Site Name

AN OPERATING MANUAL FOR SPEECH IMAGING USING MRI

MRI Site: Protocol Initiation Guide

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Section

1

Introduction

Excerpt from Mason & Perry (2017). "Use of MRI for the Study of the Velopharynx". Perspectives of the American Speech-Language Hearing Association Special Interest Groups, 2(5), 35-52.

"Magnetic resonance imaging (MRI) has substantially contributed to our understanding of the velopharyngeal mechanism over the past decade. MRI is the only imaging modality that allows for visualization of the internal musculature *in vivo*. Insights from MRI provide improved visualization of anatomic structures, especially muscles, within the oro- and naso-cavities as well as the posterior pharynx. Many studies have examined the velar musculature in adults with normal anatomy (Bae, Kuehn, Sutton, Conway, & Perry, 2011; Ettema, Kuehn, Perlman, & Alperin, 2002; Perry, 2011; Perry, Kuehn, & Sutton, 2013; Tian & Redett, 2009), adults with cleft palate anatomy (Ha, Kuehn, Cohen, & Alperin, 2007), children with normal and cleft palate anatomy (Kollara & Perry, 2014; Mason & Perry, 2016; Mason, Perry, Riski, & Fang, 2016; Tian et al., 2010a; Tian et al., 2010b), and infants with normal and cleft palate anatomy (Kuehn, Ettema, Goldwasser, & Barkmeier, 2004; Perry, 2011). These MRI studies have enhanced our knowledge of the velopharyngeal system and offer a foundation to establish the utility of using MRI clinically to improve speech outcomes for children with cleft palate and craniofacial anomalies."

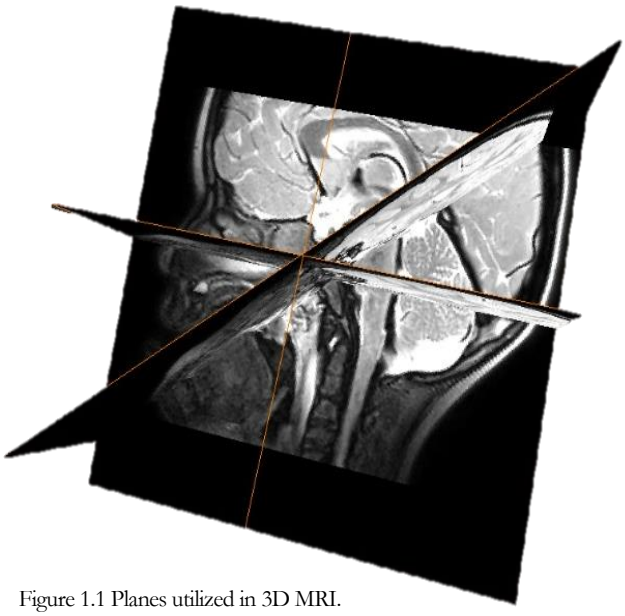

Figure 1.1 Planes utilized in 3D MRI.

PURPOSE

The purpose of this manual is to provide a guide and recommendations to facilitate the initiation of standardized MRI research protocols across clinical sites

Anatomy Overview

The velopharyngeal mechanism consists of a muscular valve that extends from the posterior surface of the hard palate (roof of mouth) to the posterior pharyngeal wall (back of throat). The purpose of the velopharyngeal mechanism is to create a tight seal between the velum (soft palate; outlined in red in the image below), and pharyngeal walls (yellow vertical line in image below) to separate the oral and nasal cavities during speech and swallowing. The velopharyngeal port (yellow circle in image) is the area that these structures must close. The velopharyngeal port (noted as double arrow in image A below) is patent (open) when breathing and for nasal consonants (/m, n, ng/).

Closure of the velopharyngeal mechanism is primarily accomplished by retraction and elevation of the velum, as seen in image B below. When the velum elevates during speech, it bends at a point referred to as the velar eminence or "velar knee". This is marked by the white arrow in the image B below. The primary muscles involved in velopharyngeal closure include the: levator veli palatini, musculus uvulae, tensor veli palatini, superior pharyngeal constrictor, palatopharyngeus, and palatoglossus.

Figure 1.2 shows a midsagittal MRI scan of the velum at rest (A), and elevated against the posterior pharyngeal wall for production of /i/ (B) and /s/ sounds (C). In the rest image the lips are together and the velum is laying on top of the tongue. During sustained /i/ the tongue arches up anteriorly within the oral cavity and the lips are slightly apart. During sustained /s/ the tongue lies flat along the floor of the mouth with the tip of the tongue behind the front teeth and the lips are also slightly apart. See Section 3.5 for additional information on imaging planes required for this study.

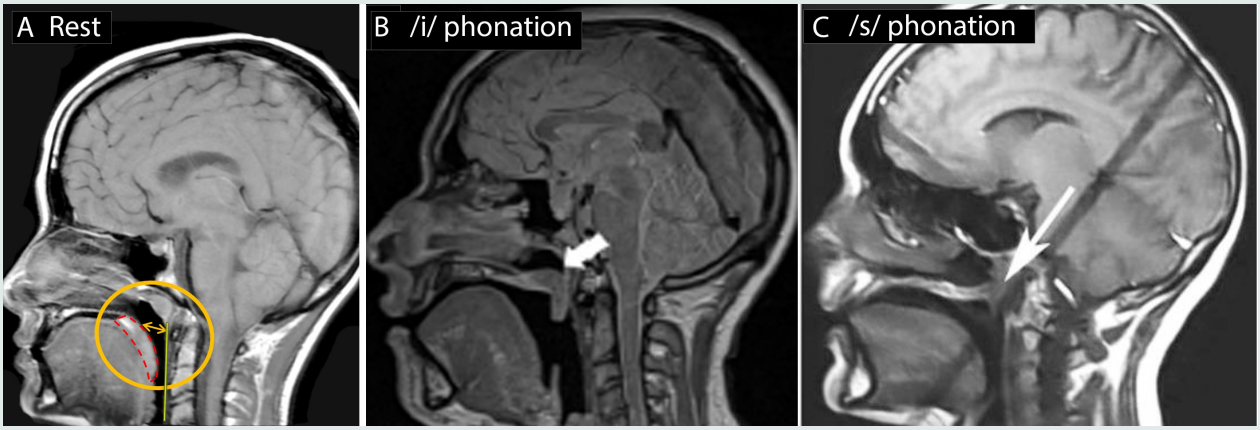

Figure 1.2. MRI scan at rest (A) and during sustained phonation of /i/ (B) and /s/ sounds (C)

Section

2

The Research Team

This research study is coordinated by investigators at the Study Coordinating Center, working alongside investigators and clinicians at your site. The research team includes members from multidisciplinary backgrounds, each bringing a unique perspective to the research program.

Fillable contact information for research team members at the Study Coordinating Center and research team members can be completed on the following page.

SECTION CHECKLIST

- [ ] Fill out the contact information for relevant research personnel and site coordinators
- [ ] Fill out the study funding information

2.1 PROJECT FUNDING

Funding for this study was supported in part by:

YOUR SITE RESEARCH TEAM CONTACT

PRINCIPLE INVESTIGATOR

Name

Phone

Email

SITE-PI/CO-INVESTIGATOR

Name

Phone

Email

RESEARCH ASSISTANT

Name

Role

Phone

Email

COORDINATOR

Name

Role

Phone

Email

RADIOLOGY

Name

Role

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Email

RADIOLOGY STAFF

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COLLABORATOR

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Section

3

MRI Protocol & Specifications

To establish the parameters necessary to run the study, initial protocol set-up is necessary.

Section 3.1 provides protocol set-up information. **Section 3.2** includes scanner specifications. These specifications should be programed on the designated study scanner and a **test scan** should occur prior to running study participants. The tests scans will be reviewed for verification and confirmation that the data needed are captured in the test scan. **Section 3.3** includes the recommended scan sequence.

Preparing for the test scan:

A member of the research team will collaborate with the radiologist, radiology technologist, radiology staff, and/or MRI physicist to schedule the test scan and protocol set-up. This may be completed in-person or via teleconference.

