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The evaluation of TheraBite and wooden tongue depressor in the treatment of trismus and health-related quality of life

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Abstract. – OBJECTIVE: This study aimed to compare the efficacy of TheraBite system and a wooden tongue depressor in head and neck cancer (HNC) patients and assess their quality of life (QoL) using modified questionnaires.

PATIENTS AND METHODS: The effects of exercise using TheraBite and a wooden tongue depressor on trismus were evaluated in 40 HNC and 10 healthy individuals. All patients performed the exercise program for 3 weeks, with a follow-up session. The patients' pre-treatment and post-treatment mouth opening (MO) values were recorded. The HNC patients completed the QoL questionnaire after the treatment.

RESULTS: The highest mean value of MO pre-treatment scores was recorded in the control group ($p < 0.05$). The differences among all the scores for QoL questionnaires were insignificant ($p > 0.05$).

CONCLUSIONS: TheraBite system increased MO compared to a wooden tongue depressor. The questionnaire revealed that radiotherapy had side effects on patients.

Key Words:
TheraBite, Wooden tongue depressor, Trismus, Quality of life.

Introduction

Trismus is a commonly seen complication in head and neck cancer (HNC) patients. It may result from tumors, trauma, temporomandibular joint disorders, inflammation, or complication following head-neck cancer surgery and radiation therapy[1-3]. The frequency of trismus in HNC patients ranges from 5% to 38%[4]. Comorbidities associated with trismus include speech problems and loss of appetite, as well as problems with oral hygiene. As a result, trismus may give rise to a loss of self-confidence[5]. Furthermore, trismus can cause mandibular immobility and lead to a reduced quality of life (QoL)[6]. Local tumor control during radiotherapy, chemotherapy, or both treatments may be overlooked because of trismus[7].

Radiotherapy (RT) is one of the major treatment modalities used for the management of head and neck malignancies. It can be used as a primary therapy for many early-stage malignancies and as an adjuvant therapy following surgical resection[8]. The loss of function and range of mandibular motion from RT appears to be related to damage and fibrosis of the muscles of mastication[9]. Okunieff et al[10] have demonstrated that an abnormal proliferation of fibroblasts is an important initial event in these reactions, although the molecular mechanisms are poorly understood. Additionally, there may be scar tissue due to radiation therapy or surgery, nerve damage, or a combination of these factors. Regardless of the immediate cause, mandibular hypomobility will ultimately result in both muscle and temporomandibular joint degeneration. Studies[8,11] have shown that muscles that fail to move through their range of motion for as little as 3 days begin to show signs of atrophy. Similarly, joints that are immobilized quickly begin to show degenerative changes in the joint, including thickening of the synovial fluid and thinning of the cartilage. The direct effect of radiation on the muscles ultimately results in fibrosis and contracture (trismus) with a gradual onset noted at about 9 weeks after treatment is completed[8,12].

Although many treatment methods for trismus have been described, there exists no specific treatment. The treatment for trismus depends on the underlying causes and should begin as soon as trismus becomes severe enough to restrict mouth/jaw opening[8,13]. Both conservative (medical or physical therapy) and surgical treatments for trismus are available[8]. Heat, cold, electrotherapy, massage, appropriate antibiotic/analgesics, exercise, hyperbaric oxygen treatment, pentoxi-

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fylline, and injections of botulinum toxins may be used as conservative treatments, whereas a coronoidectomy is performed as a surgical treatment[14].

Trismus in HNC patients is difficult to treat. Most rehabilitation methods are based on stretching the elevator muscles and the temporomandibular joint[1]. Appliances for these purposes are classified as internally or externally activated devices. Internally activated appliances exert force on the depressor muscles to stretch the elevator muscles[14,15]. Light or heavy, intermittent, or continuous, elastic or inelastic forces may be exerted through externally activated devices to employ forces by stretching the elevator muscles while depressing the mandible[14]. These appliances require fingers, a wooden tongue depressor, a screw-type mouth gag, a Shell-shaped mouth opener, tapered and threaded screw, dynamic and inflatable bite openers, and jaw motion rehabilitation systems, such as TheraBite® Jaw Motion Rehabilitation System™ (Atos Medical Inc Philadelphia, PA, USA) and Dynasplint® Trismus System (Dynasplint Systems Inc, Severna Park, Md, USA)[16].

