Research Note

Do Participants Report Any Undesired Effects in Ultrasound Speech Therapy?

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Purpose: Ultrasound visual feedback of the tongue is increasingly used as a component of speech therapy in clinical research and practice. The purpose is to offer a preliminary summary of the nature of participant-reported undesired effects related to ultrasound visual feedback.

Method: Sixty-two participants across 3 sites (mean age = 11.9 years) and 38 parents responded to a 2-item verbal questionnaire following 14–16 hr of treatment regarding any aspects of the treatment they did not like. Responses were thematically categorized.

Results: The 62 participants provided 65 distinct responses, which were categorized as follows: 31% no concerns,

40% gel-related (e.g., cold, sticky), 21% positioning of the probe (e.g., uncomfortable, annoying), 3% chin hurting (qualified as being minor in nature), and 5% other (i.e., unrelated to the use of the ultrasound). Responses from all parents suggested no concerns about the use of ultrasound; however, 8% expressed concerns unrelated to ultrasound use (e.g., fatigue).

Conclusion: These data inform clinicians and researchers about participant's experience and highlight the type of comments most likely to be encountered with ultrasound in speech therapy. Although the reported adverse effects can be considered minor, they should be weighed against the potential benefits of visual feedback in treatment.

Ultrasound imaging has been used in medicine to visualize internal body structures for over 70 years. In the past few decades, there has been an increasing interest in ultrasound as a tool to provide visual feedback of the tongue during treatment for speech sound production difficulties (Lee, Wrench, & Sancibrian, 2015; Preston, McAllister Byun, et al., 2017). A number of studies have demonstrated that a treatment program that includes ultrasound visual feedback can lead to speech sound learning (e.g., Adler-Bock, Bernhardt, Gick, & Bacsfalvi, 2007; Bernhardt, Gick, Bacsfalvi, & Adler-Bock, 2005; McAllister Byun, Hitchcock, & Swartz, 2014; Preston, Leece, & Maas, 2016; Sjolie, Leece, & Preston, 2016). As this approach becomes more common, questions may arise from clinicians, prospective clients, research participants, or institutional review boards about any perceived negative consequences. Therefore, as ultrasound visual feedback continues to be studied and applied clinically, it is incumbent upon researchers and clinicians to be mindful of any perceived unwanted

effects or inconveniences, if they exist. To align with evidence-based practice, such risks or inconveniences should then be weighed against the potential benefits. The purpose of this report is to summarize the accounts of participants (and their parents, when appropriate) related to self-reported undesirable effects of ultrasound in speech therapy. The report relies on data aggregated over several previous small-scale clinical research studies.

Several effectiveness studies have been conducted on the use of ultrasound visual feedback of the tongue. Positive treatment outcomes have been observed in the treatment of speech sound errors in a variety of populations, including individuals with persisting speech sound disorders (Adler-Bock et al., 2007; Bressmann, Harper, Zhylich, & Kulkarni, 2016; Cleland, Scobbie, & Wrench, 2015; McAllister Byun et al., 2014; Preston, Leece, & Maas, 2017; Preston et al., 2014; Shawker & Sonies, 1985; Sjolie et al., 2016), Down syndrome (Fawcett, Bacsfalvi, & Bernhardt, 2008), childhood apraxia of speech (Preston, Brick, & Landi, 2013; Preston, Leece, et al., 2016; Preston, Leece, McNamara, & Maas, 2017; Preston, Maas, Whittle, Leece, & McCabe, 2016), hearing impairment (Bacsfalvi, 2010; Bacsfalvi & Bernhardt, 2011; Bacsfalvi, Bernhardt, & Gick, 2007; Bernhardt et al., 2008; Bernhardt, Bacsfalvi, Gick, Radanov, & Williams, 2005; Bernhardt, Gick, et al., 2005; Bernhardt, Gick, Bacsfalvi, & Ashdown, 2003), glossectomy (Blyth, McCabe, Madill, & Ballard, 2016), acquired apraxia of

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speech (Preston & Leaman, 2014), and cleft palate (Cleland, Crampin, Wrench, Zharkova, & Lloyd, 2017). Ultrasound has also been used to teach the production of nonnative speech sounds (White, Gananathan, & Mok, 2017). Thus, the technology has shown promise for clinical utility in several small-scale studies. These positive effects should be kept in mind when considering the balance between risks and benefits of the treatment.

