

# TPMD CLINICAL PROTOCOL

## OSA

The OSA protocol for TPMD will be based on targeted measurements of strength and, above all, tongue **endurance**, with a follow-up schedule adapted to the type of treatment (CPAP, MAD, OMF surgery, TRP or MFT (MyoFunctional Therapy)) and explicit decision support (primary treatment, complementary treatment, or reorientation).

### 1) OSA – TPMD measurement protocol

#### a) Recommended types of measurements

- Mandatory for OSA (children  $\geq$  5 years old, adults):
  - Anterior tongue force (anterior Pmax, in kPa) – involved in maintaining oropharyngeal patency and resting tongue posture.
  - Median/posterior tongue force (median Pmax) – related to control of the tongue base, relevant for moderate/severe OSA.
  - Anterior tongue endurance (50% Pmax, time in seconds) – key parameter for assessing **long-term muscle function** and justifying TRP or MFT as a treatment option.
- Recommended according to profile:
  - Left/right lateral forces – screening for asymmetries that may promote lateralized obstruction or mandibular deviation (OAM contraindication).
  - Lip strength – useful in cases of mouth breathing, OSA associated with lip hypotonia.
  - Cheek strength – more incidental, by placing the probe between molars and buccinator muscles, and pressing on the probe with these muscles.

#### b) Conversion of IOPI standards to TPMD

- IOPI reference values (adults):
  - Typical adult anterior Pmax 40–80 kPa, average  $\approx$  63 kPa in young and middle-aged adults,  $\approx$  57 kPa in elderly subjects.
  - 95% of normal subjects, all ages combined, have an anterior Pmax  $>$  34 kPa.
  - Average endurance 15–35 s at 50% of Pmax;  $<$  10 s suggests low endurance.
- Practical principle of TPMD conversion:
  - IOPI-like devices tend to display slightly lower pressures (bias of around 5–10 kPa or  $\approx$  10–15% according to manometric comparison studies).

Parameter	IOPI standard (young adult)	Expected TPMD range (approx.)*
Anterior Pmax	60–65 kPa	50–58 kPa (–10 to –15%)
50% Pmax endurance	15–35 s	same order of magnitude

\* "Indicative conversion, to be adjusted according to TPMD internal validation data."

## 2) Measurement times and frequency (OSA)

Justification: Oropharyngeal muscle plasticity requires several weeks of regular stimulation to achieve measurable gains in strength and endurance (typically 8–12 weeks in tongue exercise programs).

General outline

- Initial assessment (T0):
  - Before starting or modifying TRP, MFT, OAM, or CPAP.
  - Complete measurements: anterior Pmax, median Pmax, endurance, ± laterality, lips.
- Intermediate follow-ups:
  - Mild/moderate OSA with TRP or MFT alone: at 1, 2, 3 months, then 6 and 12 months.
  - Severe OSA with OAM/CPAP + TRP or MFT : at 3 months, 6 months, and 12 months, with synchronized monitoring at sleep/orthodontic consultations if possible.
- End of functional treatment:
  - Complete measurement to document the functional reserve obtained (strength + endurance) and help decide whether or not to continue TRP or MFT maintenance.
  - The end of TRP or MFT treatment can be considered when Pmax and End measurements are normalized and spontaneous observation clearly indicates functional correction.
- Post-treatment follow-up (optional):
  - At 12–24 months for severe or recurrent OSA patients, especially if TRP or MFT is stopped/relaxed.

## 3) OSA analyses and comparisons

To be clearly included in the file:

- Intra-patient comparisons:
  - T0 vs. T1–T2–T3–T6–T12: variation in kPa ( $\Delta P_{max}$ ) and in % (e.g., +20% Pmax, +40% endurance).
  - Endurance/Pmax comparison: enduring but weak ("hypotonic" profile) vs. strong but not very enduring ("fatigable" profile).
  - CPAP adherence comparison
- Comparison with IOPI/TPMD standards:
  - Adults: alert threshold if Pmax < 34 kPa (5th percentile) or endurance < 10 s at 50% Pmax.
  - Young adults/adolescents: aim for a Pmax close to the age median ( $\approx$  55–65 kPa).
- Lateralized and intermuscular comparisons:
  - Difference > 15–20% between left/right lateralities  $\rightarrow$  asymmetry to be documented (compensation pattern, mandibular deviation, unilateral hypertrophy).
  - Lips and cheeks: weak lip strength in a context of mouth breathing and OSA  $\rightarrow$  argument for MFT focused on lip closure.
- Limitations of interpretation:
  - Learning effect, motivational and postural variability (head/neck); need for at least three trials per measurement, retention of the best or average.
  - IOPI conversion  $\rightarrow$  approximate TPMD, data not published for all ages

## 4) Variations depending on OSAS treatments

### a) Mild/moderate OSA – discontinuation of OAM or CPAP

- Objective: to document the capacity for muscular compensation by TRP or MFT as **the main treatment**.
  - Complete measurements at T0, then monthly M1, M2, M3, M6, M12.
  - Priority: previous Pmax + endurance 50% Pmax.
  - Clinical target: raise Pmax above the 5th percentile and endurance within the 15–30 s range, depending on age.

### b) Severe OSA with insufficient OAM/CPAP adherence

- Objective: TRP or MFT as **a supplement** to reduce AHI and improve respiratory comfort.
  - Measurements at T0 (with OAM/CPAP adherence rating), M3, M6, M12.
  - Focus on endurance and median Pmax (base of tongue).
  - Correlation of TPMD progress with: AHI, ESS, sleep quality, and machine adherence data.

### c) OSA treated by oral and maxillofacial surgery

- Pre-intervention TRP:
  - TPMD before TRP placement to screen for hypotonia and justify TRP or MFT treatment
- Post-treatment TRP/MFT:
  - TPMD measurement frequency: at 1, 2, 3, 6, and 12 months

## 5) Clinical interpretation and decision support (OSA)

Profiles to be described in the form:

- Profile A – low strength, low endurance:
  - Pmax < 34 kPa and endurance < 10 s.
  - Indications: TRP or intensive MFT in addition to CPAP, if severe OSA, poor adherence:
- Profile B – adequate strength, low endurance:
  - Pmax within the age norm but endurance < 10–15 s.
  - Interpretation: "fatigable" tongue, difficulty maintaining compensation throughout the night; TRP or MFT targeting endurance is highly relevant.
- Profile C – marked asymmetry:
  - Lateral difference > 20%.
  - Indication: targeted myofunctional work or shockwave therapy, to be discussed with the orthodontist/ENT specialist.
- Possible decisions to mention:
  - Continuation of TRP or MFT alone (mild/moderate OSA with clinical and functional improvement).
  - TRP or MFT in addition to OAM/CPAP (if severe OSA or partial improvement).
  - Referral (ENT, surgery, other device) if no TPMD progression and/or clinical failure.

## Mini-bibliography (to be included on the OSAS form)

- IOPI Medical – Normal tongue and lip strength values.
- Potter NL et al. Developmental changes in tongue strength, swallow pressures, and endurance (children).
- Adams V et al. Systematic review of IOPI tongue and hand strength/endurance.
- Youmans SR, Stierwalt JAG. Measures of tongue function related to normal swallowing.
- Robbins J et al. Effects of lingual exercise on swallowing in older adults and post-stroke patients.

## 6) Patient data collection and exchange forms – SAOS



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SAOS.xlsx