Current evidence for greater tone of the pelvic floor muscles in pelvic health conditions
PT Journal Club
January 4, 2023
Prepared by Rachel Worman, DPT, PhD(c)


“7 | AREAS FOR FURTHER RESEARCH
A core outcome set for PFM assessment would be valuable, however, this requires knowledge of the clinimetric properties of the many assessment methods currently used in clinical practice and research, and a comparison of these properties amongst the assessment methods; such knowledge is lacking. There is an urgent need for a report to compile the validity, reliability, and responsiveness of PFM assessment methods, especially for the more subjective methods of visual observation and digital palpation. The clinimetric properties of some aspects of the more objective methods of PFM assessment (simple and sophisticated tools) has been undertaken, however many gaps in testing remain. Whether any of these assessment methods provide diagnostic test accuracy of PFM function and dysfunction is unknown. Future research in this area is required.”

A partial response to the call (for measures of greater tone):
2 Worman RS, Stafford RE, Cowley D, Prudencio CB, Hodges PW. Evidence for increased tone or overactivity of pelvic floor muscles in pelvic health conditions: A systematic review. Am J Obstet Gynecol 2022;0:
• Started October 2019 (before ICS urgent call for research)
• Part 1 currently under review
  o Details tools, outcome measures
    ▪ Validity
    ▪ Reliability
    ▪ Application issues
  o Informed Part 2

Part 2: Evidence for increased tone or overactivity of pelvic floor muscles in pelvic health conditions: a systematic review

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Title
- Started with terms we thought were most accurate and current in Prospero Registration
- Maintained these terms for findability
  - Findings of the review suggest these are **not the best terms**

Introduction
- **Tone**
  - Active (AKA: myoelectric, neurogenic)
  - Passive (AKA: viscoelastic, mechanical)
- **Evidence was unclear**
  - How good is the evidence?

Objective
- **Methods**
  - Measures
  - Study design
- **Outcomes**
  - Did the papers find greater tone?
  - Differences?
    - Age
    - Sex
    - Gender
    - Pelvic Health Condition
- **Terminology**
  - Thematic groups
  - Consider the accuracy of terms
    - Based on basic science, physics, physiology

Methods
Tools to measure “how good is the evidence?”
*Completed for each condition, each tool (investigations AND signs per ICS [eg, EMG, digital palpation]) and outcome measure (eg, time to relaxation) in a study (See example supplement 6)*

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• Modified ROBINS-I (Supplement 6) for each tool
  o Risk of Bias In Non-randomized studies -of Interventions (Supplement 2)
    ▪ Quality score
• Outcome scorecard -Interpretation of Outcomes (Supplement 6)
  o 3-point system
    ▪ 3 points-Convincing
    ▪ <3 points-Inconclusive
  o (1) Healthy comparison or normative data
  o (1) Valid (Supplement 3)
    ▪ Reliable (noted + or -)
  o (1) Measurement Application Accurate
• Outcome (Supplement 6 and 7)
  o Increased tone
  o No difference
  o Decreased tone
• Outcomes score plus outcome (Supplement 6 and 7)
  o Convincing-increased, no difference, decreased tone
  o Inconclusive-increased, no difference, decreased tone
Example (Supplement 6). Bael had 2 pelvic health conditions, 2 tools, 2 outcome measures

<table>
<thead>
<tr>
<th>Author(s) and year</th>
<th>Tool</th>
<th>Outcome measure</th>
<th>Modified ROBINS-I</th>
<th>Interpretation of Outcomes</th>
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<tr>
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<td>Internal Validity</td>
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<td></td>
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<td></td>
<td>Source of population</td>
<td>Eligibility criteria</td>
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<tr>
<td>Bael et al. 2008</td>
<td>Uroflow-voiding dysfunction</td>
<td>Staccato patterns</td>
<td>0.5</td>
<td>1</td>
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<tr>
<td></td>
<td>EMG-voiding dysfunction</td>
<td>Voiding</td>
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<td></td>
<td>Uroflow-urgency</td>
<td>Staccato patterns</td>
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<td>1</td>
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<tr>
<td></td>
<td>EMG-urgency</td>
<td>Voiding</td>
<td>0.5</td>
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</tr>
</tbody>
</table>