Ultrasound imaging allows for visualization of structures within the body. The transducer is held against the skin, and water-soluble gel is typically used to improve conductance. Ultrasound transducers transmit high-frequency sound waves (well beyond the frequency range of the human ear), which are reflected at a tissue boundary (i.e., top contour of the tongue) and are received again by the transducer. These reflected waves are converted to images by a computer, which can be displayed in near real time (Lee et al., 2015). Thus, the images are generated by sound waves, not ionizing radiation that might be encountered with X-rays.

When used for speech sound remediation, the ultrasound transducer is held beneath the chin to visualize the tongue, which may require constant positioning for an extended time. Participants are taught to interpret the images while attending to the visual display (Preston, McAllister Byun, et al., 2017). This visual information is used to encourage the participant to monitor the tongue shape and to make adjustments as necessary for a clearer production of a target sound. For example, for a child who substitutes an alveolar [t] for the velar [k], the sagittal ultrasound images might reveal that the tongue tip/blade elevate for [t], rather than the tongue dorsum raising for [k]. Cueing strategies can leverage this visual information; such cues may enable participants to self-monitor their productions and adjust their subsequent tongue movements. The information may also be useful to the clinician who can have a deeper understanding of the nature of the child's misarticulation. However, the transducer must be properly positioned and must remain in place for these images to be valuable. Some approaches involve probe stabilization techniques, such as using headgear or attaching a clamp to the transducer, to keep the probe position constant (e.g., Cleland et al., 2015).

Anticipated Effects and Precautions in Ultrasound Imaging

In addition to a focus on clinical efficacy, clinical research should ethically attend to any unintended effects of treatments, such as perceived physical or psychological effects or discomfort. Therefore, speech-language pathologists and clinical researchers who use ultrasound should have an understanding of the basic underlying principles of ultrasound (Lee et al., 2015). To collect images of the tongue during speech, ultrasounds use B-mode imaging (Bressmann, 2008). These ultrasound devices are often described in the medical field as “diagnostic ultrasounds” in that the purpose is simply to collect images (vis-à-vis

“therapeutic ultrasounds,” which are used for the purposes of inducing biological changes to tissues). Thus, the types of ultrasounds used for imaging the tongue are not intended to cause biological effects because of the limited acoustic output (Barnett et al., 2000; Epstein, 2005). However, we briefly review some of the biological considerations for ultrasound imaging.

There are two potential biological effects of ultrasound on human tissue: thermal effects and cavitation (Epstein, 2005). Thermal effects are a concern if the acoustic output is great enough to heat the tissue through which it passes. It is currently believed that, when used properly, B-mode ultrasounds (used for biofeedback in speech therapy) do not generate enough acoustic output for thermal effects to be a concern (Barnett et al., 2000; Epstein, 2005). Guidelines for the duration of ultrasound scanning have been developed based on the thermal index displayed for an ultrasound device during scanning; most exposures in speech therapy are considerably less than 2 hr, which is within the realm of safe use for typical ultrasounds displaying a thermal index of < 2.0 (American Institute for Ultrasound in Medicine, 2016). Cavitation is a second biological consideration with ultrasound, such that the sound waves passing through tissue cause gas bubbles to form and to collapse. This concern exists primarily for tissues that contain gas bodies, such as the lungs or intestines. However, the tongue does not contain gas bodies. Moreover, current B-mode ultrasounds do not exceed the limits in which cavitation would be of significant biological concern (American Institute for Ultrasound in Medicine, 2015). Thus, the effects on tissue with ultrasound imaging of the tongue in speech therapy appear to be minimal.

