

**Prosthetic Surgical Voice Restoration (SVR): The role of the
speech and language therapist**

POLICY STATEMENT 2010

Royal College of Speech and Language Therapists

Advised review date 2012

Glossary of terms and abbreviations:

SVR - Surgical Voice Restoration

SLT – Speech and Language Therapist

MDT – Multi Disciplinary Team

CPD – Continuing Professional Development

RCSLT – Royal College of Speech and Language Therapists

TEP – Tracheo-esophageal Puncture (USA)

TOP – Tracheo-oesophageal Puncture

For simplicity, the abbreviation **TEP** will be used throughout this document.

PE segment – pharyngo-(o) esophageal segment (also known as neoglottis)

HME – Heat / Moisture Exchanger

(A)TSV – (Adjustable) Tracheostoma Valve

Voice prosthesis – any commercial product manufactured to shunt air between trachea and oesophagus/pharynx following surgical removal of the larynx.

Puncture – surgically created tract between trachea and oesophagus/pharynx

Tract

Fistula

} Often used to refer to tracheo-oesophageal puncture

For the purpose of this document the surgically created tracheo-oesophageal tract will be referred to as a '*puncture*' to distinguish it from a '*fistula*' which is often used to refer to a surgical breakdown/complication.

Where we refer to 'medical practitioner', we are assuming that this is a medical practitioner with knowledge and skills in both head and neck cancer surgery and Surgical Voice Restoration.

Acknowledgements

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This piece of work was commissioned by RCSLT and as such is limited to the practice of its membership. Whilst it acknowledges that other members of the Multidisciplinary Team may be involved with Surgical Voice Restoration – this is outside the scope of this document.

This document is intended to apply to the practice of Speech and Language Therapists in working within Surgical Voice Restoration (SVR). It is not intended to be a policy for Laryngectomy Rehabilitation as a whole, but solely related to the role of Speech and Language Therapists within the practice of SVR.

This final document is the result of extensive consultation with specialist SLTs and many other colleagues. The authors would like to acknowledge the contribution of specific interest groups (SIGs) and RCSLT advisers. The RCSLT is also grateful to the American Speech and Hearing Association (ASHA) and authors of the RCSLT Policy Statement “Fibreoptic Endoscopic Evaluation of Swallowing (FEES): The role of speech and language therapy” (Kelly et al., 2007) for their generosity in allowing incorporation of sections of their own guidelines into this document.

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Contents

Policy Statement

Section 1

Context

- 1.1 Background
- 1.2 Surgical Resume
- 1.3 Purpose of SVR
- 1.4 Suitability of SVR: patient groups and contraindications
- 1.5 Multidisciplinary context
- 1.6 Local arrangements
- 1.7 Facilities and equipment
- 1.8 Different types of voice prostheses
- 1.9 Models of service delivery

Section 2

Training and competency

- 2.1 Knowledge and skills
- 2.2 Methods of acquisition of the knowledge and skills
- 2.3 Level of competency and expertise
- 2.4 Maintenance of competencies

Section 3

Procedural issues

- 3.1 The SVR procedure
- 3.2 Health and safety
- 3.3 Patient and carer information
- 3.4 Consent
- 3.5 Documentation
- 3.6 Audit

Section 4

Developing and maintaining an SVR service

- 4.1 Long Term Rehabilitation issues
- 4.2 Troubleshooting and complications
- 4.3 Service Configuration
- 4.4 Costs and Budgets

Section 5

Medico-legal issues

References

Appendices

Appendix A - Equipment and Consumables

Appendix B – Suggested Knowledge/ Skills

Policy Statement

Prosthetic Surgical Voice Restoration (SVR) and management of tracheo-oesophageal puncture (TEP) prostheses has become a routine part of comprehensive voice rehabilitation for those undergoing surgery for removal of the larynx (laryngectomy).

It is the position of the RCSLT that SVR and management of the TEP and stoma related issues are within the scope of practice for Speech and Language Therapists (SLTs) with expertise and specialist training in this area.

We recognise that this is always undertaken in a multidisciplinary team (MDT) environment, and that this process is well established in a number of centres throughout the UK. Most existing services operate within an environment of mutual understanding between Speech and Language Therapy (SLT) and ENT colleagues, and these centres will already have well-established local policies. If a specialist SLT in the MDT delegates rehabilitation work to an SLT working in another setting, the specialist SLT should be available to provide expert advice and to assist with meeting the specific needs of these patients (NICE, 2004).

This Policy Statement should be read within this context and should be seen as supportive and facilitating not prescriptive or prohibitive.

Speech and language therapy practice is dynamic and changing. The scope of practice grows along with advances in technology enabling practitioners to provide new and improved methods of diagnosis and treatment. By identifying SVR as being within the scope of practice, it is not intended to limit any other new or emerging areas from being developed by SLTs to help improve diagnosis and treatment post laryngectomy. If practitioners choose to perform these procedures, indicators should be developed to continuously monitor and evaluate the appropriateness, efficacy and safety of the procedure conducted (RCSLT, 2008).

There are risks to patients in the use of TEP and the SLT should be aware of these, and follow the guidelines set out in this document.

This policy statement encompasses the following: background and evidence base, training and competencies, procedure and interpretation, health and safety, types of clinics, medico-legal aspects, patient populations and documentation.

