Atos Medical
Your voice

TheraBite® Literature Review

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1. Introduction

This literature review concerns the TheraBite® Jaw Motion Rehabilitation System™ and the TheraBite® ActiveBand™, manufactured by Atos Medical AB. The objective of this literature review is to provide an overview of clinical data relevant to the safety and performance of these products.

The TheraBite® Jaw Motion Rehabilitation System™ is a portable system which 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. Patients suffering from trismus can be found within many clinical disciplines, including speech and language pathology, radiation oncology, maxillofacial surgery and prosthodontics, otolaryngology, physical therapy, and dental surgery.

The TheraBite ActiveBand forms an addition to the TheraBite device. When the TheraBite ActiveBand is used together with the TheraBite system, it provides resistance to mouth closure. The intended use of the device is to increase muscle strength and endurance of the muscles of mastication (masseter muscle, temporalis muscle, medial and lateral pterygoid muscle). The active exercise can be used as a stand-alone treatment method, e.g. in patients compromised by cerebral lesions after stroke or painful neuromuscular disorders. Also it can be used as a complement to passive motion exercise, e.g. by patients with trismus.

Both products, the TheraBite® Jaw Motion Rehabilitation System™ and the TheraBite® ActiveBand™ will be discussed separately below.

2. Description of the Devices

2.1 TheraBite® Jaw Motion Rehabilitation System™

The TheraBite Jaw Motion Rehabilitation System is a hand operated system with adjustable range that is designed to assist users to improve the range of motion and strength of the jaw. The jaw mobilizer is held in the hand during use, with the mouthpieces placed between the upper and lower teeth. Pressure on the lever, applied by the user, provides either opening force (stretching) or resistance to closing. The TheraBite utilizes repetitive passive motion and stretching. The TheraBite Jaw Motion Rehabilitation System consists of a TheraBite Jaw Mobilizer, bite pads, range of motion scales, a patient progress log and a hand-aid.

2.1.1 TheraBite® Jaw Mobilizer

The TheraBite Jaw Mobilizer (Figure 1) utilizes repetitive passive motion and stretching to restore mobility and flexibility of the jaw musculature, associated joints, and connective tissues. The TheraBite is the only device available which provides patients with anatomically correct jaw motion. It also helps reduce patients' anxiety by allowing them to control the extent and length of each stretch. While conventional therapies offer mostly stretching to increase jaw opening, the TheraBite provides both anatomically correct stretching and passive motion for effective jaw rehabilitation therapy. The device is available in an Adult and a Pediatric version.

Figure 1 TheraBite® Jaw Mobilizer

The TheraBite is clinically proven to be more effective than exercises and tongue depressors. Since it is hand-operated, the TheraBite avoids the cost and complexity of continuous passive motion (CPM) devices. Jaw rehabilitation exercises are effective when they are carried out daily on a continual basis. The TheraBite offers a home rehabilitation program that encourages continuity and compliance, hence allowing patients to reap the full beneficial value wherever they are.

2.1.2. Bite pads

The Bite Pads are available in three versions, Regular, Edentulous (toothless) and Pediatric (Figure 2). The self-adhesive pads are attached on the mouth piece to protect the teeth during exercise.

Figure 2 Bite Pad Standard to the left, Edentoulous in the middle and Pediatric to the right

2.1.3 Range of Motion Scales

The disposable Range of Motion Scales is used to measure and monitor progress of the exercise, by the user or his/ her clinician.

Figure 3 Range of Motion Scale (RAM)

2.1.4 Patient Progress Log

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

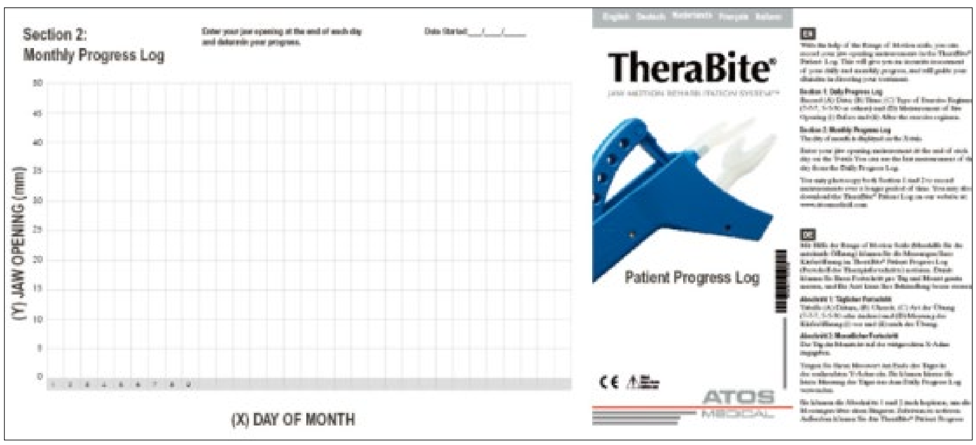

Figure 4 Patient Progress Log

2.1.5 Hand-Aid

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

Figure 5 Hand-Aid

2.2 TheraBite® ActiveBand™

The TheraBite ActiveBand forms an addition to the TheraBite device. The TheraBite ActiveBand is a silicone rubber band that can be used together with the TheraBite system. The TheraBite jaw mobilization system is an established device for passive range of motion exercises used in patients with hypo mobility of the jaw (also referred to as trismus). When the TheraBite ActiveBand is used together with the TheraBite system, it provides resistance to mouth closure. The intended use of the device is to increase muscle strength and endurance of the muscles of mastication (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™

3. TheraBite® Jaw Motion Rehabilitation System™

The TheraBite® Jaw Motion Rehabilitation System™ is a portable system specifically designed to treat trismus and mandibular hypomobility. In this section, first trismus will be described. Thereafter evidence for use of TheraBite as a treatment of trismus as well as a trismus prevention device will be presented.

3.1 Trismus

3.1.1 Definition

Trismus is defined as a tonic contraction of the muscles of mastication and results in a limited ability to open the mouth[1].

