# EXAMINING THE CLINICAL APPLICATION OF INTRA-ORAL TACTILE BIOFEEDBACK IN SHORT-DURATION THERAPY TARGETING MISARTICULATED /s/

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## ABSTRACT

This randomized, controlled, single-blind study examined the clinical utility of a tactile biofeedback device to teach correct tongue placement for the /s/ phoneme. 15 school-aged children who misarticulated /s/ were randomly assigned to an experimental group or a control group and treated with eight individual therapy sessions. The experimental group, which used tactile biofeedback via the test article, recorded a statistically significant remediation response ($p < .05$), whereas the control group, which used only traditional phonetic-based treatment, did not show a statistically significant treatment benefit. While these results suggest the test article would be a valuable clinical tool, further research is required to establish efficacy of this approach and whether these results may be replicated in larger-scale studies and non-neurotypical subject populations.

## KEY WORDS

Articulation, Speech Sound Disorders, Tactile Biofeedback, Treatment Study

## INTRODUCTION

Articulation and speech sound disorders affect as many as 7.5% of the school-age population (Shriberg & Kwiatkowski, 1994) and can negatively impact teacher perceptions of students with reduced speech intelligibility (Overby, Carrell & Bernthal, 2007) as well as inter-peer relationships among school-age children (Crowe Hall, 1991). Apart from this documented personal cost, articulation and speech sound disorders contribute to an estimated annual cost to society of between $30 billion and $154 billion in lost productivity, special education services, and medical care (Rubens, 2000). In addition, Jacoby, Lee, Kummer, Levin and Creaghead (2002) found that the various treatment methodologies in use today resulted in no measurable progress in remediating speech sound disorders for approximately 28% of the 234 pre-school and school-age children they analyzed. Given the size of this treatment-resistant cohort and the documented social and societal costs of speech sound disorders, it is incumbent upon researchers and clinical practitioners in the field to not only continue to develop improved treatment methods, but also to test these methods through rigorous treatment studies.

The literature in articulation disorders has a relatively extensive record supporting the use of traditional methods of articulation therapy (see Klein, 1996). Phonological and linguistic approaches to treatment have also shown promise in numerous treatment studies (e.g. Broen & Westman, 1990; Gierut, 1998; Major & Bernhardt, 1998; Almost & Rosenbaum, 2000; Rvachew & Nowak, 2001; Tyler & Lewis, 2005). However, therapy that implements one or more of these evidence-based treatment approaches should not only the overall comparative efficacy of a given approach but also the overall cost-effectiveness of a given approach (Gibbard, Coghlan & MacDonald, 2004). Reducing the amount of direct clinician-to-client required to remediate speech sound disorders, as is the aim of a short duration treatment regimen, would in turn reduce the overall cost of therapy (Gibbard, 1994). The field of speech-language pathology has relatively few studies (e.g. Dickson, Marhsall, Boyle, O'Hare, McCarthey & Forbes, 2009; Eiserman, McCoun & Escobar, 1990) that have focused on reducing treatment duration. The current study aims to add to the research corpus focused on short-duration treatment studies.

Jacoby et al. (2002) found that the mean number of 15-minute treatment units required to achieve one level of change according to functional communication measure (FCM) of the ASHA National Outcome Measure System (NOMS) was equal to approximately 14 hours of direct intervention. For the purposes of this investigation, one level of FCM improvement would correspond to a treatment response for a single misarticulated phoneme such as /s/. Treatment studies that can yield a treatment response - defined here as greater than 70% accuracy in producing the /s/ sound in words and words-in-sentences (Van Riper & Emerick, 1984) in pre-treatment and post-treatment assessments – in a duration of therapy that is significantly less than the mean of 14 hours reported by Jacoby et al (2002), would suggest a comparative cost savings for public and private payers of speech therapy services.

In general, the more quickly the client is stimulable to the target behavior (in this case, remediating misarticulated /s/), the more efficiently can therapy proceed toward remediation (Bernthal, Bankson & Flipsen, 2009). One increasingly popular means of accelerating stimulability to achieve therapy gains is sensory biofeedback (McAllister Byun & Hitchcock, 2012). Sensory biofeedback in speech production utilizes specially designed instrumentation that facilitates increased awareness of the target behavior in the client. In addition, sensory biofeedback provides an external focus of directed attention to the task of remediating misarticulated speech. This external focus is said to aid the retention of a newly acquired motor skill such as speech (Wulf, 2007).

An example of sensory biofeedback utilizing primarily the client's visual sensory system (termed visual biofeedback) is ultrasound. In ultrasound for speech therapy, a transducer is placed under the chin which along with a linked software interface, displays a real-time image of the surface of the speech articulators inside the oral cavity. This image allows the client to more effectively contrast his own aberrant production with that of the clinician's model of correct production (Bernhardt, Gick, Bacsfalvi & Ashdown, 2003). Ultrasound has shown positive results in remediating residual, treatment-resistant /r/ errors (Adler-Bock, Bernhardt, Gick & Bacsfalvi, 2007), and in speech disorders associated with hearing impairment (Bernhardt et al, 2003). Other visual biofeedback approaches that have a strong base of evidence supporting their use are electromagnetic articulography (Katz,Bharadwai & Carstens, 1999; Wong, Murdoch & Whelan, 2010); electropalatography (Carter & Edwards, 2004; Lee, Law & Gibbon, 2009; McAuliffe & Cornwell, 2008); visual-spectral biofeedback (Shuster, Ruscello & Smith, 1992; Shuster, Ruscello & Toth, 1995; McAllister Byun & Hitchcock, 2012).

