New Medicine Assessment

Jaw Rehabilitation Device (TheraBite®)

For the treatment of trismus and mandibular hypomobility

Recommendation: Red (specialist only) 2nd line treatment

TheraBite® is only recommended to be initiated and supplied by specialists for patients with trismus or mandibular hypomobility. TheraBite® is a 2nd line option for patients with trismus/mandibular hypomobility secondary to radiotherapy, surgery or trauma who are still experiencing problems despite regular use of passive jaw stretching exercises.

Background and context

Temporomandibular disorders (TMDs) are a group of related musculoskeletal conditions affecting the masticatory muscles, the temporomandibular joint (TMJ), and associated structures. TMDs share clinical features, such as pain in the TMJ and surrounding structures, limitation of jaw movements, and/or sounds (such as clicking, popping, grating, or crepitus) from the TMJ. [1]

Trismus means being unable to open the mouth completely. Normal full jaw opening is 40 – 50 millimetres. The measurement is taken from the edge of the lower front teeth to the edge of the upper front teeth. Trismus is not a disease, and may occur as a result of trauma, surgery or radiation treatment. The main symptoms of trismus include difficulty opening your mouth, jaw pain/stiffness, and difficulty eating/chewing/speaking/brushing teeth.

The mainstay of treatment for trismus is passive jaw stretching exercises in additional to medicines to relieve pain associated with trismus. Patients may need to be referred to physiotherapy and/or speech and language therapy for advice regarding the management of their condition. Patient may also be offered posture training, massage or acupuncture to help relax muscle spasm. [2]

Patients still experiencing jaw mobility problems may be able to try the TheraBite® Jaw Motion Rehabilitation System. TheraBite® is available in adult and paediatric sizes and listed in the NHS Drug tariff as follows [3]:

TheraBite®	Device, initial bite pads and accessories	£226.77
	Bite pads	£10.59

TheraBite® was prioritised for review following a request from Fylde Coast sub ICB location.

Summary of evidence

Summary of efficacy data in proposed use:

Date: February 2023

There is a systematic review and meta-analysis detailing the randomised controlled trials data for the treatment of trismus [4] [5]. Neither the systematic review or the meta-analysis is designed to specifically look at TheraBite®, but compare various treatments for the management of trismus (e.g. masticatory training, usual care, tongue depressors etc) and consider their relative effectiveness.

Charter et al Systematic Review (2022) [4]

There were 11 RCTs analysed identified in the systematic review, two non-randomised controlled trials, and 19 studies without a control (case-study, case-series, single-arm cohort). Of these studies 8 RCTs and both non-randomised controlled trials analysed TheraBite®. All studies had some or high risk of overall bias or did not include randomisation except for a single RCT. These studies included a total of approximately 500 participants. The primary outcome in all but one study was maximal inter-incisal opening (MIO) or change in MIO where MIO is defined as number of millimetres between the incisors of the mandible and maxilla (top and bottom incisors).

There were 18 studies that evaluated the effect of using a trismus device in patients with established trismus without a control group. These studies evaluated the effect that TheraBite® (n = 5) and nine other devices had on MIO at 3 months post-treatment. While outcomes were promising in these studies (pooled analysis demonstrated a mean improvement in MIO of 14.2 mm), their results are likely to be exaggerated given the lack of control and poor scores in the quality analysis. There were eight prospective trials that evaluated the effect of using a trismus device on MIO (TheraBite® n = 6) in patients with established trismus which implemented a control in their design. Pooled analysis of therapy which used a device demonstrated a mean improvement in MIO for TheraBite® of 5.2 mm. The significant improvement in MIO was maintained when analysis was restricted to RCTs. Pooled analysis for these studies demonstrated a mean improvement in MIO for TheraBite® of 4.6 mm.

Shao et al Meta-Analysis (2020) [5]

The meta-analysis conducted by Shao et al included two additional trials assessing TheraBite® which were not included in the systematic review by Charter et al. The authors noted that the MIO improvement was 4.48 mm (95% CI = 0.20, 8.75) after using TheraBite® for 5–10 weeks, and 6.00 mm (95%CI = 2.77, 9.23) after using TheraBite® for 3 months.

Summary of safety data:

Complications relating to trismus treatment with a device was reported in six studies. They included molar fracture (n = 1), osteomyelitis (n = 1), loosened dentition (n = 1), mandible fracture (n = 1), reconstruction plate fracture (n = 1) and fractured dental bridge (n = 1). Pain was used as a signal to cease further application of force for most dynamic stretching, however pain was also reported to be a barrier to use of the device by several patients. Additional adverse events reported included jaw fracture (n = 1) and finger numbness and pain (n = 1) using TheraBite®. [4]

Before starting any rehabilitation activity involving the TheraBite® system every user should consider the benefits of medically supervised programs. Clinicians may select and combine exercises to form programs that are appropriate for each users abilities and goals, including regular monitoring and review.