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[1, 2]. Evidence suggests that gender may be a factor in vertical mandibular opening and in general, males display greater mouth opening[3]. 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[4]. This ranges from less than 18 mm, less than less 30 mm[5], less than 35 mm[1, 6, 7], to less than 40 mm[8]. However, authors conclude after analyzing existing publications, that a cut-off point of a jaw opening of 35 mm or less, is a clinically meaningful definition of trismus[4]. The cut-off point of 35 mm is also used in studies published by van der Molen et al[9, 10]. The cut-off point has further been verified in a large cross-sectional study by van der Geer et al[11]. (2018). The authors confirmed the cut-off point of 35mm or less in the total head and neck cancer population consisting of 671 patients.

3.1.2 Consequences of trismus

Trismus affects many important aspects of daily life, such as chewing, diet normalcy, overall quality of life, difficulty eating, pain, altered facial appearance, speech difficulties, inability to practice effective oral hygiene, and inability to receive proper dental care[12]. Recent studies using the European Organization for Research and Treatment of Cancer quality of life questionnaire (Head and Neck module; EORTC QLQ-H&N35) have demonstrated a poorer quality of life in patients who responded to the single item of mouth opening[13]. This finding was mirrored in a study reporting on the quality of life of 133 head and neck cancer patients[14].

Horst[15] (1994) described that the effects of trismus include impaired nutrition, oral hygiene and lifestyle. Other authors also associate trismus with important aspects of daily life, such as chewing, diet normalcy, overall quality of life, difficulty eating, pain, altered facial appearance, speech difficulties, inability to practice effective oral hygiene, and inability to receive proper dental care[4, 12, 16-18]. In a longitudinal study of 87 head and neck 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[19].

Quality of life has further been investigated in a study performed by Lee et al. (2015)[20] Demographic data and disease/treatment information from 104 participating head and neck cancer patients were analyzed in the study. The authors found significant associations of trismus with lower body mass index, chemoradiotherapy treatment, longer time since treatment completion, and higher radiation doses. Kondo et al.[21] (2018) reported rehabilitation of trismus as a promising factor to improve functional performance.

3.1.3 Etiology of trismus

Several conditions may cause or predispose an individual to develop trismus. Trismus is frequently observed in head and neck cancer patients and postsurgical patients, but can also be found in patients with other underlying pathologies[15].

The etiology of trismus may be classified as follows: intra-articular or extra-articular (infection, trauma, dental treatment, temporomandibular joint disorders, tumors and oral care, drugs, radiotherapy and chemotherapy, congenital problems and miscellaneous disorders)[3]. These different etiologies are summarized in Figure 7.

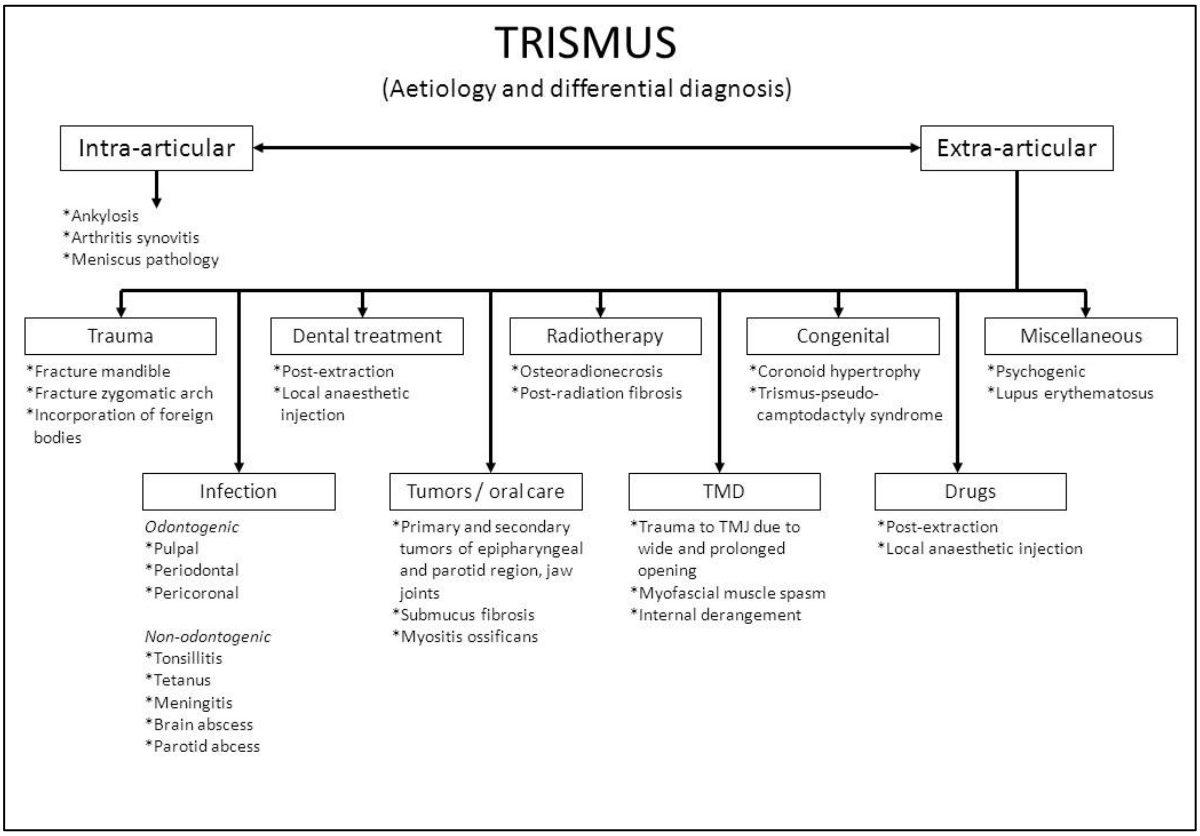

Figure 7. ***Etiology and differential diagnosis of trismus (adapted from Dhanrajani[3])***

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.

3.1.4 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 anaesthesia and performance of a dental procedure such as difficult extractions or other treatment requiring lengthy appointments[12]. 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[3].

Malkawi et al.[22] 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.

3.1.5 Incidence of trismus in patients with head and neck cancer

In about 2% of the H&N cancer patients it is present as a symptom at the time of diagnosis, being caused by tumor invasion of the muscles of mastication or because of the tumor inducing a reflex spasm of the muscles[7]. The most common cause of oncology related trismus is radiation-induced fibrosis, while postsurgical scarring may also play a role[23]. The percentages of trismus in H&N cancer patients reported in the literature vary widely. This is most likely due to the different treatment regimens used, the different tumor sites involved, and the different criteria used to define trismus. Some studies have reported that jaw opening decreases as the radiation dose to the temporomandibular joint and the pterygoid muscles increases, while others did not find such as relationship[12].