Recent studies have highlighted the strong connection between auditory and tactile or somatosensory feedback in speech perception and production (Tremblay, Shiller & Ostry, 2003; Gick & Derrick, 2009; Champoux, Shiller & Zatorre, 2011). For example, Gick and Derrick (2009) provided evidence that speech perception naturally includes a somatosensory component by demonstrating that inaudible tactile input during the perception of the voiceless bilabial stop interferes with normal adults' ability to perceive either /b/ or /p/ in a listening task. Tremblay, Shiller and Ostry (2003) found that just as humans use hearing to correct and refine speech production, they also use expected somatosensory patterns in everyday speech. In other words, if speech doesn't "feel right," then speakers will adjust their oral and facial movements to conform to how they expect speech to feel. As a natural corollary to these studies, leading psycholinguistic models of the speech production mechanism, such as Guenther's DIVA model (Guenther & Vladusich, 2012)

necessarily include a somatosensory feedback control subsystem that is "active during speech if the speaker's tactile and proprioceptive feedback from the vocal tract deviates from the somatosensory target region for the sound being produced" (p. 416). Moreover, given that consonant sounds such as /s/ require specific articulatory contacts within the vocal tract, fine-tuning a speaker's somatosensory acuity during speech production may be particularly important for consonant sounds such as /ʃ/ and /s/ (Ghosh, Matthies, Maas, Hanson, Tiede, Menard, Guenther, Lane & Perkell, 2010).

The treatment methodology of tactile biofeedback places a physical target within the oral cavity that enables a client to feel correct tongue placement and movement, and thereby refine his or her motor speech behaviors for the target sound. This additional, tactile information can then be used by the client and SLP to allow the client to perceive the correct placement of the speech articulators for a target sound and more efficiently achieve correct placement relatively early in the therapy process (Ruscello, 1995). The clinical promise of, specifically, tactile biofeedback in the treatment of articulation disorders has been the subject of previous investigations. One such investigation, Clark, Schwarz and Blakeley (1993), examined the efficacy of a tool embodiment of tactile feedback in the treatment of misarticulated American English /r/. The tool was fabricated in the form of a dental mold specially fitted with palatal targets for the tongue. This dental mold required individual fitting and fabrication for each study participant. Results of the study suggest that while the use of this tactile biofeedback embodiment was efficacious in the acquisition of treatment-resistant /r/, drawbacks were noted. Specifically, the dental mold design required costly individual fitting from an orthodontist or general dentist; the tool was reported by participants to be generally uncomfortable and, in some cases, was reported to have impeded saliva swallowing. The current study aims to provide further empirical validation for the methodology of tactile biofeedback by obtaining similar results to Clark, Schwarz, and Blakeley (1993), but with an optimized, better tolerated tool embodiment targeting the /s/ phoneme.

The focus of the current study is correcting misarticulated /s/ in neurotypical, hearing, native-English, pediatric speakers. Phonetically, /s/ is a voiceless sibilant fricative consonant requiring the speaker to effect a narrow constriction in the lingua-alveolar region of the oral cavity (Kent & Read, 2002) during production of this sound. If the precise placement of the tongue is not realized, the necessary oral constriction will in turn not be achieved and the resulting production of /s/ will sound distorted to the listener. Given this required precision, the /s/ phoneme is a commonly targeted error sound in speech therapy (Gibbon & Hardcastle, 1987; Bernthal, Bankson & Flipsen, 2009) and one that may require a variety of approaches to effectively remediate (Bleile, 2004). Ghosh et al (2010) provided evidence that somatosensory feedback may be especially valuable to the production of the English sibilant fricatives, /s/ and /ʃ/. Given these factors, /s/ was selected as the target error phoneme for this study.

The authors posit that the treatment methodology that most directly exploits the innate somatosensory speech control system described above is intra-oral tactile biofeedback. By incorporating a novel tool embodiment into therapy that consistently provides a precise lingual placement target within the oral cavity, study subjects will more effectively engage their innate somatosensory feedback mechanism in speech production and more efficiently remediate misarticulated /s/. The current study further aims to contribute to the comparatively modest research corpus focused on tactile biofeedback as well as to the treatment literature focused on short duration treatment regimens.

### Hypothesis and Purpose

The purpose of this study is to report preliminary effectiveness data on the use of a specially designed intra-oral tactile biofeedback device targeting /s/. The study proposes to test the extent to which a group of children who exhibited phonetic-based sound system errors more efficiently remediated misarticulated /s/ given this consistently applied, precise lingual placement target within the mouth during treatment. To accomplish this, the authors implemented a randomized, controlled, single blind research protocol.

The study authors hypothesize: 1) the study group utilizing intra-oral tactile biofeedback in this short-duration therapy regimen will result in a treatment response, whereas the study group treated according to traditional methods of articulation therapy will not; and, 2) intra-oral tactile biofeedback therapy, delivered as a short-duration therapy regimen, will yield greater accuracy in production of /s/, as compared to traditional methods of articulation therapy.

## METHOD

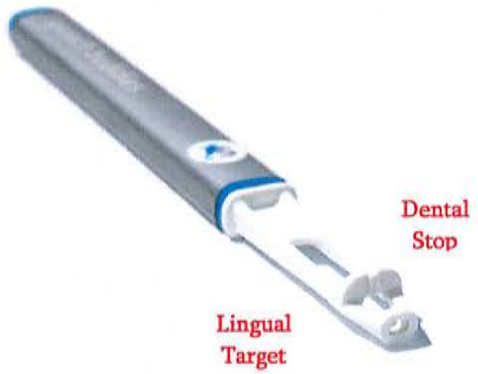


**Figure 1.** The test device and its components.

*Test Device*

The principal function of the intra-oral tactile biofeedback device, hereafter termed the test device, is to aid the participant in achieving correct lingual placement for the /s/ sound. As shown in Figure 1, the tip of the device suspends a small target 8 mm posterior to the front face of the upper front dentition. The target is a set of concentric circles 4 mm and 2 mm in diameter. While small, this target is easy to feel and provides tactile biofeedback to the user. These design parameters were optimized to most closely match correct lingual placement required across a variety of anatomical configurations. The device's dental stop and centering notch enable the consistent placement of the device target within the oral cavity, 8 mm posterior to the upper dentition. The test device prevents excessively anterior tongue placement (i.e. a frontal lisp or dental lisp) while cuing placement that is anterior enough in the oral cavity to yield a sound acoustically distinct from /ʃ/ (Bickford & Floyd, 2006). While there is some variation in the placement of the tongue tip to achieve a correctly perceived production of /s/ (McLeod, Roberts & Sita, 2006), a general tongue placement configuration is a helpful training tool in remediating /s/ (McAuliffe & Cornwell, 2008).

