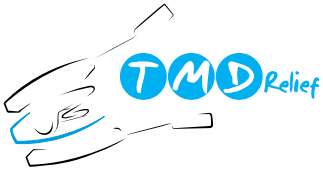


THE MODULAR DEVICE
FOR A NATURAL ALTERNATIVE
TO TEMPOROMANDIBULAR DISORDERS

EU Patent EP3285680
Class 1 non-sterile and non-measuring medical device for
the exercise of mouth muscles

Therapies and usage statistics for 2017 and 2023

Duration of therapy, dropouts, and recurrence of visits
Parameters for the effectiveness of therapy with TMD Relief

TMD Relief is the fully **modulable** device for the **natural** resolution of **temporomandibular disorders,** adapting to the patient's morphology and therapeutic needs.

This document summarizes the **statistical results** derived from data collected in 2017 regarding the **effectiveness of therapy** with TMD Relief, including the **duration of therapy,** the **quantity of dropouts,** and **recurrence of visits**.

The study clarifies not only the therapeutic effectiveness of the device but also the extent to which TMD Relief therapy influences the **doctor-patient trust relationship** and in what manner the prescription strengthens this relationship the most.

At the conclusion of 2017, data collected anonymously on therapies carried out with TMD Relief were analyzed and recorded, purely for statistical purposes and anonymously, on the dedicated form provided with the device to specialist doctors who used TMD Relief in their therapies.

The sample population with monitoring forms received in 2017 consists of 64 therapies, a sufficiently large number to define statistics on the device's usage.

The data entered in the monitoring form were analyzed, particularly focusing on:

- **Mouth opening,** i.e., the maximum non-forced mouth opening;
- **Lateral movement,** indicating the non-forced horizontal mobility of the temporomandibular joint;
- **Chronic pain,** concerning what patients reported at the beginning of therapy and during the cycle regarding chronic pain experienced due to TMD/TMJ issues.

Although present in the therapy monitoring form, the parameter related to functional limits of the temporomandibular joint was not analyzed due to the limited number of measurements and observations made by clinicians regarding this aspect.

In 2023, patients undergoing therapy with TMD Relief were asked to complete a questionnaire that adhered to the international diagnostic criteria defined for TMD (DC/TMD).

In this case, the sample population with received forms is smaller but no less relevant. There are, in fact, 10 therapies performed with a dropout rate of 0 and constant weekly checks for the first month of therapy.

The analyzed data refer to:

- **Limitation in chewing,** i.e., the joint's range of motion during meals, taking into account the different consistencies of consumed foods;
- **Joint blocks,** meaning the number of times the joint gets blocked during articulation movement;
- **Joint noises,** referring in this case to the classic "click" of the jaw;
- **Chronic pain,** which, as in the 2017 analysis, relates to the chronic pain experienced by patients before the start of therapy and during the therapeutic cycle with TMD Relief.

THERAPY AND STATISTICS 2017

DURATION OF THERAPY, DROPOUTS, AND RECURRENCE OF VISITS

The first aspect analyzed is related to the **duration of therapy**, quantified by the number of visits per patient. In relation to this aspect, "dropouts" were also considered, referring to patients who abandoned the therapy after the first session.

The analysis also took into account the different **prescription approaches to therapy followed by clinicians**, essentially divided into two methodologies:

- **Type 1** (Series 1, Figure A): **Prescription and therapy in the clinic**, where TMD Relief is not purchased in the clinic but prescribed by the specialist who then conducts therapy sessions, adjustments, and checks;
- **Type 2** (Series 2, Figure A): **Sale of the device and prescription of therapy in the clinic,** where TMD Relief is purchased in the clinic and adjusted, then followed by subsequent therapy, adjustments, and checks in the clinic;
- Series 3 presents the **overall results**.

Regarding the dropout rate for different types and overall:

- **Type 1** (Series 1, Figure A): **Prescription and therapy in the clinic 9%;**
- **Type 2** (Series 2, Figure A): **Sale of the device and prescription of therapy in the clinic 17%;**
- **Overall** (Series 3, Figure A) **15%.**

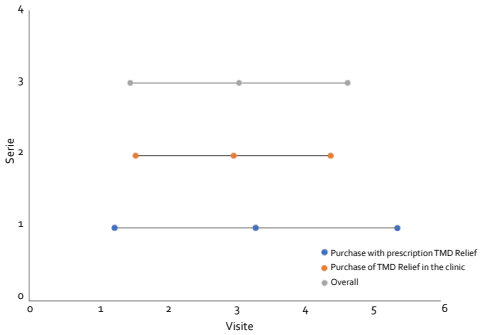


FIGURE A. RECURRENCE OF PATIENT VISITS IN TMD RELIEF THERAPY

There is a **lower dropout rate for Type 1,** almost half of the cases compared to those who purchase TMD Relief in the clinic and defer to subsequent therapy (Type 2).

