



## **Cultural adaptation of the female pelvic floor questionnaire (FPFQ) into French**

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**Title page**

Cultural adaptation of the female pelvic floor questionnaire (FPFQ) into French

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**Short title:** Female Pelvic Floor Questionnaire French Validation

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## **Abstract**

**Aims:** The Female pelvic floor questionnaire (FPFQ) is a self-administered tool on pelvic floor function. Our aim was to carry out a cultural adaptation of the FPFQ into French and to assess its psychometric properties.

**Methods:** After cross-cultural adaptation into French, acceptability and reliability of the questionnaire were assessed through a sample of 56 women in a test-retest. Discriminative construct validity was evaluated by comparing the results obtained by the FPFQ to those of other validated questionnaires. Longitudinal follow-up of the 282 pregnant women included in the PreNatal Pelvic floor Prevention trial (3PN) was used to analyze responsiveness.

**Results:** The proportion of missing data did not exceed 4% for questions about bladder function, bowel function and pelvic organ prolapse; 10% for issues related to sexual function. Question 9 was considered difficult to understand by 14% of women. After rewriting, this issue was retested in a new sample of 52 women and presented no further problems. The intra-class correlation coefficient was greater than or equal to 0.7 for all domains during the test-retest. The FPFQ was strongly and significantly correlated (Spearman  $r > 0.5$ ) with the other validated questionnaires. The French version of FPFQ recorded changes in urinary and sexual symptoms for the women involved in 3PN trial with a standardized response mean equal to 0.83 and 0.44, respectively.

**Conclusion:** The French version of the FPFQ is self-administered, reliable, valid, and can detect a change in symptoms during follow-up.

**Key Words:** Pelvic floor – Symptoms – Questionnaire – Validation studies – French

## 48 **Introduction**

49 Pelvic floor disorders (PFD) in women are common and debilitating (1). It is estimated that  
50 10-20% of women will be operated upon during their lifetime for these disorders (2). They  
51 can result in different pelvic-perineal symptoms affecting all areas of the anatomy such as  
52 voiding and anorectal difficulties, incontinence, prolapse and sexual disorders. These  
53 symptoms are often associated; 25% of patients consulting for genitourinary prolapse also  
54 suffer terminal constipation, and 33% from anal incontinence (3). They can cause functional  
55 difficulties beyond the organ concerned, for example urinary incontinence affects sexual  
56 satisfaction (4). Studies have demonstrated that treatment for one symptom can improve,  
57 worsen or even predispose another (5). Epidemiologists as clinicians need tools to assess  
58 the prevalence of symptoms associated with functional PFD and the severity of these  
59 symptoms. Many questionnaires have been developed to assess urinary incontinence (6)  
60 and urinary obstruction (7). Questionnaires investigating the symptoms of prolapse (8),  
61 sexual symptoms, anal incontinence or anorectal obstruction exist but are slightly less  
62 common (9). The Female Pelvic Floor Questionnaire (FPFQ) developed by Kaven Baessler  
63 explores all aspects of pelvic floor dysfunction: bladder, bowel, prolapse and sexual  
64 symptoms. This questionnaire was designed for the "Longitudinal Assessment of Woman"  
65 study conducted by the Betty Byrne Henderson research center in Brisbane, to collect  
66 longitudinal data on the incidence and prevalence of PFD in community-dwelling women  
67 (10). The reliability, validity and responsiveness of the tool were developed during two  
68 different studies (11,12). This questionnaire was originally in English and adapted into  
69 German (13). Translating and culturally adapting a questionnaire into another language is  
70 more interesting than creating a new instrument. This method makes it possible to compare

71 results across studies, despite different languages and cultures because the data comes  
72 from the same instrument. It also allows the study to be carried out on a larger scale with  
73 international participation. After translating and cultural adaptation, it is necessary to  
74 ensure the equivalence of the concept measured by the questionnaire through the analysis  
75 of its psychometric properties. The questionnaire must be acceptable to make data  
76 collection possible. It must be reliable and valid to properly discriminate between subjects,  
77 establish a profile or identify determining factors. To detect a change in the  
78 symptomatology of an individual in a longitudinal comparison, this tool must be sensitive to  
79 changes (14).

80 The aim of our study was to carry out the cultural adaptation of the FPFQ into French in two  
81 stages: translation and validation of the questionnaire to ensure cross-cultural relevance  
82 and conceptual equivalence with the original questionnaire.