The device does not aid in achieving frication, or in preventing the phonological processes of stopping or initial voicing. It also does not help achieve lateral tongue bracing or medial lingual grooving, oral behaviors that are considered important components of achieving correct production of /s/ (McLeod, Roberts & Sita, 2006).

The target node for the tongue tip, and the shaft of device, were also designed to minimize airflow impedance during production of /s/. Since airflow parameters are critical to the production of /s/ (McLeod, Roberts, & Sita, 2006), careful consideration was paid to the device's ability not to impede airflow. In addition, the device was designed to minimally impede the coarticulation of other phonemes in a target item such as a word. These low impedance characteristics allowed participants to correctly produce /s/ up to the word level, with the test device in place.

The device is hand-held and was designed to be maximally controllable by the clinician while providing a direct tactile target for the placement of the tongue tip during production. To use the test device, the SLP places the tooth stop against the participant's upper front teeth, with the centering ridge used as an aid to place the device in the center of the participant's upper dentition. With the test device in place, the participant was instructed to place his or her tongue on the target to achieve correct placement for /s/. Figure 2 illustrates the use of the device once it is in place.

The tip of the device, which goes into the mouth, is made of a soft, thermoplastic elastomer that has passed appropriate biocompatibility and toxicity testing required by International Organization for Standardization (IOS) 10993 standards and the U. S. Food and Drug Administration (FDA). The material is soft enough to prevent deformation or pain when bitten down upon, yet is sturdy enough to retain its shape when manipulated by the tongue. The test device used in this study was the Speech Buddy® for /s/, designed by Articulate Technologies, Inc. (San Francisco, California, USA).

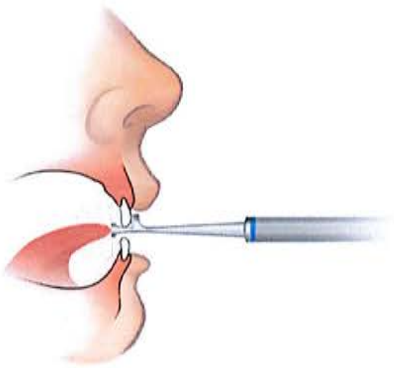

**Figure 2.** The placement of the test device within the oral cavity.

*Participants*

Twenty participants between the ages of 5:0 years and 8:11 years were enrolled in this study. Participants were recruited by advertisements in local print and online media, a directed mailer to local parents, and postings on local parenting internet listservs. All enrolled participants met the following criteria: 1) age 5:0 years 8:11 years at the time of assent and parental permission; 2) incorrect production of the /s/ phoneme (i.e. 0-20% correct) according to a picture naming test that contained 50 items; 3) receptive and expressive language skills greater than 1.5 standard deviations below the mean, as compared to normative values of the Comprehensive Evaluation of Language Fundamentals-4 Screening Test (CELF-4 Screening Test); 4) hearing function within normal limits at 500, 1000 and 2000 Hz in both ears, according to a hearing screening conducted in a quiet room with an Earscan 3 ® brand audiometer, calibrated at the beginning of the study; 5) native speakers of American English, according to pre-screening interviews with participants' parents and caregivers and the principal investigator's judgment of native language based on verbal interaction with the prospective participant; and, 6) have received less than ten hours of therapy time for a speech sound disorder that could be /s/ or any other sound, as per parent reports. The ten hours standard was specified in the protocol to aid in recruiting if necessary, but all 20 participants enrolled had no prior therapy addressing speech or language deficits.

Once screened, evaluated and enrolled in the study, each eligible participant was randomly assigned to a control group or an experimental group. There were two different speech language pathologist roles in the study. Four SLPs administered eight,

cost-free therapy sessions to the subjects, while one separate SLP, who was blinded as to which group the participant was in, performed accuracy assessments. The control group (n = 10) was administered traditional methods of articulation therapy during the eight sessions, whereas the experimental group (n = 10) was administered intra-oral tactile biofeedback as its primary cuing modality during the eight sessions. In addition to the therapy sessions, accuracy assessments were obtained before and after treatment, as well as at three specific intervals during the therapy regimen. As opposed to the therapy sessions, the accuracy of each participant's production of /s/ was determined by a different, single evaluator who was blind to the participant's inclusion in either the control or experimental group. Neither the control nor the experimental group used the test device during the accuracy assessments, which enabled to evaluator to be blinded.

All assessment and therapy sessions were conducted at Open Lines Speech and Communication, PLLC, a private practice facility in New York City. The study and site were fully approved by The Copernicus Group Institutional Review Board (IRB), the study's governing IRB. The study protocol, randomization protocol, data collection methods and statistical analysis, data storage, data forms, consenting procedures and potential conflicts of interest were all reviewed by the governing IRB. In addition, all recruitment materials, including ads in local media outlets and internet parenting listservs, were approved by the governing IRB.

***Enrollment Summary and Randomization***

A total of 24 children were identified and screened but only 20 met the inclusion criteria listed above. All pre-screenings were conducted by the principal investigator over the telephone once the participant's parent or caregiver made initial contact. All baseline evaluations to determine ultimate eligibility and to gather baseline data for the participants were conducted by a New York State-licensed, ASHA-certified Ph.D.-level clinician with over ten years of clinical experience who also acted as the study's single-blind evaluator.

