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master in de revalidatiewetenschappen en de kinesitherapie

Masterproef

Promotor : Prof. dr. Marita GRANITZER

Promotor : Prof. dr. LORENZ RADLINGER

Goedele Moermans Proefschrift ingediend tot het behalen van de graad van master in de

revalidatiewetenschappen en de kinesitherapie



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FACULTEIT GENEESKUNDE EN LEVENSWETENSCHAPPEN

Tests assessing the tone of the pelvic floor muscles in women: a review



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Preface

Writing this thesis the last two years resulted in a lot of mixed emotions, new challenges, new experiences and meeting a lot of new people. I would like to thank all the people who helped me struggle through this, sometimes difficult, period. First of all Prof. Dr. Granitzer, my supervisor, who supported and trusted me and made me grow throughout this process and who made it possible to go abroad for my thesis. Also Prof. Dr. Radlinger who was willing to receive me in Bern, Switzerland for five weeks and who helped me develop the strategy for part two of my thesis and who also brought me in contact with many people with a lot of knowledge on this topic. I would also like to thank all the specialists in Bern who were very willing to take part in the interviews, this was a very interesting and mind broadening experience: PhD-student. Helena Luginbuehl, PhD cand. Barbara Köhler, PhD-student. Monika Leitner, PhD-student. Helene Moser, Prof. Dr. Birgit Schulte-Frei, Corinne Lehman, Veerle Exelmans. A special thank you for Helene Moser who was willing to be my second reviewer and thus making it possible to publish the article later on. Next, I would also like to thank Dr. Thijs to support me with the statistics. I would also like to thank my family who had to support me during all these mixed emotions and who had to watch me practice my defense a couple of times and who read the thesis, probably too, many times.

Thank you all for everything!

Background

A lot of research has been done on the topic of pelvic floor and the dysfunctions of the pelvic floor. Urinary and fecal incontinence, sexual dysfunctions, pelvic organ prolapse are a few examples of possible dysfunctions. Although this topic has been discussed a lot in scientific research, still many people do not feel like talking about this subject because it is socially not accepted. But times are changing in a positive way. The pelvic floor and its dysfunctions are not being avoided that much anymore. The role and assessment of strength of the pelvic floor have been discussed extensively in literature. But the role of tone of the pelvic floor and its assessment are still vague and undiscussed.

The subject of this master thesis has been proposed by Prof. Dr. Lorenz Radlinger from the Bern University of Applied Sciences, Health, Switzerland. He is working on different domains of the topic of pelvic floor muscles together with PhD students. The design of the study has been determined by my supervisors in agreement with myself. The original approach of a systematic review had to be revised because no relevant articles were found. The new approach of performing a narrative search and doing interviews with specialists arose during a meeting with Prof. Dr. Lorenz Radlinger, Prof. Dr. Jan Taeymans, expert in methodology of systematic reviews, and myself. The search strategy and the composing of the interview has been done by myself. The articles have been read by me and by PhD-student Helene Moser. We decided individually which articles should be included and we extracted the info from the articles individually. I have done the interviews with specialists. Combining the info, extracted from the articles individually, has been done by me as well. Afterwards, I also linked this extracted information with the results from the interviews. I have written the thesis, with supervision of PhD-student Helene Moser and my supervisors Prof. Dr. Marita Granitzer and Prof. Dr. Lorenz Radlinger.

Tests assessing the tone of the pelvic floor muscles in women: A review

Composed according to the guidelines of BJOG: <u>http://www.bjog.org/view/0/authorInformation.html</u>

Abstract

This review aimed to describe which test procedures are relevant to assess the tone of the pelvic floor muscles (PFM) in women and to describe their psychometric properties which make them relevant for clinical use. Fourteen articles were included using four search strategies. Interviews with specialists on this topic were also done. Electromyography (EMG), digital palpation and dynamometric speculums can be used to assess tone of the PFM. Between-trial reliability of EMG is good however, the test-retest reliability is not good. Reliability studies of digital palpation do not reach consensus. Reliability of the dynamometric speculums is moderate.

Introduction

The tone of a muscle is described in literature as having both an active and a passive component (1;2). Active tone is controlled by the central nervous system and involves recruitment of muscle fibers which can be observed during EMG-measurement (1). Passive tone of the muscle is defined by its intrinsic viscoelastic properties and shows therefore no EMG-signal (1;2).

The pelvic floor is a hammock in the bottom of the pelvis (3). It supports the organs inside the pelvis and the abdominal cavity, it controls voiding and defecation, and has a sexual function (3). A PFM dysfunction can lead to problems in all three functions such as Pelvic Organ Prolapse (POP), urinary and fecal incontinence, and sexual dysfunctions (4-6). In all these conditions, the active and passive tone of the PFM can be disturbed. As for POP, the passive tone of the PFM, measured by digital palpation, may be of even greater importance than the strength of the PFM (5). Also, the passive tone of the PFM, measured by digital palpation, is important in the so-called trampoline-function during elevation of the intra-abdominal pressure such as Valsalva (6). Nevertheless, no relation between passive tone of PFM and urinary incontinence was found (6). A high passive tone of the PFM, measured by digital palpation and EMG, has also been related to dyspareunia and vaginismus (4). Also, people with a higher anxiety level are more prone to develop more muscle tone during stressful situations than persons with a low anxiety level (7). Besides that, PFM also contributes to maintain posture and to respiratory functions (8). All these previous findings lead to the fact that PFM and the tone of the PFM is an important aspect which is unfairly neglected in the scientific literature. Not much is yet known about how to measure the tone of PFM because of the specific characteristic that these muscles do not cross a joint in their course (3).

In other skeletal muscles, active tone can be assessed by detecting EMG-signals as a result of a muscle contraction (1). Passive tone, on the other hand, can be assessed by palpation and by resistance against passive movement of the limb that is being moved (2). It is often described as muscle firmness, hardness or pliability (1).

Although tone is an important aspect of PFM as it has a relationship with various pelvic floor dysfunctions and with proper functioning of the trunk, it has not received enough attention in scientific literature yet. Consequently, the measurement of the tone of PFM and their measurement properties have also not been extensively researched either. One stringent research question at this moment is therefore 'which test procedures might be considered as reliable and/or valid in testing the tone of the PFM in women'.

