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Original Research Article

Facilitating Tongue Length and Mobility Using a Novel Loop Device for Dysphagia in Stroke Survivors: Efficacy in a Quasi-Randomized Study

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ABSTRACT

Background: Dysphagia in stroke patients is primarily attributed to motor weakness and decreased voluntary motor control, leading to delayed swallowing reflexes and pharyngeal contractions. There are limited technical aids available for the rehabilitation of the tongue. This study presents an option in the form of a loop device. **Objective:** To investigate the use of a loop device for dysphagia in stroke survivors using a quasi-randomized study. **Methods:** This quasi-randomized study was conducted at a hospital on post-stroke dysphagia for 1 year. The sample was divided into either Group A (n = 6) or Group B (n = 6). Group A received tongue stretching and strengthening using the loop device. Group B received tongue stretching (manually) and strengthening intervention (tongue depressor) without using a loop device. Eating Assessment Tool (EAT10), M.D. Anderson Dysphagia Inventory (MDADI), and tongue length change measure or tongue protrusion change (TLCM) were used to check the outcome using the significant difference of means at a p-value of 0.05, considering a normal distribution and SD. Paired and independent t-tests were used for analysis. **Results:** Group A: the mean TLCM score increased from 1.56 (SD = 0.91) to 2.0 (SD = 0.82) from the pretest to the posttest (p = 0.007). The mean EAT10 score decreased from 24 (SD = 5.21) to 19.33 (SD = 6.80), (p = 0.011). In addition, the mean MDADI score increased from 53.80 (SD = 7.71) to 62.97 (SD = 12.37), (p = 0.021). The p-value was found to be significant at < 0.05. Group B: In Group B, the mean TLCM score increased from 2.23 (SD = 0.34) to 2.50 (SD = 0.41), (p = 0.014). However, the mean EAT10 score decreased notably from 19.16 (SD = 2.48) to 13.5 (SD = 3.27), (p = 0.001). Similarly, the mean MDADI score increased from 51.7383 (SD = 6.16) to 58.3967 (SD = 6.16), (p = 0.001). The p-value was found to be significant at < 0.05. In intergroup comparison, no significant difference is seen. **Conclusions:** Improvements have been observed in dysphagia using TLCM, EAT-10 scores, and MDADI after the interventions. No significant improvement of the novel device use over the traditional methods is seen in the studied measures, and both are comparable to each other. The loop device provided the intervention in an effective, hygienic, and clinically appropriate manner. The manual stretching of the tongue was not preferred by patients.

Keywords—*Oral rehabilitation, Swallowing function, Tongue mobility, Tongue strength.*

INTRODUCTION

Stroke is a medical condition characterized by decreased cerebral perfusion, which is caused by insufficient blood flow to the brain.[1] More than 50% of stroke patients experience dysphagia. However, the majority of patients regain their ability to swallow within 7 days, but after 6 months, 11–13% of them still have dysphagia.[2] Dysphagia is associated with decreases in tongue pressure, which is a measure of tongue muscle strength.[3,4] The mobility of the tongue with actual tongue protrusion, a reflection of functional tongue length, is also a factor responsible for swallowing dysfunction. The primary purposes of the tongue, in the oral phase of swallowing, are to facilitate the creation of boluses, chewing, and the passage of boluses to the throat. The tongue, being a mobile muscular structure, must have enough power and mobility to perform these tasks during the oral phase. Consequently, finding therapeutically useful interventional techniques to enhance tongue function in dysphagia individuals is desirable.[5] In clinical practice, manual tongue stretching and strengthening exercises are frequently utilized to improve oromotor performance overall by decreasing tongue shortening and enhancing tongue motility.[6]