Section 1

Context

1.1 Background

SVR is a recognised procedure for post-laryngectomy voice rehabilitation. It has been carried out by SLTs since its inception in the late 1970's (Blom et al., 1998). It involves placing a silicone (voice) prosthesis into a surgically created tract within the tracheo-oesophageal party wall, to redirect the pulmonary airstream into the oesophagus if the tracheostoma is covered. This airstream provides the energy source for vibration of the pharyngo-oesophageal segment which produces a sound source for pulmonary powered pseudo voice.

The prosthesis is a one way valve that allows air to travel posteriorly into the oesophagus, but prevents the return of oesophageal contents (saliva, food, drink) into the trachea, and thus prevents aspiration into the airway. It does not itself produce voice, it merely facilitates airflow and consequent vibration of the PE segment.

SVR procedures can be undertaken, either as a primary (at the time of laryngectomy) or secondary procedure (at some time later).

SVR practice has evolved and now includes the use of tracheostoma valves for hands free voicing and heat moisture exchangers/filters to compensate for loss of the benefits of nasal airflow (filtration, warming and humidification), laryngectomy tubes, stoma buttons etc.. The use of HME systems also compensates for reduced air resistance post laryngectomy. SVR therefore refers to more than a single procedure – it is a part of a process of voice and pulmonary rehabilitation after laryngectomy.

Since SVR procedures were first introduced, there have been several variations on the surgical approach and the type of voice prosthesis used.

1.2 Surgical Resume

Although this is a SLT document, the therapist needs to have some understanding of the basic surgical principles involved:

- a) The technique of SVR and all subsequent discussion applies only to those patients who have undergone a total laryngectomy as part of their surgical treatment
- b) Various other laryngectomy techniques such as partial sub-total or near-total laryngectomy may well require SLT expertise in the re-establishment of voice but do not include the use of a voice prosthesis as part of their management and are thus beyond the scope of this document.

c) In addition to total laryngectomy, more extensive procedures including free or pedicle flap repairs, jejeunal free graft or gastric pull up re-constructions are also amenable to SVR techniques. With proper technique, good surgical voice restoration can be achieved with these more extensive procedures. Voice may be more difficult to achieve but the considerations in this policy document apply equally to these more difficult cases.

d) Timing of the creation of the puncture and insertion of the prosthesis will vary with local practises. Whilst most departments now practise primary puncture (at the time of surgery), there is still a need for secondary puncture in some patients. The prosthesis may be inserted at the time of creation of the puncture but may equally be inserted once the puncture tract has stabilised.

e) Surgical technique is important for the successful development of voice. Consideration of SVR should start **before** the patient gets to the operating room, and in an MDT environment.

Attention to surgical details will mean significant improvement in long-term voice rehabilitation. This should include consideration of:

- preservation of as much normal tissue as possible
- preservation of constrictor muscles and their use in reconstructing a PE segment
- sternomastoid tenotomy to produce a flat neck around the tracheostoma
- a complete posterior myotomy to divide all fibres of the cricopharyngeus muscle to reduce the risk of spasm or hypertonicity in PE segment
- creation of tracheostoma and accurate placement of TE puncture, ideally 1cm down from tracheo-cutaneous junction

1.3 Aim of SVR

To assist in providing optimum communication after laryngectomy

1.4 Suitability of SVR - patient groups and contraindications

No patient should be excluded without full discussion of the options with patient and carers. Careful planning and consideration should be undertaken when considering these procedures with patients with dementia or loss of cognitive powers, poor vision, reduced manual dexterity and no carer willing to provide the necessary aftercare of a prosthesis/puncture. It should be stressed that if a patient opts for a voice prosthesis, and subsequently cannot manage it or does not like it, alternative forms of communication can still be chosen and the TEP allowed to close.

SVR is primarily an option for individuals who have had their larynx removed for oncological reasons. However, very rarely, a laryngectomy may be performed on individuals who present with a non functional larynx due to severe trauma or other disease. Laryngectomy is generally carried out in adults, but in rare circumstances, may be performed on children.

In all cases, suitability for prosthetic SVR should be assessed by the SLT as part of the MDT. Patient selection factors may include aspects such as patient's visual ability, manual dexterity, presence of a viable vibratory segment and access to appropriately trained SLTs and/or medical practitioners who can support the rehabilitation process.

Cases of overseas patients seeking SVR in the UK should be carefully considered to ensure that systems are in place in their own countries to support the rehabilitation process including availability of the prostheses and suitably skilled clinicians.

1.5 Multidisciplinary context

The SLT and the head and neck surgeon work as part of the extended Head and Neck Cancer MDT, and their joint management goals will be set initially prior to surgery, and may include assessment of the patient's potential if considering primary SVR or for producing oesophageal voice, the structure and function of the pharyngo-oesophageal structures, as well as specific prosthesis selection and placement, for secondary SVR.

Prosthetic SVR should be performed as part of a multidisciplinary team approach to laryngectomy management. The head and neck surgeon overseeing the patient's care should be involved in surgical aspects of SVR. A medical practitioner may or may not be present during some SVR procedures e.g. sizing and fitting voice prostheses. However, for complex cases, or inexperienced practitioners, a doctor with experience of SVR should be available to provide emergency medical backup for the SLT should a complication arise (see section 3.2 Health and safety).

The SLT, with their recognised role in communication rehabilitation, should take lead responsibility for SVR procedures involving prosthesis selection, prosthesis care, management and use for voice (NICE, 2004, SIGN, 2006).