Regarding the behavior and duration of therapy among those who do not drop out, a **similar pattern is observed**: a return to the clinic occurs on average three times per therapy, primarily for device checks and adjustments, until the natural conclusion of therapy.

There is also a **greater tendency** for patients to return to the clinic for follow-up and adjustment visits in **Type 1 cases (up to 5-6 visits),** as indicated by the wider confidence interval. Numerous cases are reported of **continued follow-up visits** (scheduled every six months) despite the conclusion of therapy.

NON-FORCED OPENING

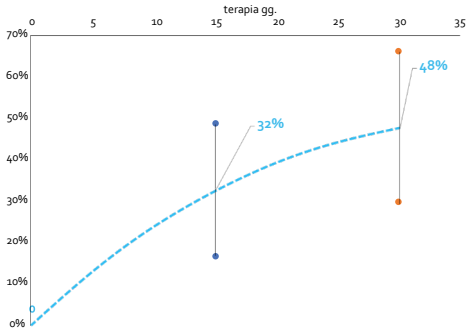


FIGURE B. NON-FORCED OPENING

The parameter of **non-forced mouth opening,** along with the assessment of lateral movement capacity, is the most frequently observed parameter by specialists in their therapies, as it is particularly **indicative of therapy effectiveness**.

The measurement is carried out using a ruler, like the one provided with TMD Relief, at the beginning of therapy and during follow-up visits for control and adjustment.

Already after only **15 days of therapy,** the functional recovery is significantly noticeable (Figure B).

Lateral movement

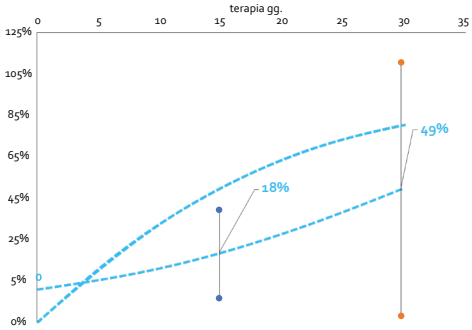


Figure C. LATERAL MOVEMENT

Similarly to non-forced opening, the **non-forced lateral movement of the temporomandibular joint** has been observed.

In this case as well (see Figure C), it is noted that after only **15 days of therapy**, functional recovery is significant.

It's worth noting (Figure C) that the confidence interval is wider compared to what is observed for non-forced opening, particularly after 30 days of therapy.

Chronic pain

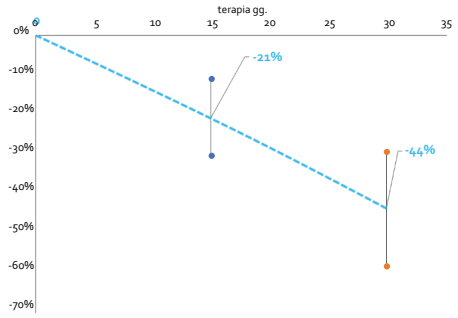
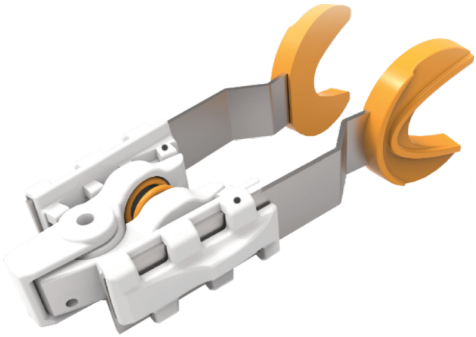


Figure D. CHRONIC PAIN

Chronic pain is assessed by asking the patient to rate it on a scale from 1 to 10.

The decrease in chronic pain follows a similar pattern to non-forced opening, although it is not measured precisely but is **assessed subjectively by the patient** (Figure D).



Therapy and statistics 2023

Duration of therapy, drop-outs, and recurrence of visits

The first factor considered pertains to the duration of therapy, quantified as the number of visits made by each patient.

It is evident that all patients underwent weekly check-ups for a total of four weeks without any dropout rate.

Chewing limitations

Among the various parameters recorded, particular attention should be given to the one related to **chewing limitations**.

This, in fact, along with the recording of the number of joint blocks, is among the most relevant aspects for the analysis of therapeutic results both as an index of the pathology itself and for the impact these aspects have on the patient's life in social and psychological terms.

