

Physical Therapy

# Treatment of myogenic temporomandibular disorder: a prospective randomized clinical trial, comparing a mechanical stretching device (TheraBite®) with standard physical therapy exercise

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**Aims:** To compare in a randomized controlled clinical trial (RCT) 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).

**Methodology:** Myogenic TMD patients were randomized for the use of the TB device or for standard PT. Mandibular function was assessed with the mandibular function impairment questionnaire (MFIQ). Pain was evaluated using a visual analog scale, and maximum inter-incisor (mouth) opening (MIO) was measured using the disposable TB range of motion scale.

**Results:** Of the 96 patients randomized (46 TB, 50 standard PT exercises), 38 actually started with the TB device and 41 with the standard PT exercises. After six-week follow-up, patients using the TB device reported a significantly greater functional improvement (MFIQ score) than the patients receiving regular PT exercises ( $P=0.0050$ ). At 6 weeks, no significant differences in pain, and active or passive MIO were found between the two groups. At 3 months, patients in both treatment groups did equally well, and showed a significant improvement in all parameters assessed.

**Conclusions:** This RCT on myogenic TMD treatment, comparing standard PT with passive jaw mobilization using the TheraBite Jaw Motion Rehabilitation System®, shows that both treatment modalities are equally effective in relieving myogenic TMD symptoms, but that the use of the TB device has the benefit of achieving a significantly greater functional improvement within the first week of treatment.

**Keywords:** Myogenic temporomandibular disorder, Myogenic cranio mandibular dysfunction, Limited mouth opening, Jaw exercises, TheraBite passive jaw motion device, Physical therapy exercises

## Introduction

Temporomandibular disorder (TMD), also known as cranio mandibular dysfunction, is one of the most common disorders of the craniofacial region. It is a collective term embracing a number of clinical problems that involve the masticatory musculature,

the temporomandibular joint (TMJ) and associated structures.<sup>1</sup> TMJ disorders may be categorized as intra- or extracapsular. Intracapsular disorders may be caused by trauma or degenerative disease, and include rheumatoid arthritis, osteoarthritis, fibrosis and articular disc displacements. Extracapsular disorders are mainly myofascial, and are far more common. They are characterized by (acute or chronic) musculoskeletal pain with masticatory muscle dysfunction, usually exacerbated by movements of

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the jaw.<sup>2,3</sup> Myogenic TMD is considered a musculoskeletal disorder of the masticatory system. It is characterized by functional disturbances of that system, in which normal range of motion (ROM) of the TMJ and the associated structures is impaired.<sup>4,5</sup> Other common names for myogenic TMD include myofascial pain, myofascial pain and dysfunction, TMJ myofascial pain syndrome or simply TMJ syndrome. For this study, the authors refer to this symptom complex as myogenic TMD.

Myogenic TMD affects more than 25% of the population, and is typically seen in relatively young women.<sup>5,6</sup> It often occurs in the third or fourth decade of life.<sup>1</sup> The pathogenesis is multifactorial. It may arise due to a combination of stress, jaw clenching (often due to anxiety and psychosocial stress), bruxism (psychogenic, unconscious or nocturnal teeth grinding), other musculoskeletal problems that strain the jaw joint (such as degenerative joint disease, internal joint derangements, cervical traction and dental manipulation), and rarely as a result of trauma.<sup>7</sup>

Presenting symptoms are mostly unilateral and include pain, joint sounds, limited jaw movement and tenderness of muscle and joint.<sup>3,5,7</sup> The (chronic) non-dental pain may originate from either muscular or articular conditions, or both. It may radiate to the ear, jaw and posterior cervical region, which is why patients are quite often referred to an otolaryngologist or neurologist. The pain is often worsened by chewing. Myogenic disorders that cause pain (i.e. myofascial pain, myofascial pain and dysfunction) are encountered frequently: approximately 50% of all TMDs are masticator myalgias or painful masticator muscle disorders.<sup>3</sup> The myofascial pain of the masticatory muscles presumably occurs due to persistent, unconscious, repetitive use of the involved muscles. Mandibular hypomobility or limited mouth opening is also frequently reported in patients with myogenic TMD.<sup>8</sup> It prevents patients from chewing or eating normally, and may impair speech and oral hygiene.<sup>8-11</sup> A possible explanation is the fact that the muscles involved in mouth closure (temporalis, masseter and medial pterygoid muscles) exert a power 10 times higher than the muscles involved in mouth opening (lateral pterygoid, digastric, mylohyoid, geniohyoid and the lower hyoid muscles).<sup>10</sup> Many patients also describe symptoms of pain and dysfunction affecting ears (tinnitus), eyes (visual changes), poor sleeping quality, lower energy, and headaches. These latter symptoms involve some or all of the frontal, temporal, parietal, occipital and neck regions.<sup>3,5</sup> The presenting symptoms often appear in

association with a stressful life event and are in some degree self-limiting.<sup>1</sup>