The aim of this review is to describe the available test procedures that assess the active and passive tone of PFM in women by describing the test procedure, strategy of scoring, the material and which test position of the patients is used during the test in such a way that it can be useful in clinical practice. The second goal of this review is to describe the reliability and validity of these test procedures.

Methods

This review is based on the PRISMA-checklist (9).

Thirty test procedures that assess strength, tone and/or movement of the PFM have been found during a literature search in the monograph written for part one of this master thesis.

In the article written for part two of this master thesis, a systematic literature search has been performed in February 2014 to search for test procedures that assess the tone of the PFM and to search for their measurement properties. This search has been done on PubMed with key words and with MeSH-terms based on a PICO that has been composed (Appendix 1). An additional search without the key words and MeSH-terms for measurement properties has also been done because this first search did not result in relevant articles (Appendix 2). This latter search did not result in relevant articles either. Therefore the conventional systematic search strategy was quit and a narrative search was performed on PubMed and Embase in February 2014 by using "pelvic floor electromyography reliability", "pelvic floor tone digital", "pelvic floor elasticity reliability" and "pelvic floor pressure reliability". This narrative search focused on EMG, digital palpation and dynamometric speculums because in part one of this thesis, it was found that these measurements can assess the active and passive tone of the PFM. Only articles published in the last ten years were included in order to comprise the articles that are most up to date.

First, the articles were screened based on title and abstract by two independent researchers. Next, if consensus was reached between the two researchers about the articles which should be included based on title and abstract, the full text was read and the references were screened for more relevant articles. The full texts were also read if it was not clear whether an article should be included based on title and abstract. Articles were included based on the following inclusion criteria: females, adults, EMG, digital palpation, dynamometric speculum, assessment of PFM tone (active and passive), reliability and validity, and language (English, German, French, Dutch, Portuguese, Spanish, Italian). Articles were excluded based on the following exclusion criteria: assessments of strength of PFM, neurological disorders and anal measurements.

Information about the test procedure, reliability and validity were extracted from the articles based on pre-designed tables. Afterwards, the information gathered in these tables were unified in one table for each test procedure (Table 1, Table 2, Table 3). These tables have been specifically designed for this review. Reliability outcomes can be Intraclass Correlation Coefficient (ICC), Coefficient of Variance (CV), Standard Error of Measurement (SEM), Minimal Detectable Difference (MDD), Cronbach's Alpha (α), weighted kappa's (κ) and Spearman's Rho (ρ).

Two independent researchers extracted the information from the articles individually.

The narrative search was combined with semi-structured interviews with specialists in PFM assessment to have insight into their perspective and opinion concerning the tone and the assessment of PFM (Appendix 3).

Results

The search with "pelvic floor electromyography reliability" resulted in nine articles in PubMed and in 17 articles in Embase (Figure 1). Six articles were duplicates, eleven were found individually in Embase and three only in PubMed. Eight articles were found to be relevant by both researchers based on title and abstract. One article was a conference abstract that was presented before the actual article was published (10). This published article was also found in the search results (11). Both researchers included eight articles. However, one article was not found in full text and the author did not respond to the requests for receiving the text by mail. In total, seven articles were included by both researchers. The search with "pelvic floor tone digital" resulted in five articles in PubMed and it resulted in 26 articles in Embase (Figure 1). Three articles were duplicates, 22 were found in Embase and two in PubMed. One article was a conference abstract (12). The original article could be found by searching PubMed with the author's name and the title of the article (13). Both researchers selected five relevant articles for this review. One article was not found in full text and was not received after emailing the authors. Therefore, four articles were included by both researchers.

The search with "pelvic floor pressure reliability" resulted in 14 articles in PubMed and 41 articles in Embase (Figure 1). Eleven articles were duplicates, 30 were found in Embase and three in PubMed. Four articles were also found by the previous searches on EMG and digital palpation and were included in these searches. This search led to one included article by both researchers.

The search with "pelvic floor elasticity reliability" led to one article in PubMed and three articles in Embase (Figure 1). One article was a duplicate, two were found in Embase and none in PubMed. One article was already included based on the search for digital palpation and both researchers included one article in this search. Articles were excluded because of various reasons (Figure 1). Fifteen articles were included in this review by both researchers after reading the titles and abstracts.

One article was excluded after reading the full text because strength of the PFM was measured, two articles were excluded because no full text was received. Therefore, twelve articles were included in this review after reading the full texts (Figure 1). The references of these included articles have been screened. No additional articles are relevant for this review.

An invitation for a semi-structured interview has been sent by email to ten PFM-specialists. Seven specialists responded. Two interviews have been done by phone, five were done during a personal meeting. They all answered all pre-composed questions (Appendix 3). Dependent on the answers of the specialist, additional questions have been asked to clarify the answer of the expert.



Figure 1 Flowchart of the four search strategies for the inclusion of articles

Electromyography (EMG)

EMG is an objective measurement to assess the neuromuscular ability of a muscle (11;14). It is used to measure the pattern of muscle activity (15), the on- or off-state of a muscle (16), whether muscle activity increases or decreases during a specific task (16), and whether a muscle becomes fatigued (16). This can be determined from the amplitude and frequency of the EMG-recording (16).

Six studies were found that assess the tone of the PFM by using EMG. The active tone of the PFM is assessed in six of these articles by asking the patient to perform a Maximal Voluntary Contraction (MVC) (11;14-18). In two studies a difference is made between the left and right side of the vagina (11;16). Only three articles assessed the passive tone by measuring the muscle activity in rest (14;17;18). Five different types of EMG are used: Multiple Array Probe Leiden (MAPLe) (14), Periform (15;16;18), Differential Suction Electrode (DSE) (11), Femiscan (11;15-17) and needle EMG (15). The first four are all probes that have to be inserted in the vagina, the latter is performed by using needles. The probes differ in size, morphology, size and position of electrodes on the probe. The tests are performed at the patients in supine (11;14-18) and standing (16;18) position.