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[18, 24]. 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[25]. The incidence of post-treatment trismus in head and neck cancer patients in a study in Swedish patients was as high as 42%[12]. Furthermore, it was found that poor physical function before the start of treatment and high tumor EBRT dosages (>50 Gy) were related to a significantly higher incidence of trismus[12]. A recent study by Jeremic et al.[26] (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.

In a study by Weber et al.[27] in 2006 the prevalence of trismus in a population head and neck patients was investigated. The results showed that patients with malignant head-neck tumors are suffering from restrictions in interincisor opening (51%) post radiotherapy and/or radiochemotherapy. The results of this study are presented in Table 1.

Table 1 Frequencies of different types of carcinoma with prevalence of trismus in patients with head and neck cancer.

Diagnosis	Frequency	Prevalence of trismus
Oropharyngeal carcinoma	37%	60%
Laryngeal carcinoma	28%	30%
Hypopharyngeal carcinoma	16%	56%
Nasopharyngeal carcinoma	8%	80%
Thyroid Gland carcinoma	6%	50%
Other	5%	80%
Total	100%	51%

In another study in irradiated head and neck cancer patients, difficulty in chewing or eating was reported by 43% of respondents. Dry mouth was reported by 91.8%, dysphagia by 63.1%, altered speech by 50.8%, difficulty with dentures by 48.5% (patient had problems inserting and taking out dentures), and increased tooth decay by 38.5% of dentate patients. Pain was common (58.4%) and interfered with daily activities in 30.8%. Mood complaints were reported by approximately half the patients. Interference of the physical condition social activities was reported by 60%. The frequency of oral side effects correlated with radiation treatment fields and dose[28].

Following this earlier study, Weber et al.[29] published another study in 2010 on oral complications in patients after surgery and radiation/chemoradiation for treatment of Head and Neck cancer. In this study authors found that about half of the patients who underwent primary treatment for oral and oropharyngeal cancer developed trismus and reported about problems with opening the mouth, eating, drinking, dry mouth, voice, and speech. This study also concluded that trismus has a negative impact on quality of life and should be a focus in the postoperative management of patients with oral and oropharyngeal cancer, and, if diagnosed, special treatment should be initialized.

Lee at al.[19] described in 2001 the incidence of trismus over time, together with risk factors (including quality of life (QoL)) for the prediction of trismus after treatment in patients with cancer of the head and neck in 87 patients prospectively. Their results showed that 41/87 (47%) patients presented with trismus, 57/80 (71%) had postoperative trismus, and 41/52 (79%) had trismus 6 months after operation or radiotherapy (trismus defined as a maximum mouth opening of <=35mm). Quality of Life variables showed that pain, eating, chewing, taste, saliva, social functioning, social contact, and dry mouth were significantly more impaired in the trismus group than among those without trismus. Postoperative differences in QoL between the two groups highlighted problems with social function and role-playing, fatigue, activity, recreation, and overall reduction in QoL.

In a prospective longitudinal cohort study by van der Geer et al[30] (2016) potential predictors for trismus were analyzed using a multivariable logistic regression analysis. The incidence of trismus was highest six months after radiotherapy and declined thereafter. Patients with tumors located in the oral cavity, oropharynx or nasopharynx, and the salivary glands or ear, and who had a longer overall treatment time of radiotherapy, were more likely to develop trismus in the first six months after radiotherapy. Maximal mouth opening was a significant predictor for developing trismus at all time points. Based on the 48 months of follow-up, the authors could determine the incidence rate of trismus to 3.6 per 10 person years at risk.

In a later study, van der Geer et al[31]. (2018) determined the prevalence of trismus in 730 head and neck cancer patients. The prevalence was 23.6%. Factors found associated with trismus were: older age; partial or full dentition; tumors located at the maxilla, mandible, cheek, major salivary glands or oropharynx; unknown primary tumor; a free soft tissue transfer after surgery; repeated irradiation; and chemotherapy. Based on the large study population consisting of patients with a variety of tumor and treatment characteristics, the authors developed a risk calculation tool to predict the risk for future patients. The authors further concluded that about one-fourth of patients with head and neck cancer will develop trismus.

Pantvaidya et al[32]. (2018) studied the prevalence of trismus in a large homogenous cohort of patients with oral cancer. Trismus was found in 72.8% of the 401 enrolled patients. Postoperative radiotherapy and preexisting submucous fibrosis were found to be significant risk factors for the development of trismus.

3.2 TheraBite, passive motion and trismus

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

3.2.1 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.

In a systematic review Dijkstra et al.[1] analyzed existing publications on the outcomes of treatment of trismus in head and neck oncology. 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.[33] also analyzed in another, retrospective study the effects of exercise therapy on trismus related to head and neck cancer or as a consequence of its treatment, and compared these effects with trismus not related to head and neck cancer. Medical records of patients were retrieved and data of 27 patients with trismus related to head and neck cancer 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 head and neck cancer 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.

In a randomized controlled study Buchbinder et al.[34] looked at a population of radiated patients who had developed trismus. 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 significant faster and the patient group was also more compliant.

Karlis & Glickman[35] investigated mouth opening of persons suffering from limited jaw motion as a result of radiation-induced trismus. 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".

In two smaller, non-randomized, studies Melchers et al.[36] and Cohen et al.[6] also describe the positive effects of TheraBite on trismus after head and neck cancer. Melchers et al. studied therapy adherence in patients 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. [37] conclude in a study in 2009 that early identification and intervention with TheraBite should be considered as an integral component of the patients cancer treatment program

Kamstra et al.[38] evaluated the effects of TheraBite in 69 head-and-neck 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. This latter finding supports the recommendations from the study published by Messing et al[37].

In a review on trismus induced by cancer therapies in head and neck cancer patients, Bensadoun et al.[39] 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. 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[39].

Tang et al.[40]. studied the effects of exercises with TheraBite on the progress of trismus in 43 patients shortly after treatment with radiotherapy for nasopharyngeal carcinoma and concluded that rehabilitation training, with TheraBite, can slow down the progress of trismus in these patients following radiotherapy-

In an article by Treister et al.[41] 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.