SECTION CHECKLIST

- [ ] Input scanning specifications on designated MRI machine(s). See Section 3.2.
- [ ] Complete the test scans
  - Non-sedated, no-contrast, and in the supine position
  - Localized to region of interest (oral-nasal cavity and throat)
  - Document site specific scanner parameters in Section 3.3
- [ ] Send test scans for verification
  - Localizer
  - 3D T2
  - 2D TSE oblique coronal *and* midsagittal scans at rest *and* sustained phonation

3.1 BROAD OVERVIEW OF MRI PROTOCOL SET UP

The protocol requires the use of a **head coil**. No neck coil is needed.

Participants will be completing a **non-sedated, non-contrast**, MRI scan in the **supine position**.

The **scan must be localized to the region of interest.** In brain MRI, the region of interest is the brain & localization to the nasion produces an image like the one below (A, Figure 3.1). However, for VP imaging, it is important to localize lower (e.g., nose tip) so that the image quality is improved in the area noted by the red box below (B, Figure 3.1).

Note that **environmental modifications are needed** when scanning young child-participants, given that this is a non-sedated scan. You should use environmental modifications that work at your site. Some examples may include using sand weights on feet, blanket wrapped tightly around the child's body, hands by their side, music or video as a way to keep focus, and cushions/wedges for head stabilizing. The parent/caregiver may also help by keeping the child's hands on their side to restrain motion and offer support. The goal of these measurements is to reduce movement of the head, limit overall body movement, and to comfort the child. More details regarding environmental and behavioral adaptations are provided in a later section.

It is important to ensure that the field of view (FOV) includes the **whole head** (lips, tip of nose, and back/top of head & below chin.), as seen below in the images. See **Figure 3.1.**

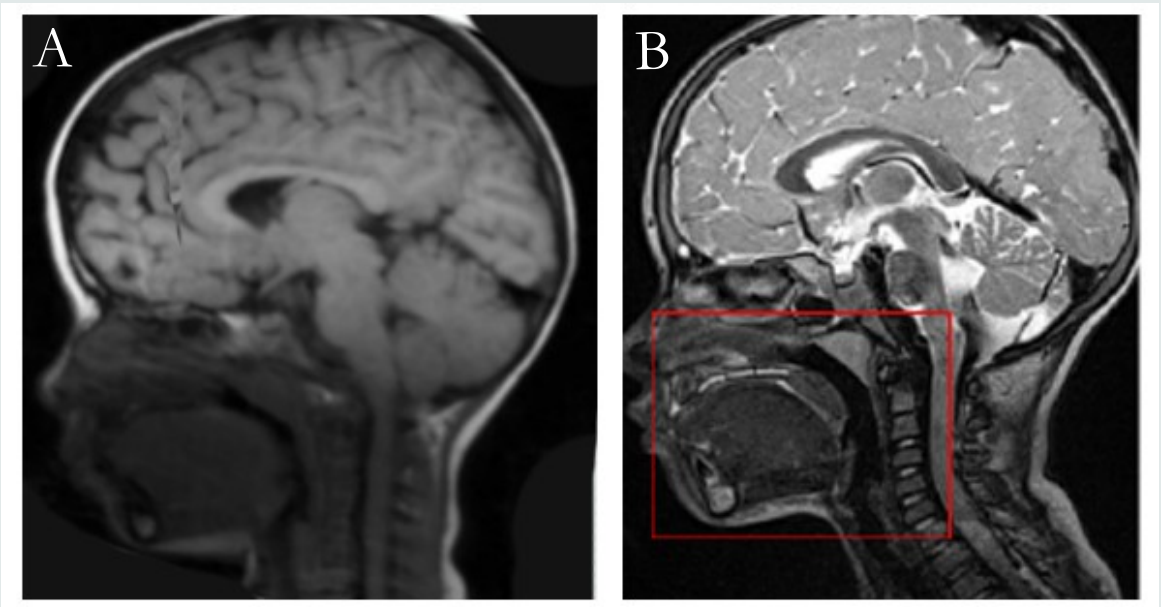


Figure 3.1. Field of View for Whole Head Scan and demonstration of how the image needs to be localized so that it produces improved contrast to the region of interest (noted in the red box) as in B, instead of the brain (as in A) which is common for brain imaging but *not* in VP imaging.

3.2 TECHNICAL SPECIFICATIONS

The below tables include *recommended* MRI 3D and 2D phonation sequences that are run after the localizer. Visualization of the velopharyngeal mechanism **at rest and during sustained phonation** is provided. Feel free to adapt these as necessary based on the type of scanner(s) available at the research site. If adapted, it is important to maintain the necessary field of view and localization.

Table 3.1. Specifications for the 3D sequence images. This is run once and obtained in the midsagittal image plane.

3D SEQUENCE PARAMETERS			
	GE 3T	**Siemens 3T**	**Philips 3T**
Pulse sequence	T2-weighted CUBE	T2-weighted SPACE	T2-weighted VISTA
Field of View	256	266	230
TE/TR	273/2500	268/2500	331/2500
Slice Thickness	0.8 mm	0.8 mm	0.9 mm
Spacing	0	0	0
Number of Slices	192	192	200
Approx. Scan Time	4:56	4:04	3:01

Table 3.2. Specifications for Phonation Task Sequence This sequence is run 6 times—under 3 conditions (rest, /i/, and /s/) and using 2 image planes (sagittal and oblique coronal)

Note: Label each scan with phonation + plane: "ee sag", "ee oblique coronal", "ss sag", "ss oblique coronal"

2D PHONATION SCAN PARAMETERS			
	GE 3T	**Siemens 3T**	**Philips 3T**
Pulse sequence	T2-weighted FSE	T2-weighted TSE	T2-weighted TSE
Field of View	220	160	220
TE/TR	79/1253	65/1600	151.71/4077.96
Slice Thickness	3.5 mm	3.5 mm	3.5 mm
Spacing	3.5	3.5	3.5
Number of Slices	6-10	4	8
Approx. Scan Time	7.8 sec	7.8 sec	8 sec

3.3 SITE SPECIFIC SPECIFICATIONS

Input the site and scanner specific parameters in the below table.

SITE SPECIFIC 3D SCAN PARAMETERS	
Scanner Brand & Type:	
Pulse sequence	
FOV	
TE/TR	
Slice Thickness	
Spacing	
Number of slices	
Scan time	

SITE SPECIFIC PHONATION SCAN PARAMETERS	
Scanner Brand & Type:	
Pulse sequence	
FOV	
TE/TR	
Slice Thickness	
Spacing	
Number of slices	
Scan time	

If you have a second scanner that will be used for this study, enter parameters here:

SITE SPECIFIC 3D SCAN PARAMETERS	
Scanner Brand & Type:	
Pulse sequence	
FOV	
TE/TR	
Slice Thickness	
Spacing	
Number of slices	
Scan time	

SITE SPECIFIC PHONATION SCAN PARAMETERS	
Scanner Brand & Type:	
Pulse sequence	
FOV	
TE/TR	
Slice Thickness	
Spacing	
Number of slices	
Scan time	

3.4 MRI SCAN SEQUENCE

The MRI protocol involves multiple, short scanning sequences. The order of scans should be:

1. **Localizer**
2. 3D T2
    a. **Possible backup sequence (2D or 3D) that has shorter scan time (1-2 min)**
3. **2D sagittal at rest**
4. **2D oblique coronal at rest**
5. **2D sagittal with sustained /i/ phonation (pronounced "eeee")**
6. **2D oblique coronal with sustained /i/ phonation**
7. **2D sagittal with sustained /s/ phonation (pronounced "sssssss")**
8. **2D oblique coronal with sustained /s/ phonation**

IMPORTANT NOTE

The 3D T2 scan is the most important scan. **REPEAT** this scan, as necessary, if motion artifacts appear. We recommend that you create a second 3D sequence that is shorter & can be run faster in the event the longer higher quality 3D sequence is unsuccessful. A shorter 3D sequence can be created by reducing the number of images and adjusting the TR and TE to create an image time that is between 1-2.5 minutes.
If you are unable to complete the 3D scan, move on to the 2D scans.

3.5 KEY IMAGING PLANES

Important: Ensuring that correct orientation of the plane *in the imaging suite* is essential for adequate interpretation of the images.