The consequences of dysphagia impact various aspects of life satisfaction and health outcomes—mealtime anxiety, reduced enjoyment of eating, and social isolation, with approximately one-third avoiding eating with others; this requires early screening.[7] It may contribute to aspiration, prolonged hospital stays, breathing problems, dehydration, malnutrition, weight loss, and ultimately, a lower quality of life and increased mortality risk.[8] It also leads to general muscle weakness and muscle loss[9], requiring comprehensive rehabilitation with therapeutic modalities.[10] Commonly reported modalities are strengthening.[11,12] However, electrical stimulation[13] has also been reported. Devices for dysphagia rehabilitation are available[14–16], but are not commonly prescribed in a developing setting and are of higher cost.[17]

Oral rehabilitation includes assessment, early detection, and management of dysfunctions in the tongue[18] and buccal physiology, along with restoration of dentation, and is not limited to prosthetic dentures. It is a comprehensive approach including a combination of therapies.[19] Rehabilitative interventions with *dysphagia as a focus have been seen as effective*.[20]

This study aimed to explore the significance of tongue-strengthening exercises, tongue stretching, and tongue motility in dysphagia management post-stroke. A simple, self-collapsible loop device for providing the exercises hygienically and stretching the tongue gradually from the base to the tip of the tongue (Figure 1) has been studied. We elucidate the potential benefits of these interventions in enhancing swallowing function and overall quality of life for stroke survivors with dysphagia. The device in the form of a loop with a handle is simple yet novel as it not only stretches and mobilizes the tongue from its very root in a circular and gradual fashion which not only elongated the tongue but also facilitates its motility and thereby is a unique rehabilitative perspective for dysphagia. It is nonobvious because the tongue muscles' *external group*, Genioglossus, Hyoglossus, Styloglossus, and Palatoglossus, and *internal group*, Superior longitudinalis, Inferior longitudinalis, Verticalis, and Transversalis, have a diverse role and distinct direction of movement, which can be re-trained by the loop device. The external and internal tongue muscles move the tongue in anterioposterior, superior–inferior, and oblique directions in a 360-degree fashion. It has an impact on the biomechanics of swallowing, the oral phase, and the chewing mechanism for bolus formation.

Objective: To investigate the use of the above loop device for oral functions in dysphagia patients using a quasi-experimental design. Specifically, the stretching and strengthening exercises are performed in a clinically precise manner, and we elucidate the potential benefits in enhancing swallowing and quality of life. Previous studies have discussed manual stretching, and the gradual fascia stretching from the base to the tip of the tongue in a circular manner is not mentioned. Specific muscle groups are strengthened in different directions of motion using the circular loop by us in the present study, as opposed to only the inferior pressure or using a wooden compressor.

MATERIALS AND METHODS

We have developed a simple loop device (a prototype) for providing the exercises hygienically and stretching the tongue gradually from the base to the tip of the tongue (Figure 1). Intellectual property right patent no. 504718 in the Indian patent office has been registered. This is named as oral rehabilitation frame (ORF).[21] (all details related to this patent registered with the Indian patent office can be accessed online: https://iprsearch.ipindia.gov.in/PublicSearch/PublicationSearch/Eregister).

Materials

Food-grade stainless steel (as the outer core of the prototype), which can be cleaned and boiled for sterilization and re-used by the same patient, and sterile copper looped wire covered in a silicone sleeve as use and throw loop has been used. A silicone rubber stopper with spring for producing a self-collapsible loop is part of the design.

FIGURE 1. Loop device for tongue exercises. Patented device prototype. IPR (patent no—504718). This device provides tongue stretching from base till the tip of the tongue in a gradual and hygienic way, where the tongue is not pulled by hands but gradually elongated with circular compression of the fascia. Strengthening is performed from various directions by encircling the loop on the tip and asking to move the tongue. The prototype handle is made of food-grade stainless steel and is of low cost. It can be boiled/autoclaved for repeated use. The loop is a non-slippery copper wire in a rubber coating, which is one-time use and throw. There is a silicone rubber stopper. The loop in the prototype is controlled manually.[21]

The looped tongue attachment in the device is a circular attachment getting tied/gripped lightly over the tongue, as seen in Figure 2, which elongates the tongue from the base to the tip; it is non-obvious and has stepped forward tongue mobilization to the facial level. The tongue elongation itself is a distinct physiological variable for oral function, and the looped attachment has specifically catered to it. The same may have a circular constrictive ring; however, we have tested a looped one, and it completely encircled the tongue as seen in Figure 3.