Recently, Pauli et al.[42] (2014) compared jaw exercise with the TheraBite to the Engstrom jaw device in 50 patients with head and neck cancer. Trismus after head and neck cancer is a symptom associated with pain and negatively affected health-related quality of life. The purpose of this study was to compare two different jaw exercise devices and the compliance to exercise. After 10 weeks, the mouth opening had improved in both groups: 7.2 mm for the TheraBite and 5.5 mm for the Engstrom. 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.

In another review on head and neck cancer patients, the effect of exercise therapy on radiotherapy-induced trismus was evaluated. Scherpenhuizen et al. 2015[43] noted a positive effect of exercise therapy with TheraBite, that yields better results than no exercise.

Similar results were seen in a prospective study by Montalvo et al. (2017)[44]. The impact of exercise with TheraBite was investigated in 15 patients with trismus secondary to head and neck cancer treatment. Although time since oncologic treatment was on average 6.2 years, a statistically significant improvement of maximum interincisal opening (MIO) was observed in 93% of the patients (14/15) after 10 weeks of TheraBite exercise. Persisting improvement could further be seen for self-reported trismus-related symptoms and health-related quality of life after 6 months of follow-up.

Pauli et al. investigated the long-term effects of structured trismus exercise in a two-year follow-up intervention with 44 patients[45]. Study participants were all head and neck cancer 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[45].

In a randomized feasibility study by Lee et al[46] the efficacy of TheraBite was compared with that of the current standard treatment with wooden spatulas to relieve or treat trismus. All enrolled patients had some sense of jaw tightening and received radiotherapy for stage three and four 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.

Kraaijenga et al.[47] evaluated the relationship between trismus and dose-effect of radiation therapy in 83 head and neck cancer 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.

3.2.2 Temporomandibular disorders

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. The study of passive motion of the jaw took off seriously with the work of Sebastian and Moffett in 1989[48]. In this article, authors conclude 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[48].

Nicolakis et al.[49] article also finds that exercise does seem to improve function and reduce pain. The study shows that such benefits are to be expected if passive (as contrasted to active) motion is utilized more frequently. Salter and colleagues[50] undertook a series of studies exploring various aspects of passive motion in animal models and humans[51-53]. 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[50]. 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.

Gassner et al.[54] 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[35] and Maloney et al.[55]

In a randomized controlled study, Maloney et al.[55] published in 2002 their findings on closed lock patients given an exercise regime of passive motion. 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[56] in 2002 sent a letter to the editor[56], 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 pain, and conversely.

Robbins [57] 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.

In a randomized pilot study presented at the Annual meeting of the American Association of Oral And Maxillofacial Surgeons, Karlis & Glickman[58] 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. 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.

Recently, Kraaijenga et. al.[59] (2014) 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 temporomandibular disorder (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.

In a randomized controlled trial Heres Diddens et. al[60](2016) studied 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 patient 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.

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 (Gassner et al.[54]) and may be caused by lack of motion (Robbins[57]). Hence, passive motion seems a good starting point in the treatment of this condition. Maloney et al,[55] and Karlis & Glickman[58] offer evidence that the passive motion provided by the TheraBite offers considerable benefit.

3.2.3 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[61]. Passive motion is thus used as a post-operative treatment after temporomandibular joint surgery.

Kaban et al.[62] evaluated the effects of a management protocol for temporomandibular joint (TMJ) ankylosis (stiffness of the joint). This protocol consisted of surgery, early mobilization 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.

These findings are supported by other publications. In an evaluation of 11 years' clinical experience, Zhi et al.[63] conclude that early postoperative exercises, appropriate physiotherapy, and close follow-up play an important role in the prevention of recurrence. Moreover, Gundlach[64] describes the outcomes of 40 patients undergoing treatment for ankylosis and also concludes that postoperative physical therapy is the second most important part for every type of treatment for ankylosis.

In a single-blinded randomized controlled trial by Schiffman et al.[65], 106 individuals with TMJ closed lock were randomized among medical management, rehabilitation, arthroscopic surgery with post-operative rehabilitation, or arthroplasty with post-operative rehabilitation. The findings of this study suggest that primary treatment for individuals with TMJ closed lock should consist of medical management or rehabilitation. The authors also stress that use of this approach could also avoid unnecessary surgical procedures[65].

Stack et al.[66] 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.[65]

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[36].

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 prevent trismus by using it during (chemo)radiation treatment, or to reduce already existing trismus. A typical patient with existing trismus will gain from 1-4 mm of jaw opening ability in the first session; however, this gain is likely to be lost within the next few hours. Only by continuing to stretch and mobilize the jaw for several sessions per day can any lasting benefit be achieved. Increased pain during the exercises should be avoided; as it can result in muscle guarding that may impair the effectiveness of the therapy and reduce compliance. The average sustainable gain is around 1 – 1.5 mm per week. The number of daily exercise sessions with the TheraBite system typically decreases over time. Ultimately, many patients are usually able to maintain the gain they have achieved by using the device just once or twice a day.

Based on literature[67-74], but merely on clinical experience two treatment programs are 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.

Regular monitoring, review, and evaluation by a properly trained clinician are essential for all treatment programs. Depending on a patient's condition and the judgment of his/her clinician, the type of program required may be modified over time.

3.4 Preventive rehabilitation including the TheraBite

In addition to being used as a rehabilitation device for treating existing trismus in head and neck 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[9, 10, 41, 75, 76] and in studies utilizing the device to perform the so-called Open Swallow Exercise[9, 75-78].

3.4.1 TheraBite and trismus prevention

Messing et al.[37] 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.[75] studied a total of 58 head-and-neck cancer 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[40].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.[9] 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 three times a day performing 3 stretches of 30 seconds. The other therapy group 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[9]. 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.[79]) showed that after the first year post-treatment many initial tumor- and treatment-related problems diminished significantly, except xerostomia (59 %).

Tang et al.[40] 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 IID 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).

A recently published Multidisciplinary Care Guideline for Head and Neck Cancer, included the TheraBite device as an integral part of the preventive exercise program[80] and a paper on dental management also mentioned the importance of trismus prevention[23].

In a systematic review, Rapidis et al. 2015[81] 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. 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.[81], it is important to determine whether the 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[82], 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.

