the
 questionnaire. Once the questionnaire has been submitted your data will not be able to be
 withdrawn, as all questionnaire are anonymous.

Feedback of the results:

- All results of the questionnaire are anonymous with no identifying information being collected.
- The results of the research will be published in a health journal and form part of the PhD study.
- If you wish to receive feedback about the results of this project, please contact one of the investigators listed at the beginning of this form.

Who do I contact if I have questions about the project?

• If you have any question or concerns about the project, please contact Chloe Walton (PhD Student) via email: chloe.walton@myacu.edu.au

What if I have a complaint or any concerns?

 The study has been reviewed by the Human Research Ethics Committee at Australian Catholic University (review number 2016-242E). If you have any complaints or concerns about the conduct of the project, you may write to the Manager of the Human Research Ethics Committee care of the Office of the Deputy Vice Chancellor (Research).

Manager, Ethics c/o Office of the Deputy Vice Chancellor (Research) Australian Catholic University

V.20140203 2

North Sydney Campus PO Box 968 NORTH SYDNEY, NSW 2059

Ph.: 02 9739 2519 Fax: 02 9739 2870

Email: resethics.manager@acu.edu.au

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

I want to participate! How do I sign up?

By clicking on the link below and completing the questionnaire.

Yours sincerely,

Chloe Walton Speech Pathologist PhD Student

V.20140203 3

Default Question Block

O Agree

By selecting **agree**, I acknowledge that:

I have read the information sheet and understand the purpose and risks of this study.

I have been informed that the confidentiality of my information will be maintained and safeguarded.

I am aware that participation is voluntary, and that I am free to withdraw at any time <u>prior to submitting</u> the questionnaire without giving a reason.

I understand that this project is directed to the expansion of knowledge in the treatment of voice disorders and it may not result in any direct benefit to me.

I am aware that research data collected for the study may be published or may be provided to other researchers in a form that does not identify me in any way.

Q 1. Which country and region do you work in?(Please write below)	O Disagree	
	Q 1. Which country and region do you work in?(Please write below)	

Q 6. Please estimate the percentage of people with a voice disorder on your current clinical caseload?
None1-25%26 - 50%
O 51-75% O 76- 100%
Q 7. Please estimate number of patients with a voice disorder due to unilateral vocal fold paralysis that you have seen within the past 12 months

Q 8. Which outcome measure/s do you use to assess a voice disorder due to unilateral vocal fold paralysis?
(Please select as many outcome measures as needed. If selected, please provide the name of the outcome measure/s)
Auditory perceptual voice assessment (e.g. GRBAS, CAPE-V)
☐ Visual perceptual assessment (e.g. Interpretation of videostrobe / laryngoscope images)
Aerodynamic assessment (e.g. maximum phonation time, S/Z ratio)
Patient self-rated assessment (e.g. VHI, V-RQOL)
Acoustic features assessment (e.g. jitter, shimmer, harmonic-to noise ration)
Other
☐ None of the above

Q 9. Please indicate how often you would use each of the following types of voice therapy for treating patients with unilateral vocal fold paralysis (Frequently - use with > 50% of patients with UVFP) (Occasionally - use with < 50% of patients with UVFP)

	Frequently	Occasionally	Never
Vocal hygiene			
Breathing/ Respiration			
Smith Accent Method Breathing (Kotby et al, 1991)			
Vocal Function Exercises (Stemple, 2004)			
Resonant Voice / Forward Resonance			
LSVT (Fox et al. 2002)			
Pushing exercises/ manoeuvers against resistance			
Twang			
Electrical stimulation			
Digital manipulation / massage			
Pitch / intonation exercises			
Non-verbal/ playful noises			
Yawn / sigh			
Easy/ gentle onset			
Cough/ hard glottal attack			
Release of constriction			
Relaxation			
Posture / positioning			

Dualtrics	Survey	Software
Juanuncs	Dui vey	Software

Q10. Are there any other additional types of voice therapy that you would use for treating unilateral vocal fold paralysis? (If yes, please list any additional types of therapy below)
O Yes
O No
Q 11. In your current main clinical setting, is voice therapy (direct and/or indirect) ever offered as the initial mode of treatment for patients with unilateral vocal fold paralysis?
(Please select the most appropriate response and list situations when this typically occurs e.g non-dysphagic patients, limited access to ENT etc.)
Always
Sometimes
□ Never
Q 12. If patients are selected for surgical intervention for their unilateral vocal fold
paralysis, at what stage is voice therapy typically offered? □ Pre-surgery only
☐ Post-surgery only ☐ Pre and Post surgery
☐ No voice therapy provided

Q 13. How many voice therapy sessions do you typically provide to patients with unilateral vocal fold paralysis?
O 1 - 5 sessions
O 6 - 10 sessions
O 11+ sessions
O Other
Q 14. In your typical practice, how often are voice therapy sessions offered for patients with unilateral vocal fold paralysis?
O Daily
O Twice / week
O Weekly
O Fortnightly
O Other

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Q 15. Which outcome measure/s do you use to determine the success of voice therapy for patients with unilateral vocal fold paralysis? (Please select as many outcome measures as needed. If selected, please provide the name of the assessment/s)
Auditory perceptual voice assessment (e.g GRBAS, CAPE -V)
☐ Visual perceptual assessment (e.g Interpretation of videostrobe/ nasoendoscipic images)
Aerodynamic assessment (e.g. maximum phonation time, S/Z ratio)
Patient self-rated assessment (e.g VHI, V-RQOL)
Acoustic features assessment (e.g. jitter, shimmer, harmonic-to-noise ratio)
Other
☐ None of the above

Q 16. Using the 5-point scale please indicate how much the following statements influence your planning and implementation of voice therapy for patients with unilateral vocal fold paralysis.

	No Influence		Neutral		Significant Influence
	1	2	3	4	5
Patient concern about their voice disorder	0	0	0	0	0
Patient compliance with therapy and home practice	Ο	0	0	0	0
Willingness to give up negative vocal habits	0	0	0	0	0
Appropriateness of the voice disorder for voice therapy intervention	0	0	0	0	0
Patient expectations of voice therapy (e.g. realistic goals)	0	0	0	0	0
Patient factors (e.g age, health or work)	0	0	0	0	0
Facility/ workplace factors (e.g. Procedures, resources or waiting list)	0	0	0	0	0
Clinical confidence to treat/ manage the voice disorder	0	0	0	0	0

Q 17. Have you received further professional development in the assessment and management of voice disorders? (If yes, please list the professional development)
O No
O Yes
Would you like to make any other comments regarding the provision of voice therapy for patients with unilateral vocal fold paralysis that from your experience you feel is relevant, or was not captured in the above questions?
Thank you for participating in this questionnaire.
To understand some of the topics covered in this questionnaire in more detail we would like to conduct further research on this topic in the form of interviews.
If you would be willing to let us contact you to provide more information about this, please click on the following link and we will be in touch.
https://acu.qualtrics.com/SE/?SID=SV_8AhhalXlpawHOiV

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Default Question Block

To understand some of the topics covered in this questionnaire in more detail we would like to conduct further research on this topic in the form of interviews.