Side effects of cancer therapy, such as pain, dry mouth, mucositis, and loss of taste and smell, have negative effects on the QoL of cancer patients[17,18]. Considering the importance of the QoL of cancer patients, specific life quality assessment questionnaires have been developed. The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Group has developed a clinical trial questionnaire for measuring QoL. The EORTC Core Quality of Life Questionnaire (QLQ-C30) is a general cancer questionnaire. The questionnaire consists of 30 questions and three scales (general health, function, and symptoms). The Research and Treatment of Cancer Quality of Life Questionnaire Head and Neck Module (QLQ-H&N35) is a specific questionnaire for HNC patients. It contains items on pain, swallowing ability, taste/smell, speech, social eating, social functioning, and sexual function. It also contains questions on oral hygiene/dental health, mouth opening, dry mouth, saliva quality/quantity, and general health. The reliability and validity of these questionnaires in different languages have been evaluated in previous studies[19].

Wooden tongue depressors, which are held together with an adhesive tape (stacked tongue depressors), or best by a rubber band at the end outside of the mouth, can be used to open and stretch the masticatory muscles in trismus[15,20]. However, the number of tongue depressors that are needed to impart a mild and tolerable stretch should be decided individually to commence the treatment and may commonly differ between the right and left TMJ. The TheraBite Jaw Motion Rehabilitation System features two plastic mouthpieces, which are inserted between the maxilla and mandible. These plastic mouthpieces exert force when the mouth is pressed closed, enabling mouth opening[2,4,16,21]. The TheraBite Jaw Motion Rehabilitation System has been shown to be more effective for trismus than other treatment options, especially for HNC patients with consequent trismus after radiotherapy.

In the present study, the efficacy of the TheraBite and wooden tongue depressor on the trismus was compared after the radiotherapy treatment for head and neck cancer patients. After the trismus treatment with TheraBite Jaw Motion Rehabilitation System and wooden tongue depressors, quality of health was assessed with an EORTC 30& HN35 questionnaire. The null hypothesis of the study was that there would be no differences in the clinical and life quality outcomes of TheraBite and wooden tongue depressor exercises for HNC patients with trismus.

Patients and Methods

The effect size calculations were made by Eta squared statistics and a medium to large class effect size was obtained for a group effect of 0.094. A total of 40 HNC patients and 10 healthy control patients (age range: 56 years, 22 females, 28 males) who were referred to the department of prosthodontics for the evaluation and treatment of trismus were included in this study. This study was conducted in accordance with the Declaration of Helsinki and was approved by our institutional Research Board and Ethics Committee (approval number: 14-6/6). The study process and procedures were explained to all participants, and all the participating patients signed a written informed consent form. The inclusion and exclusion criteria for the participants are given in Table I.

The dental treatment needs of the patients were determined and scheduled after trismus rehabilitation. Based on the pathology reports of the resected specimens, radiotherapy was applied 4 to 6 weeks after surgery. The prescribed radiation dose was 65 Gy in 30-40 days with precautions taken for the healthy side protection by a shield.

Table I. Inclusion and exclusion criteria for the participants.

Inclusion criteria for head and neck cancer patients	• Primary head and neck cancer involving the oral cavity treated with surgery and radiotherapy • Mouth opening less than 35 mm • Patients aged 18 years and older • Able to read and write sufficiently to be able to complete the validated questionnaires
Inclusion criteria for the control group	• No history of oncological treatment • Healthy but having trismus • Mouth opening greater than 12 mm
Exclusion criteria	• Mouth opening less than 12 mm and partially dentate (who would not be able to use TheraBite for avoiding excessive forces on existing teeth) • Cognitive impairment to prevent from completing the exercise protocols • Individuals with existing malignancies and/or a history of mandibular resection

Sex, tumor location, site of resection, and status of the reconstruction were derived from the hospital's database/records. Dental status (remaining teeth, resection site, soft tissue) was examined after primary treatment.