1.6 Local arrangements

The SLT must ensure that approval has been given by their employer and manager with recognition of competence to perform the procedure (see section 2.0). Use of SVR procedures must be written into the SLT's individual job description. It is good practice to inform other colleagues (i.e. MDT, referrers) of changes in procedures, prostheses used or other management issues.

1.7 Facilities and equipment

Management of the TEP is a safe procedure when performed with the appropriate equipment.

A list of suggested equipment is enclosed in Appendix A which is not exhaustive, but may serve as a guideline for setting up services.

It is essential that all aspects of the procedure and equipment used as well as rationale for choice is documented in the legal medical record as per local policy.

1.8 Different types of Voice Prostheses

The range of voice prostheses is changing rapidly with new prostheses, and products to support their use, constantly being developed by manufacturers. It is essential that SLTs working in this area are aware of the full range of available equipment and facilities to ensure the best possible outcome for each individual patient, even if they use only one type of prosthesis in their routine practice.

In the UK the most commonly used voice prostheses are: Blom Singer (distributed by Forth Medical www.forthmedical.com/) and Provox (distributed by Platon Medical www.platonmedical.co.uk/).

There are two types of prostheses: *indwelling* which are designed to be cleaned in situ and *exdwelling* which can be removed for cleaning by the patient, carer or professional. Voice prostheses are available in a range of diameters and sizes. The prosthesis lifetime can vary from a few weeks to several months. Lifestyle, cleaning regime, candida and voice use can all affect prosthesis lifetime. When the prosthesis leaks or stops functioning in any way, it should be changed for a new one as soon as is practical to prevent aspiration of food and drink into the airway.

1.9 Different models of service delivery

Most of the equipment for management of the prosthesis is convenient to use and is portable. Prosthesis management (sizing, fitting, therapy) can be performed in a range of settings, including ward locations or in a designated clinic room. The philosophy of effective team working should be applied to any SVR clinic. A skilled, competent SLT may carry out the procedures single handedly, but where the SLT is less experienced, a minimum of two persons may be required to carry out the procedures safely and effectively. This may involve two SLTs or one SLT and another individual competent in the clinic procedures e.g. clinic nurse, medical colleague.

After the tracheo-oesophageal puncture has been created, it is the SLT's responsibility to select and fit the patient with the appropriate prosthesis, to teach care and use of the prosthesis and provide vocal rehabilitation thereafter. However, some of these aspects may be delegated to appropriately trained and supervised individuals – local agreement and specific protocols should be in place when tasks are delegated to other individuals.

Section 2

Training and competency

It is the RCSLT's position that evaluating and treating patients using SVR procedures following laryngectomy is within the scope of practice of Speech and Language Therapists.

Indicators should be developed to ensure the appropriateness, efficacy and safety of the procedure.

SLTs are competent to select the most suitable voice prosthesis, to decide when to change prostheses, and when to seek help.

Speech and Language Therapists who intend to perform these procedures must ensure that in order to perform independent SVR procedures, they must have undertaken appropriate training, and demonstrate that:

- they have acquired the appropriate knowledge and skills to carry out the procedure competently and safely (see Section 2.1 - Knowledge and Skills)
- in all instances, the procedure is carried out in accordance with the policy of the employing organisation
- they have mechanisms in place to monitor the appropriateness, efficacy and safety of SVR procedures conducted
- they have a close working relationship with their other members of the MDT
- they understand and utilise the opportunity to contact RCSLT specialist advisors and their MDT colleagues for professional advice and support

2.1 Knowledge and skills

Underpinning the knowledge and skills required to carry out SVR procedures, the SLT will have achieved core competencies in laryngectomy rehabilitation. Each SLT is ethically responsible for achieving the appropriate level of training to carry out SVR procedures competently.

The core pre-requisite knowledge and skills are:

- Evidence of postgraduate education/CPD in head and neck cancer
- Advanced clinical knowledge of post laryngectomy anatomy and physiology for respiration, alaryngeal phonation, and swallowing during and following surgical and non-surgical treatment for cancer
- Current and regularly updated skills and knowledge in head and neck cancer and laryngectomy management and rehabilitation including safe management of the stoma and optimising voice.
- Experience in working independently with laryngectomee patients

- Be at Level 3 or 4 as per Cancer Rehabilitation Measures (DoH, 2008)
- Knowledge of the indications and contraindications for different voice prostheses
- Knowledge of relevant local and national and international laryngectomy policies e.g.(American-Speech-Hearing-Association, 2004, BAOHNS, 2002, NICE, 2004, SIGN, 2006) and this document

Knowledge required for voice prosthesis management

The SLT will be able to:

- Select appropriate patients for SVR as a core member of the Head and Neck Cancer MDT
- Recognise altered anatomy as it relates to voice and swallowing function post treatment – both surgical and non-surgical
- Identify elements of a comprehensive SVR assessment including both voice quality and swallowing e.g. insufflation test, videofluoroscopy examination
- Detect and interpret abnormal findings during assessment
- Select appropriate prosthesis from the range available
- Apply appropriate treatment interventions
- Make appropriate recommendations to guide management
- Make appropriate referral or request a second opinion eg, ENT, other expert SLT
- Request a second opinion from ENT when complications are suspected
- Know when and how to re-evaluate and monitor voice prosthesis use and appropriateness
- Identify elements of tracheostoma management related to SVR

Skills required to manage voice prostheses

The SLT will:

- Use, maintain and disinfect the equipment needed for voice prosthesis selection and management – sizing, fitting, troubleshooting
- Insert the voice prosthesis in a manner which minimises discomfort and risk
- Be able to administer or have access to another practitioner who will administer topical anaesthetic if required (see section 3.2)
- Monitor the patient's comfort and safety throughout the procedure
- Interpret, document and communicate steps in prosthesis management and report any relevant findings/impressions

Recognition of problems, complications and management

The SLT will know how to recognise and manage the following:

- Prosthesis: position, loss, retraction, inappropriate size
- Tracheostoma: position, stenosis
- Puncture: position, stenosis
- Partial closure of puncture

- Split party wall
- Compromised party wall
- PE segment: tonicity, stricture
- Possibility of recurrence
- Able to recommend appropriate referrals for further investigations eg endoscopy, video fluoroscopic examination

2.2 Methods of acquisition of the knowledge and skills

Competence in SVR procedures may be acquired using a range of learning methods including:

- Didactic/classroom teaching (internal/external)
- Established and accredited SVR courses
- Attendance at established SVR clinics
- Mentoring
- Supervised clinical experience, including observation and guided practice
- Peer review of clinical practice/joint practice
- Attendance at relevant conferences
- Journal clubs (critical appraisal of the literature)
- Special Interest Group (SIG) attendance

2.3 Skills and expertise

An experienced SVR clinician or ENT surgeon will verify agreed SVR competencies, with a number of procedures to be agreed locally, carried out with supervision then with help at hand before proceeding to independent practice and off site working. These should include both simple and more complex procedures, with a range of prostheses.

Appendix B outlines a range of skills which may be useful for the SLT to acquire

2.4 Maintenance of competencies

SVR practitioners are expected to maintain their skills, and seek opportunities to update and maintain them. SLTs intending to perform SVR procedures must ensure that they have a demonstrable and declared interest in this area and acquire the specific specialised knowledge and skills to become proficient.

It is essential that the SLT has undertaken experiential and theoretical training under the supervision of colleagues with specialist experience in this area.

SLTs are responsible for maintaining their competency to be involved in SVR and to ensure the pre-requisites for practice are in place. It is anticipated this would involve regular practice. SLT's have a professional responsibility to review their competencies for SVR regularly.

SLTs should be working at expert level 3 or 4 as per Cancer Rehabilitation Measures in England (DoH, 2008).

Practitioners must maintain and enhance their knowledge and skills on a regular basis, by attendance at appropriate meetings e.g. Special Interest Groups and conferences.

On-going education must be recorded in the RCSLT CPD diary.

There is currently no identified formal undergraduate or postgraduate training in SVR procedures for Speech and Language Therapists. However, information days and educational courses are run, both by manufacturers of prostheses and independent organisations.

Section 3

Procedural issues

3.1 The SVR procedure

Initial management of the prosthesis may require access to medical and nursing personnel, sterilisation and emergency equipment. It should ideally be performed within a multidisciplinary environment, and always with the agreement of the medical practitioner responsible for the patient.

It is essential that the following facilities are available when a prosthesis is being sized, fitted, changed or manipulated in the airway:

- appropriate equipment
- good lighting
- equipment in accordance with infection control procedures
- suitable chair for patient and practitioner
- suitable working surface
- protective clothing for SLT e.g. apron, gloves, mask, eye protection
- suction for initial more complex changes and where respiratory function is poor, compromised or unknown

The following may be required for some early or more complex changes where appropriate and necessary:

- suction
- access to a medical practitioner
- nursing staff support
- bed or reclining chair
- oxygen
- resuscitation facilities

Voice Prostheses changes

SLTs undergoing voice prosthesis management should be aware of, and adjust their practice according to the type of prosthesis being used, following manufacturer's guidance, and adjust practice according to the type of procedure e.g. first prosthesis change, routine change, re-sizing, introduction of HME, stoma filters or other laryngectomy equipment such as fitting and using tracheostoma hands free valves.

Sizing and trouble-shooting

SLTs should be aware of how to recognise and manage difficulties or problems as detailed in section 2.1:

Teaching the patient to self-change

Where a patient is encouraged to self change the voice prosthesis, this should be undertaken with locally approved guidelines, with robust protocols and support for the individual whilst learning these skills. This may involve visiting the patient at home to support them in acquiring this skill.

SLTs may also be involved in ensuring that district nurses, family members or carers attend to learn about care in the immediate post-operative period before discharge home.

More extensive procedures

We also acknowledge that due to progress in cancer management, and access to chemo-radiotherapy and surgery for progressively more extensive tumours, practice in the UK is changing and surgeons are required to operate as salvage surgery on irradiated tissue with associated management difficulties such as wound breakdown and salivary fistulas. These may then lead to subsequent difficulties and complications in prosthesis management, with potentially more compromised tissue.

Out of hours provision

The MDT should ensure that there are locally agreed procedures for managing out of hours prosthesis problems (prosthesis extrusion, aspiration etc). This includes ensuring adequate documentation in the medical records to allow clinicians to access the relevant information out of hours, and ensure that the clinician can access information about the recent clinical history prior to undertaking out of hours procedures.

NB. Managing emergency out of hours procedures for patients with SVR problems by people not experienced in the technique should be strongly discouraged. Temporary management of prosthesis extrusion should be limited to inserting a nasogastric tube, stent or Foley's catheter into the TEP while awaiting specialist advice.