If you would be willing to let us contact you to provide more information about this, please enter you email address below and we will be in touch.

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PARTICIPANT INFORMATION LETTER (Interviews)

Project Title:	Unilateral Vocal Fold Paralysis: Voice Therapy and Voice Outcomes	
Name of	Chloe Walton, PhD Student, Australian Catholic University	
Researchers:	Email: chloe.walton@myacu.edu.au	
	Professor Paul Carding, Deputy Head of School, National Course	
	Coordinator in Speech Pathology, Australian Catholic University	
	Email: paul.carding@acu.edu.au	
	Erin Conway PhD, Lecturer in Speech Pathology, Australian Catholic	
	University	
	Email: erin.conway@acu.edu.au	
	Kieran Flanagan PhD, Lecturer in Speech Pathology, Australian	
	Catholic University	
	Email: kieran.flanagan@acu.edu.au	
	Helen Blackshaw PhD, Programme Manager, NIHR Research	
	Fellow, University College London	
	Email: h.blackshaw@ucl.ac.uk	

Invitation to participate in the study:

- You are invited to participate in this research study described below
- Please take your time to read this form carefully to understand the aim of the project and what it will involve.

The aims of this project:

- This project is looking at how speech pathologists provide treatment to people with voice disorders, specifically unilateral vocal fold paralysis (UVFP)
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- The results of the project aim to provide recommendations for future voice therapy for patients with unilateral vocal fold paralysis.

Team undertaking the project:

- This project is being conducted by PhD student Chloe Walton and this will contribute to her Doctor of Philosophy degree at Australian Catholic University (ACU). Chloe is a speech pathologist that has clinical experience and research interest in the treatment of voice disorders.
- This project is supervised by Professor Paul Carding (Principal Investigator), Dr Erin Conway and Helen Blackshaw PhD, all experienced researchers within the field of speech pathology and research development and methodology.

What will I be asked to do?

- Participate in a semi-structured interview (face-to-face) with the PhD student to explore your clinical reasoning and rationale for the selection and provision of voice therapy for patients with UVFP.
- It is anticipated that the interview should take no longer than 60 minutes.
- The interview recordings will be de-identified and sent to a professional transcription service for transcribing prior to thematic analysis.

What are the benefits of this project?

- Your participation in this project may not directly benefit you, but the results may help us to better understand how to improve the way we treat unilateral vocal fold paralysis.
- There are no risks associated with taking part in the project.

Can I withdraw from the project?

- Taking part in this project is completely voluntary.
- You will not be paid any money for taking part in the project.
- By signing below you are consenting to participate in this project.
- You are free to stop taking part in the project at any time prior to submitting the questionnaire. Once the questionnaire has been submitted your data will not be able to be withdrawn, as all questionnaire are anonymous.

Feedback of the results:

- The interview responses will be de-identified, transcribed and stored securely to maintain privacy and confidentiality.
- The results of the research will be published in a health journal and form part of the PhD study.
- If you wish to receive feedback about the results of this project, please feel free to ask one of the investigators listed at the beginning of this form.

Who do I contact if I have questions about the project?

• If you have any question or concerns about the project, please contact Chloe Walton (PhD Student) via email: chloe.walton@myacu.edu.au

What if I have a complaint or any concerns?

 The study has been reviewed by the Human Research Ethics Committee at Australian Catholic University (review number 2016-242E). If you have any complaints or concerns about the conduct of the project, you may write to the Manager of the Human Research Ethics Committee care of the Office of the Deputy Vice Chancellor (Research).

V.20140203 2

Manager, Ethics c/o Office of the Deputy Vice Chancellor (Research) Australian Catholic University North Sydney Campus PO Box 968 NORTH SYDNEY, NSW 2059

Ph.: 02 9739 2519 Fax: 02 9739 2870

Email: resethics.manager@acu.edu.au

Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

I want to participate! How do I sign up?

By signing the attached consent form.

Yours sincerely,

Chloe Walton Speech Pathologist PhD Student

v.20140203 3



CONSENT FORM – Participant (Speech Pathologist Interview)

Copy for Researcher / Copy for Participant to Keep

Project Title:	Unilateral Vocal Fold Paralysis: Voice Therapy and Voice Outcomes	
Name of Researchers:	Chloe Walton, PhD Student, Australian Catholic University Email: chloe.walton@myacu.edu.au	
	Professor Paul Carding, Deputy Head of School, National Course	
	Coordinator in Speech Pathology, Australian Catholic University	
	Email: paul.carding@acu.edu.au	
	Erin Conway PhD, Lecturer in Speech Pathology, Australian Catholic	
	University	
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	Kieran Flanagan PhD, Lecturer in Speech Pathology, Australian Catholic	
	University	
	Email: kieran.flanagan@acu.edu.au	
	Helen Blackshaw PhD, Programme Manager, NIHR Research Fellow,	
	University College London	
	Email: h.blackshaw@ucl.ac.uk	

l,	_ (please print name in full), agree to
participate in the research study titled "Unilateral Vocal Fold	Paralysis: Voice Therapy and Voice
Outcomes" and acknowledge that:	

- I have read the information sheet and understand the purpose of this study.
- Any questions I have had have been answered to my satisfaction.
- I agree to participate in an audio-recorded interview with one of the researchers.
- I have been informed of and understand any possible risks to my health or well-being.
- I have been informed that the confidentiality of my information will be maintained and safeguarded.
- I am aware that, although the project is directed to the expansion knowledge in the treatment of voice disorders, it may not result in any direct benefit to me.

- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.
- I am aware that research data collected for the study may be published or may be provided to other researchers in a form that does not identify me in any way.

NAME OF PARTICIPANT:	
SIGNATURE	DATE
SIGNATURE OF PRINCIPAL INVESTIGATOR (or SUPERVISOR):	
SIGNATURE OF STUDENT RESEARCHER:	DATE:
	DATE:





PROSPERO International prospective register of systematic reviews

A systematic review of voice outcome measures for patients with Unilateral Vocal Fold Paralysis

Chloe Walton, Paul Carding, Erin Conway, Helen Blackshaw

Citation

Chloe Walton, Paul Carding, Erin Conway, Helen Blackshaw. A systematic review of voice outcome measures for patients with Unilateral Vocal Fold Paralysis. PROSPERO 2016:CRD42016049737 Available from http://www.crd.york.ac.uk/PROSPERO_REBRANDING/display_record.asp?ID=CRD42016049737

Review question(s)

Which voice outcome measures are currently being used to measure the treatment effect in patients with unilateral vocal fold paralysis (UVFP) following speech pathology and/or ENT surgical intervention?

Searches

Cochrane Library – keyword and MeSH headings

CINAHL Complete - keyword and CINAHL Headings

MEDLINE Complete - keyword and MeSH Headings

EMBASE - keyword and Emtree Headings

Scopus - keyword and citation tracking

Web of Science - keyword and citation tracking

PubMed - keyword and MeSH Headings

AMED - keyword and MeSH headings

SpeechBite - keyword

All from inception to the current date.

