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## VALIDATION AND STANDARDIZATION OF THE PELVIC FLOOR INVENTORIES (PELFIS) FOR WOMEN IN ENGLISH

### Hypothesis / aims of study.

To evaluate the validity and reliability of the English version of the "Pelvic Floor Inventories" (PeLFIs, 1) for women, an administered condition-specific pelvic floor questionnaire, addressing all complaints of prolapse, micturition, defecation, pelvic floor pain and/or sexual function. The PeLFIs for women is a 149-item instrument containing nine different domains, including General Health. The questions which have been selected configure, from a clinical point of view, a specific domain. The PeLFIs, validated in Dutch, has been translated into English.

### Study design, materials and methods.

Forward-backward translation of the PeLFIs was performed by native English speakers. The final English version was administered in Canada and the United States to healthy volunteers (N=74), and patients (N=254). Psychometric properties of the English version, including internal consistency, test-retest reliability, content and construct validity were examined. Two types of reliability were assessed: internal consistency and test-retest reliability (stability over time). Internal consistency was measured using Cronbach's Alpha. Test-retest reliability was assessed by intraclass correlation coefficients. Construct validity was established by comparing scores in healthy volunteers and patients (using t-tests), and by intercorrelating domains (using Pearson's correlations).

### Results.

Forward-backward translation of the English version of the PeLFIs was consistent with the original Dutch questionnaire. The English version was easily administered and there were no missing data. In total 328 questionnaires were administered. Mean age of respondents was 52 years (range 18 to 78). Mean Body Mass Index was 26 (range 17- 56). The retest was administered two weeks after the initial PeLFIs interview. Internal consistency of the questionnaire was 0.88 for the total scale. Cronbach's alpha of the domains ranged from 0.71-0.95. In the test-retest reliability the agreement rate of the two tests exceeded 95 % and the internal consistency ranged from 0.6-0.8. Between healthy volunteers and patients, the differences were statistically significant for all domains. Correlations of the domain scores were high ( $r > 0, 20$ ).

### Interpretation of results.

Our study confirms the psychometric properties of the PeLFIs for the English version with respect to reliability and validity (construct and content). Consequently, users can be confident that it reliably measures what is intended and that it provides a legitimate and valid summary of the level of complaints of prolapse, micturition, defecation, pelvic floor pain and/ or sexual function. Moreover, it can reliably quantify changes in symptom levels following treatment. Compared to other standardized questionnaires which assess parts of pelvic floor dysfunction, the PeLFIs covers all important domains.

### Concluding message.

The PeLFIs questionnaire has been translated and evaluated successfully into English and has shown adequate internal consistency and reliability.

The PeLFIs for women is, also in English, a valid instrument for measuring complaints of prolapse, micturition, defecation, pelvic floor pain and/or sexual function and can be used as a clinical and research tool, creating more uniformity in history taking for professionals active in this field.

The PeLFIs for men has been translated into English and validation is ongoing.

Table: Cronbach's Alpha and mean score ( $\pm$  SD) by domain of the Female PeLFIs questionnaire in English

Main total of items)	Total	Volunteers (n=74)		Patients (n=254)		P
	Cronbach's alpha	Mean	Std. deviation	Mean	Std.deviation	

ps (4)	0.89	2.44	5.83	31.94	6.54	
ration progress(18)	0.72	23.75	9.36	45.05	16.49	
ary incontinence (15)	0.95	19.28	18.32	29.22	26.46	
ructive miction (6)	0.80	11.86	11.48	37.88	21.00	0.0001
ecation progress (7)	0.72	4.20	6.46	11.26	12.51	0.0001
al incontinence (17)	0.90	6.54	7.29	16.23	15.05	0.0001
rticipation (6)	0.72	23.87	16.20	35.35	25.84	0.0001
c Floor pain (9)	0.80	7.90	9.88	22.18	24.14	0.0001
al function (6)	0.80	11.42	10.88	38,34	20.79	0.0001
						0.0001
						0.001
						0.001

#### References

1. Voorham-van der Zalm PJ, Stiggelbout AM, Aardoom I, Deckers S, Greve IG, Nijeholt GA, Pelger RC. Development and validation of the pelvic floor inventories Leiden (PelFIs). *Neurourol Urodyn.* 2008;27(4):301-5

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<b>Is this a clinical trial?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>Medical Ethics Committee, Leiden University Medical Center, Leiden, The Netherlands Bannatyne Campus Research Ethics Boards, University of Manitoba, Winnipeg, Manitoba, Canada</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>Yes</b>