During the period of radiotherapy, all 40 patients undertook a daily vertical and horizontal range of motion exercises without any device every 3-4 hours at the Department of Radiology for maintenance of blood circulation and remodelling[22]. However maximal mouth opening could not be measured prior to radiation therapy since the patients were referred to the clinic after they had ended their radiation therapy. Therefore, the exercises during radiation therapy could not be monitored, either.

The participants were divided into three treatment groups: an HNC group with trismus that used the TheraBite Jaw Motion Rehabilitation System (n = 20), an HNC group with trismus that used the wooden tongue depressor (n = 20), and a control group systemically healthy but having trismus (n = 10) that used the TheraBite Jaw Motion Rehabilitation System. The patients were randomly assigned to wooden tongue depressor or TheraBite groups. All control group patients used only TheraBite since it has been shown that wooden tongue depressors had less increased effect in mouth opening when compared with TheraBite[16]. The control group had no problems due to the physiotherapeutic effect mechanism (the separation of collagen fibers and increased subcutaneous matrix area leading to improved blood circulation) maintained by remodeling of the tissues for improved mouth opening[18].

The patients commenced using the wooden tongue depressor and TheraBite Jaw Motion Rehabilitation System 3-4 weeks after the radiotherapy treatment and were informed about how to use the devices (Figure 1A, Figure 1B). Initial and ongoing mouth opening (MO) (maximum range of motion-ROM) measurements

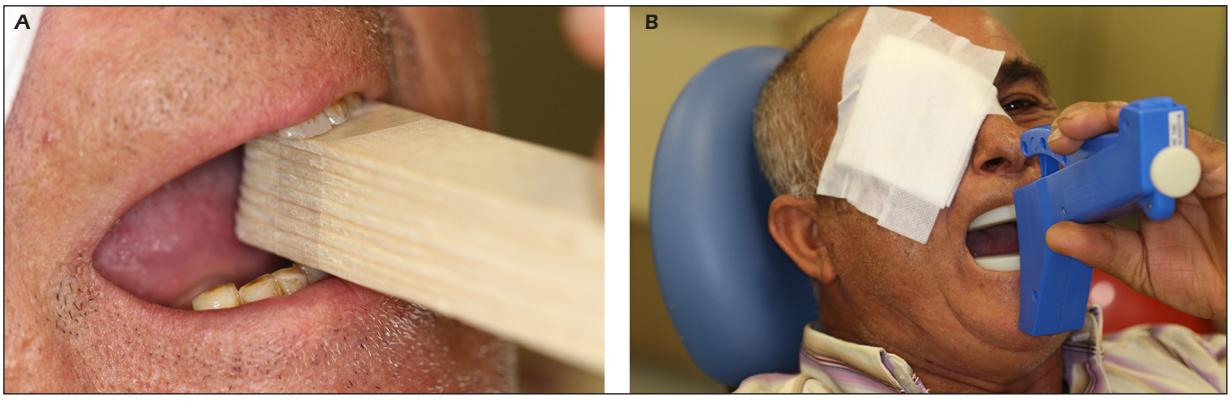

Figure 1. A, Photographs of patients using wooden tongue depressors. **B**, TheraBite Jaw Motion Rehabilitation System.

were made when the patients were sitting with support in an upright position. The patients were instructed to perform the stretching as well as the active exercises in an upright position. For TheraBite use, the patients were instructed to stretch and hold for 7 seconds with a resting time of 7 seconds and repeat this seven times successively, seven times a day (7-7-7 protocol for TMJ Joint Health and Function recommended by the manufacturer). The fine adjustment screw of TheraBite device was loosened for this protocol. In the wooden tongue depressor group, stacked standard wooden tongue depressors measuring 1.25 mm thick and 14 mm wide were used in a 5-5-30 regime. The patients were instructed to place a maximum number of depressors in-between their anterior teeth and they were informed that an additional depressor would be placed, if the maximal interincisal opening which was recorded at the moment of maximal discomfort, increased.