The prudent use of ultrasound is generally characterized as a low-risk procedure (Barnett et al., 2000; WFUMB, 1998). However, it is recommended to follow the “as low as reasonably achievable” principle to keep exposure to a minimum and to avoid any possible biological effects (American Institute for Ultrasound in Medicine, 2014; Barnett et al., 2000). Thus, images should be collected with the lowest intensity, the lowest thermal index, and the lowest duration of exposure possible. For example, participants in research or clients in speech therapy should not be exposed to ultrasound when they are not speaking or when they are not attending to the images. In addition, as participants proceed through treatment, the use of ultrasound feedback generally should be reduced, as the expected benefits are primarily for the purposes of establishing new speech movement patterns in syllables in words (rather than practicing in sentences or connected speech). Therefore, individuals who are more successful at independently producing target speech sounds will generally rely on the ultrasound feedback less than those who require additional visual support for successful productions.

Other minor physical or psychological considerations may be present. For example, the hypoallergenic conductivity gel might be perceived as being uncomfortable or anxiety-inducing due to the “medical” nature of the experience. Although ultrasound gel is water soluble

and considered hypoallergenic, a small number of patients in medical settings may show allergic reactions consistent with allergic contact dermatitis (Chasset et al., 2016). It may therefore be prudent to ask clients or participants about known skin sensitivities and to monitor the skin following the first applications of gel. In addition, there is the possibility of transmission of communicable diseases (e.g., the common cold) if the ultrasound transducer is not cleaned appropriately before and after each use. However, clinic-appropriate standard precautions, including cleaning the transducer with transeptic spray or ultrasound-approved disinfecting cloths between users, can mitigate this concern. Finally, ultrasound imaging of the tongue during speech therapy requires sitting still, applying slight pressure to keep the transducer against the skin, maintaining stability/positioning of the probe, and attending to a screen for an extended time. It is possible that these considerations may yield minor discomfort, annoyance, or mental fatigue. For example, there may be discomfort from sitting still and holding the probe in position under the chin for extended periods of time; thus, breaks should be offered if feasible (Epstein, 2005). If the probe is held in place by hand (rather than by a mechanical stabilizer), frequent repositioning of the transducer can be necessary, which may be inconvenient. In addition, some of the complaints reported anecdotally are not inconsistent with the potential inconveniences of boredom and fatigue anecdotally associated with the drill and sustained attention that is required in many speech interventions.

In a recent study, Preston et al. (2014) queried eight participants with residual speech sound errors ages 10–20 who had completed 14 hr of treatment with ultrasound visual feedback over approximately 8 weeks. The parents of the participants observed no negative side effects in their child as a result of the study nor did they report any complaints of discomfort from their child. The participants themselves perceived no issues with their mouth or chin as a result of treatment. However, some participants did report that it was “annoying” to press the probe beneath their chin while using the ultrasound and that they disliked that the ultrasound gel was “gooey” or “cold.” The present report extends these qualitative data to better understand the tolerance of ultrasound use in speech therapy.

Method

Participant Sample

Data reported here are pooled from 62 participants (42 men, 17 women) with speech sound disorders across three clinical research locations in the United States (Connecticut, Ohio, and New York). There were 34 participants at Site A, 23 from Site B, and five from Site C. The mean age was 11.9 years ($SD = 3.0$, range 7–22 years). Participants from Site A used either a Telemed Echoblaster 128 with a PV 6.5 transducer (88% of sessions) or an Interson Seemore PI 7.5 MHz USB probe (12% of sessions) when the Echoblaster was unavailable. Participants in Site B used

either an Interson Seemore PI 7.5 MHz USB probe ($n = 8$) or a Siemens ACUSON X300 ultrasound with C6-2 probe ($n = 15$). All five participants in Site C used the Siemens ACUSON X300 ultrasound with C6-2 probe. All participants were treated for 14–16 sessions lasting approximately 1 hr, and the ultrasound was used for visual feedback for no more than one half the treatment (with breaks provided during each session). The transducer was stabilized either by the participant holding it (with instructions) or by a microphone stand clamped around the transducer (no head stabilization was used). Because the participants were part of several different treatment studies, the amount of time using the ultrasound varied. The mean number of minutes using the ultrasound was 313 ($SD = 100$, range 182–432 min) over the 14–16 hr of treatment. This study was carried out in accordance with the recommendations of the institutional review boards governing each site. Written consent was provided by all participants or their guardians. In the case of the minor participants, written assent was also obtained.

