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TheraBite
Literature Review

TheraBite® Jaw Motion Rehabilitation System™

MC3028-ThEN_202306 TheraBite LitReview

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Introduction

This Literature Review concerns the TheraBite® Jaw Motion Rehabilitation System™ manufactured by Atos Medical AB, presenting an overview of the published work and clinical data for the TheraBite® Jaw Motion Rehabilitation System™.

This Literature Review contains first a description of the devices and an overview of Trismus. This is followed by an overview of the literature specifically on the TheraBite® Jaw Motion Rehabilitation System™.

Literature search for publications including the TheraBite® Jaw Motion Rehabilitation System™ was conducted in the PubMed search engine using "Trismus" and "Therabite" as key words covering a period 1993 – 2023. Search results were screened for relevant publications. Additionally, our own company database with publications on these devices was screened for relevant publications.

Publications presented in this document have been selected based on mention of the TheraBite® Jaw Motion Rehabilitation System™ or any of its accessories, regardless of the study results. Only potential omissions are those publications showing off-label use of the TheraBite® Jaw Motion Rehabilitation System™.

The present issue has been updated with new publications between January 2019 – March 2023.

The literature search has identified publications specifically including the TheraBite® Jaw Mobilizer and Range of Motion scale, which will be discussed separately below. As common for accessories, no publications specifically mentioned the accessories ActiveBand™ Kit, bite pads, patient progress log, or hand aid.

Always read the Instructions for use before starting to use any of the products. For Instructions for use, please visit www.atosmedical.com.

1. Description of the Devices

TheraBite® Jaw Motion Rehabilitation System™

The TheraBite® Jaw Motion Rehabilitation System™ consists of a TheraBite® Jaw Mobilizer, Bite Pads which protect the teeth, a patient progress log, Range of Motion Scale which is used to monitor the progress of the rehabilitation program, a Hand-Aid, and the ActiveBand™ Kit. Table 1 below presents the device history of the TheraBite® product series.

The TheraBite® Jaw Motion Rehabilitation System™ is a portable system which provides anatomically correct motion of the jaw. It utilizes repetitive passive motion and stretching to restore mobility and flexibility of the jaw musculature, associated joints and connective tissues. The system is used by patients with trismus. The TheraBite® can also be used to keep the mouth open in a stable position while performing dysphagia exercises (1).

Table 1. Device history of the TheraBite® product series (as of 2023)

Device	Year of release to market
TheraBite® Jaw Motion Reh. System™ Adult/Pediatric	2003
TheraBite® Bite Pad Regular	2003
TheraBite® Bite Pad Edentulous	2003
TheraBite® Bite Pad Pediatric	2006
TheraBite® Range of Motion Scale	2013
TheraBite® ActiveBand Kit	2006

TheraBite® Jaw Mobilizer

The TheraBite® Jaw Mobilizer, see Figure 1, is a hand-operated device that utilizes repetitive passive motion and stretching to restore mobility and flexibility of the jaw musculature, associated joints, and connective tissues. The TheraBite® provides patients with anatomically correct jaw motion. It also helps patients control the extent and length of each stretch. The device is available in an Adult and a Pediatric version.

The Jaw Mobilizer is held in the hand during use, with the mouthpieces placed between the upper and lower front teeth. Pressure on the lever, applied by the user, provides either opening force or resistance to closing.

Figure 1. TheraBite® Jaw Mobilizer

Bite Pads

The Bite Pads, see Figure 2, are designed to protect the teeth when used with the TheraBite® Jaw Motion Rehabilitation System™. The Bite Pads are available in three versions, Regular, Edentulous (toothless) and Pediatric (Figure 2). The self-adhesive pads are attached on the mouthpiece to protect the teeth during exercise.

Figure 2. TheraBite® Bite Pads; edentulous (far left), regular adult (left) and pediatric (right)

Range of Motion Scales

The disposable Range of Motion Scales, see Figure 3, is used to measure and monitor progress of the exercise, by the user or his/ her clinician. It may also be used to measure Maximal Mouth Opening (MMO) to assess/diagnose trismus.

Figure 3. TheraBite® Range of Motion Scale (ROM)

Patient Progress Log

The Patient Progress Log, see Figure 4, helps the user and his/her clinician to record the progress on a daily and monthly basis.

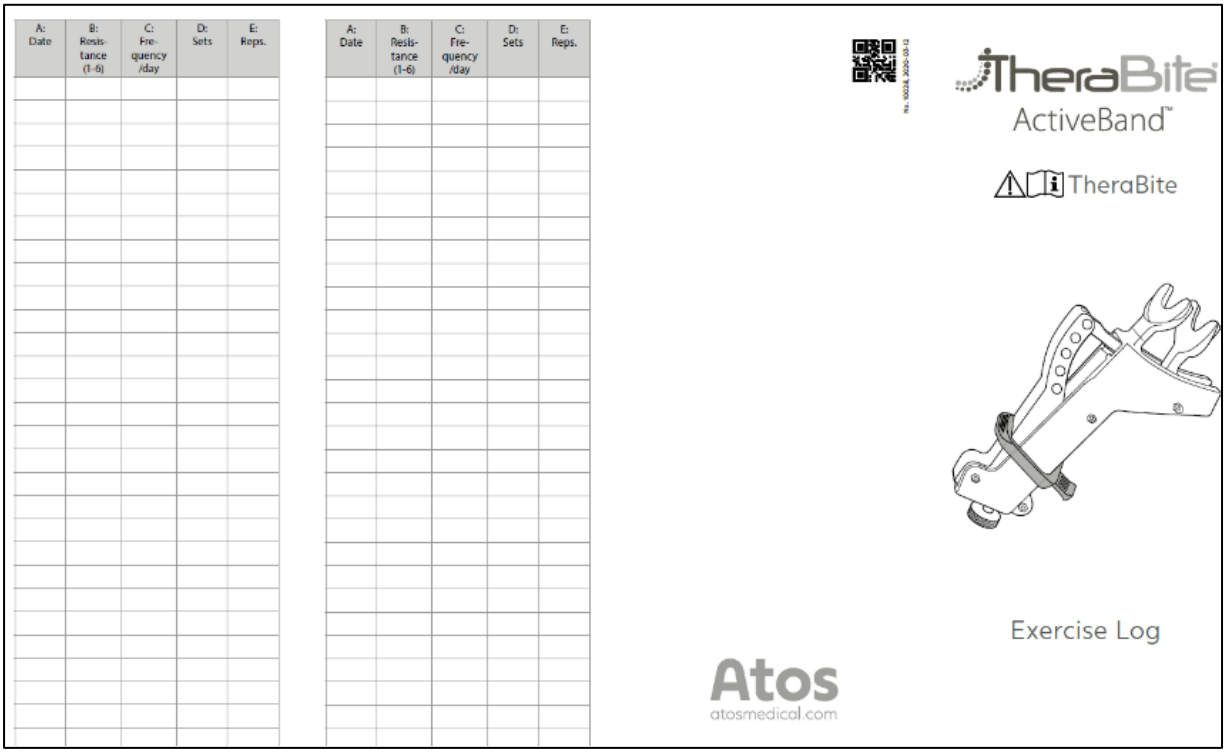

Figure 4. Patient progress log

Hand Aid

The Hand-Aid, see Figure 5, assists the user to maintain a constant opening during stretching or strengthening exercises.

Figure 5.
TheraBite® Hand-Aid

TheraBite® ActiveBand™

The TheraBite® ActiveBand™, see Figure 6, forms an addition to the TheraBite® device. The TheraBite® ActiveBand™ is a silicone rubber band that can be used together with the TheraBite® system to provide resistance to mouth closure. The intended use of the ActiveBand™ is to maintain or increase muscle strength and endurance of the muscles of mastication (i.e. chewing muscles: masseter muscle, temporalis muscle, medial and lateral pterygoid muscle). The active resistive exercise can be used in combination with passive stretching but can also be used independently.

Figure 6. TheraBite® ActiveBand™

2. Trismus

Definition

Trismus is defined as a tonic contraction of the muscles of mastication and results in a limited ability to open the mouth (2).