Management of myogenic TMD very often involves a multidisciplinary approach. Conservative treatment is considered to be the treatment of choice. Management modalities include jaw exercises, medication (muscle relaxants, sedatives to relieve pain), application of bite plates/splints, and dental care if needed. Sometimes local anaesthetic-corticosteroid joint injections or botulinum toxin injections into the masticatory muscles are given for persistent symptoms. Unfortunately, evidence of the efficacy of these treatments, based on well-designed controlled studies, is scarce.

Physical therapy (PT) is presently considered to be one of the standard and quite widely applied treatment modalities for patients with myogenic TMD. The literature has clearly demonstrated that the physical stimulus of motion is essential to maintaining the health of synovial joints, especially when there is a limited ROM.<sup>2</sup> Standard treatment usually consists of a combination of techniques to improve oral mobility (in order to discourage formation of fibrosis in and around the TMJ), to reduce musculoskeletal pain, and to reduce inflammation, even though the precise mechanisms of some actions are unknown.<sup>5,6</sup> Mixed results have been reported after completing therapeutic exercises for myogenic TMD. In a cross-sectional study of patients with a limited mouth opening not related to cancer, the mouth opening significantly increased after standard PT exercises, but 38% of the patients still had a mouth opening of 35 mm or less after treatment.<sup>12</sup> Recent reviews about the effectiveness of PT interventions in the management of myogenic TMD concluded that PT in general resulted in significant improvement over time for pain and impairment. However, due to mostly low methodological quality of the different studies reviewed, it was also concluded that more research is needed to examine the effectiveness of PT interventions.<sup>5</sup>

The research on passive motion as a treatment modality for myogenic TMD shows that many patients suffering from myogenic TMD have degenerative changes to the TMJ. These degenerative changes may be caused by lack of motion,<sup>13</sup> and seem reversible by the use of passive motion.<sup>2,14</sup> Several studies have found that passive motion can help to improve joint function, re-organize collagen and restore jaw function.<sup>15</sup> It can also decrease pain by providing significant decreases in the inflammatory process and effectively interrupting the process by which interleukin-1 creates inflammatory cytokines.<sup>14</sup>

Hence, passive motion seems a good starting point in the treatment of this condition. The TheraBite Jaw Motion Rehabilitation System® is based on this principle of passive motion. It is designed specifically for patients experiencing limited mouth opening and mandibular hypomobility. It should improve the ROM and strength of the jaw by utilizing repetitive passive motion and stretching, to restore mobility and flexibility of the jaw musculature, associated joints and connective tissue.<sup>15</sup> Previous studies offer some evidence that passive motion provided by the TheraBite® (TB) device offers considerable benefit in terms of increased ROM and decreased pain for patients with myogenic TMD.<sup>16</sup>

Considering the discussion about the effectiveness of PT exercises, presently being one of the standard treatment modalities, and whether passive motion treatment could be an alternative approach to myogenic TMD, a randomized controlled clinical trial (RCT) was initiated. The specific aim of this RCT is to investigate whether passive jaw motion using the TB device is an equivalent or more effective treatment for myogenic TMD related symptoms than the present standard PT exercise regimen.

## Methods

The present study was designed as a prospective RCT, and was undertaken at the Department of Maxillofacial Surgery of the Kennemer Gasthuis (Haarlem) in collaboration with the Department of Head and Neck Oncology and Surgery of the Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital (Amsterdam) in the Netherlands. The study was approved by the local ethical committees, and oral and/or written informed consent was obtained from each participant prior to inclusion. The study followed the guidelines of the Helsinki Declaration. Subjects with physical disability (e.g. problems manually using the standard exercises or the device), and subjects with non-myogenic underlying causes of limited mouth opening were not enrolled in the study.