For VP imaging, the key image planes are as follows:

Sagittal plane provides visualization of velar elevation and assessment of structures along the central, midsagittal plane, providing lateral views of the velum, depth of the nasopharynx, length of the velum, and adenoid dimensions.

Coronal plane provides visualization of 2D measurements of the cranial and facial structures and mesial movement of the lateral pharyngeal walls during speech using dynamic imaging methods.

Axial plane provides a superiorly based, "birds-eye" visualization of the velopharyngeal port.

Oblique coronal plane provides visualization of velopharyngeal closure in plane, a view which an axial slice cannot provide. This is particularly important in adults where the plane of closure is marked by elevation of the velar knee above the palatal plane. The oblique coronal plane is an optimal plane to evaluate the internal velopharyngeal musculature. Primarily, this plane allows for the visualization of the complete levator veli palatini muscle. By using an oblique coronal imaging plane, the levator muscle can be sampled along the full axis of the muscle.

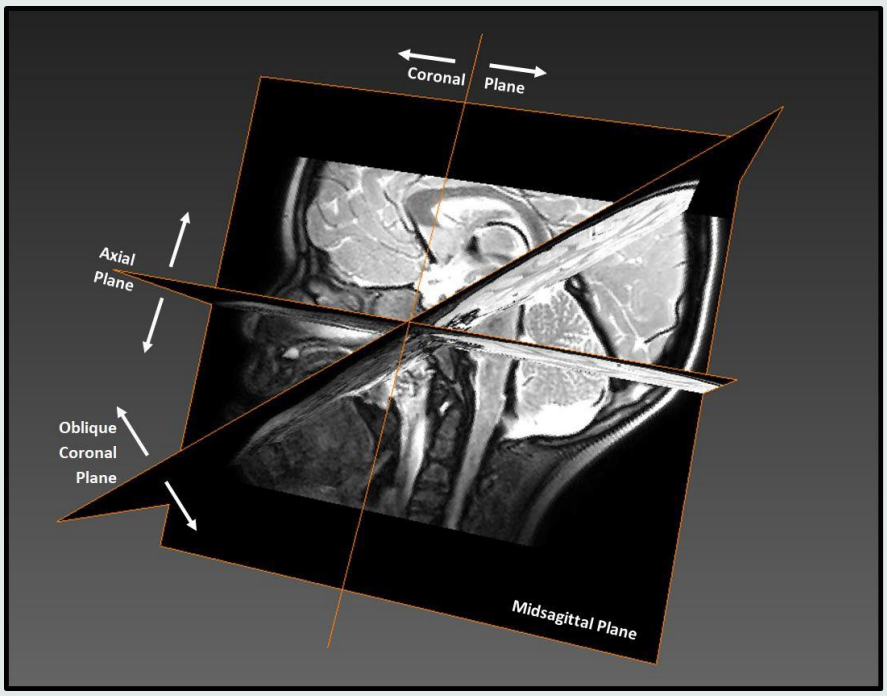


Figure 3.2: Essential imaging planes from Mason & Perry (2017)

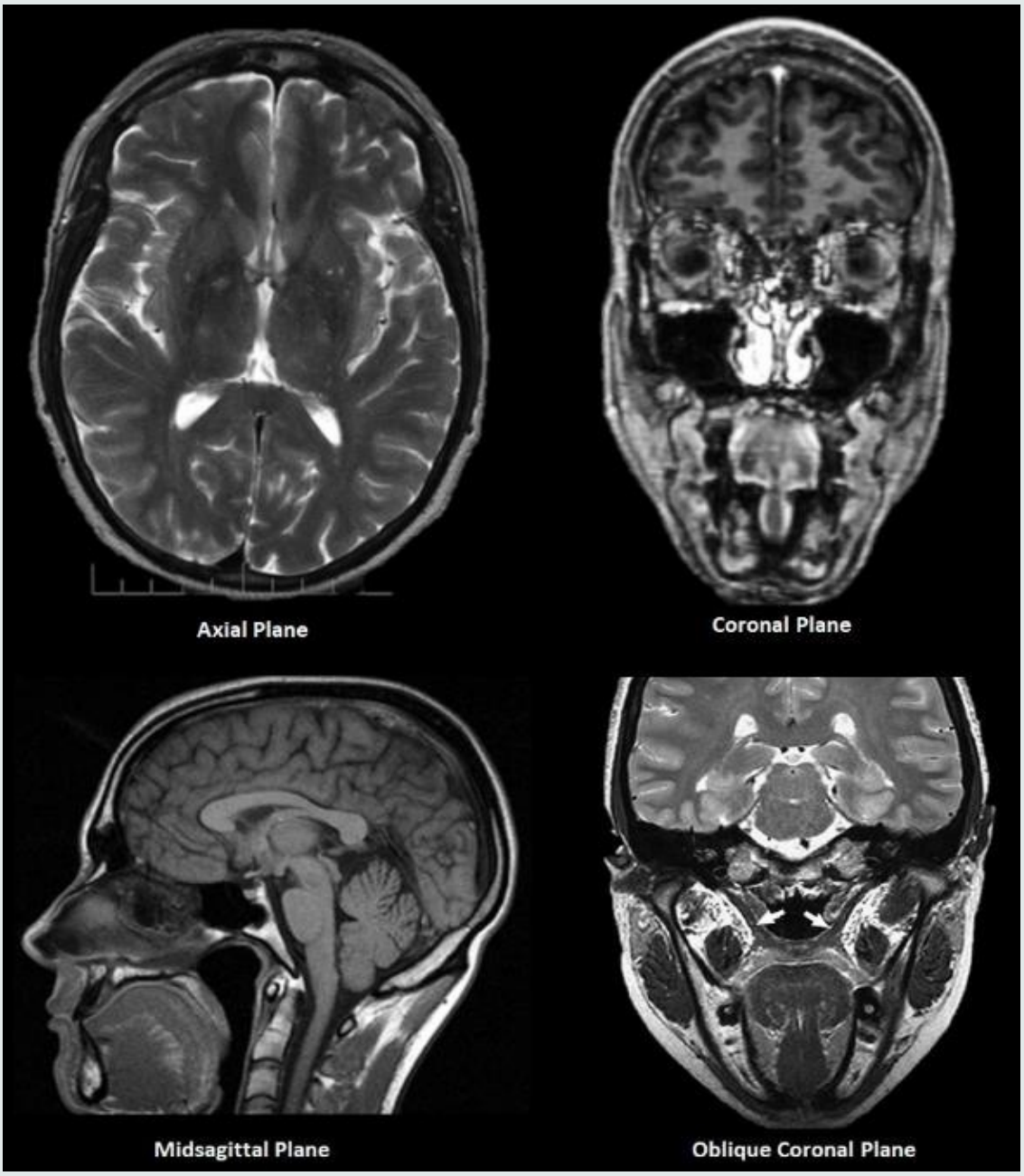


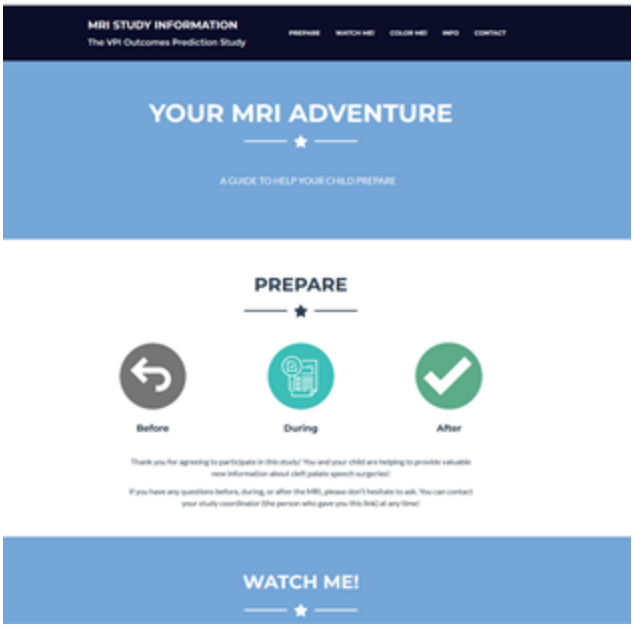
Figure 3.3: Visualization of structures within each imaging plane from Mason & Perry (2017)

