



Genioglossus Muscle Strength Training in Head and Neck Cancer Patients: Early Clinical Trial Results

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ABSTRACT

Introduction: Studies have shown that head and neck cancer patients have decreased tongue strength following both surgical and chemoradiation treatment; and this reduction can be used as a predictive measure for dysphagia. Improvements in both dysphagia and quality of life have also been associated with increased tongue muscle strength in this population. At our institution, we have developed a genioglossus muscle strength trainer that has been shown to increase tongue protrusive force in patients with history of sleep apnea. We have opened a non-randomized, open label, genioglossus muscle strengthening interventional clinical trial aimed at increasing tongue muscle strength and improving dysphagia and quality of life in head and neck cancer patients.

Methods: Patients with history of treatment for squamous cell carcinoma of the head and neck with complaints of dysphagia were eligible for the study. Demographic, clinical, and treatment characteristics were recorded. Baseline genioglossus muscle strength measurements (in Newtons) and dysphagia quality of life scores (SWAL-QOL questionnaire) were obtained from enrolled patients. Participants were then given the genioglossus muscle trainer device and instructed on an at-home exercise regimen involving using the trainer three times daily, five days per week. Genioglossus muscle strength measurements were taken, and dysphagia quality of life questionnaires were then repeated at 2 and 4 weeks.

Results: Eight patients have thus far been enrolled in the clinical trial. All patients had baseline dysphagia. Three patients previously underwent treatment with surgery followed by postoperative radiation and chemotherapy. Four patients were treated with surgery alone and one patient was treated primarily with radiation and chemotherapy. Baseline tongue muscle strength was recorded at mean 7 Newtons. All patients have tolerated using the genioglossus muscle trainer at home without complications or discomfort. Five patients have completed the 4-week training session with an average increase in protrusive force of 5.6 Newtons above baseline.

Conclusions: Preliminary data suggests protrusive tongue-training exercises utilizing a tongue trainer device is tolerated and increases genioglossus muscle strength in head and neck cancer patients. We anticipate that, upon conclusion of this clinical trial, we will be able to determine the utility of this device in increasing protrusive force and investigate the effect of this on swallowing and quality of life measures.

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BACKGROUND

Prior studies have shown a decrease in tongue strength in patients with Squamous Cell Carcinoma of the Head and Neck following treatment with both surgery and chemoradiation. Decreases in tongue strength have been shown to lead to dysphagia, and interventions are needed to improve tongue strength and QOL in this population.

The main function of the genioglossus is to protrude the tongue and plays a significant role in bolus propulsion during oropharyngeal swallowing. In patients with head and neck cancer, this muscle is commonly atrophic or fibrotic as a result of treatment.

With this knowledge, our group has developed a genioglossus muscle strength trainer designed to increase protrusive tongue force. Prior studies using this device for patients as a treatment of obstructive sleep apnea, have been shown to increase protrusive tongue force on average by 30% and we hypothesized that this device could be used to improve genioglossus muscle strength and potentially help with dysphagia in head and neck cancer patients following treatment.

METHODS

- Study design:** Nonrandomized, open label, interventional clinical trial
- Objectives:**
 - Evaluate the effect genioglossus protrusive muscle strength training has on measures of maximum tongue protrusive force in a select group of head and neck cancer patients
 - Evaluate the effect genioglossus protrusive muscle strength training has on quality of life
- Based on a power analysis, we determined a sample size of 13 patients is needed in order to detect a statistically significant increase in protrusive tongue force with $p=0.05$
- Inclusion criteria:**
 - Both males and females $\geq$ eighteen years of age
 - History of head and neck cancer involving the mucosal upper aerodigestive tract
 - Subjects must endorse either subjective or objective dysphagia or complaints about voice or speech
- Exclusion criteria:**
 - Any patients actively undergoing treatment for cancer must be at least 2 months post treatment completion
 - Patients who are unable to protrude their tongue far enough to measure tongue strength
 - Patients with severe wound healing problems and/or open wounds on the neck