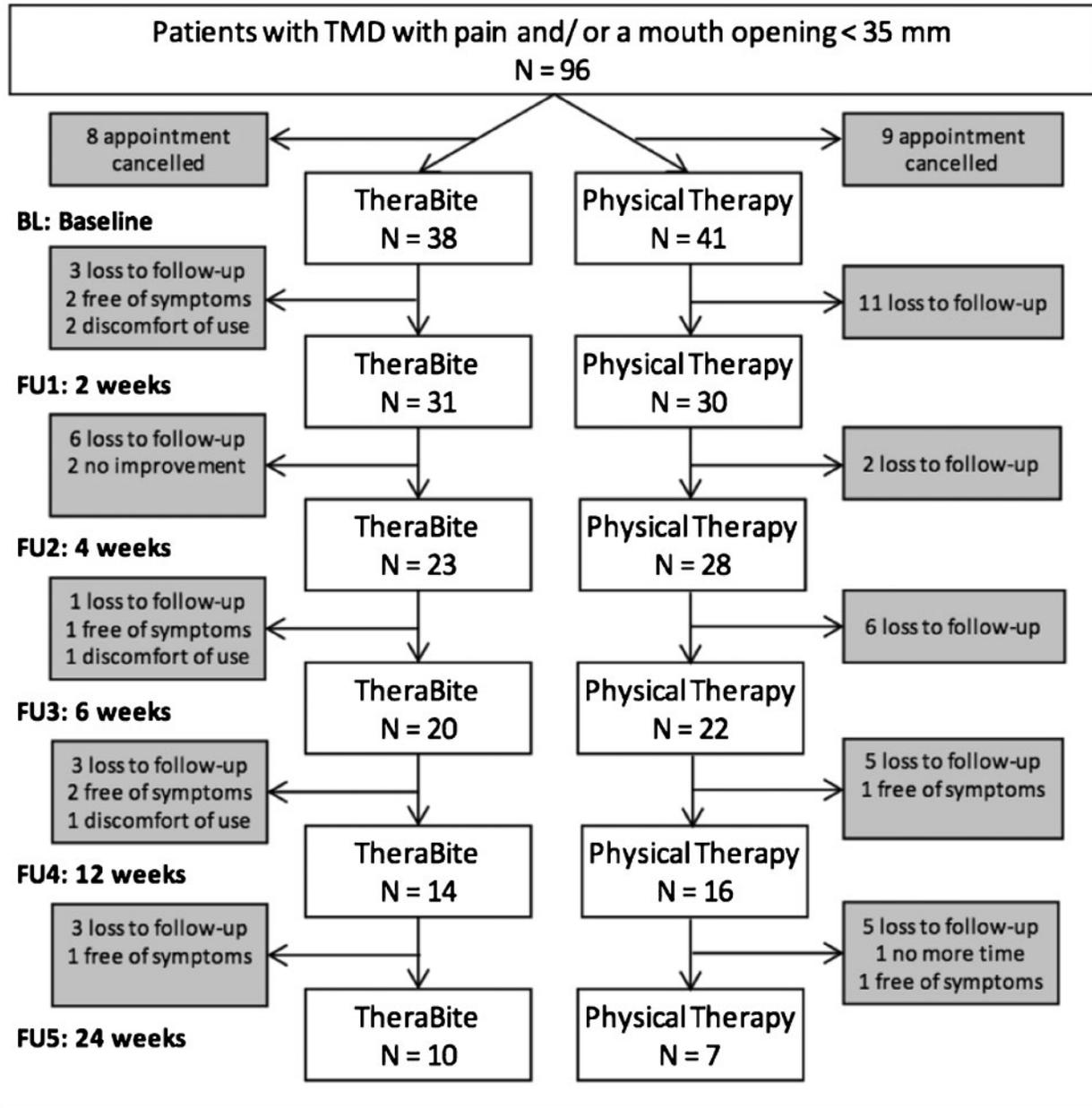
The study involved two treatment groups: the ‘standard group’, receiving regular PT exercises and the ‘experimental group’, using the TB device. After the first diagnostic clinic visit, patients were scheduled for a second visit, either as a start for the PT exercise program, or to receive the necessary treatment instructions for TB use. In the PT exercise group, each patient received the same instructions on normal jaw function and chewing, relaxed mouth opening, tongue position, head posture, and incorrectly learned habits. The actual exercises consisted of a usual combination of techniques to improve mobility