The MAPLe is a vaginal probe with 24 electrodes along the sides to measure EMG-signals from different sides and muscle layers (14). The electrodes are located at six levels along the four sides of the probe at a distance of 10 mm apart from each other (14). The probe has a diameter of 1,5 cm and can be used in vaginal and anal measurements (14).

The test-retest reliability has been tested on an ad random selected group of 20 people out of the total study population (N=168). It is, however, not clear how much time between different tests emerged. The test-retest reliability of the MAPLe, expressed in ICC, is assessed in nulliparous, parous premenopausal and parous postmenopausal women. The results for resting tone are 0,73, 0,85 and 0,80, respectively. The test-retest reliability for active tone measured by the MAPLe is assessed by MVC and by endurance contraction of 30 seconds. The results for MVC are 0,60, 0,71 and 0,77, respectively and for endurance contraction 0,74, 0,67 and 0,74, respectively (14) (Table 1).

The Periform is a pear-shaped probe with a length of 8 cm and a width of 3,4 cm (15;16). The probe has two sensoric sides with electrodes of 3,5 cm long and 1,5 cm wide (16).

Auchincloss et al. report a poor test-retest reliability for active tone measured with the Periform in supine and standing position: MVC supine left ICC 0,61, MVC supine right ICC 0,76, MVC standing left ICC 0,41 and MVC standing right ICC 0,36 (16). The between-trial reliability for active tone and passive tone measured with the Periform was excellent with an ICC between 0,87 and 0,99 (15;16;18) in supine and standing position and a SEM (μ V) between 3,0 and 8,7 (18) (Table 1).

The head of the DSE, attaching itself to the vaginal wall by suction, contains two electrodes of 0,1 cm by 0,1 cm which measure the muscle activity (11). The between-trial reliability was assessed based on three trials of MVC and the test-retest was assessed based on two trials with an interval of five to nine days. The between-trial reliability on the right side was ICC 0,964 and on the left side ICC 0,974. The test-retest reliability on the right side is ICC 0,715 and on the left side ICC 0,648 (11) (Table 1).

The Femiscan is a L-shaped probe with a length of 10 cm and a width of 2,5 cm (11;15;17). The probe has six longitudinal electrodes of 4,2 cm by 0,35 cm (11;16;17).

The between-trial (11;15;16) and test-retest (11;16;17) reliability of the Femiscan have been assessed. Keshwani et al. report an excellent between-trial reliability of active tone with ICC 0,974 for the left side and ICC 0,943 for the right side (11), Auchincloss et al. also report an excellent between-trial reliability with ICC 0,93 (15). But the between-trial reliability of the Femiscan measured by Auchincloss et al. has a greater variability with ICC between 0,70 and 0,98 (16). The test-retest reliability of the Femiscan is good with ICC between 0,78 and 0,924 (11;17) and SEM (μ V) of 1,0 (17). Auchincloss et al., however, report a poor test-retest reliability with ICC between 0,20 and 0,57 (16) (Table 1).

Needle EMG was used in the article of Auchincloss et al. to compare the changes in the PFM after insertion of a vaginal probe (15). The between-trial reliability of needle EMG is excellent with an ICC of 0,96 (15) (Table 1).

Study	Population	Probe	Reliabili	ty			ICC	SEM	CV (%)	MDD	Remarks
			Test-	Between -	Intra-	Inter-					
			retest	trial	rater	rater					
Voorham-van der Zalm et al. (2013)	N = 168 healthy	MAPLe	X (N=20)								Supine position Nulliparous, premenopausal (N=86):
							0,73				Rest tone
							0,60				MVC
							0,74				Endurance
											Parous, premenopausal (N=37):
							0,85*				Rest tone
							0,71				MVC
							0,67				Endurance
											Parous, postmenopausal (N=40):
							0,80*				Rest tone
							0,77*				MVC
							0,74				Endurance
Luginbuehl et al. (2013)	N = 10 healthy stu- dents Age: 20 – 35 BMI: 20 – 30										ICC(3,1) MDD: 95% CI SEM and MDD in μV.
	BMII. 20 00	Periform		Х			0.999**	3.0		8.3	Rest activity, supine
							0.993**	4.0		11.1	Rest activity, standing
							0.867*	8.7		24.1	MVC. supine
							0,914**	6,3		17,6	MVC, standing
Keshwani et al. (2012)	N = 20 healthy Age: 18 – 50 Avg. BMI: 24.7 ± 9.3									,	ICC(3,1) Crook lying
	···· g · = ···· = ·,· = •,•	DSE		Х			0,964**		8,6		MVC, right muscle (N=20)
							0,974**		8,8		MVC, left muscle (N=18)
									,		
			Х				0,715				MVC, right muscle (N=18)
							0,648				MVC, left muscle (N=18)
		Femiscan		Х			0,943**		11,2		MVC, right muscle (N=20)
							0,974**		11,2		MVC, left muscle (N=20)
			х				0,788* 0,924**				MVC, right muscle (N=20) MVC, left muscle (N=20)

Table 1 Reliability of EMG-measurements of pelvic floor muscles in women

Study	Population	Probe	Reliabil	ity			ICC	SEM	CV (%)	MDD	Remarks
			Test- retest	Between - trial	Intra- rater	Inter- rater					
Auchincloss et al. (2012)	N = 9 Avg. age: 31,3 Avg. BMI: 22.5										ICC(3,1) Crook lying
	7.vg. Divil. 22,0	Needle EMG		Х			0,96**		11,2		MVC
		Periform		Х			0,94**		16,5		MVC
		Femiscan		Х			0,93**		21,8		MVC
Grape et al. (2009)	N = 17 healthy, nullipa- rous Age: 20 – 35										ICC(2,1) Supine position
	, igo. 20 00	Femiscan	Х				0,88**	1,0	20,6	2,7	Rest tone, test 1 & 2 SEM and MDD in μ V.
							0,86**	1,1	23,0	3,2	Rest tone, test 1, 2 & 3 SEM and MDD in μ V.
Auchincloss et al. (2009)	N = 10 healthy, nullipa- rous Age: $18 - 40$										ICC(3,1) All MVC
	, igo: 10 10	Femiscan	Х				0,41				Supine, left muscle
							0,57				Supine, right muscle
							0,20				Standing, left muscle
							0,46				Standing, right muscle
				х			0,72		8,5		Day 1, supine, left muscle
							0,89*		14,2		Day 1, supine, right muscle
							0,98**		9,5		Day 2, supine, left muscle
							0,96**		13,6		Day 2, supine, right muscle
							0,82*		12,7		Day 1, standing, left muscle
							0,74		11,7		Day 1, standing, right muscle
							0,90**		11,7		Day 2, standing, left muscle
							0,70		11,6		Day 2, standing, right muscle
		Periform	х				0,61				Supine, left muscle
							0,76*				Supine, right muscle
							0,41				Standing, left muscle
							0,36				Standing, right muscle
				Х			0,87*		9,6		Day 1, supine, left muscle