Baseline measurements of the patients' maximal interincisal opening were made after the radiation therapy. All the measurements, including the follow-up visits were made by one prosthodontist. The baseline and the maximal interincisal opening were recorded in the patient's database. Mouth opening measurements were recorded with a caliper using the distance from the incisal edge of the maxillary and mandibular incisors. In edentulous patients, it was measured between the maxillary and mandibular alveolar ridges. All patients, whether dentate or edentulous were asked to close their mouths completely for the initial measurement and then bring to a maximum opening. The difference in movement in millimeters was recorded as the distance of maximum opening and deviation or deflection amounts of mandibular movements were also recorded. All results were assessed before treatment, after one week, 2 weeks and 3 weeks. Pre-treatment and post-treatment maximal interincisal opening scores and differences in pre-treatment and post-treatment scores were summarized using mean and range values (Table II).

After trismus therapy with TheraBite and wooden tongue depressors, 40 HNC patients fulfilled the versions of the European Organization for Research and Treatment of Cancer (EORTC) Core Quality of Life Questionnaire (QLQ-C30) and the EORTC Head and Neck Cancer Quality of Life Questionnaire (QLQ-H& N35). Subscales of health-related QoL derived from EORTC QLC-C30 related to eating, weight loss, pain, and mouth-opening scores were obtained. The EORTC QLQ H&N35 has been specifically designed to evaluate QoL in HNC patients. The subscales of the questionnaire contain items on pain, swelling, taste/smell, speech, social eating, social functioning, and sexual function. Ten items are related to problems related to dental and oral health (e.g., a dry mouth and salivary quality and quantity), a cough, mouth opening distance, weight loss/gain, nutritional supplement intake, use of feeding tubes, and use of painkillers. The non-radiated control group was included in the clinical part of the study but not for life quality assessment.

As dictated by EORTC, single-item variables and scales of QLQ-C30 and H&N35 questionnaires were transformed from 0 to 100 scores, linearly. A better functioning level of scores from a functioning scale and for the global QoL scale were determined by higher scores, while a higher score obtained from a single-item scale, or a symptom scale indicated a higher level of problems or symptoms.

Statistical Analysis

Differences in pre-treatment and post-treatment scores were analyzed using the Repeated Measures Analysis of Variance (ANOVA) and Bonferroni tests at a significance $p = 0.05$.

Table II. Mean mouth opening values (mm ± SD) for control.

Mouth opening (mm ± SD)	Control	TheraBite	Wooden tongue depressor
Baseline	29 ± 2.4037	27.5 ± 5.9657	27.5 ± 4.3577
1 week post-treatment	32.5 ± 2.9515[a]	29.500 ± 5.5201[b]	30.000 ± 4.2461[c]
2 weeks post-treatment	35.500 ± 2.6437[d]	33.000 ± 5.3302[d]	32.000 ± 4.1814[f]
3 weeks post-treatment	38.000 ± 2.7487[g]	37.000 ± 5.5048[g]	34.000 ± 2.7487[h]

TheraBite and wooden tongue depressor groups at baseline, 1 week, 2 weeks and 3 weeks post-treatment (different superscript letters in the same row indicate significant differences ($p < 0.05$) and same letters indicate insignificant differences ($p > 0.05$) among groups.

For data analysis obtained from quality-of-life questionnaires, the Shapiro-Wilk test was used. Non-parametric covariance test was used for comparisons within groups. All data were statistically analyzed by using IBM SPSS 23.0 for Windows (IBM Corp., Armonk, NY, USA) (p = 0.05).

Results

Baseline data, such as age, sex, previous surgery, and radiotherapy or chemotherapy treatment, as well as the site and stage of the disease, were broadly similar in the TheraBite and wooden tongue depressor groups. There were no significant differences among the groups in terms of sex (p = 0.7165).