**Figure 1** The TheraBite (TB) device.

and reduce pain, including massage of the masticatory muscles (to ease tension), coordination exercises (to prevent laterotrusion of the jaw joint during mouth opening), and some stretching exercises (to stretch the masseter, temporalis, and pterygoid muscles). Each patient had to visit the physical therapist four times in sessions of 30 minutes and had to perform the exercises five times a day, by linking the exercises to their daily activities like tooth brushing or going to the toilet. In the TB group, in a single session, patients were instructed how to hold the TB device in their (preferred) hand, with the mouthpieces placed between the upper and lower teeth (see Fig. 1). Subsequently, they were instructed on how to achieve and sustain a comfortable stretch of the jaw muscle, by gently applying pressure on the lever, in order to stretch their mouth opening. Patients were instructed to hold the stretch for 30 seconds and to repeat this stretch five times in succession five times a day. Both the PT treatment sessions and the single TB instruction were given by one of the two participating physical therapists.

The following outcome parameters were collected: patient perception of mandibular function, pain, active and passive ROM of the lower jaw, and compliance and subjects' familiarity with the exercises. Patient perception of mandibular function was measured using the sum score of the validated 17-item mandibular function impairment questionnaire (MFIQ),<sup>17</sup> which reliably assesses the degree of impairment of specific jaw functions.<sup>11</sup> Each item is scored on a 0–4 scale with zero being no difficulty and four being extremely difficult to perform the particular mandibular task, which results in a sum score ranging from 0 to 68. Pain was assessed with a visual analog scale (VAS) of 0 to 10, with zero being no pain and 10 being the worst possible pain. Active and



**Figure 2** Consort flowchart with patient numbers at the various observation points and numbers of patients and reasons for dropping out of the study.

passive ROM – also referred to as maximal inter-incisal (mouth) opening (MIO) – were measured with the disposable TB ROM scales. Long-term MIO effects were measured by comparing the patient's pre- and post-treatment MIO. The average gain in MIO was also calculated. Compliance and subjects' familiarity with the exercises were assessed separately by the patient self-reporting through a study-specific questionnaire. All outcomes were assessed at fixed points in time: prior to treatment (baseline), after two, four, and six weeks and also after three and six months from the start of treatment. The two latter assessments consisted of a short telephone or e-mail survey. An independent research assistant who had

no knowledge of the specific treatment modality carried out all assessments.

#### *Statistical analysis*

The primary endpoint of this RCT was defined as the difference in mandibular impairment, as assessed with the MFIQ at six weeks, after randomization between TB use versus the regular PT exercise regimen. Based on a recent, still unpublished study (preliminary results at six weeks), that showed an average post-treatment VAS pain score of 1.8 (SD 2.6) for TB use versus an average of 3.5 (SD 2.7) for PT exercises, the trial was designed to detect a significant improvement of 20% or more in the

overall score, with 80% power and a two-sided alpha of 0.05. With these assumptions, the trial needed to accrue at least 76 patients in total. All data were collected in a specially developed Statistical Package of Social Sciences database version 20.0. Statistical analysis was performed using R version 2.14.1. Because not all measurements were available at six weeks, a linear mixed-effects model was applied to fit the equally spaced repeated time measurements within patients (random factor) and between the interventions, adjusting for baseline values (fixed factors). The most appropriate random-effects covariance structure was obtained by minimizing the general information criterion. Interactions of therapy over time (as fixed factors) were tested but not found to be significant.<sup>18</sup>

## Results

Ninety-six subjects (83 females and 13 males; mean age: 38 years; range: 17–73 years) with myogenic TMD (muscle tenderness) with pain and/or a mouth opening of less than 35 mm were prospectively enrolled in this study during a four year period (January 2008–December 2011). This resulted in 50 subjects (43 females and seven males; mean age: 36 years; range: 17–73 years), who were randomized for standard PT treatment, and 46 subjects (40 females and six males; mean age: 39 years; range: 19–68 years), who were treated with the TB Jaw Motion device. All patient data at the various time points are shown in the consort flow chart in Fig. 2.

Nine subjects in the PT exercise group and eight in the TB group failed to show up at the therapy instruction visit. Also during the remainder of the study, some subjects stopped their treatment and failed to comply with their scheduled clinic visits. The consort flow-chart (Fig. 1) shows the patient cohorts at the various time points. At the three- and six-month observations, the number of subjects in both groups had decreased substantially, precluding further meaningful statistical analyses. Details on the study population, which actually started treatment, are presented in Table 1. There were no significant differences with respect to gender, mean age, or baseline measurements between both groups, neither in the original 96 patients, nor in the 79 patients who actually started treatment.