In addition to database searching additional searches will be undertaken by the authors to review 'grey literature' searching of this will include: (Potential places to search)

- Dissertation Abstracts
- Clinical trails
- World Health Organization International Clinical Trials Registry Platform
- Conference paper review
- Reviews of ASHA publication on their website
- Contacting prolific authors of voice therapy treatment/ ENT surgeons.

Types of study to be included

Studies in all languages that use pre & post voice outcome measures.





Randomised control trials,

Pseudo randomised control trials,

Comparative study (with concurrent controls),

Comparative study (without concurrent controls),

Case series.

Condition or domain being studied

Unilateral vocal fold paralysis is a common voice disorder characterized by the loss of mobility to one of the vocal folds in the larynx (voice box). The larynx houses two vocal folds which are used during respiration, phonation (voicing) and swallowing. During phonation the vocal folds come together and vibrate producing a sound, which travels up the vocal tract to the oral cavity where it is shaped into speech. A disruption to the nerve supply of the larynx can result in a paralysis of the vocal folds, if this occurs on one side it is described as unilateral vocal fold paralysis (UVFP). UVFP is typically identified by changes in voice quality due to the impaired opening, closing and vibration of the vocal folds. Changes in voice quality can result in a weak, breathy and rough voice with associated vocal fatigue.

Treatment of UVFP aims to recover or restore the closure and movement of the vocal folds typically through voice therapy exercises, surgical treatment or a combination of voice therapy and surgery. Selection of treatment type is typically based on the severity of the paralysis and the associated voice, breathing and or swallowing difficulties. To date, there is limited efficacy as to the best treatment for the management of UVFP. Further to this there is currently a lack of consensus for the most appropriate voice outcome measures for detecting a treatment effect in this patient group.

Outcome measures are tools used by health professionals in the planning, implementation and evaluation of intervention. These tools help clinicians in determining the treatment effect and are key in the reporting of clinical research. Studies which utilize behavioural (voice therapy) and surgical intervention for the management of UVFP have shown significant variability in the selection and use of voice outcome measures to assess the treatment effect. This variability both limits the potential to compare studies and overall treatment effect, and demonstrates a lack of current consensus of the most appropriate voice outcome measures for determining the treatment effect. We will review the validity, reliability, bias and timeliness of the outcome measure assessment protocol used for this patient population. The systematic review aims to determine the most appropriate voice outcome measures that are responsive to interventions overtime for patients with UVFP.

Participants/ population

Inclusion Criteria

- Studies with adult participants 18 years +
- Participants with a unilateral vocal fold paralysis (affecting either the L) or R) recurrent laryngeal nerve) diagnosed by an ear, nose and throat

surgeon (ENT) (via direct visualisation e.g. nasoendoscope)

- Presence of dysphonia/ voice disorder warranting treatment
- Intervention provided to treat the dysphonia by:
- a) Voice therapy (provided by a speech pathologist)
- b) Surgery (Provided by an ENT)
- c) Combination of surgical and voice therapy treatment





Exclusion

- Unilateral vocal fold paresis
- Bilateral paralysis
- Poorly described diagnoses (e.g. unable to differentiate paresis and paralysis)
- Superior laryngeal nerve paralysis
- Presence of dysphagia (swallowing difficulties) or breathing difficulties
- Dysarthria (Motor speech deficits) or multiple cranial nerve involvement
- Previous vocal fold and / or head and neck surgery.

Intervention(s), exposure(s)

Studies of interest will be those providing voice therapy and/ or surgical treatment for a dysphonia due to a unilateral vocal fold paralysis.

Treatment of UVFP aims to recover or restore the glottal insufficiency typically through behavioural voice therapy exercises, surgical treatment, or a combination of surgery and therapy. Selection of treatment type is based on severity of glottal insufficiency and the laryngeal functions which have been most affected e.g. breathing, swallowing or voicing difficulties.

Voice therapy is a behavioural treatment conducted by a speech pathologist aimed to improve vocal quality and reduce the severity of dysphonia (voice disorder). Voice therapy can consist of direct or indirect treatment, or a combination of both, and is often individualized for each patient to address their particular concerns and presenting symptoms. Of the evidence that is available studies report a wide range of voice therapy techniques to treat UVFP, these include: Vocal Function Exercises, resonant voice, glottal closure exercises and Accent Method Breathing.

Surgical treatment is performed by an ENT surgeon and is designed to improve the approximation of the paralysed vocal fold with the unaffected side. Surgical treatment can be temporary or permanent and can include: injections, medialisation or reinnervation. Temporary surgical treatment can include: vocal fold injections of a gel into the muscle which provides temporary improvements in glottal closure prior to being reabsorbed. Two permanent treatments for UVFP are: Thyroplasty type 1 (medialization) and non-selective laryngeal reinnervation.

Studies which use a combination of both voice therapy and surgical intervention to treat UVFP will be included in the review.

Comparator(s)/ control

Comparators or controls will be not used within this systematic review.

Context

Studies used for this systematic review will need to have provided intervention to adult patients (18 years +) with a unilateral vocal fold paralysis (UVFP).

The intervention that the participants received needs to be either:

- a) Voice therapy (Provided by a Speech Pathologist) and/or;
- b) Surgical intervention (provided by an ear nose and throat surgeon).

This intervention needs to have been used to improve the voice quality of participants (nil dysphagia or airway compromise).

Patients will need to have thorough diagnosis of UVFP affecting the recurrent laryngeal nerve (RLN) resulting in a





dysphonia.

The cause of the UVFP can include a range of aetiologies including: idiopathic, iatrogenic or other defined causes.

Studies will need to include pre/ post outcome measures using any voice outcome measures (published/unpublished) and report on the treatment effect following the surgical or voice therapy intervention.

Outcome(s)

Primary outcomes

Identify the outcome measures currently being used to measure the treatment effect in patients with UVFP.

Secondary outcomes

Comparison of voice outcome measures used between surgical and voice therapy research for patients with UVFP

Data extraction, (selection and coding)

Data will be collated into Endnote were all duplicates will be identified and then removed.

The remaining studies will then be transferred into Covidence (web-based software platform that streamlines the production of systematic reviews - https://www.covidence.org/reviews/active) were two of the authors will analyse articles for inclusion using the following method:

1. Title & Abstract screening

The Titles and abstracts of the retrieved studies will be screened. The titles and abstracts which broadly met the inclusion criteria, they will proceed to stage two were the authors will acquire full text of studies that potentially meet the eligibility criteria. Full-text articles will also be retrieved if the eligibility of the study cannot be determined due to insufficient information supplied in the abstract or absence of an abstract.

2. Full text review

The same two authors will independently assess study eligibility from the full text to ensure studies meet the inclusion criteria of the review. Any disagreements over which studies to include will be resolved by discussion and consensus or if disagreement cannot be resolved by these methods, a third author will be consulted.