Table 1 Reliability of EMG-measurements of pelvic floor muscles in women

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Study	Population	Probe	Reliabil	lity			ICC	SEM	CV (%)	MDD	Remarks
			Test- retest	Between - trial	Intra- rater	Inter- rater					
							0,90**		12,9		Day 1, supine, right muscle
							0,96**		11,0		Day 2, supine, left muscle
							0,96**		11,6		Day 2, supine, right muscle
							0,94**		11,1		Day 1, standing, left muscle
							0,87*		16,4		Day 1, standing, right muscle
							0,91**		12,8		Day 2, standing, left muscle
							0,95**		13,6		Day 2, standing, right muscle

ICC: Intraclass Correlation Coefficient, SEM: Standard Error of Measurement, CV: Coefficient of Variance, MDD: Minimal Detectable Difference, MVC: Maximal Voluntary Contraction, BMI: Body Mass Index in kg/m³, CI: Confidence Interval ICC: <0,49 poor, 0,50-0,74 moderate, 0,75-0,89 good*, ICC > 0,90 excellent** (19)

Digital palpation

Four studies were selected that assess the passive tone of the PFM using digital palpation (5;6;13;20).

Kavvadias et al. (13) did not rapport how the PFM passive tone was tested. They tested the patients in lithotomy position by using one index finger.

The inter-rater reliability for this measurement was poor (13). Two investigators each tested all patients at two moments. It was not mentioned how much time was in between tests. For visit 1 the ICC is 0,10 (p: 0,34), Cronbach's α is 0,19 and Spearman's Rho ρ is 0,07 (p: 0,84) (13). For visit 2 the ICC is 0,13 (p: 0,30), Cronbach's α is 0,23 and Spearman's Rho ρ is 0,18 (p: 0,50) (13).

The test-retest reliability for this measurement was also poor (13). For investigator A the ICC is 0,03 (p: 0,45), Cronbach's α is 0,06 and Spearman's Rho ρ is 0,00 (p: 0,99). For investigator B the ICC is - 0,36 (p: 0,92), Cronbach's α is -1,16 and Spearman's Rho ρ is -0,31 (p: 0,23) (13) (Table 2).

Slieker-ten Hove et al. (20) assessed the passive tone of the PFM by analyzing the ability to relax after a contraction by inserting 1 finger into the vagina in lithotomy position. The ability to relax is scored following an ordinal three-point scale: complete – partly – absent.

Intra-rater reliability was determined with 10 to 15 minutes between testing of the different raters. The raters showed an agreement of 87,8% after testing the patients twice and a weighted kappa of 0,76 (95% CI 0,59 – 0,87). The inter-rater reliability was 39% agreement and a weighted kappa of 0,17 (95% CI -0,01 – 0,38) (20) (Table 2).

The passive tone of the PFM is assessed by Dietz (5) by using a six-point scale: 0 - 5 (see below). Each score is described as the sensation of the state of the muscle during palpation and the resistance to palpation. This scale is refined by Dietz et al. (5) by also obtaining half grades (11-point scale), and by testing both sides of the vagina (21-point scale). The patient is tested in a modified lithotomy position by using one finger and is asked to contract the muscle a couple of times in order to relax the muscle. Afterwards, the muscle is slowly distended a few times to assess the passive tone.

- 0: muscle not palpable
- 1: muscle palpable but very flaccid, wide hiatus, minimal resistance to distension
- 2: hiatus wide but some resistance to distension
- 3: hiatus fairly narrow, fair resistance to palpation but easily distended
- 4: hiatus narrow, muscle can be distended but high resistance to distension, no pain
- 5: hiatus very narrow, no distension possible, 'woody' feel, possibly with pain: 'vaginismus'

Test-retest reliability was fair (5). The weighted kappa's (95%CI) were 0,42 (0,33 - 0,51), 0,50 (0,41 - 0,59) and 0,55 (0,44 - 0,66) for the 6-point, 11-point and 21-point scale, respectively (5) (Table 2).

Devreese et al. (6) developed an ordinal three-point scale: hypotone – normotone – hypertone. The superficial and deep muscles are scored individually. Each score is described as the feeling and movement possible during palpation. The assessment was done with the patient in lithotomy position and by using one index finger.

- Superficial part of the pelvic floor
 - Hypertone
 - Index finger can move subtle in the vagina
 - o Normotone
 - Vagina tightens as a firm band around second phalanx of the finger
 - o Hypotone
 - The vagina ring is wide and very weak
- Deep part of the pelvic floor (puborectalis and levator ani muscle)
 - Hypertone
 No
 - Normal smooth suspension of levator hammock in the distal part of the vagina
 - o Normotone
 - Distal phalanx of the finger cannot move downward in the distal part of the vagina
 - o Hypotone
 - Finger drops down into a zone of reduced muscle bulk in the distal part of the vagina

The inter-rater reliability, measured as agreement between two raters, for this scale is good for the total group (N = 80; superficial 98%, deep 96%), the continent (N = 40; superficial 100%, deep 95%) and incontinent group (N = 40; superficial 95%, deep 98%) (6) (Table 2). One hour was provided between testing of the two raters (6).