In a systematic review by Kamstra et al. (2016)[83], exercise therapy for trismus secondary to head and neck cancer, including TheraBite, was reviewed in 20 studies investigating either prevention therapy (8) or therapeutic treatment (12). 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.

3.4.2 TheraBite and the Open Swallow Exercise

As demonstrated by Burkhead et al.[76] the TheraBite can be used to perform the Open Swallow Exercise. 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.

Since laryngeal elevation is often found to be affected by radiation treatment in head and neck cancer patients[84], the Open Swallow Exercise was used by Van der Molen et al.[9] in the preventive rehabilitation program as an exercise to prevent post-treatment swallowing problems. 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[85], Masako maneuver[86], 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[9].

4. TheraBite® ActiveBand™

This literature review intends to provide support for the use of resistance training to improve muscle strength and endurance in general, support for the use of resistive training in the chewing muscles, support for the prescribed exercise regimen, and information about possible problems that the patient could experience.

Areas of interest that were included in the search were morphology and physiology of the muscles of mastication in relation to limb and trunk muscles; parameters involved in strength and endurance training; application of those parameters to the muscles of mastication; results of strength and endurance training in limb and trunk muscles; results of strength and endurance training in the muscles of mastication; parameters for normal chewing that should be considered in the composition of the exercise regime; potential negative effects of chewing exercises.

4.1 Terms and Definitions

4.1.1 Motor unit

The motor unit can be considered as the basic unit of motor activity, since it is the smallest unit that can be recruited and controlled by the central nervous system. It consists of a motor neuron and a set of muscle fibers innervated by this neuron. Most muscles possess several hundred motor units. Motor units show a large variability in morphological and physiological characteristics which result in a wide range of properties with respect to, for example, force output, contraction speed, and fatigability.

4.1.2 Muscle fibers

Not all muscle fibers are the same; the different types are Type I, IIA, IIx, and IIb. This typing is based on the type of Myosin Heavy Chain (MYHC) present in the fiber. Type one has the lowest contraction velocity and the lowest fatigability, Type IIb has the highest contraction velocity and highest fatigability. Muscle fibers have the ability to adapt. For example, during exercise against resistance, the amount of type IIa fibers reduces in favor of the slower types and disuse of the muscle causes type I fibers to convert into type IIa. Some fibers are hybrid, which means they contain two or more types of the MYHC. Hybrid fibers are not seen very often in the limb and trunk muscles, but their presence is remarkable in the chewing muscles.

4.2 Masticatory muscles

The tasks of the jaw muscles are mastication, biting, speech, and swallowing. For all of these tasks it is necessary to control the position of the mandible and apply forces. A variety of forces is needed at a variety of speeds. Because of the different nature of these tasks, the architecture of the jaw muscles is complex and the composition of the fibers (see 4 Terms and Definitions) is heterogenous[87]. The fibers of the jaw closers differ from those of the jaw openers. The jaw closers consist for 70% of type I fibers (slow) and 30% type IIa fibers (fast), the proportion of type I fibers in the jaw closers is higher because of the high daily duty time, keeping the jaw closed against gravity, and the amount of stretch[88]. The properties of masticatory muscle motor units are not exactly the same as those for the limb and trunk muscles. Van Eijden and Turkawski (2001)[89] provide a good literature review of research in the area of morphology and physiology of masticatory muscle motor units (see 4 Terms and Definitions). In general, the masticatory muscle motor units display a continuous range of contraction speeds. Hence, in masticatory muscles a finer gradation of force and contraction speeds is possible than in the limb or trunk muscles. The proportion of slow-type motor units is relatively large in the deep and anterior masticatory muscle regions and more fast-type units are more common in the superficial and posterior muscle regions. Muscle portions with a high proportion of slow-type motor units are better equipped for finer control of muscle force and a larger resistance to fatigue during chewing and biting than muscle portions with a high proportion of fast units. The presence of localized motor unit territories and task-specific motor unit activity facilitates differential control of separate muscle portions. This gives the masticatory muscles the capacity of producing a large diversity of mechanical actions.

4.3 Training parameters

Muscle exercise may be aimed towards strength, speed, endurance, or a combination of these and training methods differ significantly depending on the aim of the exercise[90]. The key factors that drive the adaptations in the neuromuscular system as a response to strength training are intensity, specificity, and transference[91].

4.3.1 Intensity

The intensity of the exercise is determined by the load, volume, and duration.

4.3.2 Load

Most daily functional activities such as for example walking, speaking, swallowing, or chewing do not require the full maximum muscle capacity; they are therefore referred to as sub-maximal. For chewing this means that the maximum bite force (maximum muscle capacity) is much higher than the actual force used during the functional activity of chewing (sub-maximal muscle capacity). However, when a muscle becomes weak and the maximal capacity decreases, the perceived effort at which the functional activities are carried out becomes greater. Attempting to carry out an activity with a muscle that is only functioning for 50% requires a greater percentage of the total force generating capacity of that muscle. This mechanism is described by Buchner and de Lateur[92]; the proportion of the full potential of force-generating capacity of the muscle in relation to the effort required to carry out a functional task is referred to as functional reserve. The smaller the functional reserve, the faster the muscle will fatigue and the greater the perceived effort to perform the task.

Exercise aimed at increasing the strength (force generation capacity) of the muscle (and thereby the functional reserve) require the use of a load that exceeds the demands that the muscle normally encounter (overload principle)[93, 94]. Therefore, the loads used during the exercises usually are progressively adjusted over time, such that the relative physical load in relation to the maximum capacity is maintained (progressive resistance)[93, 94]. Most exercise regimes recommend working with a load of approximately 60% of the single maximum voluntary contraction (60% 1RM)[90, 93, 95]. Loads greater than 60% 1RM are only used for athletes and may do harm[94, 96].

Note: This seems to indicate that for TheraBite ActiveBand it would be recommended to train at 60% (or less) of the Maximum Force needed to close the TheraBite against the resistance of the TheraBite ActiveBand.

4.3.3 Volume

The volume of the exercise is defined by: the number of repetitions in a set, the number of sets per session, the rest period between sets, the number of sessions per day, days per week, and number of weeks. Variations in these parameters may significantly alter the outcome of the training[96]. For example multiple sets usually produce a greater increase in percentage strength gain for a simple exercise than one set[97-100], training for multiple days each week gives better results than fewer days[101].