3.6 RUNNING THE VP MRI PROTOCOL
Patient Preparation

Patient Preparation

Study coordinators will prepare children for the MRI in advance. They will share with patients a website developed specifically for this study that discusses the MRI experience and what to expect. Children will be encouraged to watch the MRI video that is designed to prepare the child before the MRI study. Coloring pages are also available, which can help to familiarize the child with the MRI study. Older patients can also be directed to the site and advised to reference the section for "adults."

http://www2.ecu.edu/mriprep/



On the day of the MRI:

- MRI safety screenings used at your MRI site should be completed by the patient and parent/ guardian who will be present in the MRI room with the patient.
- If available, allow the child to view the MRI video from the website just before the study begins.
- *Patient Instructions:* Particularly for young children, discuss that he/she will enter a spaceship and that all spaceships can be noisy. Explain that "this spaceship will make noises just like in the video. When the spaceship is making noises, it is taking pictures that allow us to see their brain."
- *Patient Instructions:* Tell the child that they are to "hold very still while in the scanner. Towards the end I will tell you to make 2 sounds—an "eee" sound and a "ssss" snake sound." Tell them this is what it will sound like "eee" (hold for 7-8 seconds) and repeat with "sss" model. Particularly for children, it is beneficial to have them practice with you saying these sounds aloud. Remind them that you will tell them when they need to say these sounds. This conversation might go something like this: When I say 'go' I want you to make the "eee" sound for as long as you can. Let's try now. Ready, set, GO! "eee...". Count to 8 with your fingers, so the patient can see their progress. Consider making the sound with them to provide encouragement. After 8 seconds, tell the patient to stop. Provide positive encouragement to the patient when they are able to hold these sounds. Repeat to practice the "sss" sound.
- Particularly with children, avoid saying words that will instill fear such as "nothing will hurt you", "there is nothing to be scared of", or "if you feel scared..." Even though these are intended to comfort the child, they produce a negative association with the experience.
- Particularly for children, require that they use the restroom before starting the study.

3. 6 RUNNING THE VP MRI PROTOCOL
Patient Positioning

NOTE: P**roper positioning of the patient is crucial for the success of the MRI exam. It is important that patients are positioned the same for every MRI exam. Ensure that the patient's head is centered in the FOV with the entire head and face being visible.**

Patient Positioning

- Ensure the patient is not wearing a hooded shirt that might impact the head and neck positioning. Remove all clothing with metallic trim such as zippers, buttons, earrings, and necklaces.
- Tape a stereotactic marker (fish oil capsule) on the patient's right temple (RT)
- Provide ear protection for patients and parents (if in the scanning room) and headphones for the patient to communicate with you during the scan
- Position the head and neck so it is straight and with no extension, flexion, or rotation of the head. Cushions or foam wedges can be used to ensure a tight fit of the head within the head coil and to limit movement. Cushions under the back of the head (like a pillow) tend to create wrap around; therefore, avoid this if possible.
- Make sure that the head coil is centered on the head and the patient's head is as far up in the head coil as possible.
- Offer the patient a panic button in case of emergencies, discomfort, or claustrophobia.
- Consider additional child-friendly protocol steps outlined below based on the child's age, comfort, and resources at your site. At a minimum, children typically need a sheet/blanket to be wrapped around their uncrossed arms and feet to reduce movements. For children who are very prone to movement, have the parent/guardian lay on top of the child with their face on the child's chest and the parents hands holding the side of the child's head. Be sure to remind the parent/guardian to not speak at all to the child while in the scanner. When parents talk, this can lead to movement as the child will look to their parent to respond (unless they are a teenager).

Entering Subject Information

Enter the patient's full name, your location, and patient weight and height of the patient as you would for any standard clinical MRI data. Label the MRI scans according to the sequence name "3D T2" "2D TSE" AND indicate the condition and plane for all 2D scans "2D TSE Rest sag". The following nomenclature should be used for labeling the sequences when they are run:

"Localizer"	"2D TSE eee sag"
"3D T2"	"2D TSE eee oblique coronal"
"2D TSE rest sag"	"2D TSE sss sag"
"2D TSE rest oblique coronal"	"2D TSE ss oblique coronal"

*the name of sequence will vary by scanner type (e.g., MPRAGE, SPACE, CUBE, etc.)

3. 6 RUNNING THE VP MRI PROTOCOL
MRI Sequences

Step 1: Three Plane Localizer

- Using the localizer, make any corrections to adjust for any rotation or tilt of the head. The midsagittal should run through the lateral ventricles and through the center of the cerebellum as seen in the image. Adjust for rotation of the head by placing the axial image plane through the top of the lateral ventricles.
- The hard palate should form approximately a 90-degree angle to the spinal column, as shown in the below image.
- Ensure the image is localized to the region of interest—the oral and nasal cavities & throat.
- Ensure the FOV is placed to avoid any side-to-side wrapping of the head

Figure 3.5: Using localizer to adjust for minor head rotation and tilt

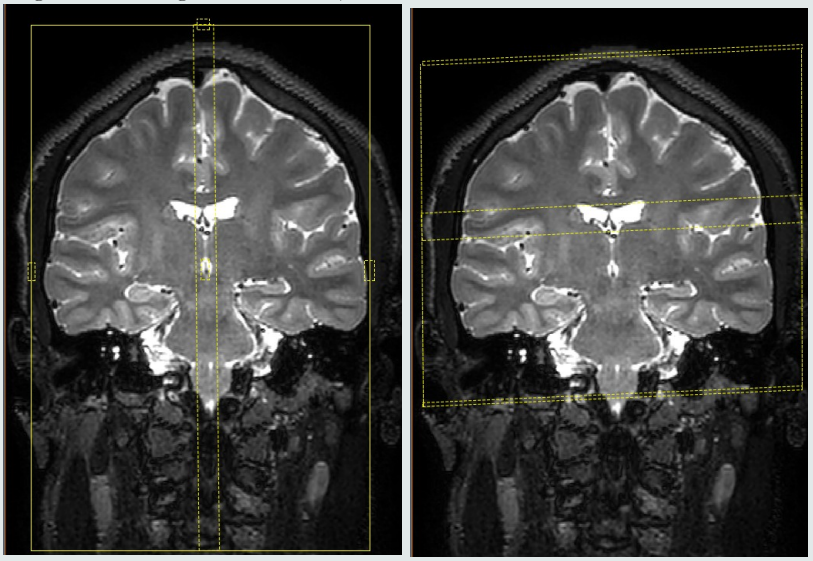
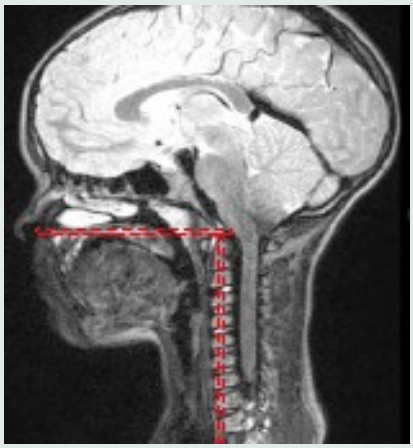


Figure 3.6: 90 degree angle formed by hard palate and spinal cord, note also the correct position of the neck with no flexion or extension.



NOTE: If the patient is not positioned properly, readjust the patient in the head coil and re-scout until the head is positioned correctly. Studies that do not include the whole head/face may not be able to be used for the purposes of this study.