The normal range of mouth opening varies from person to person, within a range of 40-60 mm, although some authors place the lower limit at 35 mm. The lower limit of 35 mm is described by Dijkstra et al. in two publications in 2004 and 2006 (2, 3). Evidence suggests that gender may be a factor in vertical mandibular opening and in general, males display greater mouth opening (4). In patients with trismus the mouth opening is reduced. Scott et al. (2008) describe that there is a lack of clarity in literature of what amount of mouth opening signifies trismus (5). This ranges from less than 18 mm, less than 30 mm (6), less than 35 mm (2, 7, 8), to less than 40 mm (9). However, a review of the literature concluded that a cut-off point of 35 mm or less is a clinically meaningul definition of trismus (5). This definition has been used in studies by van der Molen et al. (1, 10), and verified in a large cross-sectional study by van der Geer et al., 2018 (11) including 671 head and neck cancer (HNC) patients.

Consequences of trismus

Trismus affects many important aspects of daily life, such as chewing, nutrition, diet normalcy, overall quality of life, difficulty eating, pain, facial appearance, speech difficulties, inability to practice effective oral hygiene, and inability to receive proper dental care (5, 12-18). HNC patients also reported poorer quality of life caused by limited mouth opening (19), a finding that was mirrored in a study reporting on the quality of life of 133 head and neck cancer patients (20) and several studies since (18, 21). In a longitudinal study of 87 HNC patients, quality of life variables showed that pain, eating, chewing, taste, saliva, social functioning, social contact, and dry mouth were significantly more impaired in patients with trismus than in patients without trismus (21).

Quality of life has further been investigated in a study performed by Lee et al., 2015 (22) Demographic data and disease/treatment information from 104 participating head and neck cancer patients were analysed in the study. The authors found patients were significantly more likely to have trismus with lower body mass index, chemoradiotherapy treatment, longer time since treatment completion, and higher radiation doses. Kondo et al., 2018 (23) reported rehabilitation of trismus as a promising factor to improve functional performance.

Etiology of trismus

Several conditions may cause or predispose an individual to develop trismus. Trismus is frequently observed in HNC patients and TMJ postsurgical patients, but can also be found in patients with other underlying pathologies (16).

The etiology of trismus may be classified as follows: intra-articular (stiffness/immobility of joint, inflammation of joints/synovitis, fibrous disc pathology) or extra-articular (infection, trauma, dental treatment, temporomandibular joint disorders, tumors and oral care, drugs, radiotherapy and chemotherapy, congenital problems and miscellaneous disorders)(4). These different etiologies are summarized in Figure 7.

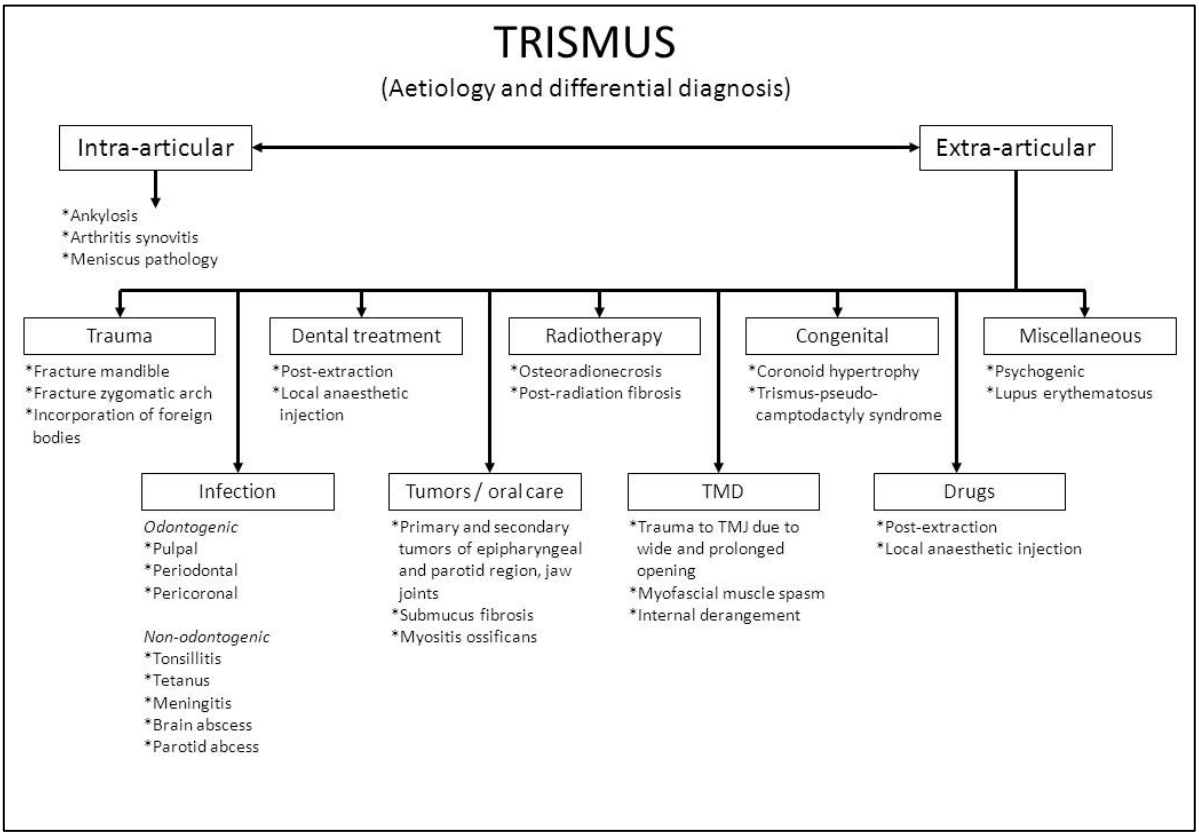

Figure 7. Etiology and differential diagnosis of trismus (adapted from Dhanrajani et al., 2002 (4))

In this literature review, the focus will be on incidence and treatment of trismus in the two largest patient groups: in patients with temporomandibular joint problems and in patients with head and neck cancer (HNC).

Incidence of trismus in patients with head and neck cancer

Trismus is reported to be present in 2%-47% of HNC patients when presenting to the clinic for the first time/prior to treatment (8, 21). It is also believed to develop in one fourth of head and neck cancer patients (25). However, the percentages of trismus in HNC patients reported in the literature vary widely. A literature review by Rapidis et al., 2015 (26) suggests a prevalence of trismus between 0-100% depending on tumour site and extension, the different treatment regimens used, and the different criteria used to define trismus. The most common cause of oncology related trismus is radiation-induced fibrosis, while postsurgical scarring (27), late tumour stage, and free tissue reconstruction (5) may also play a role.

In a study by Weber et al. (28) in 2006 the prevalence of trismus in a population of HNC patients was investigated. The results showed that patients with malignant head-neck tumours were suffering from restrictions in interincisor opening (51%) post radiotherapy and/or radiochemotherapy. The results of this study are presented in Table 2.

Table 2. Frequencies of different types of carcinoma with prevalence of trismus in patients with head and neck cancer (Weber et al., 2006). Results based on 100 HNC patients. Frequency of HNC type is based on 100 patients, and trismus prevalence is frequency of trismus within the subgroup.

Diagnosis	Frequency of HNC type	Prevalence of trismus
Oropharyngeal carcinoma	37%	65%
Laryngeal carcinoma	28%	32%
Hypopharyngeal carcinoma	16%	50%
Nasopharyngeal carcinoma	8%	63%
Thyroid Gland carcinoma	6%	50%
Other	5%	40%
Total	100%	51%

In many patients, radiotherapy is a necessary part of their treatment. However, this treatment also has complications. Limitations in jaw opening have been reported in 6–86% of patients having received radiotherapy to the temporomandibular joint and/or masseter/pterygoid muscles, with a frequency and severity that is somewhat unpredictable (15, 29). It is known that in irradiated patients, trismus can occur months or even years after radiation treatment. It is estimated that about 40% of all patients with oropharyngeal cancer will receive radiotherapy (30). The incidence of post-treatment trismus in HNC patients in a study in Swedish patients was as high as 42% (14) and between 50%-71% in other studies (18, 21). Furthermore, it was found that poor physical function before the start of treatment and high tumour EBRT dosages (>50 Gy) were related to a significantly higher incidence of trismus (14, 17). A study by Jeremic et al. (31) (2011) shows that trismus is a significantly prevalent consequence of treatment for head and neck cancer. Predictive factors include treatment with concurrent chemoradiotherapy and

bilateral inclusion of the structures of mastication in the high-dose radiotherapy volume. Patients with tumours located in the oral cavity, oropharynx, and the salivary glands or ear, and who had a longer overall treatment time of radiotherapy are also more likely to develop trismus in the first six months after radiotherapy (32).