Study	Population	Test	Reliat	oility			ICC (n)	α	К	ρ (p)	%	Remarks
			Test- retest	Be- tween - trial	Intra- rater	Inter- rater						
Kavvadias et al. (2013)	N = 17 healthy, nulliparous	Passive muscle tone				Х	0,10 (0,34)	0,19		0,07 (0,84)		2 raters Visit 1
							0,13 (0,30)	0,23		0,18 (0,50)		Visit 2
			Х				0,03 (0,45)	0,06		0,00 (0,99)		Investigator A
							-0,36 (0,92)	-1,16		-0,31 (0,23)		Investigator B
Slieker-ten Hove et al. (2009)	N = 41 Avg. age: 41 (22 – 63)	Lithotomy 1 finger Ability to relax after con- traction: - complete - partly - absent										Weighted Kappa (95%CI)
					Х				0,76* (0,59 – 0,87)		87,8	
						Х			0,17 (- 0,01 – 0,38)		39	3 raters
Dietz et al. (2008)	N = 98 with uri- nary tract dysfunc- tions Avg. age: 54,7 (19-86)	Lithotomy 1 finger Passive muscle tone: - 6- point scale - 11-point scale - 21-point scale										Weighted Kappa Fleiss-Cohen (95%Cl)
			Х						0,42 (0,33- 0,51)			6-point scale
									0,50 (0,41- 0,59)			11-point scale
									0,55 (0,44- 0,66)			21-point scale

 Table 2 Reliability of digital palpation of pelvic floor muscles in women

 Table 2 Reliability of digital palpation of pelvic floor muscles in women

Study	Population	Test	Reliat	oility			ICC (p)	α	К	ρ (p)	%	Remarks
			Test-	Be-	Intra-	Inter-						
			retest	tween	rater	rater						
				- trial								
Devreese et al. (2004)	N = 40 continent N = 40 incontinent	Lithotomy 1 index finger Passive muscle tone: - superficial: hypo – nor- mo – hypertone - deep: hypo – normo – hypertone										2 raters
		<i></i>				Х					98	Superficial, N = total
											100	Superficial, continent
											95	Superficial, incontinent
											96	Deep, N = total
											95	Deep, continent
											98	Deep, incontinent

a: <0,69 poor, 0,70-0,89 good, >0,90 excellent (19) κ: <0,40 poor, 0,40-0,59 moderate, 0,60-0,79 good*, >0,80 excellent (19)

Dynamometric speculums

Two studies, which assess the elasticity and the ability to distend the PFM by using a dynamometric speculum, were found (21;22).

Morin et al. (21) assessed the elasticity of the PFM in supine position by comparing EMG-activity during four different conditions of the speculum: 1) two branches closed, 2) two branches maximally opened, 3) changes during continuously opening and closing the two branches (= passive elastic stiffness (PES)), and 4) sustained stretch (= % loss in passive forces after one minute). The between-trial reliability of this speculum has been assessed, measured in Phi (Φ). The Φ (SEM in N) during minimal aperture measured over one trial is 0,56 (0,34) and measured over two trials is 0,57 (0,34). With a maximal aperture of the speculum, the Φ (SEM in N) measured for the passive forces exerted on the speculum over one trial is 0,81 (0,58) and measured over two trials is 0,82 (0,57). The PES was measured during opening and closing of the two branches in N/mm. The Φ (SEM in N/mm) at minimal aperture for one trial is 0,66 (0,03) and for two trials is 0,74 (0,03). The Φ (SEM in N/mm) at maximal aperture is 0,70 (0,11) for one trial and 0,75 (0,10) for two trials. The Φ (SEM in %) after 1 trial of sustained stretch is 0,54 (8,31) and after two trials 0,66 (6,37) (21). (Table 3).

Verelst et al. (22) measured the force exerted by the PFM on the speculum during five consecutive increasing diameters with the speculum inserted in the vagina: 30 mm, 35 mm, 40 mm, 45 mm, and 50 mm.

The test-retest reliability, measured in CV, is 22%, 15%, 11%, 10% and 8%, respectively (22) (Table 3).

Study	Population	Test	Reliability				Φ	SEM	CV (%)	Remarks
			Test- retest	Between - trial	Intra- rater	Inter- rater			(19)	
Morin et al. (2008)	N = 32 Avg. age: 56 Avg. BMI: 24,9 Avg. Parity: 1,2	Supine Relaxation of PFM: EMG-activity during 4 conditions: - two branches closed - two branches maximally opened - changes during continuously opening and closing the two branches								
				Х			0,56	0,34 (87,9)		2 branches closed, 1 trial SEM in N (%)
							0,57	0,34 (87,9)		2 branches closed, 2 trials absSEM in N (%)
							0,81	0,58 (25)		Maximal aperture Passive forces, 1 trial absSEM in N (%)
							0,73	1,90 (7,2)		Maximal aperture Maximal vaginal aperture, 1 trial absSEM in mm (%)
							0,82	0,57 (24,5)		Maximal aperture Passive forces, 2 trials absSEM in N (%)
							0,73	1,90 (7,2)		Maximal aperture Maximal vaginal aperture, 2 trials absSEM in mm (%)
							0,66	0,03 (22,7)		Lengthening and shortening PES at minimal aperture, 1 trial absSEM in N/mm (%)
							0,74	0,03 (22,7)		Lengthening and shortening PES at minimal aperture, 2 trials absSEM in N/mm (%)
				19			0,70	0,11 (23,3)		Lengthening and shortening PES at maximal aperture, 1 trial absSEM in N/mm (%)

Table 3 Reliability of dynamometric speculum measurements of pelvic floor muscles in women

Study	Population	Test	Reliability				Φ	SEM	CV (%)	Remarks
			Test- retest	Between - trial	Intra- rater	Inter- rater				
							0,75	0,10 (23,3)		Lengthening and shortening PES at maximal aperture, 2 trials absSEM in N/mm (%)
							0,54	8,31 (26,22)		Sustained stretch, 1 trial (% loss in passive forces after 1min) absSEM in % (%)
							0,66	6,37 (20,1)		Sustained stretch, 2 trials (% loss in passive forces after 1min) absSEM in % (%)
Verelst et al. (2004)	N = 20 healthy Avg. age: 39 Avg. parity: 2	Half sitting position Passive and active force with 5 increasing diameters								
	Avg. weight: 62		Х						22	30mm diameter
	-								15	35mm diameter
									11	40mm diameter
									10	45mm diameter
									8	50mm diameter

Table 3 Reliability of dynamometric speculum measurements of pelvic floor muscles in women

Φ: Phi, absSEM: absolute Standard Error of Measurement, CV: Coefficient of Variance, BMI: Body Mass Index in kg/m³, N: Newton

Discussion

The aim of this review was, firstly, to enlist the tests that assess the tone of the PFM in women; and secondly, to describe their psychometric properties.