Step 2: Run 3D MRI Sequence

- The 3D MRI sequence should be collected in the sagittal image plane with patient at rest. Rest condition means the lips are sealed and the patient is breathing through his/her nose.
- *Patient Instructions:* *"you will start to hear the noises, hold as still as a statue"*
- Immediately start the scan after giving the prompt and while the 3D sequence is running begin to prepare the 2D midsagittal and oblique coronal sequences by placing the location of the image planes accordingly. You may also choose to obtain the 2D oblique coronal from the 2D sagittal image.
- You should have prepared in your protocol a faster 3D sequence that can be run in 1-2.5 minutes. This should be held as a back-up in the event the longer sequence with higher image resolution shows too much motion artifacts. If needed, this faster 3D sequence should be run immediately after the longer 3D sequence.
- **If motion continues to be a negative factor, proceed to Step 3 to run the fast 2D scans.**

Step 3: Run the 2D Rapid Sequences

- The position of the midsagittal should be as shown below and should include between 6-10 slices. The exact number of slices may vary between patients. As a general guide, the sagittal images should cover from one side of the throat to the other, as seen in the figure below. Using the coronal images pulled from the 3D, determine how many slices are needed to cover this distance. It will be a fewer number of slices for children than adolescents or young adults.
- The oblique coronal slice is established using the spheno-occipital synchondrosis as a guide for placement, as seen below. This is the location where the basisphenoid joins the basi-occiput. The plane should course through this landmark. Usually this plane is at 55-60 degrees vertical axis. The oblique coronal slice should start anteriorly enough to capture the posterior edge of the bony palate. Slices should extend anteriorly enough to capture the posterior edge of the bony palate and extend posteriorly enough to include the adenoid pad and most of the palate. See the image below and additional details regarding the muscle are on the next page.

Figure 3.7: Image A shows a midsagittal slice and the location of the coronal slice (shown in red line in A and then viewed in image B). The sagittal slices should extend laterally from the throat (dark opening in center of image B) to span the width of the throat as seen in image C.

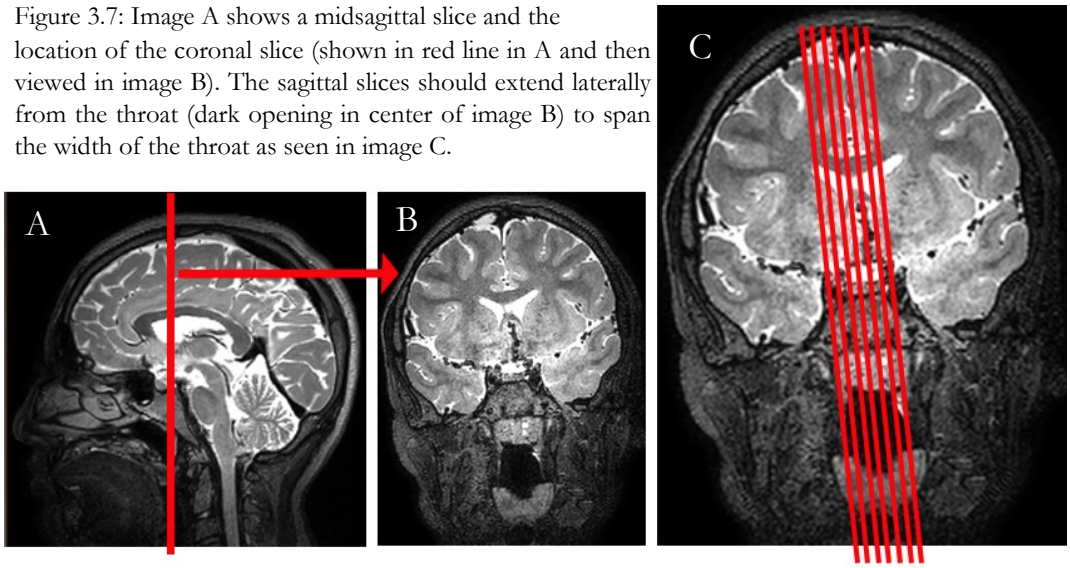
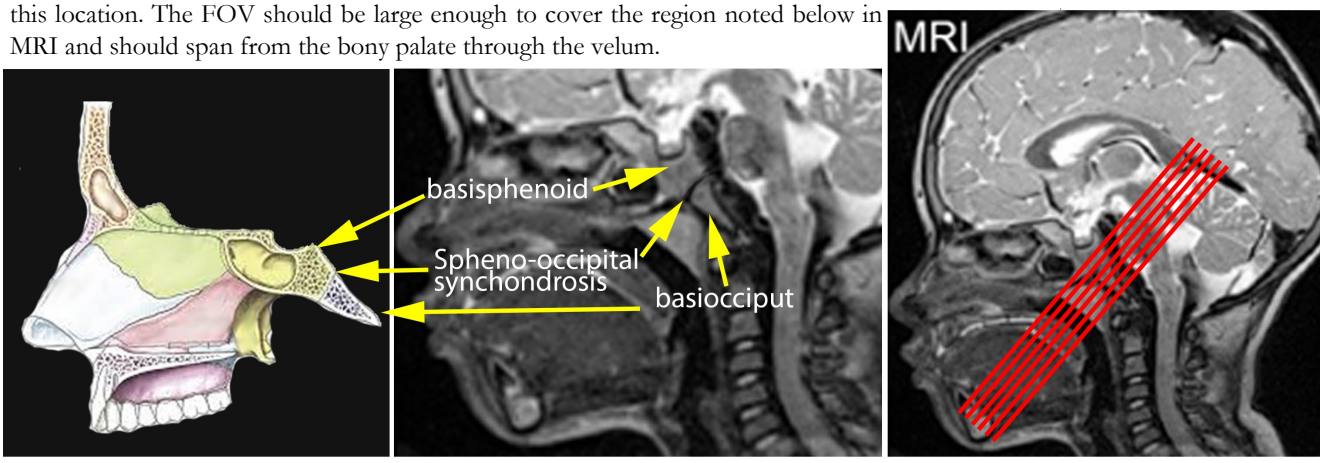


Figure 3.8: Image showing the location of the spheno-occipital synchondrosis and how to position the slice through this landmark; then expand slices on both sides of this location. The FOV should be large enough to cover the region noted below in MRI and should span from the bony palate through the velum.



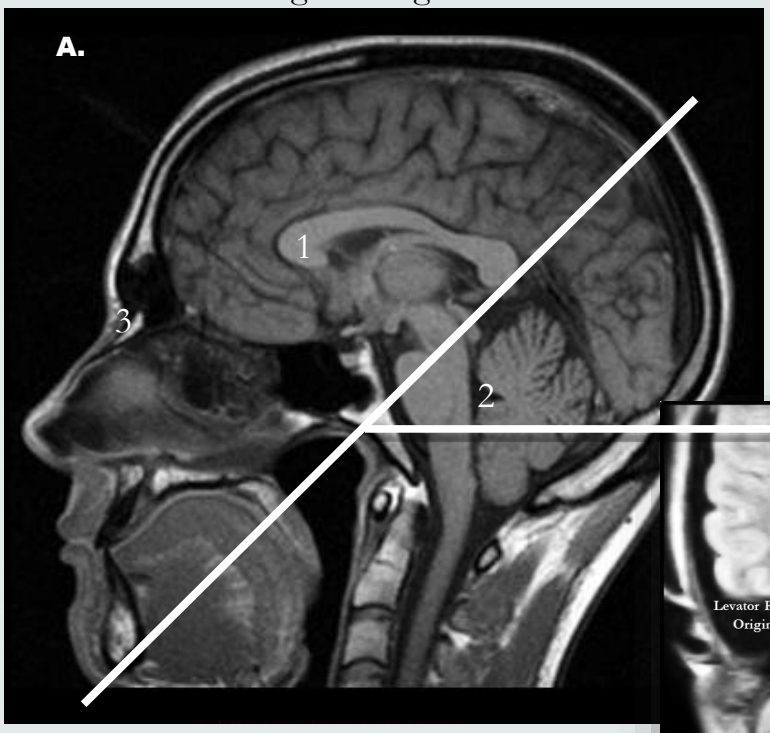
3. 6 RUNNING THE VP MRI PROTOCOL
MRI Sequences

The **levator veli palatini** (LVP) muscle lies within the **oblique coronal plane**. This muscle is the primary elevator of the soft palate during speech and often impacted in craniofacial disorders involving clefting of the palate.

Hence, obtaining a 3D scan and scans within the oblique coronal plane are essential for adequate data collection for this population.

The below image (**Figure 3.9)** provides the research team and technicians with the anatomic orientation of the LVP muscle in the midsagittal plane (white line) (A) and key landmarks observed in the oblique coronal plane (B). These images and landmarks should be observed when identifying and selecting this plane during the 2D scanning process.