Participant Questionnaire

A brief questionnaire was administered to each of the 62 participants who completed an ultrasound visual feedback treatment program. The questionnaire was administered verbally by the treating clinician following the final treatment session. Responses were audio-recorded and written down, then analyzed by a separate research assistant. The questionnaire consisted of the following two items:

1. When using the ultrasound, is there anything you do not like about it?
2. When you are not using the ultrasound, have you had any problems with your mouth that you think might be due to the uses of the ultrasound?

In addition, for participants who were under the age of 18, parents at two of the treatment sites were also questioned, when available, following the final treatment session. Responses from 38 of 40 parents were available to the following questions:

1. Since the beginning of the study, have you observed any unwanted side effects?
2. Since the beginning of the study, has your child complained about having trouble eating or pain or discomfort in or around the mouth?

It should be noted that the questions were intended to be somewhat leading to elicit responses of undesirable effects, rather than to elicit responses related to what participants liked or the perceived benefit of the experience.

Responses were thematically categorized by a researcher. Once the response categories were established, a second researcher recoded the data, and agreement was 97%. The two disagreements were resolved by consulting a third researcher.

Results

Participant Responses

Sixty-two participants provided responses to the questions above. When responses to either question elicited a response other than “No,” they were further categorized based on theme. All responses were categorized as follows: (a) no concerns, (b) ultrasound gel, (c) positioning of the ultrasound probe, (d) chin “hurt,” and (e) other. In the case of the three participants whose comments fell into more than one category, each aspect of the comment was recorded as a separate response and placed in the appropriate category. As such, the study collected 65 distinct responses from 62 participants. The results are summarized in Table 1.

Of the 65 classified responses, 20 (31%) represented no concerns in response to both questions. The remaining 42 participants provided 45 distinct responses. Twenty-six of the 65 classified responses (40%) were related to the water-soluble ultrasound gel. Participants said they disliked the feeling of the gel, describing it as “gooey,” “gross,” “slimy,” “cold,” “mushy,” or “sticky.” Fifteen of the 65 total responses (23%) were related to discomfort or annoyance while holding or positioning the ultrasound probe. The participants attributed this to various aspects of holding the probe, such as the pressure of the probe against the chin, holding the probe up to their chin and keeping it still for a long time, and the feeling of the ultrasound vibrations.

In addition, two of the 65 comments (3%) came from participants reporting that their “chin hurt” from pressing the transducer against the chin. When queried further, one of these participants qualified that the “hurt” was “only a tiny bit,” and the other indicated that there was nothing that they did not like about using the ultrasound.

Finally, two of the 65 comments (3%) comprised the “other” category. Two responses discussed aspects of the treatment unrelated to the use of the ultrasound transducer:

one disliked looking at the computer screen (for visual feedback) and the other experienced some mouth dryness after talking during treatment.

Parent Responses

In response to the first question (“Since the beginning of the study, have you observed any unwanted side effects?”), all 38 parents (100%) answered “no.” In response to the second question (“Since the beginning of the study, has your child complained about having trouble eating or pain or discomfort in or around the mouth?”), three of 38 parents (8%) reported concerns not related to the use of ultrasound. Two parents relayed that their children reported being tired after treatment, though one parent explicitly said this was not from ultrasound use. One parent reported that their child had developed a “canker sore”; however, the parent stated that their child also “bumped something with [his] teeth.”

Discussion

The adverse effects reported could generally be classified as mild. Parents may observe fatigue in their child associated with ultrasound treatment, although it is possible that other treatments might elicit similar levels of fatigue. The responses from participants suggest that using ultrasound in speech therapy may most likely result in individuals who find the gel to be uncomfortable due to its texture or temperature. Secondarily, individuals may report the positioning of the ultrasound transducer to be annoying or uncomfortable (when no head stabilization mechanism is used). These results are generally in line with those reported previously (Preston et al., 2014).