The maximum mean mouth opening (MO) values (mm ± SD) and the level of significance for all groups (control, TheraBite, and wooden tongue depressor) at baseline, 1 week, 2 weeks and 3 weeks post-treatment are given in Table II. The baseline differences between the control and TheraBite groups were significant ($p < 0.05$) while the control and wooden tongue depressor groups were insignificant ($p > 0.05$). One-week post-treatment, the highest mean value for MO was found in the control group (32.5 ± 2.9515). There was a significant difference between the values in the TheraBite and wooden tongue depressor groups ($p < 0.05$) and between the TheraBite and control groups ($p > 0.05$). In the second week post-treatment, the highest mean value for MO was obtained in the control group (35.500 ± 2.6437) and significant differences were observed among the values of the TheraBite, control, and wooden tongue depressor groups ($p < 0.05$). There were no significant differences between TheraBite and control groups ($p > 0.05$). Three weeks post-treatment, the highest mean value for MO was found in the control (38.000 ± 2.7487) group. The differences between the TheraBite and control groups were insignificant ($p > 0.05$) while the differences between the control, TheraBite, and wooden tongue depressor groups were significant ($p < 0.05$) (Table III, Figure 2).

After trismus therapy, subscale scores of health-related QoL derived from EORTC QLC-C30 related to eating, weight loss, pain, and MO were obtained. The differences in mean scores between TheraBite and wooden tongue depressor groups were insignificant ($p > 0.05$). The differences among groups in terms of life quality scores were insignificant ($p > 0.05$) (Table III).

According to the EORTC QLQ H&N35 questionnaire, there were no significant differences in terms of pain, swallowing, social eating, and social contacts, speech, taste/smell, and trismus between the TheraBite and wooden tongue depressor groups (Table IV).

Discussion

In the present study, a commonly used mouth-opening device (TheraBite) and wooden tongue depressors were used for relieving trismus in HNC patients, and their performances were compared with the healthy trismus patients who used the mouth-opening device. Since the

Table III. EORTC QLQ C30-score for head neck cancer patients ($p < 0.005$).

QLQC30	TheraBite			Wooden tongue spatula			
Variable	Mean score	Std deviation	Median	Mean score	Std deviation	Median	p
Global QoL	82.22	18.13	86.66	84.88	9.58	86.66	0.967
Physical functioning	80.66	12.77	86.66	82.33	8.98	86.66	0.899
Role functioning	93.33	22.55	100.00	95.00	9.52	100.00	0.472
Emotional functioning	79.16	22.70	83.33	82.50	12.65	83.33	0.978
Cognitive functioning	80.00	24.54	83.33	82.50	19.84	83.33	0.930
Social functioning	83.33	29.11	100.00	88.33	19.57	100.00	0.836
GS	74.58	15.40	75.00	77.08	10.77	75.00	0.823
Symptomatic scores	16.02	13.66	14.10	14.23	6.88	12.82	0.934
Fatigue	30.00	21.05	33.33	27.22	11.66	33.33	0.736
Pain	10.83	23.11	0.00	9.16	11.43	0.00	0.597
Nause/vomiting	7.50	8.50	0.00	8.33	8.54	8.33	0.755