Figure 1: Prototype genioglossus muscle trainer device

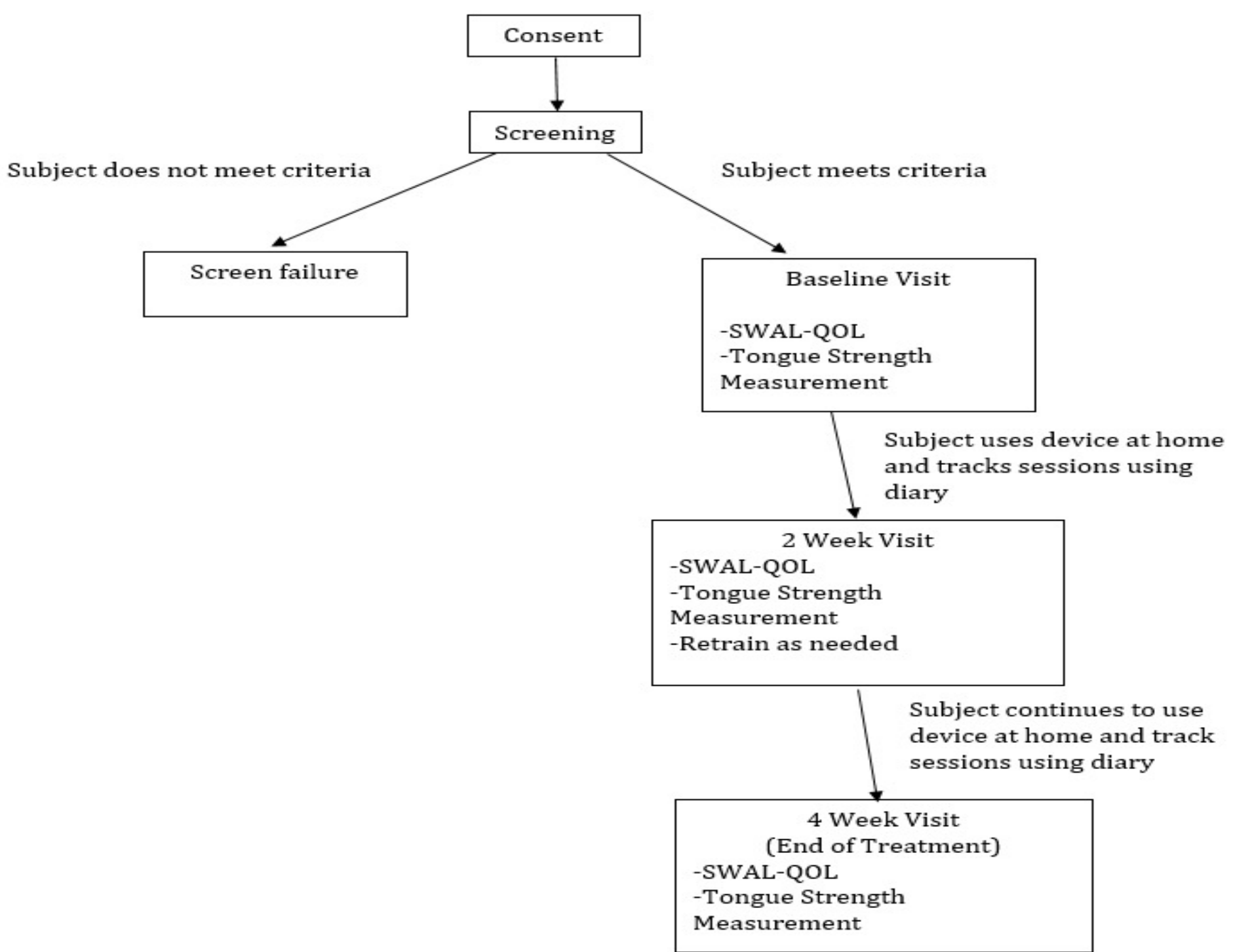


Figure 2: After obtaining informed consent, patients who were felt to be candidates for the study were screened based on our inclusion and exclusion criteria. If found to meet criteria, baseline tongue strength measurements (N) were obtained and an initial SWAL-QOL questionnaire was completed. Participants were then instructed on how to use the device and the at home training regimen. They were also asked to keep a diary to document their training sessions. Participants then returned to clinic at 2 and 4 weeks for repeat measurements and SWAL-QOL questionnaire completion.