Incidence of trismus in patients with temporomandibular disorders

There are numerous subcategories of temporomandibular disorders (TMD), a number of which may be associated with trismus. TMD may be divided into extra capsular (mainly myofascial) and intracapsular problems (including disc displacement, arthritis, fibrosis, etc.). Intracapsular problems are often caused by trauma. Trauma can be defined as a devastating event (e.g. sports injury), administration of general anesthesia and performance of a dental procedure such as difficult extractions or other treatment requiring lengthy appointments (14). It is reported in a study that in 33.4% of 779 patients that had a trauma to the temporomandibular joint, trismus occurred within one week of the event (4).

Malkawi et al. (24) published a study in 2011 in which postoperative complications following third molar extraction were described in 327 patients. Authors conclude that the most frequently reported immediate and late complications of this study were slight pain, swelling, and trismus. Extraction of two molars and bone removal was associated with more trismus. Of their patients 50.5% had a slight pain and trismus as an immediate complication and after two weeks 14.1% still reported these problems.

3. TheraBite® Jaw Mobilizer

The TheraBite® Jaw Motion Rehabilitation System™ is specifically designed to treat trismus and mandibular hypomobility. In this section, trismus rehabilitation, preventive trismus therapy, and treatment regimens using the TheraBite® Jaw Motion Rehabilitation System will be discussed. Unless specified, the mention of "TheraBite®" in the literature will be assumed to refer to the TheraBite® Jaw Mobilizer.

The TheraBite® Jaw Rehabilitation System™ is based on the principle of passive motion. Several studies have found that passive motion can help to improve joint function, re-organize collagen, and restore jaw function

Figure 8. Therabite® Jaw Mobilizer in use

(33, 34). Sebastian & Moffet showed that passive motion provides significant benefits for postoperative rehabilitation.

In their study, they find significantly greater improvement in range of mandibular motion in those persons using passive motion, as compared to the controls (33). Additionally, passive motion of the joint can activate anti-inflammatory agents (interleukin IL-3) that promote joint lubrication (34). The frequency and duration of the strain that is exerted impacts important fibroblast physiological function known to mediate pain, inflammation and ROM (34).

3.1 Rehabilitation with TheraBite®

In this section evidence for the use of passive motion and TheraBite® as a treatment for trismus in patients with head and neck cancer, patients with temporomandibular joint disorders, and post TMJ surgery patients will be presented.

Head and neck cancer

Several publications have reported on the outcomes of treatment of post-radiation and/or post-surgical trismus. These studies include systematic reviews, randomized-controlled trials and cohort studies. In addition to the treatment of post-radiation trismus, the effects of preventive exercises on the development of trismus during and after radiation have been studied. Below, publications on trismus rehabilitation are presented one by one.

In summary, for HNC patients suffering from trismus, the TheraBite® has been shown to be efficient in treating trismus and increasing Maximal Interincisal Opening (MIO) of patients (7, 35-37) and even indicated to increase exercise adherence (38). While some studies showed its superiority to other jaw stretching devices (2, 39, 40), others found no significant differences between TheraBite® and other devices (41-43, 47). Most importantly, several studies point to the importance of a structured exercise regime with the TheraBite® to be beneficial, regardless of time since oncologic treatment (44-46, 48).

Dijsktra et al., 2004 (2): In a systematic review, Dijkstra et al. analyzed existing publications on the outcomes of treatment of trismus in head and neck oncology (2). The authors reviewed 12 clinical studies with 10 or more patients and concluded that exercises using the TheraBite® system increased mouth opening most significantly with the largest effect sizes. Other treatment methods such as tongue-blade exercises, micro current therapy and pentoxifylline were found to have smaller effect sizes.

Dijkstra et al., 2007 (39): In 2007, Dijkstra et al. also analyzed in another, retrospective study the effects of exercise therapy on trismus related to HNC or as a consequence of its treatment and compared these effects with trismus not related to HNC (39). Medical records of patients were retrieved and data of 27 patients with trismus related to HNC and data of eight patients with trismus not related to cancer were analyzed. Exercises mainly included active range of motion exercises, hold relax techniques, manual stretching and joint distraction with rubber plugs (68%) and wooden tongue blades (32%). Two patients used TheraBite®. The increase in mouth opening was less in the group of patients with trismus related to HNC as compared to the increase in mouth opening in the group with trismus not related to cancer. Authors conclude that trismus related to head and neck cancer is difficult to treat with exercise therapy.

Buchbinder et al., 1993 (40): In a randomized controlled study, Buchbinder et al. looked at a population of radiated patients who had developed trismus (40). In this study, the protocol for the patients was to use the TheraBite® or tongue depressors ten times per day, opening and closing five times, and holding a stretch for up to 30 seconds. The patient group using TheraBite® outperformed the groups using unassisted exercises and tongue depressors. In addition, the rate of improvement was significantly faster, and the patient group was also more compliant.

Karlis & Glickman, 2001 (49): Authors investigated mouth opening of persons suffering from limited jaw motion as a result of radiation-induced trismus (49). They found that persons who used the TheraBite® obtained significant improvement in function as compared to the control subjects, who used tongue depressors. The protocol followed by the patients in this study was to "use the TheraBite® device/tongue depressors as often as you can tolerate each day".

Melchers et al., 2009 (38) and Cohen et al., 2005 (7): In two smaller non-randomized studies, Melchers et al. (38) and Cohen et al. (7) also describe the positive effects of TheraBite® on trismus after head and neck cancer. Melchers et al. studied therapy adherence in patients using the TheraBite® and based on their findings developed a model for optimal therapy adherence. Cohen et al. studied the effects of the use of TheraBite® in a small group of patients and conclude that the TheraBite® mechanical stretching device is effective and safe for the management of trismus in their selected group of head and neck cancer patients.

Messing et al., 2009 (44): In 2009, Messing et al. concluded that early identification and intervention with TheraBite® should be considered as an integral component of the patients cancer treatment program (44).

Kamstra et al., 2013 (35): Kamstra et al. evaluated the effects of TheraBite® in 69 HNC patients with trismus. Authors concluded that on average the effect of the treatment with TheraBite® was an increase of 5.4 mm in mouth opening. This study also concluded that

the odds of an increase in mouth opening of 5 mm or more reduces if the time from oncological treatment to start exercises lengthens (35). This latter finding supports the recommendations from the study published by Messing et al (44).

Bensadoun et al., 2010 (51): In a review on cancer therapy-induced trismus in HNC patients, Bensadoun et al. conclude that physiotherapy exercises appear to be useful in trismus management, botulinum toxin injections seem to be effective in the improvement of pain scores and masticator spasms, but not in the improvement of trismus itself, and the TheraBite® seems to be effective in the reduction of cancer-therapy-induced trismus (51). Authors recommend that if the clinical examination reveals the presence of limited mouth opening and diagnosis determines the condition is due to trismus, treatment should begin as soon as it is practical.

Tang et al., 2011 (52): Tang et al. studied the effects of exercises with TheraBite® on the progress of trismus in 43 patients shortly after treatment with radiotherapy for nasopharyngeal carcinoma. They concluded that rehabilitation training, with TheraBite®, can slow down the progress of trismus in these patients' following radiotherapy (52).

Treister et al., 2012 (53): In an publication by Treister et al., the authors report that in patients with sclerodermous oral chronic graft versus host disease suffering from trismus, the TheraBite® may be used for low load passive stretching.

Pauli et al., 2015 (54): In 2015, Pauli et al. compared jaw exercise with the TheraBite® to the Engström jaw device in 50 patients with head and neck cancer and the compliance to exercise (54). Trismus after HNC is a symptom associated with pain and negatively affected health-related quality of life. After 10 weeks, the mouth opening had improved in both groups: 7.2 mm for the TheraBite® and 5.5 mm for the Engström. The authors conclude that structured intervention with a jaw exercise device decreased pain and trismus-related symptoms, and improved mouth opening capacity in patients with trismus after radiation therapy.

