

## PERINEAL MUSCLE STIFFNESS IN WOMEN WITH AND WITHOUT VULVODYNIA: RELIABILITY OF MEASUREMENT AND DIFFERENCES IN MUSCLE STIFFNESS

### Hypothesis / aims of study

Studies report an increase in muscle stiffness (also described as tension, tone or overactivity) in the pelvic floor and perineal muscles in women with vulvodynia [1]. However, due to the lack of objective tools or standardised measures of perineal muscle stiffness to date, these findings are unconfirmed. To address this issue and provide objective data on muscle stiffness, the first aim of this study was to determine the inter-rater and intra-rater reliability of a myotonometer (the MyotonPro™) to measure the stiffness of the perineal muscles in asymptomatic and symptomatic (vulvodynia) cohorts, with the hypothesis that the reliability values would be good (Intra-class correlation coefficient [ICC]: 0.61 – 0.80) or very good (ICC: 0.81 – 1.00) [2]. The second aim was to determine if differences existed in perineal muscle stiffness in the resting state between the two cohorts, with increased muscle stiffness expected in the symptomatic cohort.

### Study design, materials and methods

This was a cross-sectional observational study involving (i) reliability testing of the MyotonPro™ to measure muscle stiffness (unit of measurement – newton metre) in the perineal muscles, and (ii) a cross-sectional comparison of muscle stiffness in two cohorts – asymptomatic and symptomatic (vulvodynia). Women aged 18 – 50 years, asymptomatic of pelvic floor dysfunction (asymptomatic cohort) and symptomatic of vulvodynia (symptomatic cohort) were recruited from the community.

Sample Size Calculations: (i) Reliability Study: To obtain an ICC value of 0.85 with 95% confidence interval for muscle stiffness,  $n = 15$  was calculated for both intra-rater and inter-rater reliability. Sample sizes were increased *a priori* to include all participants ( $n = 43$  asymptomatic and  $n = 32$  symptomatic intra-rater,  $n = 20$  inter-rater asymptomatic). Time constraints limited data collection for inter-rater reliability in the symptomatic cohort ( $n = 14$ ).

(ii) Comparison of cohorts: An *a priori* power analysis ( $\beta = 0.2$ ,  $\alpha = 0.05$ ) was conducted to determine sample size, to obtain a moderate effect size of 0.7 for muscle stiffness ( $n = 30$  each cohort). Sample sizes were increased *a priori* to include all participants ( $n = 43$  asymptomatic and  $n = 32$  symptomatic). *Post hoc* analysis of muscle stiffness data confirmed power (large effect size 1.03 – 1.30) [3].

Measurement Methods: Perineal muscle stiffness values were taken at rest and measured on both the right and left sides using the MyotonPro™. Measures were taken on two occasions, one hour apart, using standardised positions, instructions and measurement protocols.

Statistical Analysis: (i) Reliability: Intra-rater and inter-rater reliability measures were tested using the two way mixed model, averaged measures, ICC with 95% confidence intervals.

(ii) Comparison of cohorts: Two tailed, independent sample t-tests ( $p < 0.05$ ) were conducted to determine differences between asymptomatic and symptomatic cohorts.

### Results

All symptomatic participants presented with localised provoked vulvodynia. Mean pain duration was 10.39 years (range 0.42–30 years). Demographic variables of both groups are presented in Table 1.

Table 1: Summary of demographic variables of all participants

Variable	Asymptomatic $n = 43$	Symptomatic $n = 32$
Age in years, mean (SD)	30.9 (9.2)	29.25 (7.3)
Body Mass Index ( $kg/m^2$ ), mean (SD)	23.76 (3.62)	22.72 (2.84)
Parity (nulliparous / parous) $n$ (%)	32 (74) / 11 (26)	24 (75) / 8 (25)
Ethnicity		
• European-Caucasian $n$ (%)	37 (87)	26 (82)
• Asian $n$ (%)	4 (9)	2 (6)
• Indian $n$ (%)	1 (2)	3 (9)
• African $n$ (%)	1 (2)	1 (3)

(i) Reliability: The MyotonPro™ demonstrated good to very good intra-rater and inter-rater reliability in measuring muscle stiffness of the perineal muscles in asymptomatic and symptomatic cohorts. Reliability results are shown in Table 2.