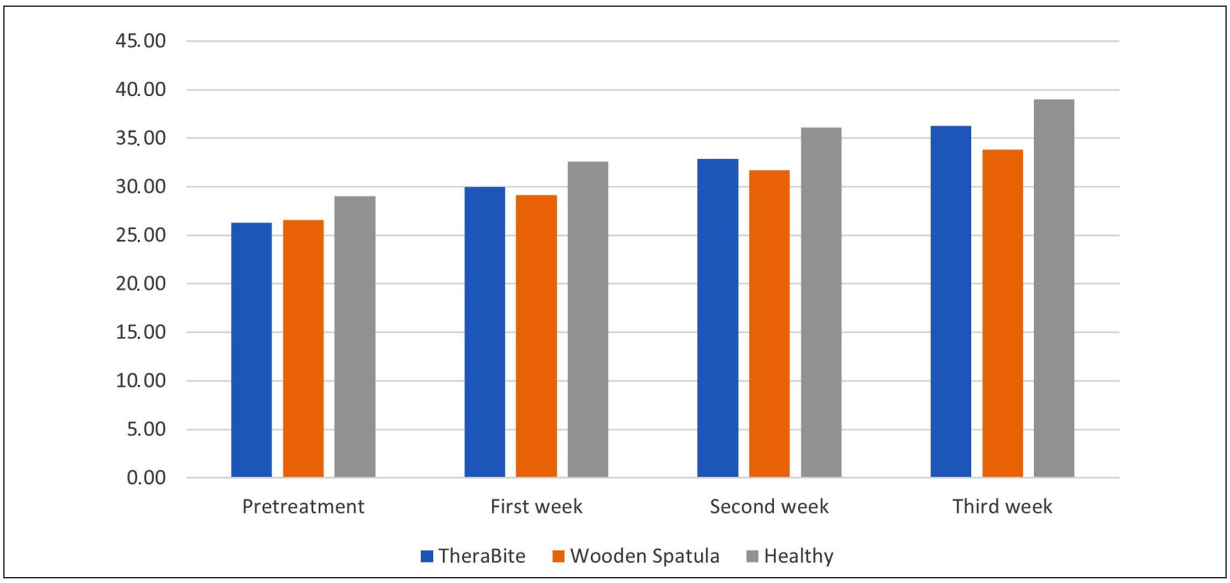

Figure 2. Mean maximum mouth opening of the patients a pre-treatment, first, second, and third week.

early period mouth opening measurements were significantly increased for TheraBite exercise groups, the null hypothesis was rejected.

Trismus is undoubtedly an important problem for HNC patients who undergo radiotherapy. According to previous studies[4,18], patients with trismus experienced substantial problems with mouth opening, swallowing, speech, and nutritional intake. In the present study, mouth opening values of less than 15 mm, between 15 and 26 mm, and between 25 and 35 mm (control) were observed in 2, 16, and 22 patients, respectively. All the patients stated that they had difficulties in chewing, swallowing, and speaking due to altered mouth opening.

Buchbinder et al[20] assessed HNC patients who were randomly divided into three groups after radiotherapy. The first group performed self-ex-

Table IV. EORTC QLQ H&N35-score for head neck cancer patients ($p < 0.005$).

QLQE35	TheraBite			Wooden tongue spatula			
Variable	Mean score	Std deviation	Median	Mean score	Std deviation	Median	*p*
Pain	45.83	24.25	45.83	47.08	22.34	58.33	0.989
Opening mouth	88.33	19.57	100.00	90.00	15.67	100.00	0.919
Dry mouth	46.66	17.60	33.33	50.00	17.09	50.00	0.541
Feeding	3.33	10.25	0.00	1.66	7.45	0.00	0.553
Sexuality	65.00	36.63	83.33	79.16	31.04	91.66	0.190
Teeth	71.66	34.66	100.00	86.66	27.35	100.00	0.115
Senses	10.00	11.34	8.33	9.16	10.08	8.33	0.880
Nutritional	11.66	16.31	0.00	6.66	13.67	0.00	0.294
Social contact	64.00	33.04	73.33	72.66	31.03	86.66	0.398
Weight gain	1.66	7.45	0.00	0.00	0.00	0.00	0.317
Feeling ill	56.66	43.39	50.00	63.33	40.32	83.33	0.600
Weight loss	33.33	0.00	33.33	33.33	0.00	33.33	1.000
Speech	57.22	33.86	44.44	67.77	33.41	72.22	0.440
Coughing	51.66	43.89	66.66	71.11	37.00	83.33	0.165
Sticky saliva	65.00	31.48	66.66	73.33	29.81	83.33	0.403
Swallowing	57.91	38.84	66.66	73.33	33.28	83.33	0.171
Social eating	74.16	32.76	91.66	90.35	14.76	91.66	0.211