Scherpenhuizen et al., 2015 (48): In another review on HNC patients, the effect of exercise therapy on radiotherapy-induced trismus was evaluated. Scherpenhuizen et al. noted a positive effect of exercise therapy with TheraBite, that yields better results than no exercise.

Pauli et al., 2016 (46): Pauli et al. investigated the long-term effects of structured trismus exercise in a two-year follow-up intervention with 44 patients (46). Study participants were all HNC patients with trismus following radiation therapy with or without chemotherapy. The intervention group reported significantly less jaw-related problems, eating limitations, muscular tension and facial pain compared to the matched control group. The positive effect of exercise was found to be persistent both in terms of mouth opening, trismus-related symptoms and health related quality of life. The authors concluded structured

exercise with TheraBite® to be beneficial for trismus patients independent of time since oncologic treatment.

Lee et al., 2018 (55): In a randomized feasibility study by Lee et al., the efficacy of TheraBite® was compared with that of the current standard treatment with wooden spatulas to relieve or treat trismus (55). All enrolled patients had some sense of jaw tightening and received radiotherapy for stage t3 and 4 oral and oropharyngeal cancer. There were no significant differences between groups in efficacy of treatment, compliance, health related quality of life, or use of health service. Both treatment groups had a general increase in mean mouth opening after six months of follow up. The authors concluded that exercises during and after radiotherapy can relieve trismus in these patients.

van der Geer et al., 2020 (43): In a randomized controlled trial, van der Geer et al. aimed to compare the effect of TheraBite® and Dynasplint on maximal mouth opening (MMO) in HNC patients. Participants were randomly assigned to two jaw exercise groups performing stretching exercises for 3 months (43). A non-significant increase in MMO between both groups was found, with an increase in MMO of 3.0 mm for TheraBite® users and 1.5 mm for Dynasplint users. However, the study was stopped prematurely due to low inclusion rate and high drop-out rate, with only 11 of 27 enrolled patients completing the study. Reasons for dropping out of the study were intensive exercise protocol, pain during exercises, fitting problems with the devices, and overall deterioration of medical conditions. The authors also highlight that the small sample size in the study may not have been large enough to detect the effects of the two stretching devices.

Montalvo et al., 2020 (56): A prospective study by Montalvo et al. aimed to explore the impact of structured exercise with the TheraBite® on trismus, trismus-related symptomatology, and health-related quality of life (HRQoL) in HNC patients, to be assessed before and after 6 months of exercise (56). Fifteen HNC patients with trismus after oncologic treatment were enrolled in the study to perform a 10-week exercise program with the TheraBite®. MIO improved significantly post-exercise (3.5 mm, 15.3%, p=0.0002) and after 6 months of exercise (4.7 mm, 22.1%, p=0.0029). Also, a significant correlation between increased MIO and fewer trismus-related symptoms was found. With time between oncologic treatment and using the TheraBite® ranging from 0.7-14.8 years, the study also indicates that structured exercise with the TheraBite® seems to be beneficial to trismus patients, independent of time since oncologic treatment.

Ezzat et al., 2021 (37): Due to progressiveness of trismus, early intervention is crucial to prevent further damage and weakening of the muscles of the mandible. Ezzat et al. present a case report of a 40-year-old woman with known squamous cell carcinoma who had undergone upper right partial maxillectomy with subsequent radiotherapy (37). Five months after radiotherapy, restoration of oral functions and facial appearance began. During a 6-week period, the TheraBite® and wooden tongue depressors were alternatively

used (4-5 stretches/day; each stretch held for 15 s). Mouth opening gradually increased from 12 mm to 20 mm during the 6-week period.

Chee et al., 2021 (47): In a systematic review by Chee et al., the purpose was to identify interventional studies for trismus management in HNC patients in which 11 RCTs with a total of 685 patients with HNC were included (47). The review found no clear consensus on the optimal intervention for trismus in this patient cohort. Six of the RCTs evaluated exercise regimes with a jaw rehabilitation device, intervention periods ranging from 3-12 months and exercise frequency ranging from 3-5 times/day. No significant benefit of an exercise regimen with a jaw mobilization/stretching device was found either initiated prior, during or after cancer treatment compared to no exercise. Only 1 study showed a significant difference in MIO for device users (Dynasplint) than those who did stretching exercises alone (57). Remaining 5 RCTs did not have significant differences in MIO regardless if they compared device exercise to no exercise control groups (58, 59), if trismus intervention began prophylactically prior to cancer treatment (1, 58, 59), or when comparing TheraBite® use to other devices (42, 58).

Temporomandibular disorders

Below, publications on rehabilitation after temporomandibular disorders are presented. In summary, research on passive motion as treatment for TMD shows that many patients suffering from TMD have degenerative changes to the joint. Many of these degenerative changes are reversible by the use of passive motion (60) and may be caused by lack of motion (61). Hence, passive motion seems a good starting point in the treatment of this condition. Evidence is presented that the passive motion provided by the TheraBite® offers considerable benefit to regular care or standard physical therapy (62-66).

Salter, 1989 (67): Salter and colleagues undertook a series of studies exploring various aspects of passive motion in animal models and humans (68-70). The research they conducted during a several-year period showed that passive motion has a significant stimulating effect on the healing of articular tissues, including cartilage, tendons and ligaments. Results also suggests that passive motion can lead to regeneration of articular cartilage through neochondrogenesis (67). Overall, their work on passive motion has contributed significantly to the understanding of the benefits of intermittent passive motion in helping to restore joint function and re-organize collagen.

Karlis & Glickman, 1994 (63): In a randomized pilot study presented at the Annual meeting of the American Association of Oral And Maxillofacial Surgeons, Karlis & Glickman found that closed lock patients reported significant improvements in function and pain when

prescribed a regime of passive motion with the TheraBite®, combined with NSAIDS (63). It was hypothesized that the findings were, at least in part, due to the speed-up of the natural progression of recovery that many TMJ patients experience. In particular, the authors hypothesized that the patients on passive motion formed a 'pseudo disk' and this accounted for the reduction in pain and increase in function.

Nicolakis et al., 2000 (71): found that exercise does seem to improve function or reduce pain. The study shows that such benefits are to be expected if passive (as contrasted to active) motion is utilized more frequently.

Gassner et al., 2000 (60): provided an additional foundation for the observations in the earlier studies. They report that passive mobilization, as contrasted to simple stretching, provides significant decreases in the inflammatory process and that passive motion effectively interrupts the process by which interleukin-1 creates inflammatory cytokines, thus decreasing pain. In addition, they found that gentle passive motion has a positive effect on proteoglycan synthesis. These findings help to explain the clinical effects with the TheraBite® in this patient group found by Karlis & Glickman (49) and Maloney et al. (62)

Maloney et al., 2002 (62): presented in a randomized controlled study their findings on closed lock patients given an exercise regime of passive motion (62). It was noteworthy that those patients receiving appliance therapy alone did not achieve any significant improvement in either pain or function. This was true for both intracapsular (joint), as well as extracapsular (muscle) patient populations. In contrast, patients using the TheraBite® appliance reported significant improvement in both function and pain. The protocol was to use the TheraBite® device five times per day, opening and closing the mouth three times per session, and holding a stretch for one minute. Commenting on this study, Gassner & Argawa (72) in 2002 sent a letter to the editor (72), in which they pointed out that the findings of Maloney are 'interactive', in that the reduction in pain allows greater function, and the increase in function provides even greater reduction in pain. Thus, according to them, the improvement in function is actually dependent upon a decrease in pain, and conversely.

Robbins, 2002 (61): provides background on the effects of motion and the lack thereof on joints and muscles. The article discusses that immobility can result in many of the symptoms of TMD. Passive motion, on the other hand, can reverse these symptoms.