### *Mandibular function impairment questionnaire (MFIQ)*

The sum score of the MFIQ was used to assess mandibular function. Almost all patients reported improved mandibular functionality after treatment, which resulted in lower MFIQ scores over time. Table 2 shows the median and inter-quartile (25–75%) range (IQR) of the MFIQ scores over time, by therapy. In the TB group, the median MFIQ score significantly dropped from 22.5 at baseline to 15.0, 10.0, and 9.5, after two, four and six weeks of treatment, respectively. In the PT exercise group these data changed from 22.0 at baseline to 22.5, 16.5 and 17.0, after two, four and six weeks of treatment, respectively. Figure 3 shows the MFIQ scores for the

**Table 1 Clinical characteristics of subjects at baseline per randomization group at the start of treatment**

Baseline measurement	TheraBite	Physical therapy	Total
No. of patients	38	41	79
Age (years)			
Mean	39.4±2.1	34.9±2.4	37.5±1.5
Range	20–68	17–71	17–73
Gender			
Male (%)	4 (10.5%)	6 (14.6%)	10 (12.7%)
Female (%)	34 (89.5%)	35 (85.4%)	69 (87.3%)
Medication			
Yes (%)	12 (32.4%)	14 (44.1%)	26 (33.4%)
No (%)	25 (67.7%)	27 (65.9%)	52 (66.7%)
MFIQ score			
Mean±SEM	24.9±2.2	24.3±2.2	24.5±1.5
Range	1–55	0–62	0–62
Pain scale (VAS)			
Mean±SEM	4.9±0.4	4.3±0.4	4.3±0.4
Range	1–10	0–8	0–10
Active MIO (mm)			
Mean±SEM	36.4±1.6	33.2±1.4	34.8±1.0
Range	18–57	20–57	18–57
Passive MIO (mm)			
Mean±SEM	37.5±1.4	37.1±1.3	37.3±0.9
Range	23–56	23–60	23–60

Note: MFIQ, mandibular function impairment questionnaire; MIO, maximal inter-incisor mouth opening; SEM, standard error of mean; VAS, visual analog scale.

**Table 2** Change in MFIQ values over time by randomization group

Randomization	TheraBite	Physical therapy	Total
	46 (48%)	50 (52%)	96 (100%)
Baseline			
Sample size	38	41	79
Median	22.5	22.0	22.0
IQR	17.2–33.8	15.0–30.0	15.0–33.0
2 weeks			
Sample size	31	30	61
Median	15.0	22.5	19.0
IQR	9.0–25.0	11.0–33.8	9.0–28.0
4 weeks			
Sample size	24	28	52
Median	10.0	16.5	13.5
IQR	4.0–16.2	10.5–29.2	6.8–24.2
6 weeks			
Sample size	20	21	41
Median	9.5	17.0	11.0
IQR	3.8–15.2	5.0–28.0	4.0–25.0

Note: IQR=inter-quartile (25–75%) range.

various time points of follow-up. The MFIQ scores for TB over time were found to be significantly different ( $P=0.0050$ ).

### Pain

The mean overall VAS for pain was 4.3, with only six patients reporting no pain at all at the initial consultation. From the time of diagnosis to the end of treatment, the pain scores decreased in both treatment groups. The pain-scores for the TB group over time were not found to be significantly different compared to the PT exercise group ( $P=0.7155$ ).

### Maximal inter-incisor mouth opening (MIO)

Active and passive MIO values were corrected for vertical overbite. In both treatment groups there was a significant improvement in active and passive MIO over time ( $P<0.0001$ ). No significant differences in improvement or average gain in active or passive MIO between the groups were found. As an example, the active MIO values over time per randomization group are shown in Fig. 4.

### Compliance and familiarity with exercises

Patient self-reporting through the questionnaire showed good compliance for both the PT exercises and the TB device. Almost all patients (>95%) reported to be completely familiar with the PT and TB exercises after having received the instructions. Moreover, the TB was reportedly easy to use.