Upon enrollment, participants were randomly assigned to the control or experimental group using the envelope method. Prior to the initiation of the study, 20 envelopes were created that included a visible sequence number (#01 to #20) on the outside of the envelope. The envelopes were opened in sequential order of randomization requests. A third party without knowledge of the study was identified to disclose randomization assignments. Randomization was not statistically driven and included include ten "experimental group" determinations and ten "control" group determinations to achieve a one-to-one randomization ratio.

Of the 20 participants enrolled in the intent-to-treat population, 15 participants were included in the per-protocol analysis due to the following reasons: loss to follow up, loss of upper front dentition during the study, concurrent therapy disclosed post-randomization. Participants are divided among the control group (n = 7) and the experimental group (n = 8). Table I summarizes participant characteristics.

Although study participants were required to have less than ten hours of previous speech therapy, all study participants had never received speech and/or language therapy in any form, targeting any deficit area. Prospective participants presenting with primarily phonologically based production errors were not excluded from participation; baseline accuracy of 0-20% was the only production-related inclusion criterion that determined. However, all enrolled participants presented with articulation-based production errors. There were no significant differences among the groups as to age, gender, raw score on the CELF-4 Screening Test (this test does not provide standard scores), pre-treatment accuracy percentage, type of /s/ distortion (frontal versus lateral), and elapsed time between the first and last therapy sessions, and amount of previous therapy, as shown in Table 1.

***Description of the Eight Therapy Sessions***

The goal of the therapy sessions was to administer nearly identical therapy to both the control and experimental group, with the exception being the fact that the experimental group used the test device, whereas the control group did not. The two groups received eight individual treatment sessions over a period of four to seven weeks. The study PI attempted to schedule two weekly sessions over four weeks. However, taking into account scheduling conflicts (e.g. vacation and illness), seven weeks was allotted to complete all eight sessions.

For both groups, each of the eight treatment sessions consisted of 45 total stimulus items, taking approximately 25 minutes to complete. The first five items trained auditory discrimination and asked the participant to discriminate between a correct versus incorrect production of /s/. The next six items trained were "warm-up" items with /s/ presented in isolation and in CV and VC syllables. After completing the "warm-up" items, the remaining 34 items trained /s/ in words in initial position (16 items), medial position (five items), and final position (13 items). These 34 stimulus items were used, randomly selected from a list of 140 total items (70 items in with /s/ in initial position, 15 items in medial position, 55 items in final position). Items were chosen to generally feature /s/ in stressed syllables and only as a singleton, and not in consonant clusters. Items were chosen to represent a wide range of vocalic and consonantal contexts. The total number of items trained was consistent for both test groups in all therapy sessions. Appendix A provides a sample therapy session, including randomized stimulus items.

The control group was treated according to a treatment manual which was developed according to phonetic-based practice principles stipulated in Van Riper (1978) and focusing primarily on phonetic placement cues. Each stimulus item began with phonetic placement techniques that described and visually illustrated to the participant correct placement. This was

| | Control Group | | | Experimental Group | | | Analysis | | |
|---|---|---|---|---|---|---|---|---|---|
| Numerical Characteristics | N | mean | SD | N | mean | SD | *t* | Df | *p* |
| Age at Baseline (months) | 7 | 89.4 | 18.2 | 8 | 76.6 | 10.1 | 1.7 | 13 | 0.11 |
| CELF-4 Screening Test[a] | 7 | 9.0 | 2.9 | 8 | 7.0 | 3.1 | 1.3 | 13 | 0.22 |
| Baseline Accuracy (%) | 7 | 1.7 | 4.5 | 8 | 0 | 0 | 1.07 | 13 | 0.30 |
| Time Between First and Last Therapy Session (days) | 7 | 37.6 | 9.9 | 8 | 32.5 | 8.5 | 1.1 | 13 | 0.30 |
| Prior Therapy (hours) | 7 | 0 | 0 | 8 | 0 | 0 | 0.0 | 13 | 1 |

| | Control Group | | | Experimental Group | | | Analysis |
|---|---|---|---|---|---|---|---|
| Binary Characteristics | N | N with characteristic | % | N | N with characteristic | % | *p* |
| Frontal Lisp | 7 | 6 | 85.7 | 8 | 8 | 100.0 | 0.47[b] |
| Male | 7 | 3 | 42.9 | 8 | 3 | 37.5 | 1.00[b] |

[a] Number above criterion score.
[b] Fisher's Exact Test, two tailed.

**Table 1. Characteristics of research participants.**

followed by the clinician producing a model of the target sound in isolation. Sound discrimination was used to contrast the target sound with the participant's error production. After correct production of the target /s/ in isolation and discrimination of the target versus the error, practice was incorporated at the word level. In each session training was conducted at the isolation, syllable and word level according to the session description above.

Therapy in the experimental group proceeded according the treatment received by the control group, except that the primary cuing mechanism was intra-oral tactile biofeedback delivered by the test device. All "warm-up" items used the intra-oral tactile biofeedback device. In addition, every other item was trained with the intra-oral tactile biofeedback device, with 17 of the 34 total items trained with the device. Practice with the device at the isolation, syllable and word levels did not constrain movement of the speech articulators. As per the experimental group treatment manual, each child was provided with his or her own dedicated test device. After each production, the subject received immediate reinforcement from the study treating clinician on whether the production of /s/ in that item was correct or incorrect; and, if incorrect, what the primary reason for the misarticulation was (e.g. the tongue was misplaced between the teeth). Each clinician recorded whether a given item was correct or incorrect in the "therapy session log" document in each participant's trial binder. The recorded judgments of accuracy were *not* included in study assessments or data analyses reported below. After each session, clinicians were instructed to thoroughly wash the test device using mild soap and water.