3.2 Health and safety

The SLT must ensure that approval has been given by their employer and manager with recognition of competence to perform the procedure. Use of SVR procedures must be written into the SLT's individual job description (RCSLT, 1999, RCSLT, 2005, RCSLT, 2006, RCSLT, 2008).

The SLT managing the clinic is responsible for adherence by any staff within his/her department to local policies. He/she should therefore be aware of policies on:

- use and care of substances hazardous to health (COSHH) with appropriate training to be undertaken if such substances are to be stored, used or disposed of within the Department.
- control of infection - disease transmission is possible via contact with equipment contaminated by saliva, blood and other body fluids. Sterilisation and storage of equipment should adhere to current infection control procedures to avoid cross infection of both patients and staff involved in the clinic. Speech and Language Therapists, therefore, should be familiar with and adhere to Universal Precautions (Centers-for-Disease-Control, 1987, UK-Health-Departments, 1998), local and institutional policies regarding the cleaning, decontamination and sterilisation and storage of equipment, and Isolation Precautions (Disease Specific and Category Specific).
- use of topical anaesthesia for successful prosthetic change. Under these circumstances Speech and Language Therapists should be aware of the protocols which need to be followed in order to administer anaesthesia, their indications and contraindications and possible drug interactions with their use. Patient Group Directions (PGD) should be developed with the MDT and involve the pharmacy department to comply with employer policy and procedures (Carding et al., 2008).

First aid and resuscitation

Due to the invasive nature of the procedure, SLTs involved in managing voice prostheses must undergo regular training in first aid and cardio pulmonary resuscitation, and training which makes reference to mouth to stoma resuscitation, with and without a voice prosthesis in situ. Resuscitation equipment and trained personnel (medical, nursing and physiotherapy) should be within easy access i.e., within the building and readily contactable.

Topical Anaesthesia and decongestants

Usually voice prosthesis management can be performed safely without any anaesthesia, but topical anaesthesia and/or nasal decongestant may be required in some cases may be applied to the TEP if required. Since May 2004 SLTs are entitled to administer topical anaesthesia under patient group directions (document MLX 294). SLTs should be aware of possible contraindications and adverse reactions.

Environments

During the process of the prosthesis change there will be periods when the airway is unprotected. Voice prosthesis management should normally be performed in an appropriate location. This may be on a hospital ward, or in a designated clinical area. If SVR procedures are to be performed outside a formal clinical environment, such as nursing homes, domiciliary settings, local policies to minimise risk should be in place. When starting to develop SVR practice, full backup with suction and MDT support should be available. It is therefore recommended that only patients with a well established tract and routine voice prosthesis changes should be seen outside of the clinical setting.

Disposal of materials

Any used items of consumable equipment should be disposed of as clinical waste or as advised by local infection control policy.

Decontamination and infection control

Disease transmission is possible via contact of equipment contaminated by saliva, blood and other bodily fluids. Sterilisation and storage of equipment should adhere to universal, local and institutional infection control policies to avoid cross infection. Patients with known infection status should be seen at the end of the clinic if possible and the nature of the infection documented. Appropriate precautions should be taken if substances hazardous to health are to be used for equipment decontamination. The practitioner should adhere to universal, local and institutional hand hygiene policies to avoid cross infection

Adverse effects of the procedure

SVR is a safe procedure but there are possible medical risks and complications associated with the use of prostheses. The following have been reported:

- Stimulation of vagal response, causing, for example hypotension, bradycardia
- Hygiene risks
- Adverse reactions to local anaesthesia
- Tissue trauma, bleeding and discomfort
- Aspiration of foods, fluids and gastric contents via the TE puncture, into the airway
- Accidental aspiration of the brush, equipment, tissue, prosthesis, tissues into the airway or loss of prosthesis, instruments, etc. into the oesophagus
- Infection of the TE puncture or mediastinum
- Tracheo-oesophageal wall separation or trauma to TEP
- Adverse reactions to adhesive preparations used in conjunction with the tracheo-oesophageal puncture
 - Creation of false tracheo-oesophageal tract
- Theoretical risk of practitioner acquiring an infection from the patient

Indications and contraindications

When considering performing any SVR procedure, the SLT must always consider possible contraindications. These are outlined in section 1.4. The rationale for performing SVR procedures on an at-risk patient must be clearly outlined in patient records. Failure to demonstrate and record careful consideration of the risks and benefits to the patient in these circumstances prior to proceeding with the procedures may constitute a breach of acceptable professional conduct (see Section 4, Medico-legal Issues).

Incident reporting If an adverse reaction occurs during any SVR procedure, appropriate medical assistance should be sought and local incident reporting procedures followed.

3.3. Patient and carer information

Patients should be fully informed about the benefits and any complications of SVR procedures as part of their management. Information should be given in verbal and written form and include management and care of the prosthesis and any other equipment. Publications by national support organisations e.g. Macmillan Cancer Support may be useful for some patients.

3.4 Consent

The NHS Good Practice in Consent (NHS-Executive, 2001) states the need for changes in the way patients are consented. It recognises that consent procedures vary between employing health service providers. SVR is an invasive procedure that carries some risks and hence a full explanation must be given and consent obtained prior to the procedure. The SLT must explain the procedure and provide written information where appropriate to the patient and/or their carer. It is recommended that the SLT reviews their departmental consent policy regularly and that it is adapted in light of local and national changes. SLT's should also review their local ENT consent document as appropriate.