Midsagittal Image Plane



The **midsagittal image** should include a view of the anatomy as shown in A. Typically, it is the image slice that shows the following anatomy structures: corpus collosum (1), 4th ventricle (2), and nasion (3). Additional slices laterally on both sides of the midsagittal plane should be included so that the images span the width of the throat, typically 6-10 slices.

Oblique Coronal Image Plane

Figure 3.9

The **oblique coronal** is an angle that courses typically through the spheno-occipital synchonrosis; Confirming the muscle is seen in the images is **critical to the success of the MRI study**. The muscle should be a visible "U" or "V" shaped muscle, as seen in the image to the right. The muscle should be the middle slice with slices anteriorly and posteriorly of the image for a total of 6-10 slices.

3. 6 RUNNING THE VP MRI PROTOCOL
MRI Sequences

Field of View

Sagittal:

- Make sure **entire head** is in field of view. Localize to **nose tip** or mouth area.

Oblique Coronal boundary box (shown in red):

- Use 3D or resting sagittal images to set oblique coronal imaging plane.
- Slice should run through the spheno-occipital synchondrosis and be similar to this image (Fig. 3.10).
- Make sure box covers area form the posterior aspect of the hard palate (PNS) to the tip of the uvula (Fig. 3.10).

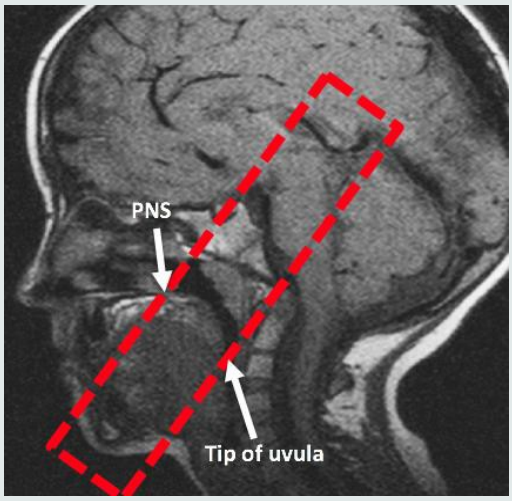
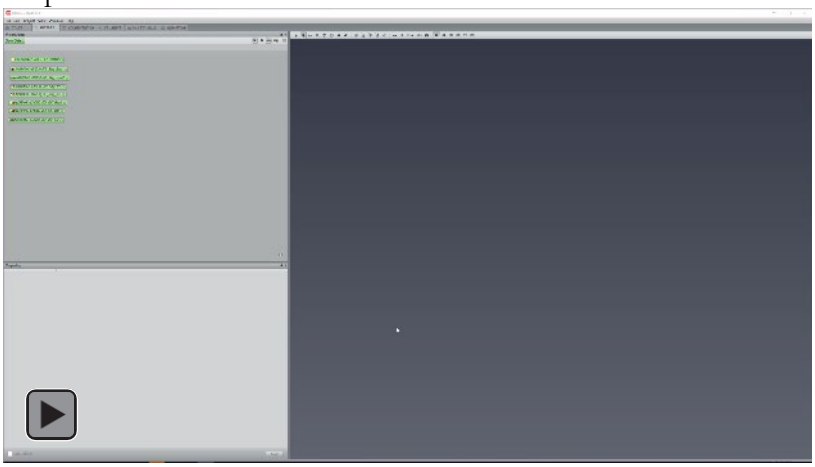


Figure 3.10

NOTE: Once you have established the correct angle for the oblique coronal, COPY these parameters exactly to the "ee" and "ss" so the angle is the same.

Video Example

Watch the below video clip to see an example of how to identify the oblique coronal plane. Note: This was completed in Amira v6.5 Volumetric Visualization Modeling software. Your software may be different. However, location of the levator muscle should be similar. When selecting this plane, make sure you are looking for the "V" shaped levator muscle. If you do not clearly see this muscle, you are likely not yet in the appropriate anatomic plane.



Video Demonstration for Identifying the Oblique Coronal Plane

Step 3: Run the 2D Rapid Sequences (continued)

The 2D rapid sequences should be run as follows and using the below patient instructions:

- Rest sagittal
- Rest oblique coronal

Patient Instructions: Through the microphone communication system in the MRI scanning room tell the patient: "You're doing really great! We will now say our sounds that we practiced. When I say go, you will hold out the 'eee' sound. Keep saying the sound until the noise turns off. [pause] Ready, take a deep breath, and go"; as soon as you say "go" hit the start button. For young kids just tell them to hold the sound till you tell them to stop & when the sequence is done, prompt them to stop. It often helps for you to hold the "eee" out with the patient for a second or two so that the patient can hear the sound.

Be sure when the child begins the sound the sequence has started at the exact same time. Delays in starting the sequence will cause the child to run out of breath during the scan.

- "eee" sagittal
- "eee" oblique coronal

Patient Instructions: "You did great, we are almost done! When I say go, you will hold out the 'ssss' [model sound] sound. Keep saying the sound until the noise turns off. [pause] Ready, take a deep breath, and go"; as soon as you say "go" hit the start button.

- "sss" sagittal
- "sss" oblique coronal

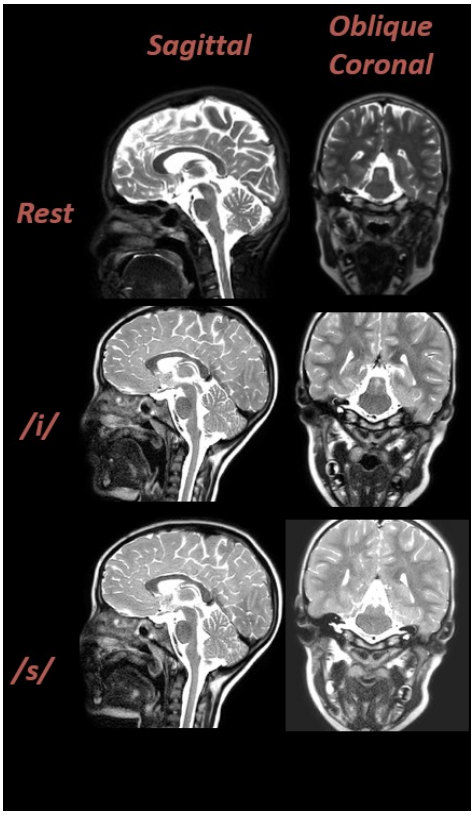


Figure 3.11: Example of the 2D Rapid Sequences across the three conditions (Rest, /i/, and /s/; pronounced "eee" and "sss") and across the two image planes (sagittal and oblique coronal.

3. 6 RUNNING THE VP MRI PROTOCOL
MRI Sequences

NOTE: Be sure you have the audio turned up loud enough so that you can confirm that the patient correctly said the sound and the sound was sustained the entire time. When the MRI data comes to the research sites, we will assume the scans were obtained correctly and matches the labeling on the DICOM files. If the speech scan was not obtained correctly, do not send the failed scan with the rest of the MRI data.

Confirming correct production of the sound

The correct sound should be confirmed by the following 2 methods:

- As mentioned, listen to the patient by turning the audio loud enough to confirm sound.
- Confirm the correct sound is used by looking at the tongue shape. For the "eee" sound the middle of the tongue should be rounded, whereas for "sss" the middle of the tongue is flat and the tip of the tongue is just behind the teeth.

Figure 3.12: differences in tongue posture between "ee" and "ss"

NOTE: One of the most important steps to ensure success with child subjects is to have no periods when there is silence. Having each scan ready and queued up for running right after one another is critically important. When children lay still with no sounds or feedback they begin to move, and this can negatively impact the whole study. In total, all sequences should be run in under 15 minutes.

When to stop the MRI study

If any of the following occur before or during the MRI study, immediately stop the study and note the failed scan. The MRI scan does not need to be rescheduled in most cases and any images acquired before stopping the study can be shared with a note of the reason for an incomplete study. **Note:** movement is typically not a reason for ending the study as most 2D rapid scans can still be acquired successfully despite movement. If your site is comfortable applying a blade technique or other methods to reduce motion, these can be applied at any point.