Where clarification is required, we will contact the study authors to request the relevant information.

Studies reported in non-English language journals will be translated before assessment (where possible). Where more than one publication of one study exists, reports will be grouped together and the publication with the most complete data will be used in the analyses. Where relevant outcomes are only published in earlier versions these data will be used. Any discrepancy between published versions will be highlighted. We will document reasons for exclusion of studies.

3. Risk of Bias assessment

(Randomised and non-randomised ROB assessments)

4. Extraction of study characteristics and other study data

The extraction form includes the following information:

- 1. General: publication status (published/unpublished), title, authors, source, contact address, country, language of publication, year of publication, duplicate publications, sponsoring.
- 2. Methods: randomisation procedure, allocation, blinding (participants, people administering treatment, outcome assessors), duration of study, design, analysis method (e.g. intention-to-treat).
- 3. Participants: number, age, diagnostic criteria, history, baseline characteristics, setting.





- 4. Interventions: interventions (dose, route, timing, duration), comparison group.
- 5. Outcomes: outcome measures used, the reporting of the reliability and validity of the outcome measures, timing of outcome measures
- 6. Results: for each outcome and time of assessment specified above, including a measure of variation."

Disagreements will be resolved by discussion and consensus or by consulting a third review author as arbiter.

Risk of bias (quality) assessment

Two review authors will assess the risk of bias in included studies using the following tools: The Cochrane Collaboration's tool for assessing risk of bias will be used for randomised controlled trials and the ROBINS- I (Risk of Bias in non-randomised studies) will be used for quantitative non-randomised studies.

Depending on the types of studies and the content it is planned that results will be synthesised for publication in the systematic review.

Strategy for data synthesis

We intend to provide a quantitative and narrative synthesis of the findings of voice outcome measures for patients with UVFP.

We anticipate there will be limited scope for meta-analysis due to range of outcomes and variety of studies. However quantitative synthesis will be used if the included studies are sufficiently homogenous. This data will be aggregated and analysed.

Additionally, the descriptive data is anticipated to be collected (from experience with the previous systematic review investigation voice therapy for patients with UVFP). This data will need to be collated and analysed using the ROB assessment prior to writing up.

Analysis of subgroups or subsets

If the necessary data are available, subgroup analyses will be done for the following subgroups: (1) people who received voice therapy, (2) people who received surgical intervention. Further to this, if the data is available subsets of the different surgical procedures (i.e. thyroplasty, reinnervation, injection).

This is a qualitative synthesis and while subgroup analyses may be undertaken it is not possible to specify the groups in advance

Dissemination plans

It is intended that this systematic review will be submitted to a Q1 (Speech Pathology / ENT journal) for publication e.g Journal of Voice.

Contact details for further information

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Australia

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Organisational affiliation of the review

Australian Catholic University, University College London

http://www.acu.edu.au/, http://www.ucl.ac.uk/ear/evident





Review team

Miss Chloe Walton, Australian Catholic University Professor Paul Carding, Australian Catholic University Dr Erin Conway, Australian Catholic University Dr Helen Blackshaw, University College London

Anticipated or actual start date

13 December 2016

Anticipated completion date

28 July 2017

Funding sources/sponsors

Australian Catholic University

Conflicts of interest

None known

Language

English

Country

England, Australia

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Humans; Outcome Assessment (Health Care); Vocal Cord Paralysis; Vocal Cords; Voice

Stage of review

Ongoing

Date of registration in PROSPERO

21 December 2016

Date of publication of this revision

21 December 2016

Stage of review at time of this submission	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

PROSPERO

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The information in this record has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.

Appendix F- Statement of Authorship

The following is a description of the contribution of the main and co-authors for each of the prepared / submitted and published manuscripts included within this thesis.

1. Chapter 2 - Perspectives on voice treatment for unilateral vocal fold paralysis. Walton, C., Carding. P., and Flanagan, K, <u>Current Opinion in Otolaryngology & Head and Neck Surgery</u>, 2018. 26(3): p. 157-161.

Author	Roles	Contribution
Walton, C (Candidate)	Study design	70%
	Writing of manuscript	
Carding, P.	Study design	20%
	Revising the manuscript	
Flanagan, K.	Study design	10%
	Revising the manuscript	

2. Unilateral Vocal Fold Paralysis: A Systematic Review of Speech-Language Pathology Management. Walton, C., Conway, E., Blackshaw, H., and Carding, P. <u>Journal of Voice</u>, 2017. 31(4): p. 509.e7-509.e22.

Author	Roles	Contribution
Walton, C. (Candidate)	Study design	60%
	Data analysis and interpretation	
	Writing of manuscript	
Conway, E.	Study design	20%
	Data analysis and interpretation	
	Revising the manuscript	
Blackshaw, H.	Study design	5%

	Revising the manuscript	
Carding, P.	Study design	15%
	Data analysis and interpretation	
	Revising the manuscript	

3. Characteristics of Voice Therapy for UVFP: A survey of Speech-Language Pathologists. Walton, C., Conway, E., Carding, P., Flanagan, K. and Blackshaw, H. (Submitted manuscript)

Author	Roles	Contribution
Walton, C. (Candidate)	Study design Data analysis and interpretation Writing of manuscript	60%
Conway, E.	Study design Data analysis and interpretation Revising the manuscript	10%
Carding, P.	Study design Data analysis and interpretation Revising the manuscript	20%
Blackshaw, H.	Study design Revising the manuscript	5%
Flanagan, K.	Study design Revising the manuscript	5%

4. Walton, C., Conway, E., Carding, P., Flanagan, K., Sav, A. and Blackshaw, H. *The Characteristics of Voice Therapy for Patients with Unilateral Vocal Fold Paralysis: Semi-structured Interviews* (submitted to the Journal of Voice, October 2018) (Submitted manuscript)

Author	Roles	Contribution
Walton, C. (Candidate)	Study design Data analysis and interpretation Writing of initial draft of manuscript	60%
Conway, E.	Study design Data analysis and interpretation Revising the manuscript	10%
Blackshaw, H.	Study design Revising the manuscript	5%
Flanagan, K.	Study design Revising the manuscript	5%
Sav, A.	Study design Revising the manuscript	10%
Carding, P.	Study design Data analysis and interpretation Revising the manuscript	10%

5. Voice outcome measures for adult patients with Unilateral Vocal Fold Paralysis: A systematic review. Walton, C., Carding, P., Conway, E., Flanagan, K. and Blackshaw, H. Laryngoscope (in press)

Author	Roles	Contribution
Walton, C. (Candidate)	Study design Data analysis and interpretation Writing of initial draft of manuscript	60%
Conway, E.	Study design Data analysis and interpretation	15%

	Revising the manuscript	
Blackshaw, H.	Study design Revising the manuscript	5%
Flanagan, K.	Study design Revising the manuscript	5%
Carding, P.	Study design Data analysis and interpretation Revising the manuscript	15%

I hereby acknowledge that my percentage contribution to listed manuscripts, as outlined above, to be accurate and true.