Assembly

The device prototype was developed using a hollow-bend steel console, and a loop was passed through it. The loop was made up of copper wire and covered by a nonslippery silicone rubber coat. The frame holder was adapted from an earbud, and assembly was done (Figure 1).

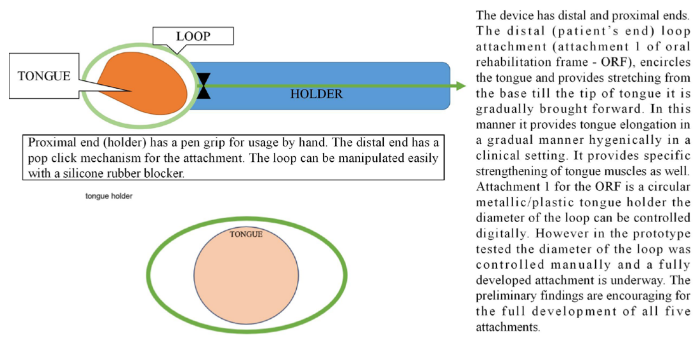

FIGURE 2. The novel ORF attachment 1 has two ends—distal and proximal. The distal (patient's end) loop attachment (in the case of attachment 1 of ORF) encircles the tongue and provides stretching from the base till the tip of the tongue, and it is gradually brought forward. It does not require the manual tongue stretching, which is a crude method and provides excessive pinching force for the tip of the tongue, and is uncomfortable for the patients.

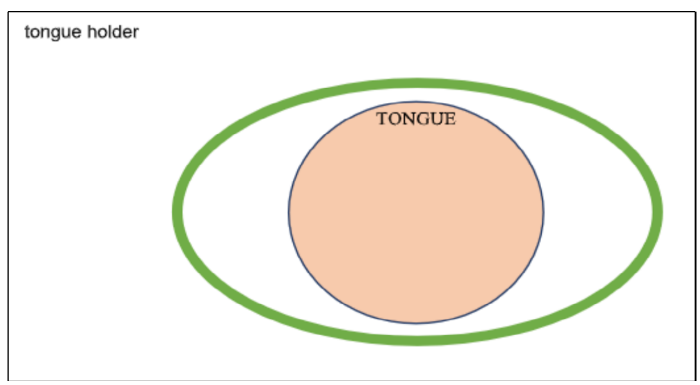

FIGURE 3. The position of the tongue in the cross-sectional view, as enclosed from the base to the tip. The loop elongates the tongue from the base till the tip, and it leads to gradual stretching of the tongue.

The prior art in this area is found but is limited in scope and specificity. For tongue examination, we find prior use of disposable wooden depressors and their modifications like in patent US5897492A * 1998-08-21 1999-04-27 Feller; Mitchell Dean Candy tongue depressor.[22] Few specific devices at the case study level[18] are available at the high end for tongue physiotherapy, but a simple solution is lacking. Devices for oral hygiene are available, but for oral physiotherapy and rehabilitation of tongue and oral function, there are restricted options like To To (a type of device)[14]; nevertheless, it lacks the simplicity for clinical inpatient applications. There is a forceps that is used to hold the tongue during surgeries, CN206080478U, China.[23] However, there are no strengthening, mobilization, manipulation, or stimulation devices with a variety of attachments for different oral functions. It forms the rationale for the development of ORF.[21]

The prototype is human safe, that is, only those materials that are intended for human use are used, as seen in Figure 1. The material involves food-grade stainless steel, a copper loop covered with non-slippery silicone, which is one-time use and throw. The risk assessment of the device has been mentioned.

The stainless steel part is angulated, meaning it is intended to go inside the mouth like a straw. Copper is known for its medicinal properties. It is strong enough to withstand human force, and the coat or outer jacket is of silicone rubber. It is nonslippery, and silicone rubber is nonreactive even at very high temperatures.