## 83 **Method**

84 The FPFQ is a self-administered questionnaire with 37 questions. Thirty-three of them  
85 assess symptoms in 4 areas (bladder, bowel, prolapse and sexual function section) and 4  
86 questions investigate the inconvenience caused by these symptoms in each area (11). Each  
87 question has four possible answers of increasing severity (usually *never*, *occasionally*,  
88 *frequently* or *daily*). It is possible to calculate a 10 point subscore for each area. Each sub-  
89 score is the sum of the marks obtained in each section of questions divided by the maximum  
90 number of points, multiplied by 10. The addition of these four subscores provides a total  
91 score out of 40. The higher this score, the more the woman suffers from PFD.

## 92 ***Cross-cultural adaptation***

93 After obtaining the agreement from the author (Kaven Baessler) to perform the cultural  
94 adaptation of the FPFQ into French, three translations of the English version were  
95 performed independently by a urogynaecologist (XF), a rehabilitation doctor (MM) and a  
96 female non-doctor, whose native language were French and who had a good knowledge of  
97 English. A summary of these three translations was revised several times by the translators  
98 until a consensus was reached (15). The back-translation was deemed unnecessary to  
99 emphasize the meaning rather than the literal translation. This version was then pre-tested  
100 with 4 French women (none of whom were doctors or caregivers), in individual interviews.

## 101 - ***Validation***

## 102 - ***Reference measurements***

103 Construct validity examines the ability of a questionnaire to measure what it is supposed to  
104 measure. It studies the correlations between the questionnaire scores and other reference  
105 measurements at a particular point in time (14). Five other questionnaires already validated

in French were chosen as reference measurement in this analysis: The ICIQ-UI-SF (International Consultation on Incontinence Questionnaire - Urinary Incontinence Short-Form) assesses urinary incontinence four questions; The IPSS (International Prostate Symptom Score) evaluates voiding difficulties via 8 questions; Contilife, a quality of life questionnaire adapted for women with urinary incontinence, comprises 28 questions divided into six sections; The PFDI-20 (Pelvic Floor Distress Inventory) assesses symptoms of prolapse and the inconvenience caused by these symptoms and is composed of 20 questions dealing with bladder (UDI-6), bowel (CRADI-8) and to prolapse symptoms (POPDI-6); The PFIQ-7 (Pelvic Floor Impact Questionnaire) is a questionnaire on the social impact of prolapse, it examines the severity of bladder (UIQ-7), bowel (CRAIQ-7) and specific prolapse symptoms (POPIQ- 7) (6-9).

#### - *Populations*

Three populations were used to evaluate the questionnaire. Two convenience samples, composed of easily queryable women in the investigators' entourage, were set up with 56 women in the first sample (No.1) and 52 women in the second (No. 2). Sample No. 1 tested understanding of the issues (acceptability) and the reliability of the questionnaire through a test-retest and the construct validity of the bladder section of the FPFQ. The issues deemed difficult to understand by sample No.1 were reformulated and then re-tested by sample No.2. Inclusion criteria for these samples were voluntary adult women in the authors' entourage (regardless of age or occupation) or an adult women consulting for reasons other than PFD. Women likely to benefit from PFD treatment or intervention were excluded, as were minors and those with neurological impairment.

128 The 282 pregnant women included in the Prenatal Perineal Prevention (3PN) study also  
129 received the questionnaire. 3PN is a multicenter, randomized study whose main objective  
130 was to compare the effect on urinary incontinence at one year postpartum of prenatal  
131 rehabilitation compared to receiving written information only (16). The data collected  
132 helped analyze the construct validity of specific questions on prolapse and bowel symptoms  
133 but also to explore sensitivity to changes through longitudinal monitoring of these women.

134 - *Administration of the questionnaire*

135 Sample No. 1 - Women completed the self-administered questionnaire twice, one month  
136 apart (test-retest). The first time, they were instructed to report difficulties in understanding  
137 and possibly propose a reformulation of the question. They also completed the  
138 aforementioned reference questionnaires.

139 Sample No. 2 - Issues considered difficult to understand by the women in sample No. 1 were  
140 reformulated and tested in sample No. 2.

141 3PN women were included in the testing during pregnancy and monitored for one year after  
142 childbirth (16). They completed the French version of FPFQ, the ICIQ-IUSF and Contilife  
143 questionnaires four separate times during monitoring. The 71 women enrolled in the 3PN  
144 study in Nîmes University Hospital completed two additional questionnaires covering  
145 prolapse symptoms (PFDI-20 and PFIQ-7).