### Discussion

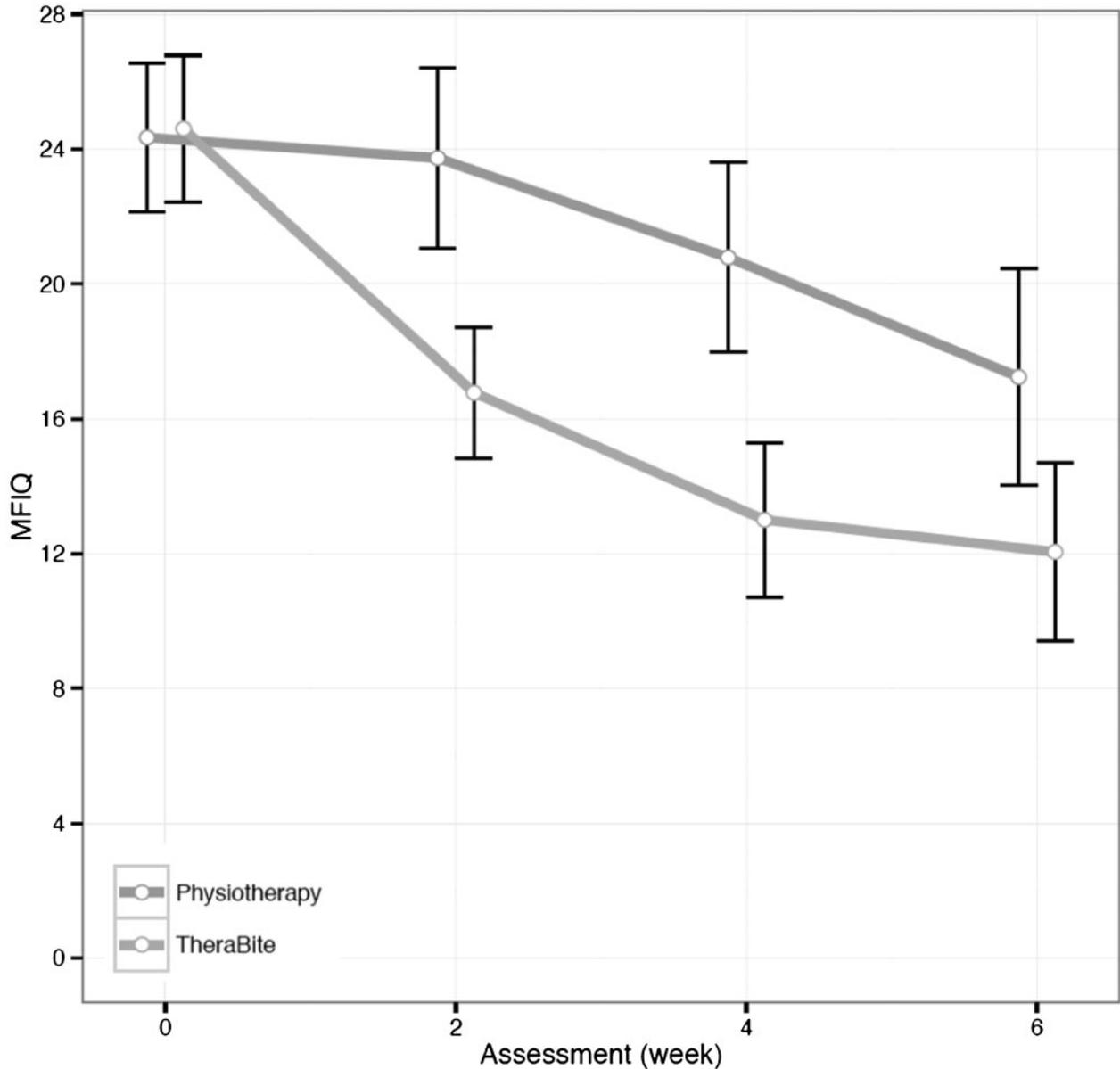
This prospective RCT on myogenic TMD treatment, comparing traditional PT exercises with use of the TB passive jaw mobilization device, demonstrates a significant faster functional improvement in the experimental (TB) group. At six weeks, mandibular

function and tasks (such as eating, drinking, speaking, etc.), as assessed with the MFIQ, had improved significantly more in the TB group compared to the group treated with standard PT exercises ( $P<0.0050$ ). Both treatment groups improved significantly for pain and for passive and active mouth opening. No significant differences between the two treatment groups were found for these parameters. These findings are in concordance with those of a similar mono-therapy study with the TB device in patients with mandibular hypomobility by Maloney *et al.*,<sup>16</sup> who found improvement of mouth opening measurements and pain scores over a four-week period.