RESULTS

Thus far, 10 patients have been enrolled and 6 have completed the study. All patients had baseline dysphagia. All patients who have completed the study have shown an overall increase in tongue strength. There have been no reports of adverse events while using the tongue trainer.

Treatment	Surgery	Chemoradiation	Surgery + CRT	Surgery + RT	Radiation
Number of participants	5	2	2	1	0

Table 1: Summary of participants treatment for head and neck cancer

	Baseline (N)	Post treatment (N)
Minimum	2	3
Maximum	17	22
Range	15	19
Mean	6	10.5
Std. Deviation	5.727	6.950
Std. Error of Mean	2.336	2.837

Table 2: Descriptive statistics for genioglossus muscle strength measurements at baseline and post treatment

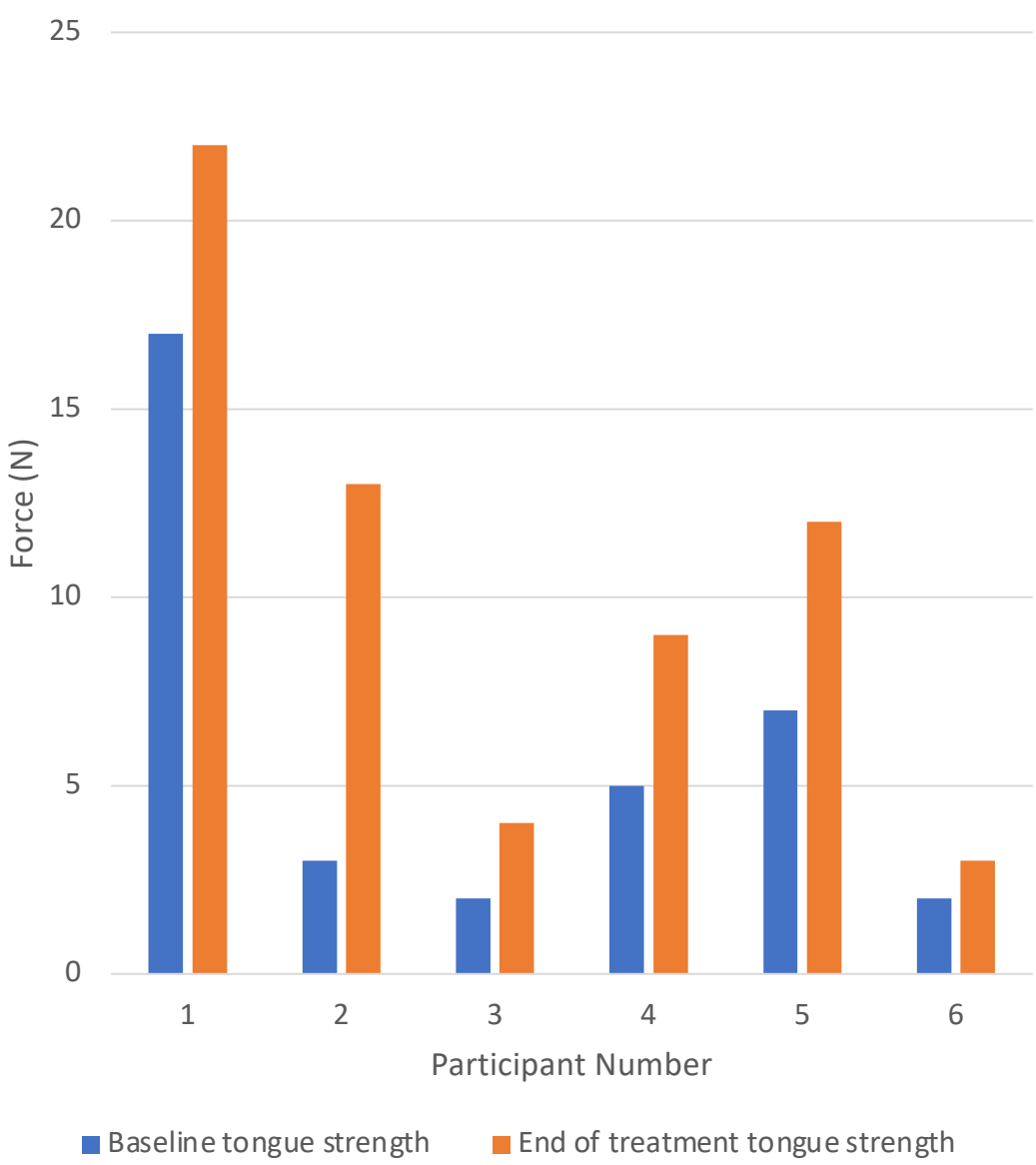