ercise, the second group performed a wooden tongue depressor exercise combined with self-exercise, and the third group performed TheraBite exercises combined with self-exercising. Differences in the mean baseline maximum incisal openings between the groups were insignificant. The authors reported that standard stretching exercises, with or without the use of the wooden tongue depressor, and the TheraBite exercises resulted in a significant increase in mouth opening values. In their study, the highest mean value for mouth opening was obtained in the TheraBite exercises combined with the self-exercise group. De Carvalho et al[23] performed a similar study on the effect of a structured exercise program on mouth opening measurements of head and cancer patients with trismus in the first and last of eight orofacial myofunctional therapy sessions and reported that the increase in mouth opening values in the patients who had undergone extensive surgery was less than the other surgery type groups. A systematic review[24] evaluated the effect of exercise therapy and no exercise therapy on jaw mobility in HNC patients with trismus. The results revealed that a majority of the selected articles exhibited a significant increase in maximum interincisal opening after exercise therapy using a jaw mobilizing device. Recent studies[25,26] revealed that devices, such as the Dynasplint system, TheraBite, and Engström jaw device, used to increase mouth opening, were effective when compared to exercise therapy. A retrospective cohort study[27] reported a 5 mm increase in the maximal interincisal opening after exercise therapy in patients with radiotherapy-induced trismus. Another study[24] also reported a significant increase in the maximal interincisal distance after exercise therapy using a device. In the current study, the HNC patients with trismus after radiotherapy were randomly divided into two groups: a wooden tongue depressor exercise group and a TheraBite exercise group. In the TheraBite exercise group, the maximum incisal opening was greater (33 ± 5.3 mm) than that in the wooden tongue depressor exercise group (32 ± 4.1 mm), post-treatment. This finding is consistent with the results in the literature. Mariano Rocabado has suggested an alternative method for trismus patients which involves using a functional maxillomandibular orthopedic appliance to perform joint distraction[28]. Efficiency has been claimed to be increased significantly especially in closed-lock temporomandibular joints but also in trismus patients. In this technique, the initial appliance should have only a light spring force; which will allow a low-grade traction to induce muscle relaxation. The traction force should gradually be increased with progressively larger sizes of spring wire or by activating the spring to increase the angle. This traction force will cause a gradual caudal distraction of the joint[28]. This trismus treatment alternative which includes wearing a device that can be passively worn without the use of hands may be further studied in a different clinical set-up.

The wealth of reflexes that emanate from the oral and pharyngeal regions provides a mechanism for the protection of the anterior portal of the gastrointestinal tract, facilitation of the oral and pharyngeal regions to transport food and liquids, and protection of the same regions for respiratory responses that can include recruiting the oral cavity as part of the upper respiratory tract. Much of this control focuses on the tongue and the complex array of muscles that alter its shape and position in the oral and pharyngeal regions. The reflexes provide the underlying framework of neural control upon which more complex motor responses can build and recruit in a functional framework. The sources and types of sensory stimuli determine the potential reflex. Some of the reflexes reflect a simple response, such as retraction of the tongue with stimulation of sensory nerves innervating the mandible or jaw-closing muscles[29]. Therefore, the use of the "gag reflex" may often quickly relieve muscle spasm/trismus. The protective reflex causes all mandibular elevators to relax and all suprahyoid and infrahyoid muscles to contract and the jaw to move straight down instead of rotating and translating. The posterior cervical muscles contract stabilizing the head. This is a survival reflex that preserves the airway preventing choking and death. The combination of the gag reflex in conjunction with the "spray and stretch" approach can often give a considerable increase in mobility. This technique uses a vapocoolant spray such as ethyl chloride spray to simultaneously stretch the contracted target muscle, passively[30]. This device-free treatment modality, making use of the body's physiological response may also be considered for resolving trismus in HNC patients.