- Patient complains of discomfort that cannot be accommodated with cushions or foam wedges
- Patient cries and cannot be quickly consoled by the parent/guardian
- Parent/guardian and/or patient express that they wish to end the study for any reason
- Patient shows other overt signs of distress, anxiety, or discomfort

3 . 7 NOTE REGARDING DENTAL APPLIANCES

Dental Appliances:

Dental appliances impact images differently. However, if the scan has already begun and the technologist notes dental appliances (braces, a palatal expander, etc.), continue the scan. It is possible that there may still be measurable data that can be obtained. Figure 3.16 demonstrates artifact from a stainless-steel dental appliance. The image on the right demonstrates a smaller dental appliance that was located just behind the central incisors. In this case, the velopharyngeal structures remain visible and usable data may result from the scan. As the dental appliance (palatal expander in middle and braces on left image) expand to cover the teeth/palate posteriorly, the image can negatively impact the region of interest.

Typically, a 1.5 Tesla imaging mitigates braces artifacts and should ideally be performed in such patients. Patients with a cochlear implant are excluded from this study and thus not considered for MRI.

Figure 3.16. Poor image quality due to dental appliance. VP mechanism remains visible, however, in some cases.

See:
Wood ML, Henkelman RM. MR image artifacts from periodic motion. Med Phys 1985;12:143-151.

Pusey E, Yoon C, Anselmo ML, Lufkin RB. Aliasing artifacts in MR imaging. Comput Med Imag Graphics 1988;12:219-224.

Section

4

Behavioral Protocol for Young Children

Overview

Normal speech production requires velar movement and active coupling between the oral and nasal cavities. Because normal speech requires an awake and alert child, to adequately assess velopharyngeal function and dimensions, it is necessary for imaging protocols to be ***non-sedated***. This means that the participant is awake and alert. Behavioral and environmental adaptations assist in establishing non-sedated MRI scans in infants and children.

Environmental modifications such as audio/visual stimuli, sleep limitation, pre-MRI education/training for parents, and mock MRI simulations are beneficial to facilitate imaging children as young as 4 years of age without any sedation (Perry, 2011; Kollara et al., 2014). When able, recommendations for an adult to be present in the scanning room with the child during the scan are facilitated. The behavioral protocol outlined below has been adapted to allow participants to adequately complete speech tasks during the MRI scan.

All patients should be screened appropriately by trained MRI technicians before undergoing the MRI scan. Steps should be taken to ensure comfort of the participants throughout the MRI scan. It is also important to ensure that the individual is **positioned with limited head flexion or extension**. Cushions can be used to ensure limited head motion during the MRI study.

Depending on site resources, researchers may find that including a research assistant, in conjunction with a Child Life specialist, is beneficial to assist in the MRI scanning behavioral protocol. **Mock MRI scanners** are additionally helpful for children who may be initially apprehensive to participate in the MRI scan. Often, the research coordinator will be able to pre-determine which children may need the mock scanner and those who will not. In a series of 150 children who completed research MRIs, our research team has only needed to run through the full mock scanner protocol once. In all child scans previously completed, there have only had 3-5 children who didn't complete the study.

Parent training can be beneficial prior to completing the MRI scan as well. This can be accomplished by providing parents with an MRI primer and child-friendly MRI information. See **Section 4.4** for access to the informational parent training site.

All participants should be acclimated to the scanning process by listening to audio samples of MRI noise *prior to* beginning their scan. Often, caregivers can complete this process at home watching the study MRI video before the scan takes place or the research assistant can complete this following the speech sample data acquisition. The research team may additionally opt to provide audio samples (also available on the MRI website) and access to the mock scanner before beginning the research scan, if needed. Audio and visual stimuli used during the scan have been helpful to assist with distraction during the scan.

To minimize any impact of motion and to increase comfort, participants should be wrapped tightly in a blanket. It is further recommended that an adult (family member or researcher) be in the scanning room with the participant for the duration of the MRI scan. For children who are likely to move, the parent may choose to lay on top of the child while he/she is in the scanner. The parent can use his/her hands to hold the sides of the child's head to reduce head movement. The weight of the parent will reduce body movements. It is critical to remind the parent to not talk to the child at any point so ensure the child does not speak or move his/her head while responding.

This protocol has been instituted at over ten research sites for prior collaborative studies and has had a high success rate (94%).

Section 4.1 outlines steps to using a mock scanner, **4.2** offers tips for running non-sedated scans, **4.3** provides a sample audio clip, and **4.4** provides information on parent training resources.

SECTION CHECKLIST

☐ Review behavioral imaging protocol and suggested environmental modifications

☐ Identify MRI Mock Scanner resources at facility

- Mock scanner available: ☐Yes ☐ No
- Child Life Specialist available: ☐Yes ☐ No

☐ Provide Parent Training Website Information to Caregiver

- Provide website link (_____) and instruct caregivers to complete steps with their child ***before*** their scheduled scan
- Provide caregivers the “Study Reminders” handout
- (Optional) Provide caregivers with printed MRI coloring book activity

4.1 MOCK SCANNER INSTRUCTIONS

Instructions for use of a mock scanner, if needed, are included below.

1. Bring participant into mock scanner room.
2. Lay clean sheet on the MRI table.
3. Show them the MRI machine, tell them what it does in simple, easy to understand terms.
4. Use a teddy bear, or other available toy, to show the child how they will wear ear plugs and put on headphones.
5. Let child know they will be able to watch a movie or show while they are in the real MRI scanner.
6. Use the toy/bear to demonstrate how the child will get to lay on the scanner. Have child watch and assist when you place the bear on the scanner.
7. Show them the head coil (the coil they wear will be a bit different than the one in the mock scanner).
8. Place the head coil on the bear.
9. If a computer or tablet is available, provide sample MRI audio sounds for the child to listen to. Tell the child that the MRI plays very loud sounds and you are going to play some sounds for them so they can get used to them.
10. Play the T2 MRI sound. It is the most similar to the one they will hear in the Phillips and Siemens scanners.
11. Go back to the mock scanner with the teddy bear on it. Talk about how the bear is going to be super still and quiet even though there will be loud sounds.
12. There is typically a remote with a single red button on it (depending on brand of mock scanner). Get the remote with the single red button on it and tell the child this is what moves the MRI table back, just like the real one.
13. Let the child push the red button and watch the table move with the bear.
14. Then tell the child it's their turn to ride the MRI table. Be excited and let them know it's like a spaceship.
15. The first time they are on it, allow them to explore the machine a bit.
16. Then, have them lay supine and have them place headphones on.
17. Place the head coil over their head.
18. Once they are in the supine position with the mock head coil, tell them you are going to push the red button and they will get to ride the MRI back.
19. Once they are "inside the scanner", let them know that we are going to play a game to see how long they can stay still as a statue.
    a. They will need to be extremely still for 1.5 minutes for the first two scans and then 5 minutes for the 3D MRI scan.
    b. Practice having them stay very still for at least 2 minutes. Tell them they have to be "still like a statue"; "no talking or wiggling".
    c. The parents can hold their hands/feet while they are in the mock scanner which they can also do, if needed, when the child is in the real scanner.
20. While the child is laying very still, let them know you are going to play the cool, loud, spaceship noises.
    a. Play the noises for **at least a full minute**
21. Once completed, let the child know they did a great job and the real MRI is going to be almost exactly like that. Reinforce that they need to be very, very still.

4.2 TIPS FOR RUNNING SCANS ON CHILDREN:

1. Let children listen to the MRI machine sounds and the loud noises from the scanner before the actual MRI scan takes place. This helps acclimate them to the scanning noise as MRI sounds are typically unfamiliar and often the biggest shock.

    a. A suggested audio clip is embedded in this manual **(see Section 4.3)**. Additional MRI audio samples can be located at: http://www.cornwarning.com/xfer/MRI-Sounds/).

2. Tell parents to dress children in warm clothes with no metal zippers or hoodies. Essentially, sweatshirt and sweatpants or PJs (with *no metal zippers or metal snaps*). This ensures they aren't cold and the hoodies don't get in the way of head placement. This information is also provided on the parent training website.