Muscle tone is defined as having both an active and a passive component (1;2). This concept was clearly reflected in the interviews with clinical specialists. Only two of them described muscle tone to be merely passive. The specialists describe the active component as "being able to contract the muscle", and the passive component as "the sensation of the muscle during palpation" (firmness, hardness, stiffness).

During the interviews all specialists stressed the importance of this review as they all presumed a relationship between PFM tone and urinary incontinence and sexual dysfunctions.

The first objective of this review was to list the available test procedures that assess the tone of the PFM in women and in particular to present how these test procedures have been used in the literature in order to make it clinically useful. In the literature, it was found that EMG, digital palpation and dynamometric speculums could be used to test the tone of the PFM.

Five different EMG-devices have been found in this review.

The MAPLe is a multiple array probe and can differentiate between the different muscle layers and between the left and right side of the PFM because it has 24 electrodes organized at six levels at the four sides of the probe (front, back, left, right) (14).

The DSE is also able to differentiate between different muscle layers and between the left and right side of the vagina because it has a very small electrode area (11). The suction head also allows the researchers to place the electrodes at any place against the vaginal wall that has to be investigated (11). The DSE and MAPLe distinguish itself from other probes in this ability to differentiate between the different layers of the PFM.

The Femiscan and Periform have longitudinal electrodes which make it impossible to differentiate between the different layers of PFM (16;17). They both have electrodes on the right and left side of the probe to distinguish muscle activity from the left and right side of PFM (11;16).

Needle EMG is used in one study to measure whether the activity of PFM changes when a vaginal EMG-probe is inserted in the vagina (15). Prior to placing the needles, an anesthetic had to be applied (15). Needle EMG has also been suggested by one of the specialists during the interview. She states however, that the use of needles in this area of the human body is inhuman.

From the interviews it appeared that six out of seven specialists also use EMG to assess the tone of the PFM. They did not specify which probes they used in clinical practice. The quality of the Voltageoutput (μ V), the pattern of the wave, is thought to be the most important source of information for the expert in assessing the tone of the PFM. They all assess the tone with EMG in supine position although one expert mentioned that supine is not the most functional position.

Four studies have been found that assess passive tone by using palpation. However, Kavvadias et al. did not report how they measured the passive tone (13). The three other scales are very different.

Slieker-ten Hove et al. reported the ability to relax after a contraction (20). Two specialists reported this ability to relax as being the passive tone during the interviews. Dietz et al. described the passive tone by using a 6-point, 11-point and 21-point scale (5), while Devreese et al. reported the passive tone by using three categories: hypo-, normo and hypertone (6). Devreese et al. also differentiated between the deep and superficial layers of the PFM (6). They all used one finger and performed the assessment in lithotomy position. It is difficult to compare these scales because they measure something different and they use a different scoring system.

Within the interviews, the specialists informed that they also assess the tone of PFM by using digital palpation, however they do not use a specific scale to report this. They specifically focus on resistance during palpation, the ability to relax the muscle and stiffness. One specialist informed that she uses the same scale as the one that is developed by Devreese et al., but without knowing that this scale is described in literature. It seems that in clinical practice a combination is made of the scales described above, but without the specific knowledge of the existence and description of these scales. The guide-lines and relevant information from scientific research do not seem to reach the specialists.

The dynamometric speculums described above were not mentioned during the interviews. One specialist mentioned that she assesses passive tone of the PFM by sensing resistance during a craniocaudal movement with her finger. Dietz et al. also distended the muscle during the performance of their assessment (5).

The second objective was to present the psychometric properties of these test procedures to be able to give a proposal for clinical use.

The MAPLe reports moderate to good test-retest reliability (14). Ultrasound and MRI were used to make sure that the probe was in the right place, and during the measurement the probe was held in place by the clinical specialist (14). This can be the reason that the test-retest reliability is better than the other EMG-probes.

The DSE has an excellent between-trial reliability and a moderate test-retest reliability. The betweentrial reliability is likely to be higher than the test-retest reliability because the electrodes are more likely to assess exactly the same motor unit. As the head of the DSE is very small, it is possible that at another test moment the electrodes measure another motor unit.

The Periform has a poor to good test-retest reliability (16). This poor result can probably also be attributed to the fact that other motor units are being measured. The between-trial reliability, on the other hand, is good to excellent (15;16;18). It was found that the tests that are performed in standing position have a lower test-retest reliability (16) but no difference is found in between-trial reliability between standing and supine positions (15;16;18).

Consensus about the test-retest reliability of the Femiscan is not found in the literature. The passive tone assessed with the Femiscan has a good reliability, but the active tone has a good to excellent reliability in one study (11) but a poor reliability in another study (16). No clear explanation can be found for these differences in results for active tone. The between-trial reliability of the Femiscan is good to excellent (11;15;16). Therefore, the DSE, Periform and Femiscan can be used within one therapy session to assess the training effect, but not as a follow-up measurement over a longer period

of time. A slightly lower test-retest reliability for the Femiscan is found in standing position (16) but no differences are detected in different positions in between-trial reliability (11;15-17). Needle EMG has an excellent between-trial reliability (15) and can thus be used within one therapy session.