Each participant's progress through the study was tracked by the principal investigator using dedicated trial binders consisting of all relevant study information for each participant. Each binder consisted of: executed parent and student consent forms; eligibility checklist to ensure fidelity with study inclusion and exclusion criteria; all pre-treatment, during-treatment and post-treatment assessments; all therapy session logs; protocol deviation reports; narrative summaries describing events that may have had a material impact on study data; adverse event reports; device malfunction reports, and post-trial questionnaires (experimental group only). The PI conducted periodic treatment fidelity checks which included weekly reviews of all trial binders as well as periodic in-session observations and telephone conversations with study clinicians.

***Assessments/Measures***

All accuracy assessment data were collected by a single ASHA-certified, licensed, Ph.D.-level evaluator with over ten years of clinical experience. The evaluator was blind as to the participant's inclusion in either the experimental or control group. The baseline and final assessments were 50 word assessments whereas the during-treatment assessments consisted of 20 words.

The assessment stimulus items were comprised of a picture-naming test containing pictures of objects or basic actions

containing /s/ in various words and in words-in-sentences, in various positions (initial, medial and final) and in various phonetic contexts. The same 50-word picture-naming test was used for the baseline assessment (the pre-treatment measure) and the final assessment (post-treatment measure). The during-treatment measures consisted of three separate 20-word tests consisting of randomly selected words from a set of 60 words. 50 of these words were the same 50 words comprising the baseline and final assessments, with an additional ten words included. No assessment items were ever used as treatment items. A list of assessment battery stimulus items can be found in Appendix B. Each participant was seen individually in a quiet therapy room for all assessments. During assessments, each participant was required to name each picture individually and each target response was scored by the single-blind assessor as either correct or incorrect, and then recorded on carbon paper.

To establish the reliability of the study evaluator, additional testing was conducted. Reliability testing used audio and video recordings of study stimulus items. The audio recorder used was the microphone attached to a JVC Everio GZ-MS120BU brand digital camcorder. The microphone had an audio sampling rate of 40 kHz, considered adequate for recording the entire acoustic signal of /s/ (Kent & Read, 2002). To establish intra-rater reliability, the evaluator was asked to judge these recorded study items on two separate occasions, 14 days apart. The same set of items was used, although they were presented in different random orderings. Inter-rater reliability was assessed using this method, which compared the accuracy judgments of the study evaluator to those of another judge, an experienced academic researcher, clinician, and former head of a leading accredited graduate clinic.

In addition, a qualitative questionnaire was given to experimental group participants at the conclusion of treatment. The questionnaire compiled participant impressions of their use of the test device. Questions posed to participants included: whether participants enjoyed using the device, whether they found the device scary, painful or uncomfortable, and if they felt the device helped them to speak better.

### *Clinician Training*

The therapy sessions were conducted by four New York State-licensed and ASHA-certified speech-language pathologists, each with at least five years of clinical experience in treating speech sound disorders in a variety of clinical settings. The speech-language pathologists were trained on the relevant aspects of the study's protocol, on how to use the intra-oral tactile biofeedback device in therapy, how to conduct therapy sessions according to traditional methods of articulation therapy, and how to perform data collection for each study group. Each speech-language pathologist received a training manual so that the information could be consulted at a later date.

The dedicated training session consisted of a 30-minute presentation conducted by the study PI and was supported by detailed instructions with concise descriptions and visual supports. Instructions were provided for number of items, types of cuing permitted for each experimental condition, and type of reinforcement to be used. Clinicians were instructed on the recording of data as to correct versus incorrect production from the participant for each item on carbon paper, though these data were not included in any formal analysis. In addition, this training session included a segment devoted to the study therapists practicing to use the test devices with each other. Cleaning and storage protocols were also covered in the training session.

### *Statistical Analysis*

Analyses were conducted using SAS (Statistical Analysis Software), Version 9.2 (SAS Institute Inc., Cary, NC, USA, www.sas.com). Independent sample t-tests and Chi-square analyses were conducted as appropriate, to test for differences between experimental and control group participants on the demographic and clinical characteristics shown in Table I. A repeated-measures Analysis of Covariance (ANCOVA) was then conducted to understand the effect of treatment with the intra-oral tactile biofeedback device on accuracy over time. Repeated-measures ANCOVA allows for both between-subject factors (in this case, treatment), and within-subject factors (in this study, time), to be tested. This statistical analysis allowed the authors to track improvements in performance among all participants with time, due to treatment, and to test treatment-specific effects, and differences in the trajectories of improvement over time, between control and experimental group members, and thus allowed the authors to more confidently attribute improvements in production accuracy of /s/ to treatment received.

## RESULTS

The primary endpoint of the study, the determination of a response, or no response to therapy, was met ($p < .004$), indicating that, analyzed as a group, the participants using the test device experienced a treatment response, whereas the control participants, as a group, did not. The secondary endpoint, a statistical difference ($p < .05$) between the control and experimental group at a 95% confidence interval, was not met ($p = .08$). This indicates that the comparative improvement the experimental group experienced over the control group was statistically significant only to a 90% confidence interval, not the generally accepted standard of 95%.

Table 2 shows the raw data collected from the participants as well as the mean accuracy and standard deviation of each group at each time point. Figure 3 shows the graph of the mean accuracy at each time point.