Kraaijenga et al., 2014 (73): compared in a randomized controlled trial the application of the TheraBite® (TB) Jaw Motion Rehabilitation System with a standard physical therapy (PT) exercise regimen for the treatment of myogenic TMD. After six weeks the patients using the TB device reported a significantly increased functional improvement. At 3 months there was no difference between the two groups. The authors concluded that the use of the TB device improves mandibular function within the first week of treatment, whereas long term both treatments are equally effective.

Heres Diddens et al., 2016 (64): studied in a randomized controlled trial the cost-effectiveness of TheraBite® as treatment for acute myogenic TMD compared to standard physical therapy. The authors compared differences in cost per quality-adjusted life-year (QALY) using a decision model to determine the probability of being TMD-free or not over a six-week treatment period. The analysis showed that patients using TheraBite® (n=46) had lower costs and a faster recovery of QoL compared to the control group of patients with standard physical therapy (n=50). The authors conclude that TheraBite® benefits both patients and society, by offering a more effective and less expensive treatment.

Reed et al., 2020 (65): provide evidence in a case series that using pentoxifylline plus vitamin E with TheraBite® is the most efficient way to reduce trismus in scleroderma patients (65). Comparing the use of pentoxifylline plus vitamin E, with and without the TheraBite® jaw exercises four times daily, they observed that jaw opening improved markedly for both patients. However, the addition of TheraBite® increased the effect of pentoxifylline plus vitamin E. No side effects or complications were observed.

Lloyd Morris et al., 2020 (74): People with Duchenne Muscular Dystrophy (DMD) and spinal muscular atrophy (SMA) develop impaired oral function because of reduced TMJ range of motion. In a case series, Lloyd Morris et al. studied whether the use of TheraBite® in this population would improve temporomandibular ROM (74). Participants (n=2 with DMD, n=1 with SMA) performed a stretching protocol with the TheraBite® for a duration of intervention between 7-30 months, with treatment frequency varying from weekly to several times per year. For DMD participants, active ROM (AROM) remained unchanged while passive ROM (PROM) increased by 40-65%, while the SMA participant presented 33% and 47% improvements in both AROM and PROM, respectively. Improved feeding functions, oral hygiene, and reduced fatigue were also reported.

Sydow et al., 2021 (75): Reduced oral aperture may be caused by systemic sclerosis. It may be improved by oral exercises, but results are often limited by low adherence. In a mixed method study published in 2021 (75), feasibility, patient satisfaction and effectiveness of two exercise programs were studied. 9 patients were included and divided into group A) using the TheraBite®, and group B) performing only mouth-stretching exercises. Patients were evaluated at baseline, at 3-months (period without intervention), at 6 months (after 3 months of intervention) and 9 months (post-intervention). Adherence was high but varying within both groups (63.7-98.9% and 48.5-97.4% in Group A and B, respectively). Although both interventions improved maximal oral aperture (9- and 7-mm increase for Group A and B, respectively), patients did not consider it feasible to continue practicing three times per day in the long-term.

Yim et al., 2022 (66): A protocol for treatment of heterotopic ossification (HO) of the TMJ was developed in 2022 (66). Based on a literature review, the proposed protocol consisted of an initial pharmacotherapy, combined with a weekly forced dilation and home physical therapy with the TheraBite®, as opposed to the usual care which consists of a surgical

treatment. The protocol was subsequently used on a patient with recurrent HO of the TMJ, the patient regained MIO and remained stable 2 years after surgery without any recurrence.

Surgery involving the temporomandibular joint

Inflammation and pain occur when inflammatory by-products (e.g. free radical, cytokines) are present in the synovial fluid due to lack of motion. Motion, on the other hand, produces anti-inflammatory properties and yields positive clinical outcomes such as reduced pain, reduced analgesic use and improved range of motion (34). Passive motion is thus used as a post-operative treatment after temporomandibular joint surgery.

Below, studies are presented on the rehabilitative use of the TheraBite® following surgery to the TMJ. Studies show that passive motion and early mobilization post-surgery have positive effects on the surgery outcome (76, 77) but that adherence to exercise program is equally important for successful rehabilitation and outcomes (78, 79).

Kaban et al., 1990 (76): evaluated the effects of a management protocol for temporomandibular joint (TMJ) ankylosis (stiffness of the joint). This protocol consisted of surgery, early mobilization including use of the TheraBite® and aggressive exercising. Patients were treated and a one-year follow-up was conducted. The results of this study show that their treatment regime was effective for treatment of TMJ ankylosis.

Stack et al., 2001 (77): describe the outcomes of a modified meniscoplasty on 117 temporomandibular joints in 60 refractive craniofacial pain patients over a ten-year period. The technique combined a conservative surgical approach with pre- and post-surgical splint therapy and aggressive post-surgical physical therapy including passive motion using the TheraBite. A 20-point visual analog scale was used to evaluate improvement in overall head, face, and neck pain as well as eye, ear and TMJ pain. No patient claimed to have been made worse by this procedure. One patient remained without benefit, and 59 patients (98%) improved. Based on the published literature one can conclude that passive motion and early mobilization after temporomandibular joint surgery has a positive effect on the outcome of this surgery. It is even suggested that passive motion could also avoid unnecessary surgical procedures.

Warwas et al., 2021 (78): In a case series, five cases of surgically treated coronoid hyperplasia were presented (78). All cases received a bilateral coronoidectomy to remove the coronoid hyperplasia followed by physiotherapy. After surgical intervention, 4 of the participants performed TheraBite® device training to retain or increase intraoperative MIO.

During the postoperative phase, physiotherapy is important to establish sufficient improvement of mouth opening. In the presented cases, the outcomes were strongly dependent on the patient's postoperative compliance to the physiotherapy. Greater maximal intercuspidal opening improvement was connected to compliant patients, while poor outcome occurred in the case of a patient that neither followed recommendations for physical therapy nor showed up for follow-up appointments."

Aryanpour et al., 2022 (79): described the case of a 4-year-old girl treated for mandibular myofibroma and severe trismus. After complete resection of the lesion, the lesion continued to expand, decreasing MIO until she could not open her mouth despite conservative jaw physiotherapy along with TheraBite® use. However, non-compliance of TheraBite® exercise regimen led to minimal efficacy of the treatment. As stated by the authors, previous publications suggest that jaw physiotherapy is the cornerstone for optimizing jaw opening in oral cancer patients with trismus, regardless of operative management. Similar results can be seen in this case report by noncompliance to TheraBite® regimen.

3.2 Preventive rehabilitation including the TheraBite®

In addition to being used as a rehabilitation device for treating existing trismus in HNC cancer patients, the TheraBite® has also been used in studies aiming at trismus prevention or as a part of a preventive rehabilitation program including both swallowing exercises and trismus prevention exercises with TheraBite® (1, 10, 53, 80, 81) and in studies utilizing the device to perform the so-called Open Swallow Exercise (1, 80-83).

TheraBite® and trismus prevention

In the section below, studies on preventive trismus rehabilitation using the TheraBite® are presented. In summary, although evidence points to preventive exercise being effective in reducing the effects of trismus (44, 80, 84, 85), the evidence on trismus prevention cannot point to a single protocol or jaw stretching device to be superior to the other (58, 86). However, compliance to exercise and an early as possible start to therapy during or after CRT treatment (26, 87) is recommended for best results. Early intervention is also essential for long-term results of exercises to be maintained (1, 88, 89).

Messing et al., 2009 (44): were the first to report on the use of TheraBite® during (chemo)radiation, as a method to prevent trismus. In a randomized, controlled, prospective study in 33 patients treated for head and neck cancer, 22 patients performed

preventive exercises with TheraBite® during the (chemo)radiation treatment, 11 patients were in the control group and did not receive any trismus prevention treatment. In the TheraBite® group mouth opening was 47 mm on average prior to the start of (chemo)radiation and 43 mm on average at mid-treatment. In the control group the average mouth opening reduced from an average of 50 mm prior to the start of (chemo)radiation to an average of 38 mm at mid-treatment. At mid-treatment follow-up, mouth opening of 9 out of the 11 patients in the control group had reduced to below 39 mm and for ethical reasons they started a preventive regimen from that point on. Hence, further comparisons between treatment and control were not possible.