Results & Discussion
Risk of Bias Analysis

- 236 measures in 151 studies
  - Low risk: 13 measures
    - 11 of these provided convincing evidence
  - 94% measures:
    - Moderate risk: 153 measures
      - 4 convincing measures
    - High risk: 70 measures

Study Design Analysis

- 57% cross-sectional
- 2% cross-sectional plus longitudinal
- 41% longitudinal studies
  - 87% had no comparison group
  - RCT
    - 7 fully powered
    - 1 pilot

Key message: Not enough quality longitudinal evidence to suggest cause (eg, tone causes pain or that pain causes tone or anything else)

- Examples of other considerations (not exhaustive list):

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Comparison Groups Analysis

- Most papers used pre and post intervention outcomes as their comparison.
  - Assumes tone is elevated at baseline, and authors considered that this interpretation was supported if tone could be reduced by intervention.
  - Reduction of tone from a “normal” level, in the absence of healthy controls, cannot be excluded.
    - Many botox studies ineligible due to no tone measure
    - Problem: botox is not only a muscle relaxant
      - Analgesic
      - anti-inflammatory agent.
      - Unclear what component is reducing the pain
        - Commonly assumed it is tone reduction

Analysis of Tool & Outcome Measure (Supplement 3)

- 8 measurement tools categories identified
  - EMG, dynamometry, manometry (sometimes referred to as perineometry), digital palpation, defecography, ultrasound, MRI, and other
- 103 different outcome measures were derived from these tools
  - Time to relaxation
- Most tools are indirect and combined measures of tone
  - Most indirect measures have not been validated against a direct measure
    - Implication: most measures are not convincing and do not distinguish between active and passive properties of tone

Analysis of Condition Group

- Most studies cover pain conditions
- List of conditions (Supplementary data 7)

Analysis of age

- Adults-93% of studies

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• Females-92% of studies

Analysis of Outcomes
• Convincing evidence: 15 measures, 12 studies
  o Increased-10 measures
    ▪ All pain conditions
    • 9/10-taken at rest
    • 1/10-taken during straining
  o No Difference-5 measures
    ▪ Pain-3 measures
    ▪ Urogenital-2 measures
    • All taken at rest
• Inconclusive evidence 221 measures, 139 studies

Thematic Analysis of Terminology
• 216 Terms
• 6 clusters
  o Combined (passive +/- active), function/dysfunction, neuropathologic, pain, condition/diagnosis
• Hypertonic
  o Thematically grouped as a combined measure (not neurologic)
  o Never used in neurologic context
• Spasm
  o Involuntary contraction
    ▪ Thematically groups as neuropathologic
  o Used 1x in neurologic conditions (Parkinson’s)
• Terminology comments
  o Tone
    ▪ Best overarching term that encompasses many outcome measures interpreted to measure stiffness, but not all are actual (technically speaking) measures of stiffness
    ▪ Under the arch

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• Stiffness
  o Very specific physics measure with output (e.g., F=N\cdot m)
    ▪ Dynamometer gives this output

  o Select terms congruent to muscle property tested
    ▪ EMG » Higher activity
    ▪ Combined measure » Greater tone

  o Avoid unclear terms
    ▪ Hypertonicity (in absence of neurologic pathology)
    ▪ Non-relaxing (not appropriate at rest)

  o Avoid terms mixing properties and symptoms
    ▪ Tension myalgia
    ▪ Implies pain is synonymous with tone
      ▪ In physics, tension is related to tone but is different
        ▪ Tension: “In physics, tension is described as the pulling force transmitted axially by the means of a string, a rope, chain, or similar object, or by each end of a rod, truss member, or similar three-dimensional object; tension might also be described as the action-reaction pair of forces acting at each end of said elements. Tension could be the opposite of compression.” (Wikipedia, Tension (physics))
          ▪ Not a direct measure for this in the pelvic floor
            ▪ Related (proportional) to stiffness, but not the same thing

  o Consider relation to time or reference standards
    ▪ Increased tone (implies increase from early measure)
    ▪ High tone (implies reference to standard)

  o Higher activity or greater tone (between individuals)