As shown in Table 2 and Figure 3, the control and experimental groups showed similar baseline performance and response to untrained items at the first and second interim assessments; however, there is a change at subsequent probes. In addition, the

| Subject | Baseline | Interim #1 | Interim #2 | Interim #3 | Final | Change |
|---|---|---|---|---|---|---|
| | | | Experimental Group | | | |
| 01 | 0 (0%) | 2 (10%) | 5 (25%) | 16 (80%) | 37 (74%) | (74%) |
| 03 | 0 (0%) | 10 (50%) | 17 (85%) | 19 (95%) | 48 (96%) | (96%) |
| 05 | 0 (0%) | 7 (35%) | 9 (45%) | 16 (80%) | 44 (88%) | (88%) |
| 07 | 0 (0%) | 10 (50%) | 10 (50%) | 12 (60%) | 37 (74%) | (74%) |
| 09 | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | (0%) |
| 11 | 0 (0%) | 0 (0%) | 0 (0%) | 17 (85%) | 37 (74%) | (74%) |
| 14 | 0 (0%) | 16 (80%) | N/A | 18 (90%) | 44 (88%) | (88%) |
| 19 | 0 (0%) | 16 (80%) | 20 (100%) | 20 (100%) | 49 (98%) | (98%) |
| Mean % (SD) | 0.0 % (0.0) | 38.1% (32.7) | 43.6% (38.9) | 73.8% (32.2) | 74.0% (31.5) | 74.0% (31.5) |
| | | | Control Group | | | |
| 02 | 0 (0%) | 8 (40%) | 10 (50%) | 10 (50%) | 14 (28%) | (28%) |
| 06 | 0 (0%) | 15 (75%) | 20 (100%) | 20 (100%) | 50 (100%) | (100%) |
| 12 | 0 (0%) | 0 (0%) | 0 (0%) | 1 (5%) | 0 (0%) | (0%) |
| 15 | 0 (0%) | 0 (90%) | 0 (0%) | 0 (0%) | 0 (0%) | (0%) |
| 16 | 6 (12%) | N/A | N/A | 11 (55%) | 45 (90%) | (78%) |
| 17 | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | (0%) |
| 18 | 0 (0%) | 20 (100%) | 20 (100%) | 20 (100%) | 50 (100%) | (100%) |
| Mean % (SD) | 1.7% (4.5) | 35.8% (42.1) | 41.7% (47.6) | 44.3% (44.4) | 45.4% (49.1) | 43.7% (47.4) |

**Table 2.** Data set of assessment accuracy: number correct (percentage correct).

| | n | Response | No Response |
|---|---|---|---|
| Experimental Group | 8 | 7 (87.5%) | 1 (12.5%) |
| Control Group | 7 | 3 (42.8%) | 4 (57.1%) |

**Table 3.** Response using threshold of 70% accuracy.

experimental group demonstrated increased response accuracy, while the control group plateaued. The control group showed minimal improvement in probe testing after the second interim assessment. However, the experimental group showed a continued increase in mean accuracy after the first half of treatment, as measured by the third assessment and the final assessment. The change in accuracy from the baseline to the final assessment was greater for the experimental group (mean = 74.0%, S.D. = 31.5, n = 8) than for the control group (mean = 43.7%, S.D 47.4, n =7). Variance in treatment response within the control group was considerable due to the inconsistent and binary pattern of response rate; three subjects showed a measurable treatment response, whereas four showed no measurable treatment response.

***Statistical Analysis***

The primary hypothesis was tested using a one-way repeated-measures ANCOVA to compare performance over time for the experimental group versus the control group to determine the effect of the intra-oral tactile biofeedback therapy. Performance at baseline was the covariate. There was a significant interaction between time and group, $F(3,35) = 5.46$, $p = .004$, showing that the experimental group demonstrated a significant response, while the control group did not.

Post hoc comparisons between different group-time conditions showed that the experimental group performed significantly better at the final assessment and third interim assessment than at the first interim assessment ($t = 3.99$, $p < .001$, $t = 3.97$, $p < .001$, respectively). Additionally, the experimental group also performed significantly better at final assessment and third interim assessment than at the second interim assessment (t =

2.96, p = .006, t = 2.94, p = .006, respectively). No other post-hoc comparisons between different time and group combinations were statistically significant.

A two sample t-test was used to examine the secondary hypothesis of the difference between the control and experimental group. A one sided t-test was used and assumed equal variances between the groups. At $\alpha = .05$ the change was not statistically significant ($p > .05$) with $t = 1.48$ and $p = .08$, while a significant response was generated using $\alpha = .10$, indicating a trend finding.

In addition to the per-protocol analysis, an additional analysis was performed on the intent-to-treat population of $n = 20$, using the method of last measured observation carried forward for the additional five participants using the same statistical methods outlined above. The results also yielded a similar, insignificant response for $\alpha = .05$ with $t = 1.52$ and $p = .07$.

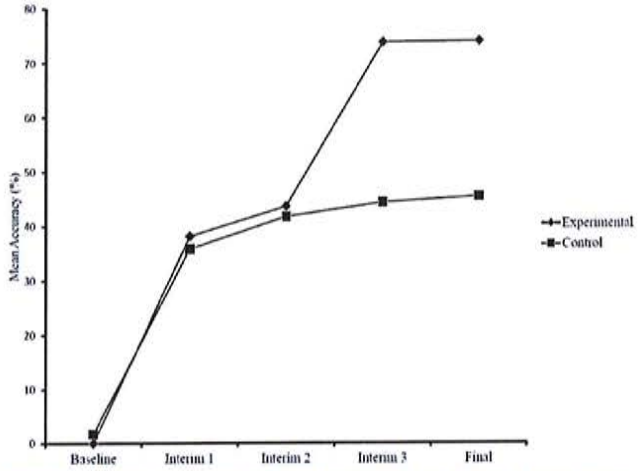


**Figure 3.** Mean accuracy of production of /s/ at each time point.

*Rater Reliability Results*

Intra-rater correspondence among the recorded study stimulus items was 95%. Inter-rater correspondence among the items was 94%. According to the standards in the field set by McCauley and Swisher (1984), these reliability measures were in the acceptable range and suggest the study blinded evaluator was a reliable judge of correct versus incorrect /s/ production.

*Post-Trial Questionnaire Results*

The post-trial questionnaire showed that all of the participants had no adverse reactions to the device, there were no device malfunctions, and no participants found the tool uncomfortable or painful. One participant reported not to have enjoyed using the device.