Carnaby-Mann et al., 2012 (80): studied a total of 58 HNC patients treated with chemoradiotherapy that were randomly assigned to usual care, sham swallowing intervention, or active swallowing exercises (including use of the TheraBite® for trismus prevention). The intervention arms were treated daily during chemoradiotherapy. The primary outcome measure was muscle size and composition. The secondary outcomes included functional swallowing ability, dietary intake, chemosensory function, salivation, nutritional status, and the occurrence of dysphagia-related complications. The swallowing musculature demonstrated less structural deterioration in the active treatment arm. The functional swallowing, mouth opening, chemosensory acuity, and salivation rate also deteriorated less in this group. Mouth opening 6 weeks post-cancer treatment was significantly better in the pharyngocise group (p=.047) than in the usual care and sham group (40.1 mm vs. 32.3 mm vs. 34.1 mm resp.)

Van der Molen et al., 2011 (1): conducted a preventive rehabilitation trial comparing two different therapy regimens designed to prevent trismus and swallowing disorders following chemoradiation therapy for head and neck cancer. To prevent trismus, patients were instructed to use the TheraBite® (N=27) three times a day performing 3 stretches of 30 seconds. The other therapy group (N=28) performed mouth opening exercises 3 times daily (opening mouth as far as possible 3 times 30 seconds, move jaw as far as possible to the right/left each 3 times 30 seconds, move jaw in circular motion 3 times).

Despite the fact that patients using the TheraBite® practiced significantly fewer days in total and per week, and they only did 3 stretches of 30 seconds, 3 times per day, and not the movements to the left, right and circular motions, these patients showed similar results compared to the group of patients who did the other range-of-motion exercises (1). Results of a one year follow-up study showed that three patients in regular exercise group had developed trismus, while in the TheraBite® group none of the patients had developed trismus (10).

Two-year follow-up results of this study, Van der Molen et al. (88), showed that after the first year post-treatment many initial tumor- and treatment-related problems diminished significantly, except xerostomia (59 %).

Karsten et al., 2020 (89): In a follow-up study for the same patient group (1), Karsten et al. assessed long-term functional outcomes and quality of life more than 10 years after CRT and preventive swallowing rehabilitation were performed (89). Fourteen of the 22 patients at 6-year follow-up were evaluable (90), none of the patients continued the (preventive) exercises after 1-year post CRT. Overall, functional status and quality of life of the patients who performed the preventive rehabilitation was well-maintained at 10 or more years after CRT treatment, with swallowing, trismus, and speech related outcomes only moderately deteriorated from 6- to 10-years. Dysphagia increased in 5 out of 10 patients, and for trismus related outcomes, follow-up showed that median mouth opening had deteriorated from 51 to 45 mm. However, no patient had a mouth opening at or below the cut-off value of 35 mm for trismus.

Tang et al., 2011 (52): conducted a study in 43 patients following radiotherapy for Nasopharyngeal Cancer. Patients were randomly assigned to receive a rehabilitation program including swallowing exercises and TheraBite® exercises to prevent progress of trismus. Although the device is said to be used as early as possible with the aim to prevent progress of trismus, and the use of the device is initiated when the patient is hospitalized, it is unclear how soon after radiation the patients started the exercises. The results showed that mouth opening in the rehabilitation group reduced slightly from 1.89 mm to 1.7 mm, and that in the control group the mouth opening reduced significantly from 1.8 mm to 1.1 mm. Although the mean interincisor distance in patients of both groups decreased after the 3-month follow-up, the decrease in the rehabilitation group was less than that of the control group (0.19 +/- 0.5 cm vs. 0.69 +/- 0.56 cm, p = 0.004).

Messing et al., 2012 (91) and McCaul, 2012 (27): A Multidisciplinary Care Guideline for Head and Neck Cancer, included the TheraBite® device as an integral part of the preventive exercise program (91) and a paper on dental management also mentioned the importance of trismus prevention (27).

Rapidis et al., 2015 (26): In a systematic review, the authors concluded that exercise therapy is the mainstay of the treatment of trismus and should start as soon as possible (i.e after surgery, and during RT), indicating that the prevention of trismus, rather than its treatment, is the most important objective (26). The authors refer to TheraBite® indicating that while it may show efficacy in achieving improved jaw opening and trismus, the effect can be short-lived and potentially complicated. According to Rapidis et al. (26), it is important to determine whether trismus is the result of the treatment (i.e medical or surgical) or is the first sign of a recurrence. If mouth opening decreases despite exercises, especially when it is associated with pain, then a recurrence must be seriously considered.

Retèl et al., 2015 (92): assessed the cost-effectiveness of TheraBite®, used as part of a Preventive Exercise Program (PREP), compared to Speech Language Pathology (SLP) sessions as part of usual care (UC) in the Netherlands. The total health care costs per patient were estimated to be 5,129 euros for TheraBite® and 6,915 euros for SLP sessions.

Treatment with TheraBite® also yielded more quality-adjusted life-years (1.28) compared to SLP intervention (1.24). They concluded that TheraBite® as part of a preventive exercise program in Dutch Head and Neck Cancer patients is probably more cost-effective (less costly and more effective) than purely SLP sessions as part of a standard exercise program.

Kamstra et al., 2016 (87): In a systematic review , exercise therapy for trismus secondary to head and neck cancer, including TheraBite®, was reviewed in 20 studies investigating either prevention therapy (N=8) or therapeutic treatment (N=12) (87). The authors concluded that most studies (both therapeutic and preventive) found an increase in mouth opening after exercise therapy. Authors further concluded that compliance with the exercise and early start of therapy is important for good result and that there was no exercise therapy that was clearly superior to the others.

Karlsson et al., 2020 (93): Due to the lack of both a standardized treatment for radiotherapy-induced trismus and long-term follow-up data, in a prospective study, Karlsson et al. performed a 3-year follow-up to examine effects of jaw exercise for treatment of trismus, studying MIO, trismus-related symptoms, and health-related quality of life (HRQOL) (93). 50 HNC patients, with matched controls, were enrolled 3-6 months after radiotherapy and performed 10 weeks of jaw exercise, using either the TheraBite® or the Engström jaw device. At the 3-year follow-up, 41 of the 47 (87%) intervention patients no longer had trismus. 32 of 47 (68%) continued performing the exercises, and 26 of 32 (81%) still performing exercises no longer had trismus. In the control group, 19 of 32 (59%) no longer had trismus; 14 of 43 (33%) were exercising, and 7 of 14 (50%) no longer had trismus. At the 3-year follow-up, the intervention group had a significantly ($p<0.001$) improved mean MIO (40.1 mm) compared with the control group (33.9 mm). The intervention group also reported less trismus-related problems and improved HRQOL compared to control group. The study concluded that jaw exercise should be initiated early, in a structured manner and continued long-term.

Shao et al., 2020 (86): In a meta-analysis, Shao et al. investigated effectiveness of exercise therapy combined with a jaw-mobilizing device in the prevention and treatment of cancer treatment-induced trismus (86). 13 RCTs, published before 2020, involving 733 patients were identified with six studies addressing MIO and seven studies evaluating preventive outcomes of trismus. MIO was found to significantly improve from 4.48 to 14.20 mm when exercise therapy was performed adjuvant to the use of a jaw-mobilizing device. The studies evaluating preventive trismus incidence found no significant difference between standard usual care and exercise therapy following the use of a jaw-mobilizing device. Jaw-mobilizing devices identified in the RCTs were Therabite®, Engström, tongue depressor, rubber hose, Dynasplint, and EZ bite.

Bragante et al., 2020 (58): In an RCT from 2020 (58) investigating the preventive effect of two interventions (exercise therapy with or without TheraBite®) in HNC patients undergoing RT, no significant effects on MMO between intervention and control groups were found at

12 months follow-up. Exercises in intervention group consisted of warm-up, stretching, and masticatory training, with or without TheraBite® stretching steps. Control group received a usual care guidance without particular exercises included.