146 - ***Statistical Analysis***

147 *Acceptability* - The incidence of difficulty understanding questions and the number of  
148 unanswered questions were indicators of acceptability. The non-response rate per question  
149 was calculated from sample No. 1 and from all 3PN patients on the data collected during the  
150 first completion of the FPFQ.



*Reliability* - The test-retest performed by sample No. 1 was used to analyze the reproducibility of the tool in clinically stable women. To compare the scores between the two evaluations, an intra-class correlation coefficient for sub-scores of each section and the total score was calculated. A value greater than 0.7 was considered acceptable (17). Concordance was measured for each FPFQ question component through a weighted Cohen Kappa coefficient. A Kappa coefficient up to 0.20 is classically poor, from 0.21 to 0.40 mediocre, from 0.41 to 0.60 moderate, from 0.61 to 0.80 good and beyond 0.80 excellent (18). The Bland-Altman method explored the correlation based on the score obtained (19).

*Internal consistency* - This analysis was carried out using data collected from sample No. 1 and 3PN women during the first FPFQ questionnaire. Cronbach's alpha was considered acceptable from 0.7.

*Construct validity* – Data from the FPFQ were compared with reference data collected for inclusion in sample No. 1 and 71 3PN women at the Nîmes CHU. Longitudinal follow-up of 3PN women allowed the change measured by the FPFQ questionnaire to be compared to those recorded by the reference measurements between the different assessments. Calculation of correlations from score differences allows data to be matched. Four statistical correlation levels were established: strong  $r > 0.5$ ; moderate  $r = 0.36$  to  $0.5$ ; poor  $r = 0.35$  to  $0.2$ ; absent  $r < 0.2$  (20). To assess association strength, the Pearson and Spearman correlation coefficient was used.

Construct validity is far more robust if the investigators establish prior hypotheses about probable correlations between the test questionnaire and the reference measurements (14). Seventy-five prior assumptions (using 4 levels of correlation defined in the previous paragraph) were established on data collected at baseline.

174    *Responsiveness* - Pregnancy and postpartum periods are characterized by a risk of pelvic  
175    floor disorders that are often transient (21). Longitudinal follow-up of 3PN patients was  
176    used to assess changes in pelvic-floor symptoms associated with pregnancy and childbirth.  
177    The degree of variation was assessed by the Standardized Response Mean (RMS) (22).

178    -    ***Ethics***

179    All women gave consent before participating. For samples No. 1 and No. 2, women included  
180    did not undergone any intervention or modification of their support related to their  
181    participation. Thus our work complied with French statutes and regulations, which authorise  
182    observational surveys without approval of an ethics committee. Collected data were  
183    processed according to the recommendations of the CNIL (Commission Informatique et  
184    Libertés, French Data Protection Authority- <http://www.cnil.fr/english/>). Questionnaires  
185    used in samples No. 1 and No. 2 were strictly anonymous.  
186    The 3PN study received an institutional review board approval by the Comité de Protection  
187    des Personnes Sud-Ouest-et-Outre-Mer in September 2007 (#2007-A00641-52).

188

## 189 **Results**

190 For the translation and cultural adaptation, 6 intermediate versions were needed before  
191 obtaining a version judged to be suitable and consistent with the original questionnaire. The  
192 pre-test did not lead to any changes.

193 The average age of women was 42 years in sample No. 1, 44 years in the second and 29 in  
194 3PN. 3PN women were all nulliparous and the mean parity was 2.0 and 1.3 in samples 1 and  
195 2 respectively. These women had a low symptomatology with an FPFQ total score of less  
196 than 10 out of 40 (Table I-II).

197 *Acceptability* - Of the 56 women in sample No. 1, the proportion of missing data did not  
198 exceed 4% for questions about bladder, bowel and prolapse symptoms; this figure was 10%  
199 for sexuality-related issues. For the 3PN women, the missing data did not exceed 4%  
200 regardless of the type of question. Significantly less information was given in questions  
201 about sexuality than the others, in both samples ( $p < 0.0001$ ). Question 9 "Votre jet urinaire  
202 est-il faible ou prolongé?" was considered difficult to understand by 14% ( $n = 8$ ) of the  
203 women in sample No. 1. According to them, the terms "faible" and "prolongé" had opposite  
204 meanings. This was the literal translation of the original question: "Is your urinary stream /  
205 flow weak or prolonged?". This question was changed as follows: "Votre jet urinaire est-il  
206 faible ou ralenti?" and was retested with sample No. 2. In this new sample, the  
207 reformulated question 9 posed no further problem.