3.5 Documentation

SVR and voice prosthesis management procedures should always be recorded as part of the patient's record as per local policy. Documentation should be kept according to the RCSLT professional guidelines. Individual policies will vary, but we would recommend the following as a minimum.

Departmental records should include all the patient's referral details along with any assessments, letters and reports.

The details of the SVR procedures carried out, including any untoward incidents, complications or emergencies and the management thereof, must be entered into the patient's health record. Untoward incidents must be further reported in accordance with local policy.

There may be differences between local policies about recording of information in Speech and Language Therapy notes, within the medical record and within the patient held record. Recording should be done in accordance with local departmental policy.

Recorded material is part of the patient's record, and therefore should be kept in accordance with local policy. The clinician should employ a system in order to facilitate retrieval and identification of recorded data, whilst maintaining patient confidentiality.

Procedures should be developed according to each service's requirements for out of hours access and documentation. Patients and their carers should be made aware of, and given written information regarding procedures to be followed if emergency aid is required out of SLT working hours.

It is the role of the SLT to be aware of the variance in information about laryngectomy and SVR and to educate and inform other services about the fundamental differences between laryngectomy and tracheostomy.

3.6 Audit

SVR services should be audited on a regular basis within a local clinical governance framework. As mandatory national audit systems emerge, clinicians may be required to contribute SVR data e.g. DAHNO in England .

Section 4

Developing and maintaining a SVR service

4.1 Long Term Rehabilitation issues

Following initial intensive input with the laryngectomee and their carers, the SLT involved in SVR should be aware of, and be able to address, issues involved in long term rehabilitation post-laryngectomy.

These might include:

- Traditional/non-SVR voice rehabilitation – use of communication aids, electronic larynx, teaching oesophageal voice as replacement or adjunct to SVR
- Air insufflation testing prior to secondary puncture to assess the viability of the PE segment for voicing.
- Stoma care – including stoma covers, humidification, Heat Moisture Exchangers, stoma filters, laryngectomy tubes, stoma buttons.
- Handsfree/Tracheostoma valves
- Trouble shooting long term stoma care eg narrowing of the stoma.
- Party wall problems e.g. thinning party wall
- Extruding prostheses
- Tissue health of TEP
- Granulation tissue formation/ change in the appearance of the tissue surrounding the tract or stoma may be a warning sign and the patient should be referred back to the MDT

4.2 Troubleshooting and complications

At each prosthesis change there should be an analysis of the reason for the change and prosthesis type, size, site of leakage, prosthesis deterioration, tissue change. Indications for changing the prosthesis should be recorded at each change.

SLT's should be aware of, and be able to identify rationale for a range of troubleshooting procedures and management options:

- botulinum toxin
- videofluoroscopic examination for voice and swallowing difficulties
- use of anti-fungal medication
- stomoplasty
- stricture dilatation
- range and choice of prosthesis types
- anticipating the difficult prosthesis change
- dysphagia
- peripheral leakage
- radiotherapy – management of TEP during treatment
- need for voice prosthesis diameter change
- ‘buried’ prostheses
- false tract
- tissue breakdown/fistula formation
- puncture closure
- abandoning SVR
- reflux management
- deteriorating physical and cognitive status of the patient
- management of TEP during radiotherapy
- holiday planning and out of district patients e.g. consideration of provision of spare voice prosthesis and emergency presentation whilst on holiday

A full range of techniques, products and facilities should be available for swallowing and voice rehabilitation and electronic larynx equipment should be provided for those who need it (NICE, 2004, SIGN, 2006).

SVR should be available for all patients who undergo laryngectomy, normally at the time of primary surgery. This service should be supported, with specialist SLT input on wards, appropriate rehabilitation services and equipment. The specialist SLT should be involved in the training of nurses and medical staff to carry out basic troubleshooting for these patients so that they are able to deal with common problems such as leaking or blocked voice prostheses and breathing and swallowing problems that may occur out of hours (NICE, 2004, SIGN, 2006).

N.B. Issues regarding tissue management should be referred to the head and neck surgeon.

Manipulation of the tract eg management of granulation tissue, forceful insertion of non standard dilators, should be avoided by the SLT. These issues should be noted and referred for a medical opinion at an appropriate level, as should issues regarding pain and/or bleeding.

Candida

The need for frequent voice prosthesis changes due to obstruction or leaking may indicate a candida fungal infection. In time, all prostheses will suffer from candidal attack. Attention may need to be given to appropriate treatment of this infection by the SLT and MDT.

Laryngopharyngeal / extraoesophageal reflux

It may well be the speech and language therapist, because of their regular contact with the patient, and involvement in prosthesis management and communication who first identifies reflux as a possible problem, and therefore refer back to Head and Neck Surgeon for discussion and appropriate management.

- Laryngopharyngeal reflux may be a factor in the development of (long-term) complications. A significant proportion of patients with Head and Neck Cancer also suffer with reflux – this can lead to problems both in the immediate post operative situation and in the longer term (Koufman, 2002, Vaezi et al., 2006)..
- Problems may include
 - failure to achieve voice
 - persistent sore throat
 - dysphagia or stricture formation
 - poor voice prosthesis survival
 - risks to TEP tissue health
 -
- Such problems should raise the suspicion of reflux. There should be careful investigation (it is often difficult to diagnose) and treatment should be aggressive (it often requires very high doses of medication etc to control).