Karsten et al., 2022 (84): The aim of this study was to assess swallowing, mouth opening and speech function during the first year after radiation-based treatment (RT) after introduction of a dedicated preventive rehabilitation program for stage III-IV oropharyngeal carcinoma (OPC) (84). Participants were asked to perform a preventive rehabilitation program from start of RT up until at least 3 months after treatment. The protocol consisted of a set of exercises three times a day: range-of-motion (stretch exercise with TheraBite®) and three muscle strengthening exercises. No data on adherence to the protocol was collected. MIO was measured in millimeters using the TheraBite® ROM scale. Trismus, speech problems, and swallowing function first deteriorated up to six months, and subsequently improved up to 12 months but did not return to baseline levels. 25%, 20% and 58% of patients with objective dysphagia, trismus, and speech problems, respectively, showing that despite preventive measures, functional limitations are still a prevalent problem in this cohort.

Charters et al., 2022 (94): In a systematic review, efficacy (MIO and patient reported outcome results) of different trismus therapy devices, adverse events, consumer experience and cost of the different devices were compared (94). Out of 32 included studies, 5 used devices in a preventive manner, whereas the remaining 27 studies used devices in the context of established trismus. The trismus devices showed improved MIO in 23 of the rehabilitation programs, whereas MIO improvement was not observed in the prevention studies. The TheraBite® was the most common trismus device, with a mean increase in MIO of 10.0 mm and a cost of $499 AUD. Adverse events reported from the use of trismus devices included mandibular and molar fractures.

Although efficient in improving MIO of patients with established trismus, the role of trismus devices in preventing trismus during radiotherapy remained unproven. For HNC patients in particular, poor adherence to treatment regimens paired with barriers such as cost of device, pain, and safety concerns indicated that more work is required to understand how to optimize trismus rehabilitation and prevention (94).

Wang et al., 2022 (85): A meta-analysis by Wang et al. was presented in 2022 with the purpose of investigating prophylactic exercise interventions for preventing trismus and difficulty in mouth opening in HNC patients (85). In total, 11 randomized controlled trials (n=805) covering interventions, including usual care, exercise alone, a combination of exercise and instrument (e.g. TheraBite®, Dynasplint, or similar) exercise with phone call follow-ups, and tri-integrated intervention strategy (exercise, instrument, and phone call follow up) were included in the meta-analysis. The authors conclude that preventive exercise may effectively preserve mouth opening both in the short- and long-term and reduce trismus in patients undergoing HNC treatments. The most efficient way of doing this

would be through a strategy combining exercise and instruments with phone call follow-ups. The main study limitation was that eligible RCTs did not report findings by cancer site or stage. It would be desirable to be able to distinguish effects of treatment strategies on different cancer sites.

TheraBite® and prevention of swallowing problems

Burkhead et al., 2007 (81): As demonstrated by Burkhead et al., the TheraBite® can be used to perform the Open Swallow Exercise (81). This exercise is conducted using the TheraBite® to maintain a mouth opening of 50% of the maximum interincisal opening while swallowing with the tip of the tongue positioned upwards. Research using sEMG has shown that in healthy individuals, the Open Swallow Exercise generates higher activity in the suprahyoid muscles that are important for laryngeal elevation.

Van der Molen et al. (2011) (1): Since laryngeal elevation is often found to be affected by radiation treatment in HNC patients (95), the Open Swallow Exercise was used by Van der Molen et al. in the preventive rehabilitation program as an exercise to prevent post-treatment swallowing problems (1). Patients were instructed to place the mouthpiece between their teeth and slowly squeeze the TheraBite® until the mouth was opened at 50% of the maximum mouth opening. Then patients were instructed to put their tongue as far as possible up and forwards and then to swallow. This exercise was performed three times per day and repeated ten times. The regular exercise group performed 'conventional' swallowing exercises three times per day (gargling for 10 seconds, repeated three times; effortful swallow (96), Masako maneuver (97), and the Mendelssohn Maneuver five times each). Ten weeks post treatment the group of patients that had performed the Open Swallow Exercise with the TheraBite® device showed significantly less residue after swallowing on videofluoroscopy (1).

3.3 TheraBite® treatment regimens

The TheraBite® Jaw Rehabilitation System™ is based on the principle of passive motion. One of the hypothesized benefits of the TheraBite® System is that it not only stretches the connective tissue that causes trismus but also allows for proper mobilization of the temporomandibular joint, thus addressing a secondary cause of pain and tightness (50).

Figure 9. Use of the TheraBite® Jaw Rehabilitation System™, red arrows visualize jaw motion exerted by the pressure applied on the lever.

A treatment program with TheraBite® should be chosen according to the medical condition of the patient and the underlying etiology. The device can be used to reduce already existing trismus or in preventive rehabilitation to reduce effects of trismus by using it during (chemo)radiation treatment. Increased pain during exercise should be avoided as it can result in muscle guarding that may impair the effectiveness of the therapy and reduce compliance.

Based on literature (98-105), two treatment programs are the most commonly used with TheraBite®: the '7-7-7' program and the '5-5-30' program.

The commonly used treatment program for persons with limited mobility of the temporomandibular joint is '7-7-7'; 7 stretches performed 7 times per day, each stretch held for 7 seconds. Although repetition is central, this program takes no more than 10 minutes per day.

An example of a treatment program, more suitable for patients with trismus caused by radiation induced fibrosis or surgical scarring of soft tissues, features longer stretches in a sequence of '5-5-30': 5 stretches performed 5 times per day or more, each stretch held for 30 seconds.

4. TheraBite® Range of Motion Scale

The TheraBite® Range of Motion (ROM) scale, Figure 10, is a disposable scale used to measure and monitor progress of exercise, measured either by the treating clinician or the patients themselves. Below we present a series of publications in which the ROM scale has been used, with one study showing data that the ROM scale is a more reliable and reproducible measurement tool than a digital calliper (106).

Figure 10.
TheraBite® Range of Motion scale in use.

Kraaijenga et al., 2019 (107): evaluated the relationship between trismus and dose-effect of radiation therapy in 83 HNC patients. Maximum interincisal opening (MIO) was measured using the TheraBite® range of motion scale pre- and at 3-months post-radiation therapy. At follow-up, 17% of patients had developed trismus. The median MIO was 46 mm (range 36-69 mm) at baseline and decreased to 43 mm (21-65 mm) post-treatment. Authors found that both baseline MIO and radiation dose level to the ipsilateral masseter muscle (iMM) and/or ipsilateral media pterygoid muscle (iMPM) were significant associated with trismus development. The authors concluded that baseline MIO measurement is highly predictive and clinically relevant for exploring dose-effective relationships of trismus development.

Sandler et al., 2019 (108): In a study by Sandler et al., the TheraBite® ROM scale was used to measure jaw ROM in a pilot study investigating the effects of early vs. late jaw exercise intervention on postoperative jaw opening and QOL measures (108). The study found that timing of jaw exercise had no significant impact on jaw opening, although greater jaw opening was significantly associated with improved QOL.

Kumari et al., 2019 (109): In a 2019 study, MIO in children aged 4 to 15 years (n=602) was studied (109). MIO gradually increased with age in both genders and was strongly correlated with height and weight. The TheraBite® ROM scale was used for determining MIO.

Karsten et al., 2020 (89): In a 10-year follow-up of an RCT comparing preventive swallowing, with and without the TheraBite®, in HNC patients treated with chemoradiotherapy, trismus-related outcomes (MIO) were measured using the TheraBite® Jaw Range of Motion Scale with a mouth opening of 35 mm or smaller as a criterion for trismus (89).

Lloyd Morris et al., 2020 (74): Lloyd Morris et al., studied the effects of TheraBite® use on TMD ROM for people with Duchenne muscular dystrophy (DMD) and spinal muscular atrophy (SMA) (74). Measurements of Active ROM (AROM) were done using the TheraBite® ROM scale, whereas Passive ROM (PROM) was measured with the scale on the TheraBite® Jaw Mobilizer.

Cuellar et al., 2020 (110): A study by Cuellar et al. presented an adapted clinically relevant protocol that may be used to track physiological changes in lingual and jaw musculature over time in individuals with dysphagia due to neurodegenerative diseases (110). The protocol uses the TheraBite® ROM scale to obtain lingual and jaw ROM values.