Conclusions
• few studies that provide convincing evidence for increased tone
  o primarily in female pain conditions
• Majority of studies use methods that preclude convincing interpretation.
• Terminology is frequently unclear and incongruent with the reported measure
• Limited studies with controls and normative data
• “increased tone” on an initial evaluation is incorrect
• “increased tone” can be used on subsequent testing sessions

• Unclear if greater tone is a source of cause
  • More high level longitudinal studies with controls required
• Gaps in knowledge for male, transgender and pediatric populations.

To advance evidence in this field:
  • Consider inclusion of clearly defined control/comparison groups,
  • Use of validated outcome measures
  • Careful application of methods
  • Clear use of terminology and definitions

Further comment (beyond the study):
  • Points to multi-measure assessment (no tool is perfect, they each tell us something different. Understand what the tool is really telling us and alternative interpretations)
  • EMG is the only measure of activity and must be considered as an adjunct to any combined measure
  • Pointing toward instrumented testing
  • Testing for tenderness on palpation is not a substitute
  • Tone should still be measured in some way
  • Limits to tools (most especially digital palpation...when measuring tone)

USEFUL REFERENCES
From Supplement 7. Table of conditions and measures.

<table>
<thead>
<tr>
<th>Condition</th>
<th># Papers (% total)</th>
<th># Parti (% total)</th>
<th>Measurement tool</th>
<th>Total by tool</th>
<th>Con ↑</th>
<th>Con ND</th>
<th>Con ↓</th>
<th>Inc ↑</th>
<th>Inc ND</th>
<th>Inc ↓</th>
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</thead>
<tbody>
<tr>
<td>Interstitial cystitis/bladder pain syndrome</td>
<td>6</td>
<td>155</td>
<td>Digital palpation</td>
<td>4</td>
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<td>0</td>
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<td>4</td>
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<td>EMG</td>
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<td>EMG (HD)</td>
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<th>MRI</th>
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<td>6</td>
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</table>
**WHAT IS HAPPENING IN CLINICAL SETTINGS?**
- First 3 case reports from data sets (alpha order)