Signature:		Date: 27/9/1/8
Co- Author: Dr.Paul Carding		
Signature:_		Date: 21 / 9 / 20 LA
Co-Author: Dr Erin Conway		
Signature:		Date: <u>8,9,20</u> (8
Co- Author: Dr Kieran Flanagan		
Signature:		Date: <u>28,09</u> <u>20</u> 18
Co- Author: Dr Helen Blackshaw		
Signature:		Date://
Co- Author: Dr Adem Şav	1	
Signature		Date: 4 1/0/2018

PhD Candidate: Chloe Walton















itle: Perspectives on voice treatment

for unilateral vocal fold paralysis

Author: Chloe Walton, Paul Carding, and

Kieran Flanagan

Publication: Current Opinion in

Otolaryngology and Head &

Neck Surgery

Publisher: Wolters Kluwer Health, Inc.

Date: Jun 1, 2018

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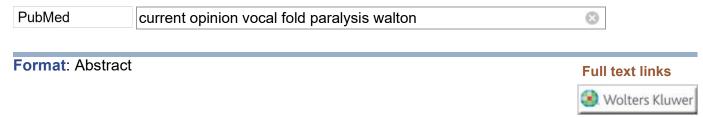
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1 of 1 3/10/2018, 8:50 pm



See 1 citation found using an alternative search:

Curr Opin Otolaryngol Head Neck Surg. 2018 Jun;26(3):157-161. doi: 10.1097/MOO.00000000000000450.

Perspectives on voice treatment for unilateral vocal fold paralysis.

Walton C¹, Carding P, Flanagan K.

Author information

Abstract

PURPOSE OF REVIEW: Unilateral vocal fold paralysis (UVFP) is a common cause of neurogenic dysphonia resulting in glottal insufficiency. To restore glottal sufficiency and reduce the presenting dysphonia, treatment involving either surgical intervention, voice therapy or a combination of the two is typically provided. Currently, there is no consensus for the most effective voice treatment for UVFP. This results in an inability to compare current studies, and a lack of treatment effectiveness for the management of UVFP. This study aims to review the most recent literature for the management of dysphonia due to UVFP to establish the current evidence base for voice treatment options.

RECENT FINDINGS: There was found to be a lack of consistency in the rationale, selection and timing of the surgical intervention and/or voice therapy being provided for patients with UVFP.

SUMMARY: Further consensus is required for the rationale and selection of voice treatment prescriptions for the management of UVFP in order to improve treatment effectiveness and voice outcomes in patients with UVFP.

PMID: **29465437** DOI: <u>10.1097/MOO.000000000000450</u>







LinkOut - more resources

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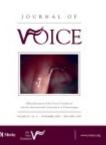












Unilateral Vocal Fold Paralysis: A Title:

Systematic Review of Speech-

Language Pathology

Management

Chloe Walton, Erin Conway, Helen **Author:**

Blackshaw, Paul Carding

Publication: Journal of Voice

Publisher: Elsevier Date: July 2017

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Unilateral Vocal Fold Paralysis: A Systematic Review of Speech-Language Pathology Management.

<u>J Voice</u>. 2017 Jul;31(4):509.e7-509.e22. doi: 10.1016/j.jvoice.2016.11.002. Epub 2016 Dec 19.

Walton C¹, Conway E², Blackshaw H³, Carding P⁴.

Author information

Abstract

OBJECTIVES: Dysphonia due to unilateral vocal fold paralysis (UVFP) can be characterized by hoarseness and weakness, resulting in a significant impact on patients' activity and participation. **Voice therapy** provided by a speech-language pathologist is designed to maximize vocal function and improve quality of life. The purpose of this paper is to systematically **review** literature surrounding the effectiveness of speech-language pathology intervention for the management of UVFP in adults.

STUDY DESIGN: This is a systematic review.

METHODS: Electronic databases were searched using a range of key terms including dysphonia, vocal fold paralysis, and speech-language pathology. Eligible articles were extracted and reviewed by the authors for risk of bias, methodology, treatment efficacy, and clinical outcomes.

RESULTS: Of the 3311 articles identified, 12 met the inclusion criteria: seven case series and five comparative studies. All 12 studies subjectively reported positive effects following the implementation of **voice therapy** for UVFP; however, the heterogeneity of participant characteristics, **voice therapy**, and **voice** outcome resulted in a low level of evidence.

CONCLUSIONS: There is presently a lack of methodological rigor and clinical efficacy in the speech-language pathology management of dysphonia arising from UVFP in adults. Reasons for this reduced efficacy can be attributed to the following: (1) no standardized speech-language pathology intervention; (2) no consistency of assessment battery; (3) the variable etiology and clinical presentation of UVFP; and (4) inconsistent timing, frequency, and intensity of treatment. Further research is required to develop the evidence for the management of UVFP incorporating controlled treatment protocols and more rigorous clinical methodology.

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KEYWORDS: Speech pathology; Unilateral vocal fold paralysis; Voice therapy

PMID: 28007326 DOI: <u>10.1016/j.jvoice.2016.11.002</u>

[Indexed for MEDLINE]

1 of 2

JSLHR-S-18-0284 manuscript decision

Journal of Speech, Language, and Hearing Research <onbehalfof@manuscriptcentral.com>

Thu 9/6/2018 4:54 AM

To:Chloe Walton < Chloe. Walton@acu.edu.au>;

Cc:julie.liss@asu.edu <julie.liss@asu.edu>;

JSLHR-S-18-0284: "Characteristics of Voice Therapy for patients with Unilateral Vocal Fold Paralysis: A cross-sectional survey of Speech-Language Pathology practice"

Dear Ms. Walton,

I have reviewed your Research Article along with reviewers.

We are interested in publishing it in the Journal of Speech, Language, and Hearing Research; however, the Research Article still requires some revision. We ask that you revise with respect to the changes suggested.

Please ensure you display the changes to your revised manuscript by using either the highlighter function in MS Word, track changes or by using bold, underlined or colored text. This will greatly help peer reviewers evaluate your revised submission.

Please use the following comments to guide your revisions.

REVIEWER COMMENTS TO THE AUTHOR(S)

We ask reviewers to provide lists of strengths and weaknesses in the categories of "Importance," "Justification/Rationale," and "Clarity and Format." If your manuscript was submitted as a research article, research note, or review article, then reviewers were asked to also respond to the additional categories of "Methods/Approach," "Results/Findings," and "Discussion/Conclusions."

Reviewer responses are organized into the above categories to help you interpret reviewer feedback. If a section has no feedback from a reviewer, then he/she skipped that section.

IMPORTANCE DESCRIPTION

Reviewers are asked to consider items including whether an important question is addressed and whether the manuscript has potential to advance the discipline.

IMPORTANCE STRENGTHS

Reviewer: 1

Importance Strengths: The presented work is interesting since it provides a practical vision of how to work in speech therapy in UVFP.