The inter-rater reliability of digital palpation in the study of Kavvadias et al. and Slieker-ten Hove et al. is poor (13;20) but the inter-rater reliability of Devreese et al. is excellent (6). All raters were blinded. Kavvadias et al. did not mention the time between the testing of the raters, Slieker-ten Hove et al. left 10 – 15min between testing by the different raters and Devreese et al. left one hour in between. The difference in scoring could not be checked because Kavvadias et al. did not mention how they performed the test. The scoring system of Slieker-ten Hove et al. and Devreese et al. is approximately the same. Within the interview, one specialist said that inter-rater reliability of digital palpation can be trained. This learning ability can be the reason why the inter-rater reliability in the article of Devreese et al. is this high.

The intra-rater reliability measured for the scale of Slieker-ten Hove et al. is good (20). The test-retest for the scale of Kavvadias is poor (13) and for the scale of Dietz et al. poor to moderate (5). However, the specialists reported during the interviews that the intra-rater reliability is thought to be good and the inter-rater reliability is poor for digital palpation. The reliability of EMG is thought to be good by the specialists.

The validity of digital palpation has not been mentioned in the literature, but from the interviews the specialists claimed that the validity is excellent. Most specialistst, however, questioned the validity of EMG because of cross-talk.

During the interviews, the specialists gave many reasons for the possible differences in EMGmeasurements between days: the state of bowel and bladder, level of stress, lubrication of the vagina and the hormone-cycle.

The test-retest reliability of the dynamometric speculum is moderate to good (21;22). The reliability has been measured in Phi, which is not the most recommended unit to be used in reliability studies. The measurements have been done in a passive way by performing a distention of the two branches. Such a distention, however, can be painful at maximal aperture. This way of measuring seems a very important division of PFM-tone measurement because it is a new approach of measuring the stiffness of the PFM and thus the passive tone.

Only two databases have been searched for literature. This is a limit of this review. However, the references of the included articles have been screened and no additional articles were found that should be included. Therefore it is less likely that literature has been missed by not searching in additional databases. Another possible limit is the fact that the systematic database search had to be interrupted and this review therefore is not a systematic review. However, the literature is not extensively available yet and could thus not be found by doing the search in a systematic manner. The interviews with specialists completes the information extracted from literature and is therefore a clinical useful addition.

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In conclusion, EMG, digital palpation and dynamometric speculums can be used to assess the active and passive tone of PFM. Reliability studies of EMG revealed that between-trial reliability is good but the test-retest reliability is not good. Reliability studies of digital palpation, however, do not reach consensus. The specialists stated that intra-rater reliability is good but inter-rater is not good. The reliability of the dynamometric speculums is moderate to good. However, this type of measurement needs to be investigated more because not much literature is available yet.

Thus, EMG is recommended to assess learning effects within one session but not in between different days. The DSE, Femiscan and Periform might be recommended to measure differences between trials based on their between-trial reliability. Digital palpation on the other hand, can be used to assess tone of the PFM over a longer period of time on the condition that the measurements are done by the same person. The most appropriate for this, based on inter-rater reliability, is the scale developed by Devreese et al.

In the future, further development of other test procedures and equipment to test the tone of the PFM is recommended. Currently, devices that assess force (N) and muscle activity (μ V) simultaneously are missing. Next, the ability to assess muscle stiffness of the PFM should be more explored, possibly by dynamometric speculum-like devices. The standardization of test procedures, especially in testing the tone, should be described more. Finally, the influence of stress and anxiety of the person on the tone of PFM seems worth to be examined more thoroughly.

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Disclosure of interests

None

Contribution to authorship

Goedele Moermans planned, organized and wrote the whole article. Helene Moser and Goedele Moermans both did the literature search, inclusion of articles and extraction of information individually.

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Ref Type: Generic

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Appendix 1

(Column 1 key words OR column 1 MeSH) AND (Column 2 key words OR column 2 MeSH) AND (Column 3 key words OR column 3 MeSH) AND (Column 4 key words OR column 4 MeSH) NOT (Column 5 key words OR column 5 MeSH)

No limits were used.

Result: 2 articles

Р	1	C	0	NOT
patient, population, problem	Measurement method	Comparison /	Component that was measured	
		Construct of interest		
Keywords (free-text):				
#37	#38	#39	#40	
#1	#3	#22	#24	#27
females	"modified oxford scale"	pelvic floor	Reliability	fecal incontinence
women	"oxford grading scale"	pelvic floor muscle	Reliability study	faecal incontinence
adult	"modified oxford grading scale"	pelvic floor musculature	Rater reliability	anal incontinence
	"oxford grading"	pelvic-floor	Interrater reliability	cadaver
#2		pelvic-floor muscle	Inter-rater reliability	animals
urinary incontinence	#4	levator ani	Interobserver reliability	diabetes
urinary continence	"digital palpation"	levator ani muscle	Intra rater reliability	neurological disease
"stress urinary incontinence"	"palpation"		Intra-rater reliability	surgery
"urge urinary incontinence"	"digital assessment"	#23	Test-retest reliability	male
"mixed urinary incontinence"		muscle tone	Test retest reliability	pregnancy
continent	#5	muscle tonus		questionnaire
incontinent	"visual observation"	muscle hypotonia	#25	muscle strength
continen*		muscle hypertonia	Validity	muscle contraction
incontinen*	#6	muscle hypertonicity	Validity of results	pelvic organ prolapse
	"PERFECT scheme"	muscle activity		
	"PERFECT"	muscle activation	#26	
			Specificity	
	#7		Sensitivity	
	"brink scale"			
	"brink score"			
	"brink"			
	#8			
	"ortiz scale"			
	"ortiz"			
	#9			
	"Devreese A"			

clinical evaluation pelvic floor		
#10		
"digital assessment scheme of pelvic		
floor"		
#11		
"tampon scale"		
#12		
"perineometer"		
"PFX"		
"kegel perineometer"		
"kegel"		
"sensupower perineometer"		
#13 "FMC"		
"sEMG"		
"electromyography"		
"surface electromyography"		
"myomed" "periform"		
pomonii		
#14		
"ultrasound"		
"transperineal ultrasound "		
#15 "sola ovia"		
"colpexin pull"		
"colpexin sphere"		
"Kolpexin"		
#16		
"magnetic resonance imaging"		
"dynamic MRI"		
МК Imaging "MR examination"		
"MRI"		