Mouth exercises are considered to be effective interventions for the reduction of myogenic TMD associated symptoms,<sup>5,19</sup> and also the results of the present study, one of the few RCTs in myogenic TMD, confirm that the treatment modalities applied are associated with a reduction of mandibular function impairment and pain, and an increase in mouth opening over time. The difference in outcome between both approaches, exercising with the TB device versus PT exercise treatment, is the time necessary to reduce symptoms, for which the use of the TB device seems to have a significant advantage in the short-term.

Therapeutic outcome studies in which reliable and valid instruments are used to evaluate mandibular function impairment in patients with TMJ complaints are scarce.<sup>20</sup> In this study, the authors chose to use the MFIQ. This questionnaire has the advantage of clear operational criteria (for example eating an apple), and furthermore, it has been recommended as a valid and (moderate to high) reliable instrument to measure changes in mandibular impairment.<sup>17</sup> However, an observed improvement between pre- and post-therapeutic outcome variables not only reflects therapeutic effects, but also the natural course of the disorder and inconsistency in measurement designs. Therefore, the authors took into account that an improvement of at least 10 units on this 0 to 68 scaled questionnaire, as described by Kropmans *et al.*,<sup>11</sup> was needed for a therapeutical intervention to be successful.

In a disorder where spontaneous remissions are not infrequent and most treatment modalities do not have a very strong scientific basis, adding a no-treatment group would be ideal in order to assess a possible placebo effect. However, the vast majority of patients had considerable complaints both of pain and limited mouth opening, and only symptomatic treatment of the pain was deemed not an acceptable option. Moreover, many more patients would have