The TheraBite® is not intended to be used by:

- Individuals who have or may have a fracture in the maxilla or mandible (upper or low jaw) or other weaknesses of bones of the jaw.
- Individuals with infections of the jaw, osteomyelitis (inflammation of bone and bone

marrow), or osteoradionecrosis (necrosis of bone due to radiation) of the jaw. [6]

Strengths and limitations of the evidence:

Strengths

- The TheraBite® Jaw Motion Rehabilitation System is an anatomically correct and portable system which uses repetitive passives motion to stretch connective tissue, strengthen weakened muscles and mobilise joints.
- There is some clinical trials evidence suggesting that TheraBite® may be effective in improving/maintaining maximal inter-incisal opening (MIO).
- The device may also reduce muscle/jaw pain associated with trismus and mandibular hypomobility.
- The design of the device allows gradual changes to the range and speed of jaw opening. This may reduce patient anxiety and improve compliance.

Limitations

- There is a lack of randomised controlled trials with large patient numbers.
- There was some or high levels of bias in several of the RCTs assessing TheraBite®.
- Compared to standard care (jaw stretching exercises), TheraBite® is relatively expensive.

Commissioning considerations:

Innovation, need and equity implications of the intervention:
The TheraBite® Jaw Motion Rehabilitation System is an additional treatment option for patient who are still experiencing problems despite regular use of passive jaw stretching exercises.
Financial implications of the intervention:
No prevalence data is available but given that trismus is a condition which is secondary to trauma, surgery, or radiation treatment, and that a proportion of patient will respond to standard care (jaw stretching exercises), the number of eligible patients is likely to be very small. Assuming that bite pads are changed every 3 months the annual cost per 100 patients treated is approximately £25,000.
Service Impact Issues Identified:
No additional service impact would be anticipated due to the supply of TheraBite®.
Equality and Inclusion Issues Identified:
Include the summary of the outcome of the screening tool.
Cross Border Issues Identified:

GMMMG haver classified TheraBite® “Do not Prescribe”. Pan Mersey do not have any advice regarding the use of TheraBite®.
Legal Issues Identified:
N/A
Media/ Public Interest:
N/A

References

[1] National Institute for Health and Care Excellence, "NICE Clinical Knowledge Summary - Temporomandibular disorders (TMDs)," August 2021. [Online]. Available: https://cks.nice.org.uk/topics/temporomandibular-disorders-tmds/. [Accessed February 2023].

[2] Facial Palsy UK, "Trismus Patient Guide," January 2023. [Online]. Available: https://www.facialpalsy.org.uk/support/patient-guides/trismus/. [Accessed February 2023].

[3] NHS Business Services Authority, "NHS Electronic Drug Tariff," 2023 February. [Online]. Available: http://www.drugtariff.nhsbsa.nhs.uk/#/00655804-DA/DA00655687/Part%20IXA-Appliances. [Accessed 2023 February].

[4] E Charters et al, "Trismus therapy devices: A systematic review," *Oral Oncology,* p. 105728, 2022.

[5] CH Shao et al, "Exercise therapy for cancer treatment-induced trismus in patients with head and neck cancer: A systematic review and meta-analysis of randomized controlled trials," *Radiotherapy and Oncology,* vol. 151, pp. 249-255, 2020.

[6] Atos Medical, "TheraBite Manual," 2020. [Online]. Available: https://www.atosmedical.co.uk/product/therabite-jaw-rehabilitation-system/. [Accessed February 2023].

Grading of evidence (based on SORT criteria):

Levels	Criteria	Notes
Level 1	Patient-oriented evidence from: • high quality randomised controlled trials (RCTs) with low risk of bias • systematic reviews or meta-analyses of RCTs with consistent findings	High quality individual RCT= allocation concealed, blinding if possible, intention-to-treat analysis, adequate statistical power, adequate follow-up (greater than 80%)
Level 2	Patient-oriented evidence from: • clinical trials at moderate or high risk of bias • systematic reviews or meta-analyses of such clinical trials or with inconsistent findings • cohort studies • case-control studies	
Level 3	Disease-oriented evidence, or evidence from: • consensus guidelines • expert opinion • case series	Any trial with disease-oriented evidence is Level 3, irrespective of quality