- Patients who develop reflux related post Laryngectomy problems may have/need life long treatment.

Prosthesis modification

Prosthesis modifications are documented as a recognised procedure (Blom et al., 1998, Hilgers et al., 2008). This entails using a commercial product modified for a specific patient. Clinicians will need to seek clarification from their employers about the use of modified products in their patient population. This will include risk assessment and clinical governance mechanisms.

Examples of modified products include prostheses with enlarged flanges, disc modification, washers, hinged / weighted flaps.

4.3 Service Configuration

The NICE guidelines for head and neck cancer management (NICE, 2004) give the following recommendation:

“SVR should be available for patients who undergo laryngectomy, normally at the time of primary surgery. This service should be adequately supported, with specialist SLT support on wards, appropriate rehabilitation services & equipment”

RCSLT recognise this as both a highly specialised and costly service, and would actively support members’ need for staffing, training and equipment budgets for the provision of this expert service which is vital for post- laryngectomy rehabilitation.

4.4 Costs and Budgets

SVR services and provision of a comprehensive service to this population involves the SLT using a range of specialist and often expensive equipment and consumables. The service should be funded at an appropriate level so that a range and variety of voice prostheses and accessories are available for use, and to ensure the patient receives the most effective service possible. Systems should be in place to ensure that ‘value for money’ and economic concerns do not compromise optimal care for the individual.

Section 5

Medico-legal issues

This document is the RCSLT's official statement of professional practice for SLTs participating in SVR procedures. Adherence to its content and recommendations are the professional responsibility of the individual therapist and will ensure professional indemnity through the individual's employer. Failure to comply with the details of this policy statement, without a clearly documented and acceptable rationale for any change, and given individual circumstances, may amount to a breach of acceptable professional conduct. The RCSLT acknowledges that professional practice continues to grow and develop. Members should contact the RCSLT for advice about any areas of practice development relevant to this policy.

The SLT must ensure that approval has been given by the employing authority or directorate, with recognition of competence to perform the procedure, adherence to local health and safety policies and adequate professional liability insurance cover, either through the employer, the professional body or professional union.

The SLT must have knowledge and understanding of:

- potential risks to patients
- the appropriate environments in which procedures may be undertaken
- appropriate emergency medical procedures and back-up
- procedures/precautions which protect both client and clinicians from accidental exposure to disease
- department/institution policies with respect to required approval/qualifications for performance of the procedures
- professional liability/indemnity issues
- legal requirements regarding client confidentiality
- avenues of continuing professional development in the area

Policy Review

A review of this policy in two years (2012) is advised.

Appendix A

Equipment and consumables

This list of suggested equipment is not exhaustive, but may serve as a guide for setting up services.

Equipment

Focussed lighting or headlight

Dressings trolley

Good quality suction

Selection of suction ends e.g. plastic Yankauer , Zoellner ear

Locking haemostats

Tilley forceps

Scissors

Micropore tape or similar

Lubricating water soluble gel

Tracheo-oesophageal dilators

Tracheo-oesophageal sizers

Selection of voice prostheses in range of sizes, diameters and types

Foley catheters

Spigots

Blades

Sharps box

Prosthesis cleaning brushes

Jobson Horn probes

Food colouring dye

Mirrors

Suture material

Gel cap kits

Air insufflation test kits

Selection of laryngectomy tubes

Selection of baseplates and filters/HME's

Tracheostoma valves and attachments

Tube tapes

Shower guards

Manometer

Materials for prosthesis modification

Consumables

Gloves

Apron, visor, eye protection (see: infection control)

Instrument dishes

Sterile water

Clinical wipes

Tissues

Skin preparation wipes

Cotton tip buds

Paper cup

Milk

Fluid

Patient held record book with emergency contacts

CSSD bags

Dressing packs/towels

Gauze swabs

Silicone adhesive

Adhesive removal wipes

Topical anaesthesia – as per local policy

Sharps (blades/scissors etc.) and sharps disposal box – as per local policy

Range of catheters for down sizing or puncture ‘retrieval’

Written material for patient and/or carer

Selection of Tracheostoma covers/filters

Appendix B

Prosthetic Surgical Voice Restoration (SVR)

Speech and language therapy - suggested knowledge/skills

	Date	Initials
Sizing, fitting and using voice prosthesis		
1. Preparation for fitting the prosthesis - therapist		
Knowledge of effective lighting, inserter devices, lubricants.		
Knowledge of the different insertion methods for different prostheses		
Knowledge of risks associated with prosthesis insertion and removal		
Knowledge of safety measures to prevent aspiration of prosthesis.		
2. Measuring tracheoesophageal wall length		
Indications and contraindications for initiating prosthesis fitting.		
Use of gauges and sizers to measure puncture length		
3. Selecting type and style of voice prosthesis		
Knowledge of features of different prostheses: - method of insertion Difference in diameters - indwelling/non-indwelling - opening pressure - construction materials / special features eg large oesophageal flange, increased resistance and how related to patient's needs		
4. Preparing puncture for prosthesis insertion		
Knowledge of use of tracheoesophageal dilators or stents		
5. Ensuring the prosthesis is capable of shunting lung air into oesophagus		
Knowledge of factors that could interfere with prosthesis function		
Knowledge of testing procedures used to identify prosthesis involvement in patient's failure to produce tracheoesophageal sound.		
6. Checking patient is comfortable with prosthesis in place		
Knowledge of manoeuvres used to check for prosthesis related discomfort		
7. Checking for leakage around or through prosthesis		
Knowledge of procedures used to determine site of leak		
Knowledge of causes of, and remedies for leaking around and through		