## DISCUSSION

The results of this investigation suggest that the addition of an intra-oral tactile biofeedback device enabled significant gains across the short-duration treatment period and support the test device's use as a viable treatment option in articulation therapy. Results of qualitative participant questionnaires also showed that none of the experimental group participants reported that the device was painful, uncomfortable or scary. This further suggests that the current embodiment of the intra-oral tactile biofeedback device has the potential to be a generally well-tolerated clinical tool by neurotypical children. In addition, all study subjects were naïve to treatment at enrollment. Generally, the inclusion of treatment-naïve subjects in behavioral research eliminates the effect of prior treatment on observed results (He, Deng, Li, Chen, Jiang, Wang, Huang, Collier, Gong, Ma, Zhang & Li, 2012). This would lend support to the assertion that the changes observed in subjects' accuracy of /s/ production in this study were directly due to the therapy they received.

The results reported above show that participants can be identified as responders and non-responders. Table 3 shows responders and non-responders, using a threshold of 70% production accuracy on the pre-treatment vs. post-treatment assessments, based from a 70-80% performance criteria accuracy range identified by Van Riper and Emerick (1984). The consistency of the experimental group's treatment response provides further evidence of the utility of biofeedback approaches in treating articulation disorders. Seven out of eight participants in the experimental group were identified as responders, and one participant with 0% accuracy at final assessment was deemed a non-responder. Conversely, in the control group, only three out of seven participants were identified as responders with the remaining four showing little to no response. There were no baseline or otherwise measured clinical characteristics that could distinguish the non-responders in either group. This rate of non-response of 43% grossly corresponds to the 28% rate of non-response observed by Jacoby et al (2002).

For the three responders in the control group, traditional methods of articulation therapy may have been all these children needed to learn and habituate correct /s/. For the other four non-responders, either traditional methods were not adequate to achieve a learning breakthrough, or more time in therapy was required. In either case, that seven of eight experimental group participants responded to treatment in this short-duration therapy regimen would suggest that having access to all potentially useful sensory components for learning (i.e. including the tactile component) may increase the chances that a short-duration therapy program would be effective.

Despite their consistent misarticulations of /s/, at the outset of treatment all study participants were able to achieve the necessary sibilant frication for /s/ and no participant manifested any commonly described phonological process (e.g. stopping). Therefore, all participants' attempted productions of /s/ were realized as incorrect lingual placement within the oral cavity. For both experimental conditions, according to each group's treatment manual, the focus of therapy was on training correct

oral configuration, and differentiating participants' trained, correct realizations of /s/ versus previous, incorrect realizations of /s/. The treatment gains achieved by control group participants can be attributed to the effectiveness of traditional methods in achieving clinical gains. Given that the experimental group's primary cuing method was intra-oral tactile biofeedback, the treatment gains achieved by the experimental group can be attributed to the ability of the device to position the tongue tip in the correct region of the oral cavity while simultaneously not impeding the airflow necessary to achieve frication for /s/. Verbal directions were used to enhance the salience of the new, correct oral configuration for /s/. In addition, cues were used to aid the participants in auditorily discriminating correct and incorrect acoustic realizations of /s/. While these techniques are hallmarks of traditional methods of articulation therapy (Van Riper & Emerick, 1984), the primary learning modality in the experimental group was tactile biofeedback delivered via the test device.

The results reported above also provide preliminary evidence supporting the therapeutic corollary to the somatosensory feedback mechanism described in experiments involving normal control adults not presenting with speech sound deficits (Champoux, Shiller & Zatorre, 2011; Gick & Derrick, 2009; Tremblay, Shiller & Ostry, 2003). In addition, these results provide further clinical support of the validity of a distinct somatosensory input in psycholinguistic models of speech production, such as Guenther's DIVA model. The results also seem to corroborate suggestions by Ghosh et al (2010) that given the precision required to produce sibilant fricatives, this class of speech sounds may be especially appropriate targets for therapy involving somatosensory feedback.

Despite these apparent strengths and the significant findings with respect to the study's first hypothesis, the inclusion of additional subjects may have resulted in a significant (e.g. $p < .05$) finding for the study's secondary hypothesis. The study was limited by the cost of study personnel and the inclusion of treatment-naïve participants, which significantly extended the study's recruitment calendar. Absent these constraints, the enrollment of an additional eight to ten participants may have made the results more definitive.

As per the description of study participants above, this study included only pediatric participants whose language and hearing functions were determined to be within normal limits. The data obtained would apply to those children who present with a similar cognitive, language and hearing profile. Additional studies are required to determine whether these results can be applied to those with hearing impairments, concomitant language disorders or cognitive impairments.

This study was designed to examine the effect of intra-oral tactile biofeedback in treating solely misarticulated /s/. No other speech errors in participants' speech sound systems were systematically assessed or treated. For this reason, a standardized assessment that may have revealed severity of involvement and level of stimulability for the production of /s/ was not included in the study's assessment battery. While the majority of participants presented with /s/ as their sole misarticulated phoneme, the lack of attention to the participants' other potential treatment needs would suggest the results obtained may not be generalized to treatment outcomes targeting the child's whole speech sound system.

Traditional methods of articulation therapy were selected as the treatment control for this study. This was due to traditional methods' comparative advantage in achieving favorable treatment outcomes in treating /s/ (Powell, Elbert, Miccio, Strike-Roussos & Brasseur, 1998). In addition, the authors felt that the use of the test device for /s/ was most complementary with traditional methods, rather than, for example, phonological approaches. In contrast, other studies have found that phonological therapy approaches are comparatively effective (e.g. Pamplona, Ysunza & Espinosa, 1999). The results obtained in this study would not bear upon this apparent discrepancy and are best interpreted as preliminary evidence supporting tactile biofeedback in itself, rather than evidence supporting tactile biofeedback in lieu of a particular leading treatment methodology.