Van Hinte et al., 2020 (106): A study conducted by van Hinte et al. aimed to test-retest reliability of measurement on MMO, shoulder and neck function, lower and upper body strength, level of mobility, and walking ability on HNC survivors (106). MMO was measured intra- and extra orally using the TheraBite® ROM scale and a calibrated digital caliper, respectively. MMO showed no significant difference between the cardboard ruler and the digital caliper at the test measurement ($p = 0.08$), but MMO measured using the digital caliper was significantly larger (10.1%) at the retest measurement compared to the card ruler ($p<0.001$), indicating higher inter-measure reliability with the TheraBite® ROM scale.

Wang et al., 2022 (85): In a retrospective case series conducted between 2016 and 2020, 49 HNC survivors suffering from radiation-associated trismus received manual therapy (MT) targeting the muscle of mastication (85). Study results suggest that MT improved MIO with a medium to large effect size in HNC survivors. The TheraBite® ROM scale was used to measure MIO in study subjects.

5. Summary and Conclusions

The TheraBite® Jaw Motion Rehabilitation System™ and its accessories can be used to increase mouth opening and improve jaw mobility in patients with trismus.

Trismus may lead to several complaints that affect quality of life in a negative way. Examples of such complaints are problems with eating, drinking, chewing, oral hygiene, endotracheal intubation, oral inspection, and speaking. The TheraBite® Jaw Motion Rehabilitation System™ is based on passive motion and has been shown to be effective in the treatment of trismus after radiation therapy, in patients with trismus and/or pain due to temporomandibular disorders, and in patients after temporomandibular joint surgery.

Several studies consistently show a good performance of the TheraBite® System leading to increased mouth opening and often also reduced pain, which in turn can be expected to reduce related complaints and improve quality of life. They also point to the importance of a structured exercise regime with the TheraBite® to be beneficial, regardless of time since oncologic treatment.

More recently, studies are focusing on the prevention of trismus and chewing problems, rather than only treating once diagnosis of trismus is established. Although prevention of trismus has not been confirmed, clinical data shows that the TheraBite® can be efficiently used in a preventive rehabilitation program to reduce the effects of trismus and swallowing problems in patients with head and neck cancer undergoing (chemo)radiotherapy. The key to stable and long-lasting effects of jaw mobility exercise are high compliance to exercise and to start as early as possible, in parallel or right after (chemo)radiotherapy.

The TheraBite® Range of Motion Scale has been shown to be an efficient and reliable tool to measure mouth opening in several patient groups. It is a tool that does not need calibration to be used, improving reliability between measurements regardless of when and who performs the measurement.

The TheraBite® ActiveBand™ specifically trains the muscle group needed to generate the chewing forces. It gives patients with chewing problems the ability to start the training at a low level and gradually increase and will provide a type of exercise that is close to the functional act of chewing.

In conclusion, the TheraBite® Jaw Motion Rehabilitation System and the TheraBite® Jaw Mobilizer is clinically proven to be effective in treating trismus and offers a home rehabilitation program, encouraging continuity and compliance.

Although there is no consensus in the literature on the optimal jaw stretching device or rehabilitation program for prevention of trismus, early intervention and adherence to exercise routine is essential for long-term effects on mouth opening.

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Appendix 1 - Overview of newly added publications

The latest update of this Literature Review was in 2019. For the current version, the newly added publications are listed in Table 3 below.

Table 3. List of publications added to the current version of this Literature Review.

Authors	Title	Product	Comment
Kumari et al., 2019 (109)	The normal range of maximal incisal opening in pediatric population and its association with physical variables	ROM scale	Observational prospective cohort study
Sandler et al., 2019 (108)	Effects of jaw exercise intervention timing on outcomes following oral and oropharyngeal cancer surgery: Pilot study	ROM scale	Prospective pilot study
Ezzat et al., 2021 (37)	The role of exercise therapy in managing post-radiotherapy trismus in head and neck cancer	TheraBite® Jaw Mobilizer, ROM scale	Trismus rehabilitation, case report
Montalvo et al., 2020 (56)	Impact of exercise with TheraBite® device on trismus and health-related quality of life: A prospective study	TheraBite® Jaw Mobilizer	Trismus rehabilitation, prospective study
Shao et al., 2020 (86)	Exercise therapy for cancer treatment-induced trismus in patients with head and neck cancer: A systematic review and meta-analysis of randomized controlled trials	TheraBite® Jaw Mobilizer	Trismus rehabilitation, systematic review/meta-analysis
Lloyd Morris et al., 2020 (74)	Improving Temporomandibular Range of Motion in People With Duchenne Muscular Dystrophy and Spinal Muscular Atrophy	TheraBite® Jaw Mobilizer, ROM scale	Rehabilitation of improved ROM, case series
Reed et al., 2020 (65)	Dental management of scleroderma patients using pentoxifylline plus vitamin E with and without TheraBite(®) to reduce trismus: Two case reports and brief review of literature	TheraBite® Jaw Mobilizer	Trismus rehabilitation, case series

Karsten et al., 2020 (89)	Long-term swallowing, trismus, and speech outcomes after combined chemoradiotherapy and preventive rehabilitation for head and neck cancer	TheraBite® Jaw Mobilizer, ROM scale	Trismus prevention and rehabilitation, prospective study
Van der Geer et al., 2020 (43)	The use of stretching devices for treatment of trismus in head and neck cancer patients: a randomized controlled trial	TheraBite® Jaw Mobilizer	Trismus rehabilitation, randomized controlled trial
Bragante et al., 2020 (58)	Efficacy of exercise therapy during radiotherapy to prevent reduction in mouth opening in patients with head and neck cancer: A randomized controlled trial	TheraBite® Jaw Mobilizer	Trismus prevention, case study
Van Hinte et al., 2020 (106)	Reproducibility of measurements on physical performance in head and neck cancer survivors; measurements on maximum mouth opening, shoulder and neck function, upper and lower body strength, level of physical mobility, and walking ability	ROM scale	Reproducibility measurements on physical performance in HNC survivors
Cuellar & Oommen, 2021 (110)	Objective physiological measures of lingual and jaw function in healthy individuals and individuals with dysphagia due to neurodegenerative diseases	ROM scale	Dysphagia treatment and jaw movement, clinical protocol
Warwas et al., 2021 (78)	Trismus Due to Hyperplastic Coronoid Process: Series of Five Cases and Review of Literature	TheraBite® Jaw Mobilizer	MIO rehabilitation, Case series
Chee et al., 2021 (47)	Interventions for Trismus in Head and Neck Cancer Patients: A Systematic Review of Randomized Controlled Trials	TheraBite® Jaw Mobilizer	Trismus rehabilitation, systematic review

Sydow et al., 2021 (75)	A mixed method study exploring patient satisfaction and feasibility of two exercise programmes in systemic sclerosis-associated microstomia	TheraBite® Jaw Mobilizer	Trismus rehabilitation, randomized clinical trial
Karlsson et al., 2021 (93)	Jaw exercise therapy for the treatment of trismus in head and neck Cancer: a prospective three-year follow-up study	TheraBite® Jaw Mobilizer	Trismus rehabilitation and prevention, prospective study
Aryanpour et al., 2022 (79)	Mandibular Myofibroma and Severe Trismus: A Complex Case and Review of Complications	TheraBite® Jaw Mobilizer	Pediatric trismus rehabilitation, case report
Wang et al., 2022 (85)	Exercise for Trismus Prevention in Patients with Head and Neck Cancer: A Network Meta-Analysis of Randomized Controlled Trials	TheraBite® Jaw Mobilizer	Trismus prevention, meta-analysis
McMillan et al., 2022 (111)	Manual Therapy for Patients With Radiation-Associated Trismus After Head and Neck Cancer	ROM scale	Trismus rehabilitation, retrospective case series
Chambers et al., 2022 (94)	Trismus therapy devices: A systematic review	TheraBite® Jaw Mobilizer	Trismus prevention and rehabilitation, literature review
Yim et al., 2022 (66)	Treatment of Temporomandibular Joint Heterotopic Ossification: A Novel Protocol With Multimodal Therapy Based on Literature Review and Presentation of a Unique Case Report	TheraBite® Jaw Mobilizer	TMJ heterotopic ossification protocol
Karsten et al., 2022 (84)	Dysphagia, trismus and speech impairment following radiation-based treatment for advanced stage oropharyngeal carcinoma: a one-year prospective evaluation	TheraBite® Jaw Mobilizer	Trismus prevention, prospective study/Literature review

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