Reviewer: 2

Importance Strengths: This study is very meaningful research targeting world wide SLPs who have experienced UVFP to establish and develop more standard protocol for successful delivery of voice therapy for patients with UVFP.

IMPORTANCE WEAKNESSES

Reviewer: 1

Importance - Weaknesses: The type of study used does not allow to answer the three main questions postulated in the introduction.

Reviewer: 2

Importance - Weaknesses: This study is a survey-based research and quantitative and qualitative study but most of questions require very basic, general information and so need to strengthen the qualitative question parts to get more in-depth data regarding voice therapy for UVFP to reflect current their clinical practice.

IMPORTANCE OTHER COMMENTS

Reviewer: 1

Importance - Other comments:

Reviewer: 2

Importance - Other comments:

JUSTIFICATION/RATIONALE DESCRIPTION

Reviewers are asked to consider items including whether the work is well-motivated, is appropriately grounded in theory and prior literature, and falls within the mission of the journal.

JUSTIFICATION/RATIONALE STRENGTHS

Reviewer: 1

Justification - Strengths: The work is well-motivated and is appropriately grounded in theory and prior literature.

Reviewer: 2

Justification - Strengths: This topic deals with very interesting issue and well- matched in the mission, aims, and scope of JSLHR and provide the clear goals and rationale.

JUSTIFICATION/RATIONALE WEAKNESSES

Reviewer: 1

Justification - Weaknesses: There are some other questions that could have been asked.

When is the additional techniques more useful in your opinion?

At what time of therapy? What are the factors, findings in the perceptual analysis or aerodynamic measures that push the use of one or another technique?

Reviewer: 2

Justification - Weaknesses: In introduction, previous research findings should be described more in detail about voice therapy for UVFP systematically and the differences between current and previous studies. Also in discussion, compare systematic review (2016) and current findings and provide clinial implications.

JUSTIFICATION/RATIONALE OTHER COMMENTS

Reviewer: 1

Justification - Other comments:

Reviewer: 2

Justification - Other comments:

METHODS/APPROACH DESCRIPTION

Reviewers are asked to consider items including whether the overall strategy, methodology, research design, and techniques are clear, well-reasoned, appropriate, and current.

METHODS/APPROACH STRENGTHS

Reviewer: 1

Methods - Strengths: It is interesting the use of extensive questionnaires to know the reality of the speech therapy treatment in this pathology.

Reviewer: 2

Methods - Strengths: Survey procedure and data analysis are well conducted.

METHODS/APPROACH WEAKNESSES

Reviewer: 1

Methods - Weaknesses: .

Reviewer: 2

Methods - Weaknesses: During development and application of questionnaire, some procedure methods are not clear.

We would like to suggest some methodology to elaborate and give more information to clarify. Please include the author(s) who developed questionnaire (e.g. specialized in this area, requirement etc.) and procedure the questionnaire evaluation (e.g. content validity, face validity, supplement and revise process). From Q13 to Q 15 in questionnaire, when respondents select 'other', please let them explain the information in detail.

In Q 16, if there is no answer, please let them provide the statement and evaluate using 5-point scale. Voice therapy and voice evaluation

METHODS/APPROACH OTHER COMMENTS

Reviewer: 1

Methods - Other comments:

Reviewer: 2

Methods - Other comments:

RESULTS/FINDINGS DESCRIPTION

Reviewers are asked to consider items including whether planned data analyses were conducted appropriately, tables and figures are clear, and appropriate use of supplemental material is incorporated.

RESULTS/FINDINGS STRENGTHS

Reviewer: 1

Results - Strengths: It is worth highlighting figure 1, since it clearly shows the content of the therapy.

Reviewer: 2

Mail - Chloe.Walton@acu.edu.au

Results - Strengths: The results findings are well demonstsrated with tables and figures.

RESULTS/FINDINGS WEAKNESSES

Reviewer: 1

Results - Weaknesses: Table number 1 in the section of I would like to see differently the number of patients with UVCP, 1-9, 10-20, 20-30, 30-40 and + 50 patients since the most significant sample n is in this range.

Reviewer: 2

Results - Weaknesses: The results would need to be sufficiently described. In content of voice therapy, inhalation phonation is very popular voice therapy technique for UVFP in my country. Did you demonstrate the common voice therapy only in figure 1?

Please include the acoustic measures pre and/or post-therapy in Figure 3.

In some cases, doctor's referral about voice therapy for UVFP to SLP is very important factors which impact voice therapy. What do you think about this concern?

In Table 3, justification for voice therapy, there is no question regarding Table 3 in appendix A. Please clarify this information from the questionnaire.

Please provide information what is reference of appropriateness for voice therapy.

RESULTS/FINDINGS OTHER COMMENTS

Reviewer: 1

Results - Other Comments:

Reviewer: 2

Results - Other Comments:

DISCUSSION/CONCLUSIONS DESCRIPTION

Reviewers are asked to consider items including whether implications of the study have been considered and, where appropriate, clinical implications have been addressed.

DISCUSSION/CONCLUSIONS STRENGTHS

Reviewer: 1

Discussions - Strengths: .

Reviewer: 2

Discussions - Strengths: Current findings are well interpreted within the theories and previous studies. In addition, limitations of this study are mentioned.

DISCUSSION/CONCLUSIONS WEAKNESSES

Reviewer: 1

Discussions - Weaknesses: The discussion could deepen more in the why of the use of a type of therapies and not others, if the time that is treated is sufficient for the objectives since these must be individualized according to their study.

Reviewer: 2

Discussions - Weaknesses: Some apects related to voice therpy for UVFP were not addressed.

DISCUSSION/CONCLUSIONS OTHER COMMENTS

Reviewer: 1

Discussions - Other comments:

Mail - Chloe.Walton@acu.edu.au

Reviewer: 2

Discussions - Other comments: The questionnaire developed in this study need to ask more information and discuss based on the characteristics of variability of patients' characteristics about glottal gap size, vocal fold position (e.g., paramedian, medial position etc), vertical level of VF, injection applied for voice therapy to be more successful or efficient, and/or long-term effectiveness with pre or post therapy or both etc. In further research, these factors should be also investigated to provide evidence and rationale of voice therapy for UVFP.

CLARITY AND FORMAT DESCRIPTION

Reviewers are asked to consider items including whether the paper is clearly written, is in APA style, and uses person-first language and language that is free of bias.

CLARITY AND FORMAT STRENGTHS

Reviewer: 1

Clarity - Strengths: It has been easy to read and understand the study.

Reviewer: 2

Clarity - Strengths: This paper is well written in APA style and included appropriate references up to recent

studies.

CLARITY AND FORMAT WEAKNESSES

Reviewer: 1

Clarity - Weaknesses: .

Reviewer: 2

Clarity - Weaknesses: The information given this study is general not special when compared with previous

studies.

CLARITY AND FORMAT OTHER COMMENTS

Reviewer: 1

Clarity - Other Comments:

Reviewer: 2

Clarity - Other Comments: It would be also interesting about 'Is voice therapy needed for UVFP?' "Is voice therapy successful for UVFP? 'If needed, what(severity, palsy pattern, SLN vs. RLN, palsy position), when, how?', percentages of successful vs. unsuccessful voice therapy outcome depending on various clinicians(content, dosage, timing), patients(adherence, motivation etc), other factors.