This is a preliminary study designed to examine the clinical utility of an intra-oral tactile biofeedback device in remediating misarticulation of the /s/ phoneme in a cohort of neurotypical, hearing children. The results reported above were achieved in a short duration therapy period and suggest that intra-oral tactile biofeedback has the potential to reduce the expected time required to treat misarticulated /s/. In closing, it is worth noting that the majority of pediatric speech sound disorders may be effectively and efficiently treated by traditional methods of articulation therapy (Powell et al, 1998). However, a significant number of pediatric subjects remain resistant to treatment despite the use of these traditional approaches (e.g. 28% of pre-school and school-age children, according to Jacoby et al, 2002). The results obtained in this study provide evidence for intra-oral tactile biofeedback as a cost-effective alternative to traditional approaches to articulation therapy, when such approaches have previously failed to achieve desired clinical results.

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## DECLARATION OF INTEREST

The Copernicus Group IRB monitored the study to ensure that there were no conflicts of interest that would jeopardize subject enrollment, data collection, and data analysis. The first author is co-founder and Chief Scientific Officer of Articulate Technologies, Inc. and is compensated on a part-time, consultant, fee-for-service basis, and by an equity stake in the company. The statistical analysis was performed by the second author, an independent consultant, who does not have a financial interest in the study sponsor.

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## APPENDIX A
### Sample Session and Guide to Use of Stimulus Cue

| Cue Number | Cue | Type | Control Group | Experimental Group |
|---|---|---|---|---|
| | | Auditory Discrimination | | |
| 1 | sip - tip | n/a | traditional cue | traditional cue |
| 2 | thin - sin | n/a | traditional cue | traditional cue |
| 3 | sack - Zack | n/a | traditional cue | traditional cue |
| 4 | walrus - walruh | n/a | traditional cue | traditional cue |
| 5 | fussy - futhy | n/a | traditional cue | traditional cue |
| | | Warm Up | | |
| 6 | S | isolation | traditional cue | tactile cue |
| 7 | S | isolation | traditional cue | tactile cue |
| 8 | suh | initial syllables | traditional cue | tactile cue |
| 9 | suh | initial syllables | traditional cue | tactile cue |
| 10 | us | final syllables | traditional cue | tactile cue |
| 11 | us | final syllables | traditional cue | tactile cue |
| | | Therapy | | |
| 12 | south | initial | traditional cue | tactile cue |
| 13 | saga | initial | traditional cue | traditional cue |
| 14 | cinnamon | initial | traditional cue | tactile cue |
| 15 | self | initial | traditional cue | traditional cue |
| 16 | syrup | initial | traditional cue | tactile cue |
| 17 | sickle | initial | traditional cue | traditional cue |
| 18 | send | initial | traditional cue | tactile cue |
| 19 | sat | initial | traditional cue | traditional cue |
| 20 | sap | initial | traditional cue | tactile cue |
| 21 | city | initial | traditional cue | traditional cue |
| 22 | safe | initial | traditional cue | tactile cue |
| 23 | soil | initial | traditional cue | traditional cue |
| 24 | silver | initial | traditional cue | tactile cue |
| 25 | simple | initial | traditional cue | traditional cue |
| 26 | city | initial | traditional cue | tactile cue |
| 27 | said | initial | traditional cue | traditional cue |
| 28 | fossil | medial | traditional cue | tactile cue |
| 29 | lesson | medial | traditional cue | traditional cue |
| 30 | juicy | medial | traditional cue | tactile cue |
| 31 | recipe | medial | traditional cue | traditional cue |
| 32 | wrestle | medial | traditional cue | tactile cue |
| 33 | princess | final | traditional cue | traditional cue |
| 34 | grace | final | traditional cue | tactile cue |
| 35 | chase | final | traditional cue | traditional cue |
| 36 | loss | final | traditional cue | tactile cue |
| 37 | mass | final | traditional cue | traditional cue |
| 38 | gross | final | traditional cue | tactile cue |
| 39 | grease | final | traditional cue | traditional cue |
| 40 | class | final | traditional cue | tactile cue |
| 41 | across | final | traditional cue | traditional cue |
| 42 | hiss | final | traditional cue | tactile cue |
| 43 | chase | final | traditional cue | traditional cue |
| 44 | brace | final | traditional cue | tactile cue |
| 45 | ace | Final | traditional cue | traditional cue |

## APPENDIX B
### 50 Word Baseline and Final Assessments

| Cue Number | Cue | Word position |
|---|---|---|
| /s/ in Words | | |
| 1 | Sock | initial |
| 2 | Sun | initial |
| 3 | Six | initial |
| 4 | Seal | initial |
| 5 | Cereal | initial |
| 6 | Salt | initial |
| 7 | Saw | initial |
| 8 | Seven | initial |
| 9 | Sing | initial |
| 10 | Circle | initial |
| 11 | Soup | initial |
| 12 | Sink | initial |
| 13 | Submarine | initial |
| 14 | Sick | initial |
| 15 | Soccer Ball | initial |
| 16 | Castle | medial |
| 17 | Messy | medial |
| 18 | Muscle | medial |
| 19 | Motorcycle | medial |
| 20 | Dinosaur | medial |
| 21 | Missile | medial |
| 22 | Glasses | medial |
| 23 | Sausages | medial |
| 24 | Eraser | medial |
| 25 | Medicine | medial |
| 26 | Dress | final |
| 27 | Mice | final |
| 28 | Chess | final |
| 29 | Glass | final |
| 30 | Rice | final |
| 31 | (Shoe) Lace | final |
| 32 | Ice | final |
| 33 | Grass | final |
| 34 | Goose | final |
| 35 | House | final |
| 36 | Octopus | final |
| 37 | Cactus | final |
| 38 | Gas | final |
| 39 | Face | final |
| 40 | Bus | final |
| /s/ in Words in Sentences | | |
| 41 | Sit(ting) | initial |
| 42 | Santa (Claus) | initial |
| 43 | Sandwich | initial |
| 44 | Soap | initial |
| 45 | Whistle | medial |
| 46 | Baseball | medial |
| 47 | Mouse | final |
| 48 | Dice | final |
| 49 | Lettuce | final |
| 50 | Moss | final |