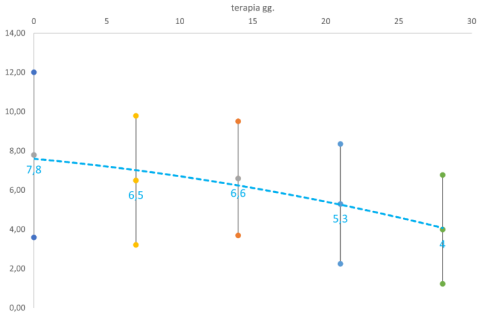


FIGURE E. CHEWING LIMITATIONS

Already after just **15 days of therapy**, the functional recovery is remarkably significant. At the end of 30 days, the average values are more than halved (Figure E).

Joint blocks

A similar trend is noted regarding **joint blocks of the temporomandibular joint**.

Also in this case, it is observed that after just **15 days,** functional recovery is particularly significant (Figure F).

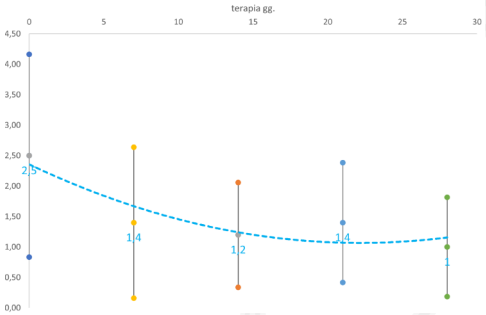


FIGURE F. JOINT BLOCKS

Joint noises

Significant improvement is also observed in the analysis of **joint noise** trends.

In this case as well, already at the end of the first **15 days** of therapy, patients notice a clear improvement that tends to stabilize in the following two weeks (Figure G).

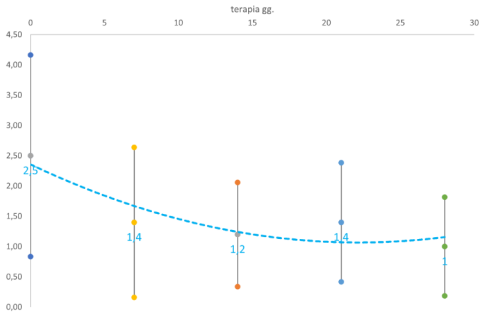


FIGURE G. JOINT NOISES

Chronic pain

As can be inferred, the decrease in chronic pain follows the trend of the previous parameters, although it is not precisely measured but assessed subjectively by the patient (Figure H).

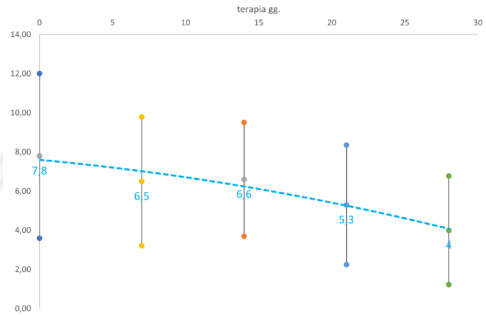
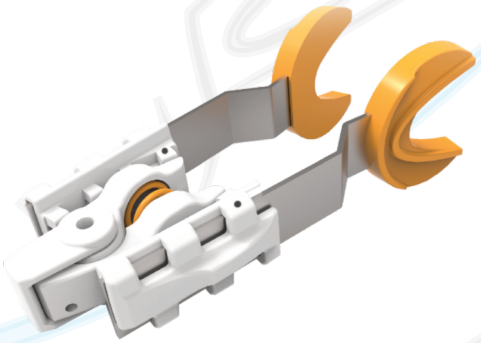


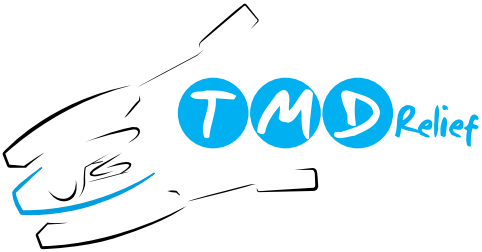
FIGURE H. CHRONIC PAIN



www.tmdrelief.eu
info@tmdrelief.eu

Syde srl
P.IVA/VAT IT06538010486
Registered office: Via L. da Vinci 16, 50132 Florence FI
Operational office: Piazza Costituzione 5, 50041 Calenzano FI

info@tmdrelief.eu
055 8873364
www.tmdrelief.eu



TMD Relief

EU Patent EP3285680

Class 1 medical device, non-sterile and non-measuring, for the exercise of mouth muscles

CE

NON-STERILE
FOR PERSONAL USE

MADE IN ITALY