Table 2: Muscle Stiffness Reliability (ICC) Values in Asymptomatic and Symptomatic Cohorts

Cohort	Perineal Muscle Side	Intra-rater ICC (95% CI) $n = 43$ asymptomatic $n = 32$ symptomatic	Inter-rater ICC (95% CI) $n = 20$ asymptomatic $n = 14$ symptomatic
Asymptomatic	Right	0.85 (0.73, 0.92)	0.70 (0.23, 0.88)
	Left	0.80 (0.62, 0.89)	0.77 (0.41, 0.91)
Symptomatic	Right	0.91 (0.81, 0.96)	0.83 (0.46, 0.94)
	Left	0.88 (0.75, 0.94)	0.86 (0.57, 0.96)

ICC: Intra-class correlation coefficient; CI: confidence interval

(ii) Comparison of cohorts: A significant difference in muscle stiffness at rest between the cohorts was measured, with the symptomatic cohort demonstrating significantly higher values than the asymptomatic cohort, as shown in Table 3. In the symptomatic cohort, right hand dominant participants exhibited significantly increased muscle stiffness on the left side as compared to right side ( $p = 0.000$ ).

*Table 3: Comparison of Muscle Stiffness of Perineal Muscles in Asymptomatic and Symptomatic Cohorts*

<b>Muscle Side</b>	<b>Asymptomatic Stiffness (N/m) Mean (SD)</b>	<b>Symptomatic Stiffness (N/m) Mean (SD)</b>	<b>Mean Difference (95% CI)</b>	<b>p Value</b>	<b>Magnitude of Difference (Cohen's d)</b>
<b>Right</b>	118.25 (22.57)	142.85 (25.65)	24.61 (13.47, 35.74)	0.000	1.03
<b>Left</b>	122.27 (19.98)	155.05 (28.99)	32.77 (21.50, 44.04)	0.000	1.30

*N/m: newton metre; SD: standard deviation; CI: confidence interval*

#### Interpretation of results

(i) Reliability: Muscle stiffness of the perineal muscles can be reliably and objectively measured using the MyotonPro™ in women with and without vulvodynia.

(ii) Comparison of cohorts: The measures of muscle stiffness obtained for the perineal muscles in this study support previous observations of increased muscle stiffness in women with vulvodynia. This is the first study to document this finding using a reliable objective measure of muscle stiffness. It is possible that the difference in muscle stiffness in the perineal muscles between asymptomatic and symptomatic women could be detected via digital palpation. However, as current palpation scales have not been validated against a reference standard, it is unknown if the mean difference found between the two cohorts is detectable by palpation alone, or if the size of this difference is too small to be determined by palpation.

#### Concluding message

Perineal muscle stiffness can be measured using an objective and reliable tool. Future research to develop a digital palpation scale using the MyotonPro™ as a reference standard would facilitate accurate diagnosis of increased, reduced, or normal muscle stiffness and assist with the clinical management of perineal muscle, and potentially levator ani muscle, dysfunction. Further studies are required to investigate the cause of the increased muscle stiffness in women with vulvodynia.

#### References

1. Gentilcore-Saulnier, E., et al., Pelvic floor muscle assessment outcomes in women with and without provoked vestibulodynia and the impact of a physical therapy program. *Journal of Sexual Medicine*, 2010. 7(2): p. 1003-1022
2. Altman, D.G., *Practical statistics for medical research*. 1997, London: Chapman & Hall.
3. Cohen, J., *Statistical power analysis for the behavioural sciences*. 2nd ed. 1988, Hillsdale, NJ: Lawrence Erlbaum Associates.

#### Disclosures

**Funding:** Financial support for this research was provided by the Physiotherapy New Zealand Scholarship Trust Fund (Grant received in 2012) and the Physiotherapy Research Foundation (T12-CWH001). No financial relationship exists between the author and the manufacturer of the MyotonPro™. **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** The study received approval by The University of Melbourne Human Ethics Committee (HREC Number 1238707) and (HREC Number 1340233). All participants provided written informed consent. **Helsinki:** Yes **Informed Consent:** Yes