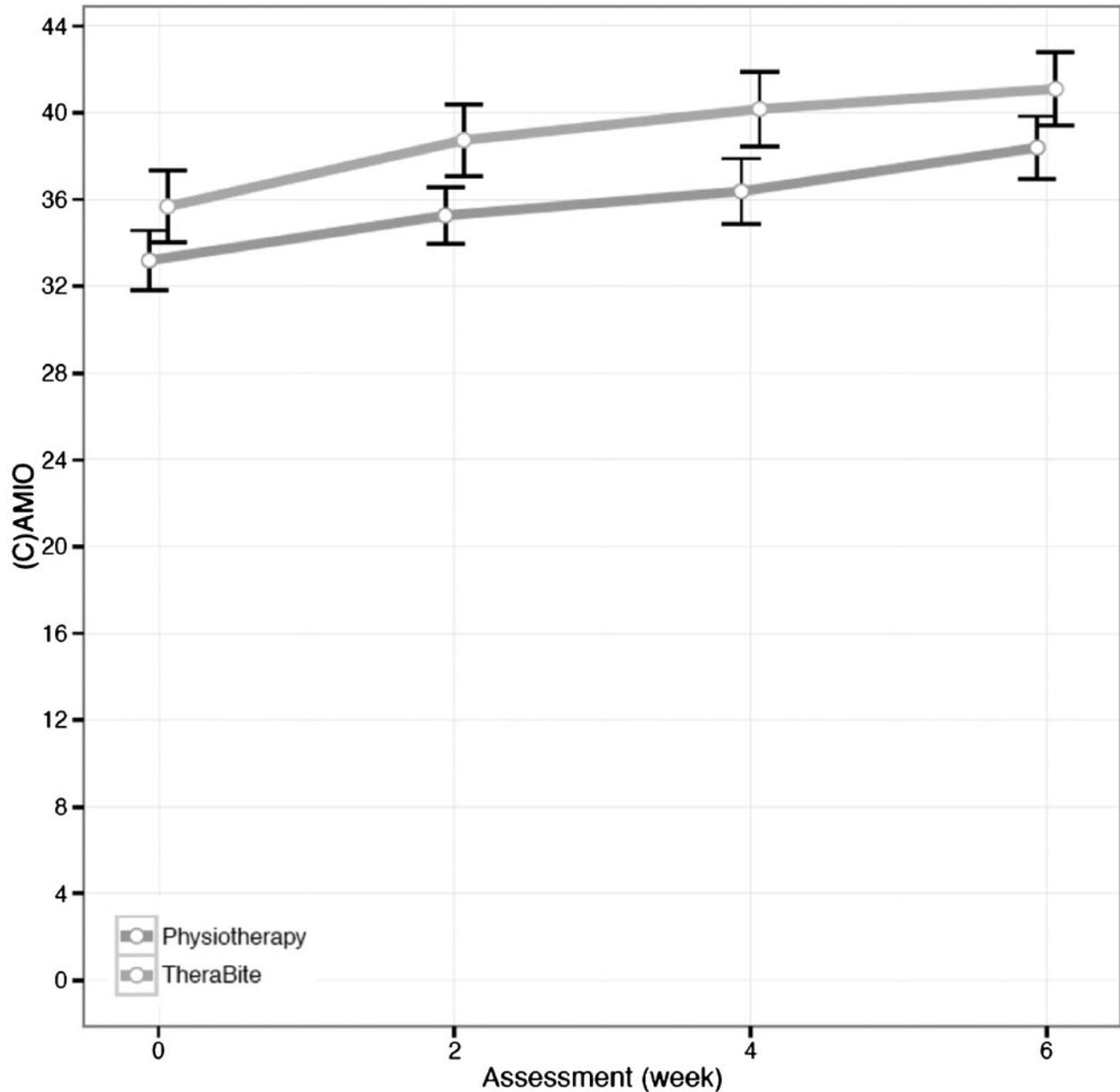


**Figure 3** Mandibular function impairment questionnaire (MFIQ) values with standard error of mean at the various time points (per randomization group). At six weeks, the improvement in the MFIQ values for the TB group is significantly better than for the PT group ( $P=0.0050$ ; see also Table 2).

been required in a study with three different treatment groups, which is not a feasible option in a single clinic.

Another weakness of this study is that, as often is the case in clinical studies, there were quite a few dropouts and missing data, already starting between the time of diagnosis and randomization and the actual start of the therapy program. Subsequently, several patients stopped with the TB or the PT exercises during the follow-up period. Fortunately, the distribution of dropouts over both treatment groups was very similar, causing no significant differences between both randomization groups. As can be seen in the consort flow chart (Fig. 2), in the TB

group, reasons to stop were that some patients had no complaints of pain and/or limited mouth opening anymore, while a few others reported discomfort with the device or insufficient improvement. In the case of the PT exercises, most dropouts were no-shows and non-responders to reminders for the later appointments. Most likely, these patients also quit the exercises because, in the mean time, they had become free of symptoms. In accordance with the authors' findings, Craane *et al.*<sup>21</sup> recently illustrated that patients with TMD related muscle pain almost always improve over time, independent of any provided PT. The improvements in that study – in terms of reduced pain and improved jaw function – were achieved in the



**Figure 4** Active mouth opening (AMIO) in mm with standard error of mean; there was a significant improvement in AMIO over time in both treatment groups ( $P < 0.0000$ ). No significant differences in improvement or average gain in active MIO between both randomization groups were found.

first few months and remained stable over a period of one year. Also, epidemiologic studies about the long-term (5-year) follow-up results for myogenic TMD have found that remission of myofascial pain in the masticatory muscles occurs in roughly one-third of the patients.<sup>22</sup> Therefore, the conclusion seems valid that several treatment modalities can be effective in reducing pain and improving mandibular function and mouth opening over time, but there might be a difference in the time necessary to reduce these symptoms, as suggested by the present study.

The authors have not (yet) looked into the possible cost-effectiveness of the use of the hand-operated TB

device instead of the standard PT exercise treatment. Treatment with the TB device requires a one-time outpatient consultation only for providing the necessary counselling about myogenic TMD and for giving instructions for self-training with the device (home exercise program), and therefore only requires involvement of the diagnosing/treating clinician. Since the patient can carry out the exercises easily at home, a minimum number of appointments are needed, which may also reduce indirect costs such as traveling, time off from work, etc. Moreover, the patient owns the TB device, so there are no additional costs when long-term use is indicated to sustain a

lasting benefit. PT exercises on the other hand, require a referral and several (in this study, at least four) visits to a physical therapist, preferably specialized in myogenic TMD. Further research investigating the cost-effectiveness of self-training with the TB device in comparison with regular PT is planned.

## Conclusion

This RCT on myogenic TMD treatment, comparing standard PT exercises with passive jaw mobilization using the TB device, shows that both treatment modalities are equally effective in relieving myogenic TMD symptoms in the long-term, but that the use of the TB device has the benefit of achieving a significantly greater and more rapid improvement of mandibular function within the first week of treatment.

## Disclaimer statements

**Contributors** None.

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**Conflicts of interest** None.

**Ethics approval** The study was approved by the Protocol Review Board of the Netherlands Cancer Institute.

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