OTHER COMMENTS FROM REVIEWERS

Reviewers have the opportunity to enter additional comments not covered in other sections.

Reviewer: 1

Brief Final Comments to the Author

(There are no comments.)

Reviewer: 2

Brief Final Comments to the Author
(There are no comments.)

EDITORIAL COMMENTS:

- * Please go to https://mc.manuscriptcentral.com/jslhr to submit your revised manuscript and a detailed response to our comments by 28-Nov-2018. We prefer resubmission within the timeline, but if you need an extension, please discuss this with me.
- * Do not submit your revision as a first or new draft. If you decide to submit your work to a different journal, you must notify me that you wish to formally withdraw your manuscript from further consideration before submitting somewhere else, even to another ASHA journal.
- * In the manuscript file, all text should be double-spaced, including the References listing.
- * References should be in APA style, 6th Edition. The Reference style should be consistent. Capitalize only first word of item title (and subtitle). Journal names should be listed in full and in italics. Please the following formats and use them as templates:
- 1. Basic APA Format for Books

Author, A. A. (Year of publication). Title of work: Capital letter also for subtitle. Location: Publisher.

2. Basic APA Format online journal reference

Author, A. A., & Author, B. B. (Date of publication). Title of article. Title of Journal, volume number, page range. Retrieved from (http web address).

3. Basic APA format for an edited book

Author, A. A., & Author, B. B. (Year of publication). Title of chapter. In A. A. Editor & B. B. Editor (Eds.), Title of book (pages of chapter). Location: Publisher.

4. Basic APA Format print journal paginated by volume

Author, A.A., (Year of publication). Title of article. Title of Journal, issue number, page numbers.

5. Basic APA Format print journal paginated by issue

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- * Please remove all shading from your tables. Bold text is allowed.
- * We noted blank cells in your table. Please double check to make sure that they follow APA guidelines. Blank cells in APA-style tables always indicate "data not applicable." En dashes indicate "data not

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[obtained]/[reported]/[available]." Correlation tables are exempt.

- * Table notes should be in this order: general notes, abbreviation key, asterisk notes (p values/significance), then lettered footnotes. General table notes begin with "Note." in italic.
- * Please do not embed figures in your manuscript file. Each figure must be submitted as a separate graphics file. Acceptable file formats include JPEG (.jpg, .jpeg), PNG (.png), TIF (.tif, .tiff), PDF (.pdf), Excel (.xls, .xlsx), or PowerPoint (.ppt, .pptx) file. Be sure to include figure callouts in the manuscript and figure legends after the References section of your manuscript. Note:
- Please note that all figures must have a minimum resolution of 200 dpi (preferably 300 dpi or greater).
- Please include figure legends (captions) in the manuscript file immediately following the references.
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Contact the Editorial Office at jslhr@asha.org, if you have any questions.

Thank you for submitting to the Journal of Speech, Language, and Hearing Research. We are looking forward to receiving your revised manuscript.

Sincerely,

Dr. Michelle Ciucci Editor Journal of Speech, Language, and Hearing Research

7 of 7

Successfully received: submission An in-depth investigation into the Characteristics of Voice Therapy for Patients with Unilateral Vocal Fold Paralysis for Journal of Voice

Journal of Voice < EviseSupport@elsevier.com>

Thu 10/4/2018 4:14 PM

To:Chloe Walton < Chloe. Walton@acu.edu.au>;

This message was sent automatically. Please do not reply.

Ref: JVOICE_2018_381

Title: An in-depth investigation into the Characteristics of Voice Therapy for Patients with Unilateral Vocal Fold Paralysis Journal: Journal of Voice

Dear Miss. Walton,

Thank you for submitting your manuscript for consideration for publication in Journal of Voice. Your submission was received in good order

To track the status of your manuscript, please log into EVISE® at: http://www.evise.com/evise/faces/pages/navigation/ (NavController.jspx?JRNL_ACR=JVOICE) and locate your submission under the header 'My Submissions with Journal' on your 'My Author Tasks' view.

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Kind regards,

Journal of Voice

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1 of 2 4/10/2018 4:15 PM

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cs-author@wiley.com

Mon 10/1/2018 11:19 PM

To:Chloe Walton < Chloe. Walton@acu.edu.au>;

Dear Chloe Walton,

The Laryngoscope

"Voice Outcome Measures for Adult Patients with Unilateral Vocal Fold Paralysis: A Systematic Review" Article ID: LARY27434

Thank you for your recent communication regarding the use of your article.

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Maria Atienza

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----- Original Message ------

From: Chloe Walton [chloe.walton@acu.edu.au]

Sent: 9/28/2018 9:13 AM

To: onbehalfof@manuscriptcentral.com; cs-author@wiley.com

Subject: Permission to include PDF of manuscript in PhD Article ID: LARY27434 [Case Number: 03522449]

{5000W00001HfpwHQAR.0030W00003Z1tNeQAJ}

Dear Laryngoscope,

I am writing to seek permission to please include a PDF version of my published manuscript within my PhD permission. I have less than a week until my PhD by publication is due for submission.

1 of 2 3/10/2018, 8:57 pm

Article ID: LARY27434

Article DOI: 10.1002/lary.27434 Internal Article ID: 15610877

Article: Voice outcome measures for adult patients with Unilateral Vocal Fold Paralysis: A systematic review

Journal: The Laryngoscope

Author email address: chloe.walton@acu.edu.au

For me to include a PDF version of the manuscript - my university Australian Catholic University requires written permission from the journal to include the publication.

Please let me know your thoughts and if you agree to the inclusion.

Thanks,

Chloe

ref:_00Dd0eeku._5000W1HfpwH:ref

2 of 2

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Format: Abstract	Full text links
Laryngoscope. 2018 Sep 19. doi: 10.1002/lary.27434. [Epub ahead of print]	Full Text Online Library

Voice Outcome Measures for Adult Patients With Unilateral Vocal Fold Paralysis: A Systematic Review.

Walton C¹, Carding P¹, Conway E¹, Flanagan K¹, Blackshaw H².

Author information

Abstract

OBJECTIVES: Unilateral vocal fold paralysis (UVFP) typically results in marked changes in **voice** quality and performance and has a significant impact on quality of life. Treatment approaches generally aim to restore glottal closure for phonation and improve vocal function. There are a wide range of **voice** outcome measures that are available to measure the treatment effect. Careful selection of **voice** outcome measures is required to ensure that they are adequate for purpose and are psychometrically sound to detect the treatment effect. This article aims to critically evaluate the literature for **voice** outcome measures that are used for patients with UVFP.

STUDY DESIGN: Systematic review.