	#17			
	dynamometer			
	#18			
	"manometer"			
	#19			
	"vaginal cone"			
	#20			
	"balloon catheter"			
	#21			
	#ZI			
	vaginai probe			
MeSH (Medline):				
#41	#42	#43	#44	
#28	#30	#33	#34	#36
urinary incontinence	Ultrasonography	pelvic floor	Reproducibility of results	Operative Surgical Procedure
urinary incontinence. stress	Ultrasound	pelvic floor disorders	Reproducibility of Findings	disease. Nervous System
urinary incontinence, urge			Validity of Results	Nervous System Disease
	#31	#46	Reliability and Validity	Neurologic Disorders
#29	functional MRI	Muscle tonus	Validity and Reliability	Diabetes mellitus
fomalo	Magnetic Reservance Imaging	Muscle hypotopia	Poliability of Posults	Experimentation Animal
womon	Magnetic Resonance Imaging		Reliability of Results	
women		Muscle hyertonia		Animal Research
adolescent	#32			cadaver
adult	Electromyography			fecal incontinence
				male
	#46			male urogenital diseases
	Manometry			pregnancy
				questionnaires
				muscle strength
				muscle contraction
				Pelvic Organ Prolapse

Appendix 2

(Column 1 key words OR column 1 MeSH) AND (Column 2 key words OR column 2 MeSH) AND (Column 3 key words OR column 3 MeSH) AND (Column 4 key words OR column 4 MeSH) NOT (Column 5 key words OR column 5 MeSH)

No limits were used.

Result: 10 articles

Р	1	C	0	NOT
patient, population, problem	Measurement method	Comparison / Construct of interest	Component that was measured	
Keywords (free-text):			·	·
#37	#38	#39	#40	
#1	#3	#22	#23	#27
females	"modified oxford scale"	pelvic floor	muscle tone	fecal incontinence
women	"oxford grading scale"	pelvic floor muscle	muscle tonus	faecal incontinence
adult	"modified oxford grading scale"	pelvic floor musculature	muscle hypotonia	anal incontinence
	"oxford grading"	pelvic-floor	muscle hypertonia	cadaver
OR		pelvic-floor muscle	muscle hypertonicity	animals
	#4	levator ani	muscle activity	diabetes
#2	"digital palpation"	levator ani muscle	muscle activation	neurological disease
urinary incontinence	"palpation"	skeletal muscle		surgery
urinary continence	"digital assessment"		muscle tension	male
"stress urinary incontinence"			tension	pregnancy
"urge urinary incontinence"	#5		pressure	questionnaire
"mixed urinary incontinence"	"visual observation"		vaginal resting pressure	pelvic organ prolapse
continent			rest pressure	
incontinent	#6		muscle contraction	
continen*	"PERFECT scheme"			
incontinen*	"PERFECT"			
	#7			
	"brink scale"			
	"brink score"			
	"brink"			
	#8			
	"ortiz scale"			
	"ortiz"			
	#9			
	"Devreese A"			
	clinical evaluation pelvic floor			

#10 "digital assessment scheme of pelvic floor"		
#11 "tampon scale"		
#12 "perineometer" "peritron" "PFX" "kegel perineometer" "kegel" "sensupower perineometer"		
#13 "EMG" "sEMG" "electromyography" "surface electromyography" "myomed" "periform"		
* "ultrasound" "transabdominal ultrasound " "transperineal ultrasound "		
#15 "colpexin" "colpexin pull" "colpexin sphere" "Kolpexin"		
#16 "magnetic resonance imaging" "dynamic MRI" "MR imaging" "MR examination" "MRI"		
#17		

	"dvnamometer"			
	#18			
	"manometer"			
	manometer			
	#10			
	#19			
	vaginai cone			
	#20			
	#20			
	"balloon catheter"			
	#21			
	"vaginal probe"			
MeSH (Medline):				
#41	#42	#43	#44	#45
#28	#30	#33	#34	#36
urinary incontinence	Ultrasonography	pelvic floor	Muscle tonus	Operative Surgical Procedure
urinary incontinence, stress	Ultrasound	pelvic floor disorders	Muscle hypotonia	disease, Nervous System
urinary incontinence, urge			Muscle hyertonia	Nervous System Disease
	#31			Neurologic Disorders
#29	functional MRI			Diabetes mellitus
female	Magnetic Resonance Imaging			Experimentation, Animal
women				Animal Research
adolescent	#32			cadaver
	Electromyography			fecal incontinence
				male
	#46			male urogenital diseases
	Manometry			pregnancy
				questionnaires
				muscle strength
				muscle contraction
				Pelvic Organ Prolanse

Appendix 3

Questionnaire about diagnostics of hypo- and hypertone pelvic floor muscles

- 1. Because the literature uses the term muscle tone in different topics, I would like to know what you understand under the term "muscle tone of the pelvic floor"?
- 2. Do you think the muscle tone is important concerning pelvic floor? Why? Why not?
 - 2.1. What do you think of the relationship between muscle tone of the pelvic floor and (in)continence?
 - 2.2. What do you think of the relationship between muscle tone of the pelvic floor and sexual dysfunctions?
- 3. How do you assess the pelvic floor muscle?
 - 3.1. What do you look for when you use digital palpation to assess the pelvic floor?
 - 3.2. Do you measure muscle tone of the pelvic floor in practice?
 - 3.3. What measurement do you use to measure the tone of the pelvic floor?
 - 3.4. Are there enough measurements on the market to assess the tone of the pelvic floor?
 - 3.5. Do you have an impression of the validity and reliability of these tests from your own perspective?
- 4. Do you have any suggestions about possible modifications of test procedures to assess the tone of the pelvic floor?
- 5. Is there an aspect of pelvic floor muscle testing that is not described yet in the literature that you think is of importance?
- 6. Is there anything you want to add about tone of the pelvic floor?

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Richting: master in de revalidatiewetenschappen en de kinesitherapie-revalidatiewetenschappen en kinesitherapie bij neurologische aandoeningen Jaar: 2014

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Voor akkoord,

Moermans, Goedele

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