The number of repetitions significantly affects the outcome. Campos et al.(2002)[102] compared low-repetition exercises (4 sets of a maximum of 3-5 repetitions with 3 minutes rest in between sessions), with medium-repetition exercises (3 sets with a maximum of 9-11 repetitions with 2 minutes rest in between), and high-repetition exercises (2 sets of 20-28 repetitions at maximum with 1 minute rest in between). Their outcomes showed that maximal strength improved significantly more for the Low Rep group compared to the other training groups, and the maximal number of repetitions at 60% 1RM improved the most for the High Rep group. In addition, maximal aerobic power and time to exhaustion significantly increased at the end of the study for only the High Rep group. All three major fiber types (types I, IIA, and IIB) hypertrophied for the Low Rep and Int Rep groups, whereas no significant increases were demonstrated for the High Rep group. If the goal of the exercise is to build strength and endurance 8-12 repetitions per set are usually most effective, while if the goal is to build strength a lower number of repetitions (6-8) provides better outcomes[94, 96].

Apart from the effectiveness of the exercise regimen, the regimen that is chosen may also affect patient compliance[96].

Chewing is a highly repetitive movement. It takes for example an average number of 36 chews in a duration of 24 seconds on average to chew a tender and juicy piece of meat before it can be swallowed, a tough and dry piece of meat requires an average of 45 chews in a duration of 31 seconds on average before it can be swallowed[103].

Note: Based on the available information and the highly repetitive nature of the chewing act, resistance training aimed towards endurance seems to be indicated. Therefore, 5 sets with a high number of repetitions (30) with one-minute rest in between sets are recommended. In speech language pathology it is common to advise 3 exercise sessions a day. Since this also relates to chewing 3 meals a day, the same is recommended for these exercises. Future dose response studies may give more insight in this aspect of the training.

4.3.4 Duration

In addition to the load and the volume of the exercises, the duration for which they are carried out is also of importance. Responses of the muscle and the neural system to resistance exercises are dependent on the length of time the exercise is carried out. The first change occurs after only a short period (~2 weeks): the muscle strength increases as a result of a change in muscle contractile activity[104]. Longer periods of training lead to an actual change in the muscle. Brown et al. (1990)[105] showed that elderly individuals showed muscle hypertrophy and changes in fiber types after a 12 week training program.

Upon commencement of strength training, the larger proportion of the initial strength increment seems to be accounted for by neural factors (changes in the voluntary neural drive of the muscle and manner in which the motor unit is activated) and thereafter both neural factors and hypertrophy (enlargement of the muscle fiber) seem to take part in the further increase in strength, with hypertrophy becoming the dominant factor after the first 3 to 5 weeks[95]. Fiber-type shifts in combination with neural factors, may account for the early changes in strength, before the muscle undergoes hypertrophic changes[90]. The exact length of time it takes for hypertrophy to occur as a response of strength training is not very clear, it can occur as early as 5 weeks into the training program but longer durations are also seen[90, 95, 106]. In addition to the morphological changes in the muscles at the later phases of the resistance training, structural changes have also been observed in the central nervous system[107].

Note: Since changes in the muscle during the exercise period are gradual and different changes are achieved over time, it is recommended to use the TheraBite ActiveBand for 12 weeks. Results may vary from individual to individual and some patients may achieve the required goal within a shorter period of time.

4.3.5 Specificity

Specificity indicates how closely the exercise relates to the functional outcome that is targeted (task specificity). For example, subjects undergoing swim training, demonstrated a training effect in endurance and cardiovascular performance during swimming but not during running[108].

Just targeting towards endurance or strength of a muscle or muscle groups may not be enough to achieve improved performance on a specific task. The closer the task is to the functional outcome (swallow to improve swallowing, walk to improve walking, chew to improve chewing) the better the expected outcome. For example, the greatest strength gains occur at or near the training velocity[109], thus exercises should preferably be carried out the velocity of the functional movement.

In rehabilitation it is not always possible to carry out the functional task as an 'exercise', therefore general strength training of the muscles that are used for the specific functional task often precedes the functional task. For example a progressive 8 week training program of tongue resistance exercises has been found to cause muscle hypertrophy of the tongue and improved swallowing, thus the strength training actually had an impact on the functional task[110].

Specific aspects of chewing that can be targeted are the number of repetitions (see 0), the length of the chewing cycle, the velocity of the jaw movement, and the degree of mouth opening during chewing. The number of repetitions during chewing is high, in young subjects an average of 36 chews is required for tender meat and an average of 45 for tough meat, for elderly subjects the number of chews is even higher: 47 average for tender meat and 57 average for tough meat[103]. Similarly, Peyron et al. (2004)[111] also found that the number of chewing cycles need to chew a variety of food hardnesses increased with age and with food hardness. The length of a chewing cycle averages 689 msec[112]), the opening and closing times have nearly equal durations[113]. The cycle durations do not change with the hardness of the food, but the excursive range (rotation and translation of the jaw) and the velocity increased for harder chewing gum[113]. The degree of jaw opening is highest at the beginning and becomes smaller as the food is chewed more[113].

Maximum jaw opening (interincisal distance) lies around 12 mm for hard foods and 9 mm for soft foods[114]. In a graph by Peyron et al. (2004)[111] showing the vertical jaw movement as a result of food hardness and age, it can be seen that the vertical opening is larger for the harder foods, does not change with age, and lies between 13 and 17 mm for all hardnesses. In addition to the up and down movement, the jaw also moves from the front to back and left to right for several millimeters[114]. Lucas et al. (1986)[115] did find that the number of chewing cycles before the swallow, and the maximum vertical displacement increase with an increase in food weight. For example, 0.5 grams of peanuts takes on average 10.75 chewing cycles at an average vertical displacement of 11 mm, and chewing 8 grams of peanuts takes on average 39.35 chewing cycles and a vertical displacement of 16 mm[115].

Note: Chewing requires good tongue function, check tone, dentition, and good strength and endurance of the muscles of mastication. The TheraBite ActiveBand provides the ability to exercise strength and endurance of the muscles of mastication involved in the vertical movement of the jaw. The exercise with the TheraBite ActiveBand does not resemble normal chewing, but specificity of the exercise can be optimized by performing the exercise at normal chewing velocity, normal chewing cycle duration, and a normal vertical displacement of around 15 mm that feels comfortable to the patient. The TheraBite adjustment knob provides the ability to set the device at the optimal vertical mouth opening to perform the exercise.