METHODS: Nine databases were searched for UVFP treatment studies published since 2003 (n = 2,484 articles). These articles and their references were screened using inclusion/exclusion criteria, including population characteristics, treatment, **voice** outcomes, and study findings. Data from the included articles was extracted and appraised with respect to multidimensionality, timing, selection rationale, validity, reliability, and responsiveness to change of the **voice** outcome measures.

RESULTS: A total of 29 studies met the inclusion criteria for the **systematic review**. These studies showed considerable variability in the rationale, selection, and application of **voice** outcome measures for reporting the treatment effect for patients with UVFP.

CONCLUSION: There is currently a significant disparity in the selection and use of **voice** outcome measures for patients with UVFP. A set of principles around selection rationale, validity, reliability, and responsiveness to change is proposed to enhance the judicious selection of **voice** outcome measures for this patient group. Laryngoscope, 2018.

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KEYWORDS: Unilateral vocal fold paralysis; dysphonia; outcome measure; voice

PMID: 30229922 DOI: <u>10.1002/lary.27434</u>

1 of 2 3/10/2018, 8:39 pm

3rd Laryngology Society of Australasia 2018 | Abstract Accepted Confirmation

Laryngology Conference 2018 < laryngology@consec.com.au>

Fri 27/07/2018 4:52 PM

To: Chloe Walton <chloe.walton@myacu.edu.au>;

Dear Chloe

Thank you for submitting an abstract for the 3rd Laryngology Society of Australasia Conference 2018 to be held at the Adelaide Convention Centre, Australia from 2-4 November 2018.

We are pleased to inform you that **your abstract has been accepted** into the program by the Conference Organising Committee.

Due to the large number of abstracts submitted, the conference committee carefully reviewed all abstracts and have offered poster presentations to a number of people who requested oral presentations.

Please ensure you review your abstract/s details below as your **presentation type** may have changed.

Speaker Presentations

Title	Characteristics of Voice Therapy for UVFP: A Mixed-
	Methods Approach
Paper Status	Accepted
Presentation Type	Oral Presentation
Presenting Author	Miss Chloe Walton Affiliations: Australian Catholic University
Title	Are we measuring what we say we're measuring? Voice outcome measures for Unilateral Vocal Fold Paralysis
Paper Status	Accepted
Presentation Type	Oral Presentation
Presenting Author	Miss Chloe Walton Affiliations: Australian Catholic University

Could you please take this opportunity to email laryngology@consec.com.au by COB Friday 3 August 2018 AEST if you are no longer able to present your abstract and would like to withdraw it from the program.

Please check your abstract in the online portal, using your user name and password, to ensure your submission does not require any corrections, the abstract is correctly

formatted, to update results, or make any other amendments. The portal will close to any changes by **Monday 27 August 2018.**

Presentation Portal

Registration

It is a requirement that all presenters register for the conference. Register by **Thursday 16 August 2018** to secure the discount early bird registration rate. Please click on the below link to complete your registration.

Registration Portal

<u>To assist you with preparation for the conference please take note of the following requirements:</u>

Please ensure that all conflict-of-interest and acknowledgement of funding sources are listed on your submission.

Oral Presentations

Oral Presentations will be given 10 minutes (8 minutes presentation + 2 minutes question time).

Papers should be presented using PowerPoint projection (16:9 size). Overheads will not be permitted. Please bring your PowerPoint presentation slides on a USB to the speaker's preparation room on arrival at the conference so they can be loaded onto the conference lap top computers. Please also bring a back-up of your presentation.

Poster Presentations

Posters should be 84cm wide and 119cm high. Posters should include author and coauthor's names, a short title, the name of the institution where the work was carried out and the following sections: Abstract, Introduction, Methods, Results, Conclusions and Recommendations. Each poster will be allocated a poster number closer to conference. The poster number will indicate where your poster will be positioned/displayed at the conference.

If you have any questions please do not hesitate to contact the conference organisers on 02 6252 1200 or email laryngology@consec.com.au

AVA National Meeting Invitation

Georgia Magarey < georgia@voicetherapy.com.au>

Tue 8/7/2018 2:34 PM

To:Chloe Walton < Chloe. Walton@acu.edu.au>;

Dear Chloe,

Thank you for your time today, it was much appreciated. As discussed, the Australian Voice Association would be delighted to invite you to our upcoming National Voice Meeting in Adelaide, SA. The conference will be held at the Adelaide Convention Centre on Thursday 1st November 2018, from 0800-1800 - the day prior to the LSA conference. The delegates will be made up of Speech Pathologist, Voice Teachers, Physiotherapist and ENTs.

The theme for the conference is Voice On! The Road to Recovery with our International Keynote Leda Scearce.

We request a presentation of 15 minutes total as per our theme and as per our discussion, a focus on outcome measures and the practicalities of using them in the clinical setting. If you wish to discuss further and provide a different title than "Outcome Measures", please do not hesitate.

We are able to offer you the following:

- complimentary registration

If you can confirm via email that you accept our invitation, you can then register for complimentary registration via the link and with the coupon below:

https://www.australianvoiceassociation.com.au/product/voice-on-the-road-to-recovery/

AVANVM2018

You can register (purchase) your attendance and then apply the coupon when you go to checkout. This ensures that if you require accommodation it can be accessed at the discounted meeting rate along with registering any dietary requirements.

If you could send me a photo (jpeg please) and a bio as soon as you can that would be much appreciated.

Kind Regards,

Georgia Magarey

Mobile:

1 of 1 19/09/2018, 2:26 pm

AUSTRALIAN VOICE ASSOCIATION



GENERAL SECRETARIAT

2nd Floor, 11-19 Bank Place, Melbourne VIC 3000 Phone: 03 9642 4899

Fax: 03 9642 4922

Email: ava@australianvoiceassociation.com.au
Website: www.australianvoiceassociation.com.au

Chloe Walton

30 April 2018

Dear Chloe,

The Australian Voice Association is thrilled to be able to offer you a Student Encouragement Award for 2018. We congratulate you on your academic achievements thus far and trust that your interest in voice is further fostered by the tangible parts of this Award.

Firstly, you will be registered with 12 months complimentary membership of the AVA. This means you will receive the three copies of our newsletter VOICEPRINT as it is published throughout the year and be given access to the membership section of our website. We also offer you free registration to one AVA workshop or conference that you may like to participate in this year. The networking and collegial support that exists for AVA members is a truly positive part of our association. We hope you can take advantage of these opportunities.

Finally, Plural Publishing, which has a specialist catalogue of text books on all aspects of voice, has offered a book prize up to the value of US\$150 to our winners; you will be able to choose one relevant to your strand of study or special interest. To redeem this, I ask that you email Kirstin Banach *kristin@pluralpublishing.com* and she will facilitate your choice of this prize.

Congratulations again on being one of the winners of the 2018 Award. We trust it acts as encouragement to continue your special interest in studying and promoting voice. If you feel AVA can support you further, please feel free to speak with us. We hope that you will consider a continuing relationship with AVA - we warmly welcome young and enthusiastic professionals.

With best wishes

Dr Georgina Harris AVA National Vice President Convenor – AVASEA 2018