3. When positioning the patient on the scanning table, use a warm blanket (white sheet) to wrap around the child's body with their arms at their side. Tuck the blanket tightly underneath them. Essentially, swaddling them in it. Make sure the child's hands are by their sides with their arms straight. It is necessary to wrap their hands inside the blanket to limit extraneous movements.

4. **Tell parents: Try not to talk to them or have anyone in the MRI room talking to them while the scans are going. Otherwise, the child talks/responds & moves their head to look at the person speaking to them.**

5. If available, make sure the movie or DVD is on during the "at rest" scans.

6. Spend some time telling parents to talk about the MRI like it is a fun opportunity to be in a machine that is like a spaceship. This will help ensure the child does not see the MRI as a scary experience but a fun opportunity.

7. Make sure children are as still as possible during the scan(s). Have caregivers or radiology techs tell them that even moving their feet will move their head, so they have to be as **still as a statue**. This is important.

8. **Progressing through the scans as quickly as possible is the most important thing you can do**.

    a. Whenever there is a dead time of no scanner running, be sure to *talk to the child over the intercom to tell them they are doing good,* how many more scans there are, and remind them to hold still.

    b. If there is dead time with no noise and you don't communicate to the participants, they may become worried and confused as to what is going on and then they move.

NOTE FOR RADIOLOGY TECHNICIANS:

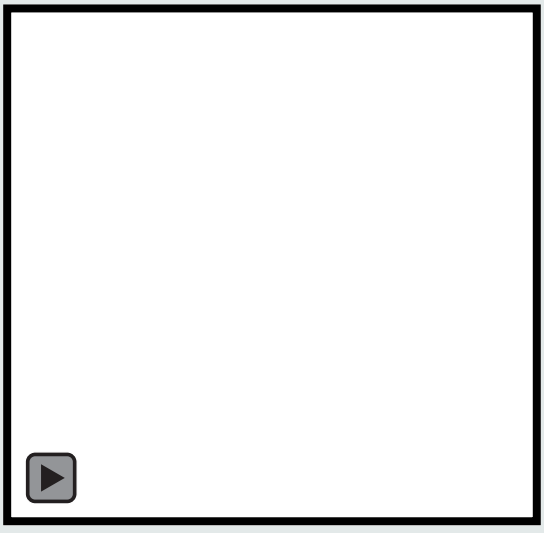
Set up the scans *while one is going on*. And, whenever there is a down time of no scanner, be sure to talk to the children over the intercom to tell them they are doing good, how many more scans there are, and remind them to hold still.

NOTE

Most children do not need the additional step of practice with a Mock MRI activity when parent preparation has occurred.

4.3 SAMPLE MRI AUDIO CLIPS

Click the below icon to play an audio file with sample T2 MRI sounds. Audio primers are helpful to support the behavioral protocol outlined above (Sections 4.1 & 4.2).



4.4 RESOURCES FOR PARENT TRAINING

A **website** has been created that researchers and/or site-PIs can provide to parents during the informed consent process. This website includes information needed to help the child participant prepare for the MRI scan such as what will happen before, during, and after the scan and an animated video overview. A downloadable coloring book is also provided on the website.

The MRI parent training website can be accessed by navigating to the link below.

PARENT TRAINING WEBSITE

https://www2.ecu.edu/mriprep/

Optional: The following page includes an editable copy of a parent handout with reminders and tips. Site collaborators can update the contact information and provide this to parents as well.

NOTE

Print the parent/caregiver study form and input information related to your specific study site! Provide this form during the consent process.

Parent/Caregiver Study Reminders

Thank you for agreeing to participate in this study! You and your child are helping to provide valuable new information about secondary speech surgeries!

A few reminders for the study and tips to remember:

- ☐ When you arrive for your MRI, a member of the study team, _____ (___-___-____) will meet you. They will be helping you navigate to the radiology suite so that the MRI can be taken around _____ PM .
  - ☐ The radiology suite is located on _____.
  - ☐ Your MRI will be completed on _____.
- ☐ Bring comfortable clothes for your child to wear in the MRI scanner. Suggested items are:
  - ☐ Pajamas (without any metal zippers or snaps)
  - ☐ Sweatshirts (without hoods)
  - ☐ Sweatpants
  - ☐ Comfortable long sleeve t-shirts
  - ☐ Socks

- ☐ Work through the coloring book with your child and begin to prepare them for the MRI ahead of time.
- ☐ We like to say the MRI is like riding a spaceship. Let them know the MRI will be loud and they will get to wear really cool headphones.
- ☐ Make sure you do not use the words “scary” when describing the MRI.
- ☐ Make sure they know that all they need to do is be “still as a statue” and then they will be asked to say 2 easy sounds.
- ☐ They will be able to watch a movie or listen to music during the MRI scan.
- ☐ You will be able to go into the scanning room with your child while the MRI is taking place.

If you have any questions before, during, or after the MRI, please don’t hesitate to ask. You can contact _____ at _____ or ___-___-____.

Thank you for your participation in this study

Section

5

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Section

6

Appendix A: Online Resources

1. **Parent Training Website**

2. **MRI audio clips:**
   http://www.cornwarning.com/xfer/MRI-Sounds/

3. **General MRI Information:**
   http://mriquestions.com/index.html

Appendix B: MRI Coloring Book

The MRI Coloring Book can be located at:
 **http://www2.ecu.edu/mriprep/**

Appendix C: Site Specific Notes

Site Name:

Order of MRI scans:

Other Information/Notes:

Appendix D: MRI Summary/Checklist

Patient Preparation

- ☐ Complete MRI safety screening & remove clothing with hood or metallic trim and jewelry
- ☐ The patient's name, weight, and height are entered
- ☐ Child viewed MRI movie again & practiced sustaining "eee" and "sss" for 10 seconds

Patient instructions (for children): *"this spaceship will make noises just like in the video. When it makes noises, it is taking pictures that allow us to see your brain. You are going to need to hold very still while in the scanner and near the end I will tell you when to make the 2 sounds we practiced"*

Patient Positioning

- ☐ Fish oil capsule taped to right temple (RT)
- ☐ Ear protection and headphones provided
- ☐ Neck is positioned straight with no tilt and with no flexion or extension
- ☐ Patient's head is as far up in the head coil as possible

Run VP MRI Protocol

- ☐ Make any minor adjustments for rotation or tilt of head; remove and reposition head entirely if needed
- ☐ Verified no wrap around
- ☐ Ensured FOV covers whole head and signal strength is greatest at region of interest

Scans are completed and labeled as follows:

Patient instruction: *"Ok we are now going to start, hold still like a statue"*

- ☐ Localizer
- ☐ 3D [sequence name]
  - ☐ Set up 2D sagittal images using localizer or 3D & have it ready to run immediately after 3D
- ☐ 2D [sequence name] rest sag
  - ☐ Use 3D data or 2D Rest sag to set up rest coronal image plane using spheno-occipital synchonrosis as a guide for correct angulation of the slices
- ☐ 2D [sequence name] rest oblique coronal
  - ☐ Levator muscle is visible in sagittal image plane and FOV spans to include part of tongue and into brain and slices span to run from tip of bony hard palate to include most of the velum
- ☐ 2D [sequence name] eee sag

Patient instructions: *You're doing really great! We will now say our sounds that we practiced. When I say go, you will hold out the 'eee' sound. Keep saying the sound until the noise turns off. [pause] Ready, take a deep breath, and go"; as soon as you say "go" hit the start button.*

  - ☐ The patient said the correct sound "eee" and for the required length of scan
- ☐ 2D [sequence name] eee oblique coronal
  - ☐ The patient said the correct sound "eee" and for the required length of scan
- ☐ 2D [sequence name] sss sag

Patient instructions: *"You did great, we are almost done! When I say go, you will hold out the 'ssss' [model sound] sound. Keep saying the sound until the noise turns off. [pause] Ready, take a deep breath, and go"; as soon as you say "go" hit the start button.*

  - ☐ The patient said the correct sound "sss" and for the required length of scan
- ☐ 2D [sequence name] sss oblique coronal
  - ☐ The patient said the correct sound "sss" and for the required length of scan

MRI Data Saved/Transfered

- ☐ MRI data are saved and transfered to data collection center