Risk Assessment of the Device

The device was used by the author, and it did not induce any choking. The patient is placed in a comfortable sitting position, and the therapist is standing in front of the patient. The therapist is wearing gloves and is using a mask during the therapy, as seen in Figure 1. Two ends of the device are of such a design that they can reach the tongue easily, as seen in Figure 2.

Protocol

Ethical Considerations

Ethical considerations were presented to the Institutional Ethics Committee of The School of Medical Science and Research & Sharda Hospital. The human issues were approved in the committee meeting dated 08/01/2024. Ref No- SU/SMS&R/76-A/2024/31. Informed consent has been received from all participants. This work conforms with the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Study Design and Setting

Study design: randomized study. Study setting: Sharda Hospital. Study subjects: poststroke dysphagia. Study duration: 1 year. Instrumentation: tongue rehabilitation frame prototype, wooden compressor, transparent ruler, cotton gauge, and gloves. Independent variables: (1) tongue stretching and (2) tongue strengthening. Dependent variables: (1) tongue length, (2) swallowing abilities, and (3) tongue strength. Sample selection: criteria-based.

Participants

Sample size: N = 12. Inclusion criteria: all types of stroke patients with dysphagia, both male and female, age group: 60–75 years, score of less than 90 in M.D. Anderson Dysphagia Inventory (MDADI). Exclusion criteria: duration of stroke more than 1 year; GCS below 13; uncontrolled diabetes mellitus; uncontrolled hypertension; and previous history of chewing tobacco. Random group allocation by the chit method. The flow of the participants' recruitment is seen in Figure 4.

Data Collection

Data were obtained by the researcher using tools assessment at the baseline before starting the therapy. The tongue length was measured with the help of a transparent flexible ruler by placing it at the base of the incisors. Swallowing was assessed using the EAT-10 tool and the MDADI, which includes a questionnaire regarding swallowing ability for assessing tongue functions.

Data Analysis

Analyses were carried out using SPSS. A *p*-value of 0.05 was considered significant. Paired and independent *t*-tests were used for data analysis.

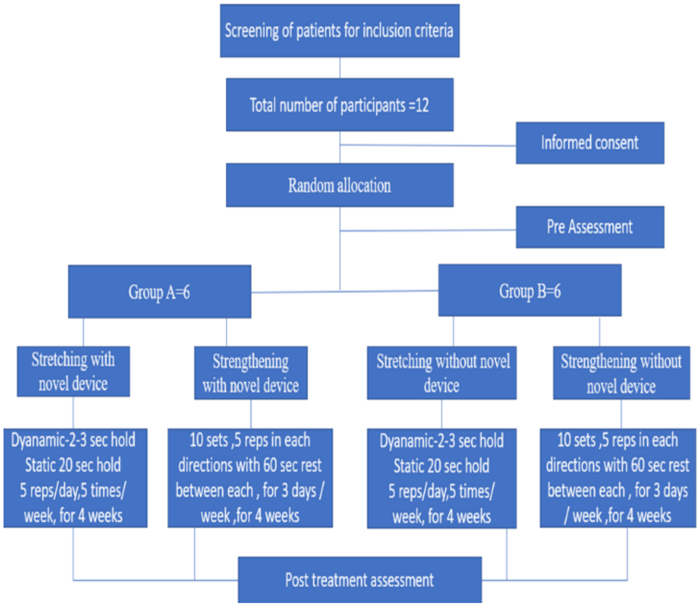

FIGURE 4. Flow chart of study procedure as per the CONSORT criteria of the randomized controlled trials.