208 *Reliability* - In sample No. 1, 56 women completed the FPFQ once and 51 twice. The  
209 concordance of responses between the two assessments ranged from 58.3% [95% CI 43.2-  
210 72.4] to 94.1% [83.8-98.8] depending on the issues, with a median of 80.0%. Average kappa  
211 was equal to  $0.6 \pm 0.1$  with a minimum of 0.3 [95% CI 0.1-0.4] and a maximum of 0.8 [95% CI

0.6-1.0]. The intraclass correlation coefficient was greater than or equal to 0.7 for the overall score and each sub-domain (Table I). On average, the change in the FPFQ total score and subscores was less than 10% between the two assessments (Table I). The Bland-Altman test was able to identify a lower response concordance among the most symptomatic women with a marked increase in the difference in overall score in women with a score higher than 6 out of 40 (Figure 1).

*Internal consistency* - Internal consistency was satisfactory with a Cronbach  $\alpha$ -factor greater than 0.7 for all areas of the FPFQ in sample No. 1 (Table I) and in the 3PN sample (Table II).

*Construct validity* - The FPFQ was strongly and significantly correlated (Spearman  $r > 0.5$ ) with the ICIQ-UI-SF ( $r = 0.7$ ), the IPSS ( $r = 0.7$ ) and Contilife ( $r = -0.7$ ) in sample No. 1. Strong and significant correlations were also found in 3PN women recruited in Nimes, between the FPFQ and other reference tests (Table III). The kinetics of the scores during the longitudinal study was similar between the various assessment tools (Figure 2). The differences in scores recorded by the FPFQ were highly correlated with those measured by ICIQ-UI-SF, Contilife and PFDI-20. Correlations were lower ( $r$  between 0.1 and 0.6 depending on the section) between the FPFQ and PFIQ-7 (details not shown).

Correlations between the FPFQ and the reference measurements were consistent with the assumptions in 15 cases (20%), higher in 56 cases (75%), and lower in 4 cases (5%).

*Responsiveness* - 3PN women showed a significant ( $p < .0001$ ) decline in bladder symptoms between late pregnancy and two months postpartum (SMR = 0.83); increased sexual symptoms between late pregnancy and two months postpartum (RMS = -0.30;  $p = 0.001$ ) with a significant decrease at 12 months postpartum (SMR = 0.44;  $p < 0.0001$ ). Bowel symptoms were stable over time with a standardized mean response of less than 0.2

235 between successive assessments. These women had a slight increase in prolapse symptoms  
236 between months 6 and 9 of pregnancy ( $-0.25$ ;  $p < 0.001$ ). These symptoms then remained  
237 stable during postpartum ( $SMR < 0.2$ ).

## 238 **Discussion**

239 The results of the FPFQ were significantly and strongly correlated with those found in the  
240 reference tests. Significant changes in bladder and sexual symptomatology were recorded  
241 during longitudinal monitoring of women in the 3PN study.

242 The lack of a specific reference test for sexual symptoms did not assess the construct  
243 validity of this section of the FPFQ. The significant increase in the sexual subscore at 2  
244 months postpartum in 3PN women, however, is an argument for its validation. This increase  
245 is consistent with the increase in prevalence of sexual dysfunction observed after delivery  
246 (23). Despite this limitation, one advantage of our study is that it explores the main  
247 psychometric properties of the French FPFQ, including analysis of sensitivity to changes,  
248 which is rarely performed during the validation of a measurement tool.

249 The proportion of questions unanswered was satisfactory, not exceeding 10% despite the  
250 taboo nature of incontinence. This result obtained from both sample No. 1 and the 3PN  
251 study demonstrates the acceptability of the tool. The wording of questions in the final  
252 version posed no comprehension difficulties. We believe the combination of specialist  
253 translators and a naive translator yielded a translation retaining the meaning of the original  
254 concept in a language understood by the target population. A back-translation was not  
255 deemed necessary. This procedure tends to favor a literal translation that amplifies unclear  
256 language in translations (15). The comprehension difficulties regarding question 9 raised by  
257 sample No. 1 is an illustration of this problem. The literal translation of "weak or prolonged"  
258 into "faible ou prolongé" modified the meaning of the phrase. In French, the term  
259 "prolongé" (prolonged) can have two different meanings: temporally prolonged (lasting  
260 longer than usual) or spatially prolonged (extended in distance). This second interpretation

suggests a stronger, more effective urinary stream which was judged by women to contradict the term "weak". The term "ralenti" ("slowed" in English) was therefore chosen to remain faithful to the original meaning.