A small percentage (3%) reported that it may “hurt” to hold the ultrasound probe beneath the chin; the additional qualifications provided by these children suggest

Table 1. Participant responses to two queries about perceived risks/inconveniences in ultrasound visual feedback.

Response category	Number of responses	Examples
No concerns in response to both queries	20	Not applicable.
Comments about gel	26	<ul style="list-style-type: none">• The gel is cold.• The gel was kind of sticky.• I don't really like how the gel feels, but I'm okay with it.• I don't like the gel. It's ok, but kind of gross.• The goo—it's squishy and slimy.• I don't like the gel because it distracts me.
Comments about ultrasound on chin	15	<ul style="list-style-type: none">• It's uncomfortable when it presses on my chin.• Pressing up was slightly uncomfortable.• (I didn't like) Holding my hand still to hold the ultrasound.• I had trouble keeping the ultrasound steady.• Pushing on your neck was uncomfortable.
Comments about “hurt”	2	<ul style="list-style-type: none">• My chin kinda hurt sometimes; there's not really anything I didn't like about it.
Other	2	<ul style="list-style-type: none">• My neck hurts a tiny bit after a long time holding it up. Just a tiny bit—not too much.• I didn't like that you have to look at the screen.• Mouth gets dry due to talking.

that this experience is relatively minor in degree. These responses may be parallel to some of the comments about the constant pressure of the ultrasound beneath the chin being “uncomfortable.” (Holding the transducer beneath the chin may be akin to holding an object about the size of a spoon beneath the chin.) Consequently, if such experiences are reported, it would be appropriate to question individuals about the relative magnitude or degree of discomfort or “hurt” to ensure that their welfare is adequately monitored. It should be noted that participants reported here did not complain about “hurt” during treatment, only when directly queried after treatment; certainly, evidence of pain during any form of treatment should be appropriately monitored, and discontinuation should be considered.

There are limitations to this type of brief survey. A more detailed survey could ascertain additional risks or inconveniences not identified in this short two-item questionnaire. For example, further questions explicitly quantifying the relative magnitude of discomfort may be useful. Although informal monitoring of the well-being of participants is inherent in treatment, more frequent formal questioning (rather than at the completion of a series of sessions) may help to mitigate concerns. In addition, determining the relative influence of the ultrasound versus the drill-based treatment might help to better understand effects such as fatigue or annoyance related to speech therapy in general versus those associated with the ultrasound. An anonymous survey could also provide further information that is not attainable from face-to-face questioning. Finally, it may be helpful to determine participants’ perspectives as to whether they believed the benefits outweighed the inconveniences. For example, the two individuals who mentioned “hurt” showed no evidence of discomfort during treatment (only mentioning this term when questioned), and their speech improved measurably; thus, they may or may not have perceived these benefits to have outweighed the undesirable effects.

Risks or inconveniences should be considered against potential benefits in all clinical and research endeavors. As discussed elsewhere, numerous studies have explored the clinical benefits of using ultrasound visual feedback to improve speech sound production (e.g., Bacsfalvi & Bernhardt, 2011; Cleland et al., 2015; Preston et al., 2013, 2014), and it is therefore incumbent upon clinicians and researchers to consider the relative benefits of improved speech production against the possible unwanted effects. Although our view is that the undesired effects reported here are minimal and that ultrasound is generally well tolerated, it may be helpful to inform clients or research participants of the possibility that they might find the gel to be uncomfortable; that the constant holding, positioning, or repositioning of the probe may be annoying; or that they may experience chin discomfort. To guard against such effects, it may be helpful to schedule breaks, which may prevent mental and physical fatigue or discomfort, and provide a respite from any discomfort caused by the probe or gel.

This report offers a preliminary description of expected adverse effects from the use of ultrasound in speech

therapy in clinical research. The observations presented here provide some guidance on likely reports of research participants or clients. Such information may be useful to researchers, clinicians, clients, parents, participants, and institutional review boards who wish to understand the anticipated effects of this type of treatment in research. Clinically, evidence-based practice requires informed decision making by clinicians and clients/caregivers (Dollaghan, 2007), and these data may be of value in that decision-making process.

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