Procedure

A total of 12 patients were divided into either Group A ($n = 6$) or Group B ($n = 6$). The distribution was based on the chit method. Group A received tongue stretching and strengthening using the novel device. Group B received tongue stretching and strengthening intervention without using a loop device. During the therapy, firstly, we placed the patient in a comfortable sitting position. For stretching, the patients were instructed to protrude their tongue and insert it into the loop of the device. The therapist pushed the loop to the base of the tongue and tightened it to grasp the tongue securely. Then, while maintaining the force according to the patient's comfort level, the therapist stretched the tongue and gently moved it toward the tip, providing intermittent stretches in between. Stretching was also applied in medial, lateral, superior, and inferior directions. Both dynamic and static stretching techniques were employed. For dynamic stretching, the tongue was held for 2–3 seconds, and for static stretching, it was held for about 20 seconds before guiding it back into the mouth. Stretching was performed in each direction with five repetitions per day, five times a week, for 4 weeks. For strengthening, during the therapy sessions, a wooden compressor was used to provide resistance alongside the novel device. The patients were instructed to protrude their tongue, and the therapist held the wooden compressor against it, applying resistance in forward, lateral (both right and left), and vertical (up and down) directions. The training was divided into 10 sets, each comprising 5 repetitions in each direction, with obligatory rest periods of 60 seconds between sets. This regimen was followed for 3 days a week over the course of 4 weeks.

RESULTS

Participants

Based on the methodology employed by Buscemi et al. (2022)[24], tongue motility has been measured as the distance between the lower lip and the tongue's greatest protrusion point during an active movement. In this study, 12 patients were randomly divided into two groups using the chit method. Group A ($n = 6$) received tongue stretching and strengthening intervention using a loop device. Group B ($n = 6$) received tongue stretching and strengthening intervention without using a loop device.

Loop Device Versus Conventional Use

The loop device provided tongue exercises clinically and effectively, and the pressure was applied from the base to the tip. Manually, more force and pulp-to-pulp grip give a less clean experience to the therapist and the patient. Table 1 summarizes the pre- and post-intervention measures for the tongue length change measure (TLCM), eating assessment tool (EAT-10) (Belafsky et al., 2008)[25], and MDADI (Alsubai et al., 2022)[26] for Groups A and B. The t-values and significance level (level of sig. < 0.05) indicate the statistical comparison between the groups for each measure. Figure 5 indicates the results graphically with actual p and t values.

TABLE 1. Summary of group comparison between Group A and Group B. The statistical significance has not been witnessed; the clinical acceptance of the novel device was better. [*Tongue Length Change Measure (TLCM), Eating Assessment Tool* (*EAT-10), and M.D. Anderson Dysphagia Inventory (MDADI).*]

Measures	Gr A Mean ± SD	Gr B Mean ± SD	*t*-value	Sig. (two-tailed)
Pre TLCM	1.6 ± 0.9	2 ± 0.34	–1.676	0.125
Post TLCM	2 ± 0.8	2.5 ± 0.4	–1.321	0.216
Pre EAT 10	24 ± 5.21	19.16 ± 2.48	2.05	0.086
Post EAT10	19.3 ± 6.8	13.5 ± 3.27	1.893	0.088
Pre MDADI	53.80 ± 7.71	51.73 ± 6.16	0.513	0.619
Post MDADI	62.97 ± 12.37	58.39 ± 6.16	0.812	0.436

Note: Gr means Group. Sig. means significance.

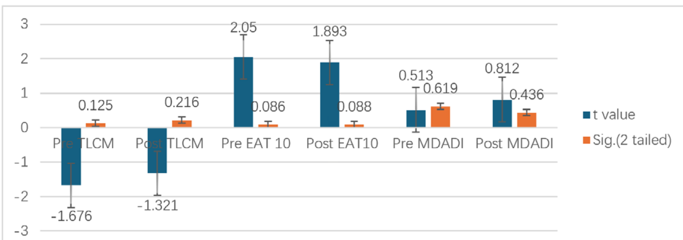

FIGURE 5. The bar graph shows the comparison of pre- and post-intervention measures between Groups A and B for tongue length change measure (TLCM), eating assessment tool (EAT-10), and M.D. Anderson dysphagia inventory (MDADI). The *t* values and actual *p* values are used.

Factors Associated with Loop Device

A two-tailed significance analysis has been used. The patient's position is comfortable, and the tongue is being elongated and assisted by the device. It is an active assisted/resisted movement of the tongue muscle and therefore can increase the functionality of the tongue, as seen in Figure 6.