Radiation therapy has acute and late side effects, and QoL can be severely affected. Pauli et al[26] investigated the effect of exercise with devices on trismus and QoL in HNC patients. Their study consisted of three steps: (1) warm-up movements without devices, (2) passive stretch-

ing, with the device, and (3) active exercises. The patients in their study were randomly divided into two exercise groups: a TheraBite exercise group and an Engström jaw mobilization exercise group. Patients with trismus and HNC were enrolled as a control group. They detected a significant difference between the patient groups and the control group after 3 months[26]. The present study included three groups: an HNC group with trismus that used the TheraBite Jaw Motion Rehabilitation System, an HNC group with trismus that used the wooden tongue depressor, and a control group with trismus that used the TheraBite Jaw Motion Rehabilitation System. At first week post-treatment; the differences between TheraBite and wooden tongue depressor groups and the differences among the TheraBite, control, and wooden tongue depressor groups were significant. In the second week; the differences among the TheraBite, control, and wooden tongue depressor groups were significant ($p < 0.05$). Also, the differences among the control, TheraBite, and wooden tongue depressor groups were significant in the third week. These findings indicate the benefit of early exercise therapy, especially with TheraBite for HNC patients after surgery and radiotherapy before the maturation of any scar tissue. However, as a limitation of the current study, a control group that had used a wooden tongue depressor may have also been included.

Melchers et al[27] reported factors that affected continuous use of the TheraBite exercise device in trismus patients after treatment for HNC. They revealed that the most important factors were self-motivated exercise demand and perceived effect, as well as self- discipline and goal setting and belief that the goal was attainable. Pain and anxiety affected adherence to the TheraBite exercises in a positive or negative way. In the current study, exercising due to internal motivation was shown to be based on perceived positive effects, self-discipline, and goal setting.

Recent studies[31,32] revealed that the compliance with the EORTC QLQ-C30 and the head and cancer-specific module (EORTC QLQ-H&N35) were high and the questionnaire was well accepted by patients. The number of missing items was very low. In the present study, patient compliance was also high, and only sex item was missing.

In a study by Aplak et al[17] on 102 HNC patients who completed the EORTC-QLQ-C30 and QLQ H&N35 questionnaires, the authors reported low scores for pain, social eating, taste, and trismus. In a study by Kim et al[33], 133 oropharyngeal cancer patients who had undergone surgery or radiotherapy completed the EORTC QLQ-C30 and QLQ H&N35 questionnaires. In the radiotherapy group, higher symptom scores were obtained for dry mouth, weight gain, and painkiller use. The symptom scores in the surgery group were better than those in the radiotherapy group. Boscolo-Rizzo et al[34] administered the EORTC QLQ-C30 and H&N35 questionnaires to 57 oropharyngeal cancer patients, 31 of whom had received chemoradiotherapy after surgery and 26 patients of whom had received radiotherapy. In their study, the scores for pain, fatigue, swallowing problems, social eating, and functioning were better in the chemotherapy group than in the radiotherapy group, and dental problems, mouth opening, and sticky saliva scores were high. In the present study, when QoL was assessed using the EORTCQLQ-C30 and H&N35 questionnaires, the results revealed that pain, difficulty in mouth opening, loss of taste, dental problems, and social eating subscale scores were higher in oral cavity cancer patients. These data were consistent with the findings in the literature. There were no significant improvements in the quality of life between TheraBite and wooden tongue depressor groups in the present study which means that patients benefited from both therapies independent of the physical therapy venue.

Conclusions

From a clinical point of view, early exercising with TheraBite prevented scar tissue formation and the life quality questionnaires revealed that exercising was shown to be based on perceived positive effects, self-discipline, and goal setting, and thus based on internal motivation.

The TheraBite exercise was found to be more effective than the wooden tongue depressor exercise and significantly improved maximal incisal opening both in the TheraBite and control groups. The EORTC QLQ-C30 and H&N35 questionnaires showed that QoL scores were high and that patients had serious complaints.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Authors' Contribution
Conceptualization: MHŞ and BG; methodology: MHŞ; supervision: MHŞ; resources: MHŞ, BG; materials: MHŞ; data collection and/or processing: MHŞ; analysis and/or interpretation: MHŞ; literature search: MHŞ; writng manuscript: MHŞ; critical review: BG.

Ethics Approval
The Research Ethics Committee of the Ege University approved the investigation (No. 14-6/6), and it was conducted according to the principles expressed in the Helsinki Declaration.

Informed Consent
The subjects received written information on the purpose and procedures of the study, and they gave written informed consent.

Availability of Data and Materials
The raw data can be obtained upon request from the authors.

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