Figure 3: Comparison of patients baseline protrusive tongue strength (N) and post treatment protrusive tongue strength (N).

Average Change in Tongue Strength (N=6)

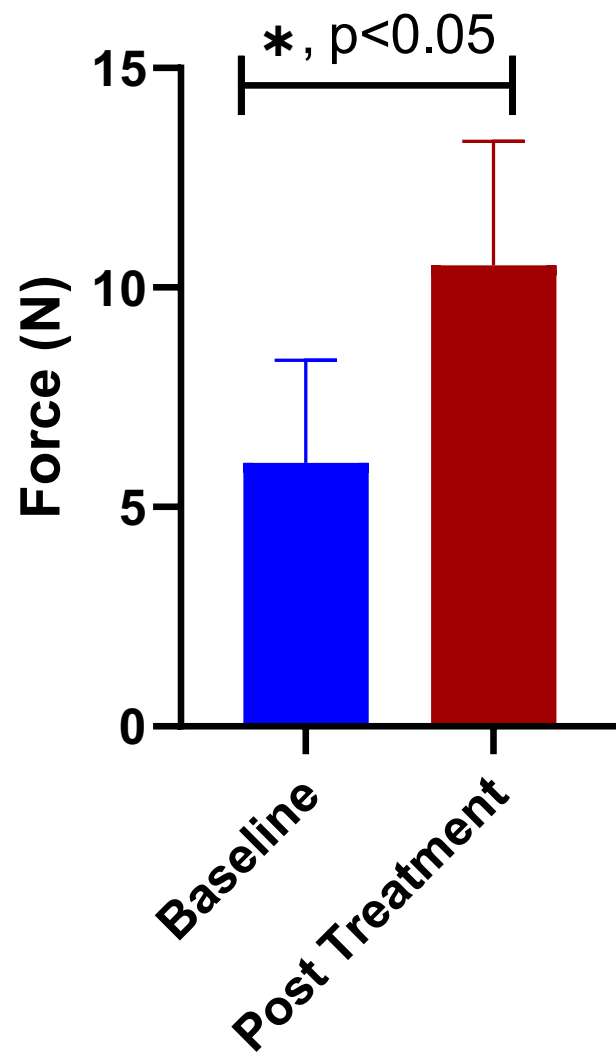


Figure 4: Average baseline genioglossus muscle protrusive strength was 6 (N). Post treatment average 10.5 (N) was statistically significant ($p<0.05$).

CONCLUSIONS

Preliminary data suggests protrusive tongue-training exercises utilizing a tongue trainer device is well-tolerated and increases genioglossus muscle strength in treated head and neck cancer patients. Following conclusion of this trial, we hope to determine the utility of this device in increasing protrusive tongue force and investigate the effect of this on swallowing and quality of life measures.