FIGURE 6. Tongue stretching and strengthening—a loop device is being used for tongue exercises. It allows stretching and strengthening exercises from the base to the tip of the tongue, affecting the intrinsic and extrinsic muscles of the tongue. It comprises a collapsible loop and a holder that is designed to enter the mouth. Written informed consent was obtained from all participants in the study.

TABLE 2. Cohen's d (effect size) for the tongue length change measure (TLCM), eating assessment tool (EAT-10), and M.D. Anderson dysphagia inventory (MDADI) scores for the groups after the intervention were given. Cohen's d = M1–M2/s pooled where s pooled =√[(s 12+ s 22) / 2] and rYl = d/√(d2 + 4). Note: d and rYl are positive if the mean difference is in the predicted direction.

S. No.	Measure	*r* (Effect Size)
1.	TLCM Group A	–0.22
2.	TLCM Group B	–0.55
3.	EAT10 Group A	0.36
4.	EAT 10 Group B	0.69
5.	MD Anderson Score Group A	–0.40
6.	MD Anderson Score Group B	–0.47

The paired sample *t*-tests revealed significant differences between pretest and posttest scores for both Group A and Group B in measures of TLCM, EAT10, and MDADI (all *p*-values < 0.05). Specifically, for Group A, TLCM scores increased significantly, while EAT10 scores decreased, indicating improvement in swallowing function and reduction in dysphagia severity. Similarly, MDADI scores significantly improved, suggesting an overall enhancement in swallowing-related quality of life.

In contrast, Group B also demonstrated significant improvements in TLCM and MDADI scores. However, the decrease in EAT10 scores was greater compared to Group A, indicating a potentially greater reduction in the severity of dysphagia. These findings suggest that interventions in both groups were effective in improving the swallowing function and quality of life. The study shows that, between groups, no significant results were found for Group A and Group B in tongue length ($p > 0.05$), Table 1, and within groups, significant results were found for Groups A and B in tongue length ($p < 0.05$), Table 3.

TABLE 3. Paired *t*-test for Group A and Group B for all variables, namely, Tongue Length Change Measure (TLCM), Eating Assessment Tool (EAT-10), and M.D. Anderson Dysphagia Inventory (MDADI).

Paired Comparison of the Groups												
Groups A & B paired analysis	TLCM				EAT 10				MDADI			
	m ± σ	SE	*t*	*p*	m ± σ	SE	*t*	*p*	m ± σ	SE	*t*	*p*
Group A Pre- and post-paired	−0.43 ± 0.24	0.98	−4.3	0.007	4.66 ± 2.87	1.17	3.9	0.11	−9.17 ± 6.79	2.77	−3.3	0.02
Group B Pre- and post-paired	−0.26 ± 0.17	0.07	−3.73	0.01	5.66 ± 1.36	0.55	10.15	0.01	−6.65 ±1.97	0.80	−8.27	0.01

DISCUSSION

To our knowledge, this study is the first to use a simple, low-cost loop device that offers a practical solution for delivering targeted therapy to dysphagic individuals by stretching and strengthening the tongue muscles. By gradually stretching the tongue from the base to the tip, the device aims to enhance tongue strength and mobility, thereby improving the swallowing function.

The study employed a quasi-experimental design to evaluate the effectiveness of the device in comparison to traditional manual exercises. However, both groups showed significant enhancements in tongue length and swallowing functions.