prosthesis		
Teaching the patient to care for prosthesis		
8. Understanding factors which affect the working condition of the prosthesis		
Knowledge of frequency of cleaning, and procedures used to clean the prosthesis when it is in the puncture		
Knowledge of frequency of cleaning, and procedures used to clean the prosthesis when it has been removed		
Knowledge of the effects of Candida on the prosthesis, and methods of controlling its growth.		
9.Using the prosthesis for voicing		
Knowledge of behaviours which facilitate tracheoesophageal sound.		
Knowledge of behaviours counterproductive to generate tracheoesophageal sound.		
Teaching the patient to place the prosthesis		
10. Inserting the prosthesis - patient		
Knowledge of effective lighting, inserter devices, lubricants and adhesives.		
Knowledge of using catheters or stents to assist insertion.		
Knowledge of the relationship of prosthesis features to ease of insertion.		
Knowledge of risks associated with prosthesis insertion and removal		
Knowledge of safety measures to prevent aspiration of prosthesis.		
Resolving problems related to sound production		
11. Identifying causes of failure to produce sound		
12. Identifying causes of excessive vocal effort		
13. Remediating failure to produce sound		
14. Remediating excessive vocal effort		
Knowledge of causes and alleviation of symptoms associated with puncture stenosis or closure.		
Knowledge of causes and alleviation of symptoms associated with puncture management.		
Knowledge of causes and alleviation of symptoms associated with impedance of airflow through the prosthesis.		
Knowledge of causes and alleviation of symptoms associated with impedance of airflow through the oesophagus.		
Resolving problems related to leakage from TEP site		

15. Identifying causes of leaking through prosthesis		
16. Identifying causes of leaking around prosthesis		
17. Remediating leakage through or/and around prosthesis		
18. Teaching patient to identify leakage related to prosthesis		
Knowledge of testing procedures to determine location of leak.		
Knowledge of causes and alleviation of symptoms associated with prosthesis deterioration.		
Knowledge of causes and alleviation of symptoms associated with changes in puncture size.		
19. Resolving problems relating to tissue changes		
Knowledge of normal post laryngectomy anatomy and appearance of stoma, trachea, surgical puncture, and neck..		
Recognise tissue changes – normal post laryngectomy and abnormal		
Knowledge of procedures for consultation with, or referral to doctor for further evaluation and treatment needed.		
20. Resolving problems related to Stoma Size.		
Knowledge of adaptive devices where stoma is too large for manual occlusion		
Knowledge of methods of overcoming need for tracheostomy tubes or stoma buttons		
Tracheostoma Valves		
21. Selecting appropriate candidates for Tracheostoma Valves		
Knowledge of Tracheostoma Valve structures and functions		
Knowledge of the function, application, use and care of the tracheostoma valve.		
Identify factors which contraindicate or complicate Tracheostoma valve use and retention		
Knowledge of methods of measuring intratracheal pressure during speech.		
Knowledge of the causes of excessive intratracheal pressure.		
Knowledge of the relationship between peristomal configuration and tracheostoma valve retention.		
22. Fitting the Tracheostoma Valve		
23. Applying Valve Housing to Peristomal area		
Knowledge of procedures used to prepare peristomal area.		
Knowledge of manufacture's instructions related to fitting tracheostoma valve.		
Knowledge of alignment of housing with stoma.		

Selecting appropriate Tracheostoma valve		
24. Knowledge of types and features of available tracheostoma valves		
Knowledge of advantages and disadvantages of range of tracheostoma valves available		
Knowledge of tracheostoma valve sensitivity and adjustments		
Selection of appropriate type of tracheostoma valve to suit each patient		
25. Teaching the patient (or carer) to care for Tracheostoma valve		
Knowledge of manufacturer's cleaning instructions – tracheostoma valve and housing.		
Knowledge of range and functions of tracheostoma valve housings		
26. Applying the housing and tracheostoma valve		
Knowledge of procedures used to prepare peristomal area.		
Knowledge of adhesive and solvents related to tracheostoma valves.		
Knowledge of manufacturer's instructions relating to attachment.		
Knowledge of alignment of housing with stoma.		
27. Teaching the patient to use tracheostoma valve		
Knowledge of the relationship between intratracheal pressure, valve closure, and retention of housing seal.		
Knowledge of the optimum methods of using tracheostoma valve for voicing		
Knowledge of limitations of tracheostoma valves		
28. Safety precautions when using Tracheostoma Valve		
Knowledge of safety precautions when using Tracheostoma Valve		
Knowledge of methods used to prevent valve loss.		
29. Maintaining the seal of tracheostoma valve housing		
Knowledge of methods of reducing airflow resistance in the prosthesis.		
Knowledge of methods of reducing airflow resistance in the oesophagus and pharyngo-oesophageal segment.		
Knowledge of methods of modifying the tracheostoma valve housing including: - altering the shape of the existing housing - construction a customised housing from a mould of the peristomal area - enlarging the housing surface with adhesive tape		
Knowledge of range of available adhesive materials and methods of attachment		
Knowledge of range of remedial actions to resolve problems related to maintaining the seal of tracheostoma valve housing		

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