4.3.6 Transference

Transference is used as a term to describe the effect of cross-training and non-specific strength training to improve performance in related functional tasks. Research involving this principle shows that practice of specific movement can positively influence performance in functional activities by improving soma sensatory processing and optimizing neuromuscular training patterns. Isolated strength training tasks preceding or in conjunction with the functional task results in greater function outcomes than with the training of the functional task alone[116, 117]. Isolated strength training has been shown to be effective in frail elderly with significant muscle weakness, most possibly due to an increase in physiologic reserve[92].

Note: The TheraBite ActiveBand is a useful exercise tool to increase muscle performance in patients with weakened chewing muscles. If the patient is able to chew safely, it may be advised to chew foods in conjunction with doing the exercises.

4.4 Training effect of exercise in limb and trunk muscles

There are a number of studies available that show that exercise training can improve muscle performance, both in healthy subjects and patients. In patients, for example, high-intensity resistance training improved muscle strength in patients with idiopathic Parkinson's disease[118]; weight lifting training led to significant increases in strength performance and in upper limb muscle hypertrophy in the elderly[105]; a review study considering the elderly concludes that ' the studies reviewed in this article suggest that exercise training in elders is a potential means of reducing the burden of impairments and ultimately improving function'[119]; moderate-intensity strength training leads to a significant gain of strength in post-polio patients[120]; strength training can increase strength and may improve motor activity in people with Cerebral Palsy without adverse effects[121]; low-load resistive muscle training improved functional capacity as reported by rheumatoid arthritis patients (class II and III RA)[122]; another study on the effect of resistance training in rheumatoid arthritis showed that high-intensity strength training is feasible and safe in selected patients with well- controlled RA and leads to significant improvements in strength, pain, and fatigue without exacerbating disease activity or joint pain[123]; a third study on exercise in RA showed that a short term intensive exercise program in active RA is more effective in improving muscle strength than a conservative exercise program and does not have deleterious effects on disease activity[124]; a systematic review on the outcomes of resistance training after stroke concluded that 'There is preliminary evidence that progressive resistance strength training programs reduce musculoskeletal impairment after stroke'[125]; an 8-week progressive resistance program of the lower extremities in MS patients led to increased muscle performance leading to improvements in walking and decreased fatigue[126].

4.5 Training effect of exercise of muscles of mastication

In the literature, some studies are available that study the effect of chewing exercises on the muscle. Those chewing exercises are performed by having the subject chew on a special type of hard chewing gum or other substance for a given amount of time.

Kiliaridis et al. (1995)[127] compared a 'chewing group' with a control group (all healthy subjects). The test group chewed a hard chewing gum for one hour per day for 28 days. Results showed that maximum bit force increased significantly and measures two weeks after the training showed that the effect remained. Subject with weak initial bite force showed the most improvement. Endurance (as determined by the length of time the subject could persist maximal clenching) did not increase. Dysfunction as an effect of fatigue (after 30 minutes of intense chewing) decreased after the 4 week training period with 1 hour daily chewing[128].

Kawamura and Horio (1989)[129] measured maximum biting force and chewing performance in healthy adult subjects before and after 4 weeks of chewing training with "Chewing Ability Enhancing Substances (CAES)". CAES are made of glucomannan and the number of chewing strokes and chewing time until the last swallowing action are much larger when chewing CAES than usual. After the training period, maximum bite force and chewing performance were clearly increased. However, this increased chewing ability began to return to the control level gradually 2 weeks after the cessation of the training.

Hellman et al. (2011)[130] evaluated and compared long-term training effects of different motor tasks on masseter and temporal muscles. Motor tasks were repeated three times for chewing, nine times for maximum biting (MB) and 24 times for the coordination tasks (CT). After 10 weeks from baseline a significant difference for coordination tasks was found. The authors conclude that the masticatory muscles are remarkably prone to motor adaptation if demanding CT must be accomplished.

Ohira et al. (2012)[131] investigated the effects of gum chewing exercise on the maximum bite force (MBF) and the masticatory performance of preschool children. After 4 weeks of exercise, MBF and masticatory performance value were significantly increased in the exercise group compared with those of the control group. These increases were maintained for 4 weeks after exercise had finished.

The studies above demonstrate the effect of chewing exercises in healthy subjects. However, the fact that Kiliardis et al. (1995)[127] find that the exercises had a greater effect in the subjects with the weakest muscles, shows that this type of exercise may be beneficial for a variety of patients with weak chewing muscles.

Kawazoe et al. (1982)[132] studied the effect of therapeutic exercises of the stomatognathic system (no specific description of the exact exercises) in patients with progressive muscular dystrophy and conclude that those exercises were effective in improving masticatory function.

Ingervall and Bitsanis (1987)[133] studied the effect of chewing exercises on facial growth in long-faced children, the chewing material they used was a tough material consisting of resin of a pine tree.

Note: Although much of the exercise literature is based on the limb and trunk muscles and one could debate whether the same principles apply to the chewing muscles that have a somewhat different fiber type composition, the results of the above-mentioned studies do support the expected effect of chewing training on strength and endurance of the chewing muscles.

4.6 Potential patient groups that should avoid this type of exercise

It is possible that using the TheraBite ActiveBand could cause increased joint pain in TMD patients. Physiologically relevant exercise (chewing bubble gum for 6 min) increased masticatory muscle pain in both female and male TMD patients and, unexpectedly, also in female control subjects. One hour after chewing, the pain remained above pre-test levels for female patients but not for the others[134]. Sustained clenching for 10 minutes at 49 N caused decreased joint space in the temporomandibular joint[135].

It should be kept in mind that chewing results as the combination of effective tongue movement to bring and keep the food between the teeth and form a bolus, effective cheek tone to keep the food between the teeth and avoid it from entering the buccal space, rotation and translation of the mandible, and effective use of the muscles of mastication. TheraBite ActiveBand only attempts to influence the latter. Proper diagnosis of the origin of the chewing problem is therefore warranted.

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. Recent studies also show that the TheraBite can be useful in the prevention of trismus and swallowing problems in patients with head and neck cancer undergoing (chemo)radiotherapy.