Tongue protrusion was studied by Cho et al. (2021)[27], who found a correlation between decreased maximal tongue protrusion length and poststroke dysphagia, highlighting the importance of assessing tongue function in dysphagic patients. Shimizu et al. (2021)[28] observed that low tongue pressure was associated with poor swallowing function in sarcopenic dysphagia patients, emphasizing the significance of tongue strength in swallowing physiology. Buscemi et al. (2021)[24] introduced a tongue muscle normalizing technique focusing on resetting deep tongue receptors, which led to improvements in tongue relaxation and tension reduction. This technique, although different from the intervention in our study, underscores the potential benefits of addressing tongue muscle function in dysphagia management. Hwang et al. (2019)[5,29] demonstrated the efficacy of tongue stretching exercises in improving oromotor function and tongue motility in dysphagic patients poststroke, aligning with our intervention's emphasis on tongue stretching and strengthening. Van den Steen et al. (2020)[30] investigated the effectiveness of tongue-strengthening exercises in patients with chronic radiation dysphagia, reporting improvements in tongue strength and swallowing parameters. While their focus was on a different patient population, the positive outcomes support the notion that targeted exercises can enhance tongue function and swallowing ability, as seen by others.[31,32]

Sakai et al. (2019)[33] explored the diagnostic accuracy of tongue strength and lip force for sarcopenic dysphagia in older inpatients. Their findings suggested a relationship between increased tongue strength and improved swallowing function, corroborating the importance of tongue muscle strength in dysphagia management. The findings of this study provide valuable insights into the effectiveness of tongue stretching and strengthening interventions using a novel device in improving swallowing function and reducing dysphagia severity among stroke patients. Both Group A and Group B demonstrated significant improvements in various outcome measures, including TLCM, EAT-10 scores, and MDADI scores, as seen in Table 1 and Figure 5. However, the clinically acceptable method of device-based stretching is more acceptable and hygienic in nature than manual stretching.

The significant increase in TLCM scores in both groups indicates an improvement in tongue muscle length by the loop device and manual stretching, which is essential for proper bolus formation and propulsion during swallowing. This improvement suggests that the tongue stretching and strengthening exercises, facilitated by the novel device, effectively targeted the tongue muscles, leading to enhanced tongue mobility and function. The effect size as seen in Table 2 indicates a greater effect by manual stretching because it applies more force to the tongue.

Furthermore, the significant decrease in EAT-10 scores observed in both groups reflects a reduction in dysphagia severity following the intervention. Dysphagia can significantly impact a stroke patient's quality of life and nutritional status, and the improvement in EAT-10 scores suggests that the intervention successfully addressed swallowing difficulties, leading to enhanced eating ability and overall well-being. The effect sizes (*r*) as seen in Table-2 are in the medium to moderate category and the groups are compared.

Similarly, the significant increase in MDADI scores indicates an improvement in swallowing-related quality of life among participants. Dysphagia can have profound psychosocial implications, affecting an individual's confidence, social interactions, and emotional well-being. The improvement in MDADI scores suggests that the intervention not only improved the physiological aspects of swallowing but also had a positive impact on the participant's overall quality of life. The effect sizes as seen in Table 2 are of a comparable nature, and both interventions are equally effective.

The findings of this study are consistent with prior research on tongue rehabilitation in dysphagic individuals.[18–20] Studies by Steele et al. (2016)[34] and Kang et al. (2012)[35] have reported similar benefits of targeted tongue exercises in improving swallowing function and tongue strength. These findings underscore the importance of incorporating tongue stretching and strengthening exercises into dysphagia rehabilitation programs to optimize outcomes for patients.

Future Research

While this study provides promising results regarding the efficacy of tongue stretching and strengthening interventions, there are several avenues for future research to explore. Firstly, longitudinal studies with larger sample sizes and longer follow-up periods are warranted to assess the long-term effects of the intervention on swallowing function and dysphagia severity among stroke patients.

In addition, future research could investigate the optimal frequency, duration, and intensity of tongue stretching and strengthening exercises to maximize therapeutic outcomes. Furthermore, exploring the potential synergistic effects of combining tongue exercises with other rehabilitative interventions, such as neuromuscular electrical stimulation or traditional swallowing therapy, could enhance the efficacy of dysphagia management strategies. This may require the holder to be fixed with different attachments, as seen in Figure 7. Moreover, investigating the underlying mechanisms of how tongue stretching and strengthening exercises contribute to improved swallowing function could provide valuable insights into the pathophysiology of dysphagia and inform the development of targeted interventions.