**From Supplement 5. Inconclusive evidence.**

<table>
<thead>
<tr>
<th>Study</th>
<th>Participant condition</th>
<th>Compariso n/group/data</th>
<th>Tx</th>
<th>Study design</th>
<th>Sex/gend er</th>
<th>Age (years)</th>
<th>Sample size</th>
<th>Tool</th>
<th>Outcome measure</th>
<th>Issue</th>
<th>Stud y Outcome</th>
<th>Evidence</th>
<th>Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bannister (2009)</td>
<td>Bowel: constipation (chronic constipation)</td>
<td>Pre- vs. post-treatment</td>
<td>Physical therapy</td>
<td>Case report; EMG amplitude (Report of data)</td>
<td>M</td>
<td>56</td>
<td>P=1</td>
<td>sEMG (rectal)</td>
<td>(µV): rest</td>
<td>No norm</td>
<td></td>
<td>Rest: pre-4.9µV, post-treatment-2.1µV</td>
<td>IC-↑</td>
</tr>
<tr>
<td>Study</td>
<td>Diagnosis</td>
<td>Treatment</td>
<td>Case Report</td>
<td>Physical Therapy</td>
<td>Treatment</td>
<td>Unclear Measurement Scales</td>
<td>Coordinatio n</td>
<td>Hypertonicity</td>
<td>Bilateral Symmetry</td>
<td>Hyperactivity</td>
<td>Overactivity</td>
<td>Pain Control</td>
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<td>Cozean (2017)</td>
<td>Pain: combined (interstitial cystitis, deep dyspareunia, severe urgency/frequency, nocturia &amp; low back pain)</td>
<td>Nil</td>
<td>Physical therapy</td>
<td>Case report; Post-treatment outcome (Report of findings)</td>
<td>F</td>
<td>43</td>
<td>P=1</td>
<td>Digital palpation</td>
<td>Myofascial stiffness in muscle AND presence of twitch, spasm or trigger point: noted if present (no scale presented); coordination: relax after contraction (no scale presented); hypertonicity &amp; symptom reproduction: severe/strong: pain &gt;7/10, moderate: 4-6/10</td>
<td>Unilateral Symmetry</td>
<td>Hypertonic, spasm, overactive, stiffness, tension myalgia/muscle spasm</td>
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<tr>
<td>Naess et al. (2015)</td>
<td>Pain: Vestibulodynia (Provoked vestibulodynia)</td>
<td>Healthy controls</td>
<td>N/A</td>
<td>Cross-sectional case-control; between group (t-test)</td>
<td>F</td>
<td>18-38 Mean 24.3 [SD 4.7]</td>
<td>P=35, C=35</td>
<td>Manom. (vaginal); sEMG (vaginal with anal probe)</td>
<td>Manom.: rest, MVC, endurance EMG: rest (before contraction), MVC (mean 10s), hold (10s)</td>
<td>EMG: non-norm</td>
<td>Manom.: rest P&gt;C (p=0.02), MVC/endurance: P vs. C NS (p=0.57/0.21) EMG: rest/MVC: P vs. C NS (p=0.28/0.15); hold: P&gt;C (p=0.04).</td>
<td>Overactivity, restriction of opening, increased tone, elevated activity</td>
<td></td>
</tr>
</tbody>
</table>

**From Table.** Convincing evidence.

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<td></td>
<td>Source of population</td>
<td>Eligibility criteria</td>
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<tr>
<td>Bannister 2009</td>
<td>EMG</td>
<td>Rest</td>
<td>0.5 0 1 0 0 0 0 0 1 1 0 0 0 0 0 3.5</td>
<td>0 1 0 + 1</td>
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<tr>
<td>Binford et al. 2013</td>
<td>Digital palpation</td>
<td>Relaxation</td>
<td>0 0 0.5 0 0 0 0 1 0 0 0 0.5 0 0 0 0 2</td>
<td>0 0 1 + 1</td>
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<tr>
<td>Observation</td>
<td>EMG</td>
<td>Descent on valsalva</td>
<td>0 0 0.5 0 0 0 0 0 0 0 0 0.5 0 1 0 0 1</td>
<td>0 0 1 - 1-</td>
</tr>
<tr>
<td>Cozean 2017</td>
<td>Digital palpation</td>
<td>Relax after contract</td>
<td>0.5 0 0.5 0 0 0.5 0 1 0 0 0 0 0 0 2.5</td>
<td>0 0 0 + 0</td>
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<tr>
<td>Naess et al. 2015†</td>
<td>Manometry</td>
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<td>Rest</td>
<td>1 1 0.5 1 0.5 1 1 1 1 1 1 1 1 12</td>
<td>1 1 0 + 2+</td>
<td>+</td>
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Resources
https://www.ics.org/2021/abstract/516 (note: updated search and data since this was published)
The pelvic health podcast (Lori Forner et al.), New Years Episode
The in your pants podcast (Susie Gronski), January Episode
Upcoming poster presenter (CSM 2023, San Diego)

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### OUTCOME SCORECARD

Reference Supplementary Data 2 & 3

Give it a try next time you read an article that talks about tone.

<table>
<thead>
<tr>
<th>Study</th>
<th>Tool</th>
<th>Outcome Measure</th>
<th>Muscle Property Measured</th>
<th>Valid Measure Yes-1 No-2</th>
<th>Healthy Control (or Normative Data) Yes-1 No-2</th>
<th>No Application Issues True-1 Untrue-0</th>
<th>Evidence of Reliability Yes-*</th>
<th>Other Measures in Study Yes+</th>
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