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. Recent studies also show that the TheraBite can be effectively used in a preventive trismus and swallowing rehabilitation program in head and neck cancer patients undergoing (chemo) radiation.

The TheraBite ActiveBand will give patients with chewing problems the ability to start the training at a low level and gradually increase. The TheraBite ActiveBand will provide a type of exercise that is close to the functional act of chewing. It specifically trains the muscle group needed to generate the chewing forces. Chewing a bolus properly is not only determined by the strength and endurance of the chewing muscles; dentition, tongue/buccinator function, and jaw mobility also play an important role. Increased strength and endurance of the muscles of mastication are an important aspect of efficient chewing without being limited by fatigue.

Despite the fact that chewing exercises (by chewing on a hard substance) seem to have a functional effect on the muscles of mastication, this type of exercise has not found widespread use. The cause of this could be that although exercising by means of chewing on a hard substance is functional, the forces that are used cannot be quantified and there will be a group of patients that is not able to chew at all, or that will not have sufficient control over the chewing gum and will be at risk for aspiration of the gum.

The relevant clinical data that is available is sufficient to support the use of TheraBite ActiveBand as an exercise to improve strength and endurance of the muscles of mastication. It can be expected that an increase in strength and endurance of these muscles will improve chewing efficiency and reduce fatigability of the chewing muscles.

The TheraBite Jaw Motion Rehabilitation System and the TheraBite ActiveBand are clinically proven to be effective in treating trismus, and in improving muscle strength and endurance of the muscles of mastication, respectively. Both offer a home rehabilitation program, encouraging continuity and compliance.

6. Suggested articles and book chapters for further reading

In Table 2 presents various book chapters describing the use of TheraBite, as well as some more studies, with a brief summary.

Table 2 Suggested articles and book chapters for further reading

Reference: Larsen[136] (1992) **Brief summary:** This book chapter stresses the importance of close postoperative follow-up in deciding the success and failure of any proposed treatment for the fractured condyle.
Reference: Bell[137] (1995) **Brief summary:** This book chapter focuses on the importance of rehabilitation after orthognathic surgery in which TheraBite a modality used to assist in mouth opening when range of motion is limited.
Reference: Giuliano[138] (1995) **Brief summary:** This paper discusses trismus (mandibular hypomobility), addressing its etiologies, relevant anatomy and pathophysiology, with the medical and nursing care of trismic patients commonly seen in the otolaryngology setting. It aims to raise awareness among ORL nurses about the sometimes subtle presentation of trismus and about the important role ORL specialists can play in detecting and treating this debilitating disorder.
Reference: Mannhelmer[139] (1995) **Brief summary:** In this book by Pertes & Gross (Clinical management of temporomandibular disorders and orofacial pain) Mannheimer indicates the use of TheraBite after arthroscopy or arthrotomy.
Reference: Reich[140] (1995) **Brief summary:** Prof. Reich studied the use of the TheraBite System in a wide range of patient population and found it was useful in improving jaw function in patient populations ranging from post-surgical cases to trauma-induced trismus.
Reference: Gaziano[141] (2002) **Brief summary:** Gaziano emphasizes at the evaluation and management of oropharyngeal dysphagia in head and neck cancer patients. Range of motion exercises is mentioned as an important dysphagia treatment for head and neck cancer patients who have structural or tissue damage. The deleterious effects of radiation therapy on nutritional status are also stressed.
Reference: Mannhelmer[142] (2002) **Brief summary:** This publication recommends active or gentle passive TMJ mobilization (TheraBite) to reduce the inflammatory process, inhibit the formation of adhesions, and commence restoration of function.
Reference: Lazarus[143] (2007) **Brief summary:** This book chapter discusses the rehabilitation of patients with head and neck cancer and provides an overview of rehabilitation strategies across the allied health profession.

Reference: Voisin & van Reck[144] (2005), oral presentation **Brief summary:** In a randomized controlled study 72 patients with acute and chronic pain were randomized in 6 groups. These groups included 3 groups of patients using TheraBite alone and/or in combination with bite plane and physiotherapy and a control group. The exercise regimen for TheraBite was 6 sessions/day including3 stretches of 60 seconds for a period of 6 weeks. The greatest improvement was found in the three groups in which TheraBite was used. The patient group in which only TheraBite was used experienced the most significant pain reduction from 5.75 on a VAS Scale to 0.48. This study is also looking at the long term effect on treatment on the patients.
Reference: Gibbons & Abulhul[145] (2007), peer reviewed published article **Brief summary**: Persistent restriction of mouth opening after coronoidectomy to treat bilateral coronoid hyperplasia, may be the result of soft tissue fibrosis. Authors presented the use of a mouth-opening appliance that helps to overcome this problem and improves long-term results.
Reference: Fernandez et al.[146] (2008), peer reviewed published article **Brief summary**: Bilateral hyperplasia of the coronoid process is infrequent. It consists of an elongation of the coronoid process of the mandible and is, accordingly, a mechanical problem, limiting mouth opening. This article looks at the case of a 28 year-old male with significant limitation on opening his mouth, secondary to bilateral hyperplasia of the coronoid process. Authors reviewed the literature and analyzed the diagnostic and therapeutic procedures used, paying special attention to the surgical approaches to the coronoid process and emphasizing the importance of early post-operative rehabilitation, describing our experience with the TheraBite. The satisfactory result of the procedure is marked by the stable recovery of the mouth opening, achieved by a good combination of surgical and physiotherapeutic techniques.
Reference: Messing et al.[80] (2012) **Brief summary:** This article shares the integrated approach that enables an oncology team of professionals at address the needs of H&N-patients. A clinical pathway that focuses on medical, functional, psychosocial, and nutritional requirements that ensure optimal outcomes, is presented.
Reference: McCaul et al.[23] (2012) **Brief summary:** This article provides an overview of oral and dental management in head and neck cancer patients, including the causes and consequences of trismus, prevention and long-term treatment.
Reference: Pauli et al.[147] (2014) **Brief summary:** This prospective intervention study investigated the impact of structured exercise on trismus. Results showed that jaw mobilization exercise with TheraBite® was effective and improved the mouth opening capacity significantly. The patients who underwent structured exercise after cancer treatment reported less trismus-related symptoms and improvements in HRQL (Health related Quality of Life) compared to a matched control group.

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