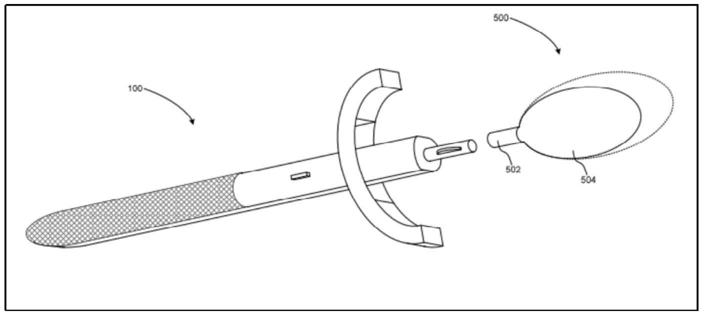

FIGURE 7. The conceived holder with the looped device is seen as an automatic control with a bite block in place. It is proposed as a digitally controlled platform for the attachment of all five distinctly functional heads of the ORF.

Relevance to Clinical Practice

The findings of this study have significant implications for clinical practice in the management of dysphagia among stroke patients. Tongue stretching and strengthening exercises using the novel device offer a safe, noninvasive, and cost-effective approach to improving swallowing function and reducing dysphagia severity. Health care professionals, including speech-language pathologists and rehabilitation therapists, can incorporate these exercises into their treatment protocols for stroke patients with dysphagia. The use of the device provides a hygienic and standardized method for delivering tongue exercises, ensuring consistency and reproducibility in clinical practice.

The observed improvements in swallowing-related quality of life underscore the importance of addressing dysphagia beyond physiological outcomes. Integrating patient-centered approaches that focus on enhancing overall well-being and functional outcomes can optimize dysphagia management and promote holistic patient care in any setting without significant financial burden.

Limitations

There may be limitations in the study, such as (1) The study's sample size of 12 patients may limit the generalizability of the findings. A larger and more diverse sample would enhance the robustness and external validity of the study results. (2) The study's follow-up period of only 5 weeks, including a 4-week therapy session and a 1-week follow-up, provides limited insight into the long-term effectiveness and sustainability of the intervention. Longer-term follow-up assessments would better elucidate the durability of the observed improvements in swallowing function and dysphagia severity. (3) While the study assessed various outcome measures, such as TLCM, EAT-10 scores, and MDADI scores, additional objective measures, such as instrumental assessments like video-fluoroscopy or fiber-optic endoscopic evaluation of swallowing (FEES), could provide more comprehensive insights into the swallowing function. (4) The study was conducted at a single center, which may limit the generalizability of the findings to other clinical settings with different patient populations, resources, and health care practices. Multicenter studies involving diverse patient cohorts would enhance the external validity of the study findings. Blinding of the patients is undertaken, but therapists were aware of the intervention as it is obvious and cannot be concealed.

Generalizability

Patients with dysphagia may enhance their dietary intake and quality of life through improvements in tongue strength and mobility and swallowing, as described by Abe et al., 2020.[36] Therefore, the novel device can be used for tongue exercises in stroke patients suffering from dysphagia, for improvement of functioning and quality of life.

CONCLUSIONS

The study underscores the clinical efficacy of tongue stretching and strengthening interventions using the loop device, among stroke patients with dysphagia. The significant improvements observed in TLCM, EAT-10 scores, and MDADI scores highlight the multifaceted benefits of the interventions in both groups.

AUTHOR CONTRIBUTIONS

D.V. and M.S. designed the work; D.V. acquired and analyzed data; D.V. and M.S. drafted, revised, and approved the manuscript. All authors agree to be accountable for all aspects of the work.

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FUNDING

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DATA AVAILABILITY STATEMENT

Data supporting reported results can be found at https://doi.org/10.6084/m9.figshare.26816143.

CONFLICTS OF INTEREST

The authors have no conflict of interest to report. The loop device is a patent, IPR patent no. 504718.

FURTHER DISCLOSURE

A related preprint can be found at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5558069.

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