The questionnaire showed stable results over time, during the test-retest, with an acceptable intraclass correlation coefficient in all sections of the FPFQ. Average difference did not exceed 10% between the two assessments. Our hypothesis is that a variation of less than 10% is not clinically significant as the smallest significant variation in quality of life was estimated at 15% for other surveys on the same subject (8). Despite high response consistency during the test-retest, weighted kappa coefficients were poor for certain issues. This result is explained by a low prevalence of certain responses because overall, sample No. 1 was not particularly symptomatic. The kappa coefficient is very sensitive to frequency of response and the extreme modalities of certain questions were never indicated (24). Response consistency was lower among the most symptomatic women according to the Bland-Altman test. This result can be explained by the fact that bladder and bowel symptoms are closely related to lifestyle and therefore likely to change over a short period of time in the absence of medical or surgical intervention.

The results of the FPFQ were strongly correlated with those of other symptom questionnaires (ICIQ-UISF, IPSS and PFDI-20). This result was also observed with specific quality of life reference tests (Contilife and PFIQ-7). It demonstrates that the French version of the FPFQ measures the same concept as the reference tests. These correlations were much higher than we had predicted. We found strong correlations for different areas; for example, the bowel section of the FPFQ was strongly correlated with the prolapse section of the PFDI-20 ( $r = 0.6$ ) and the bladder section PFIQ-7 ( $r = 0.5$ ). This result highlights common

association of different symptoms for the same woman (3). The interdependence between sections highlights the importance of symptom assessment in general with multidisciplinary care in clinical practice.

Longitudinal follow-up of 3PN patients highlighted identical score kinetics for the FPFQ and most other reference tests (ICIQ-UI-SF, Contilife and PFDI-20). Changes in symptomatology recorded by the FPFQ (RMS significant) and correlations between score differences measured by the FPFQ and those measured by the ICIQ-UI-SF and the Contilife PFDI-20 reflect good responsiveness. These correlations were weaker between the FPFQ and PFIQ-7. There is a lower sensitivity to change for the PFIQ-7 for PFDI-20, which justifies this difference in outcome (25).

## **Conclusion**

The FPFQ offers an extensive evaluation of bladder, bowel and sexual function, pelvic organ prolapse. It is self-administered, which makes it a good tool to gather information deemed embarrassing or taboo. Based on the analysis of its psychometric properties, it is acceptable, understandable and properly discriminates between topics. Designed, developed and validated for the community-dwelling women, the questionnaire is an attractive research tool in this context. Its responsiveness allows it to be used as an evaluative instrument in multicenter clinical trials or in the longitudinal monitoring of patients, or measuring physiological changes during the life of a woman. These studies can be undertaken internationally as the FPFQ exists in English, German and French.



304 **Thanks**

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308

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## **Tables and figures**

Table I Reliability - Internal consistency: Scores obtained in the FPFQ by sample No. 1 women in the test-retest; intraclass correlation coefficient (ICC) and its confidence interval 95% (95% CI ICC); Cronbach alpha coefficient calculated on the data collected during the first assessment.

\* In the test-retest, 56 women completed the FPFQ once and 51 completed the questionnaire twice (a month apart.)

\*\* The sex score of the FPFQ was calculated twice for 34 women. Of these, 3 were not sexually active because of pelvic floor disorders in at least one of the two assessments; the maximum score of 10 was assigned to this section. Seventeen women were not sexually active for reasons not related to pelvic floor disorders in at least one of the two assessments. For these women, no mean difference for the sex subscore was calculate.

Table II Internal consistency: Scores obtained in the FPFQ by patients in the 3PN clinical trial and Cronbach alpha coefficients calculated at baseline (n = 272\*).

Missing data higher than 2 for each sub-score did not allow the calculation of that sub-score. In the absence of a sub-score, the total score was not calculated.

\*Ten women included in the trial did not complete the questionnaires.

\*\* The sexsubscore could be calculated for 232 women. Of these, 4 were not sexually active because of pelvic floor disorders; the maximum score of 10 points was assigned to this section of the questionnaire. Nineteen women were not sexually active in the sample for reasons not related to pelvic floor disorders.

Table III Construct Validity: Correlations between FPFQ scores on inclusion from patients enrolled in the 3PN study at Nîmes CHU (n = 71); Spearman correlation coefficient.

Figure 1: Representation of the difference in Total score of the test-retest based on mean score, as calculated by the Bland-Altman method - Sample No. 1 (n = 51)

Figure 2: Evolution of scores and sub-scores obtained in the FPFQ, the ICIQ-UI-SF, Contilife, the PFDI-20 and PFIQ-7 during longitudinal monitoring of 3PN patients recruited at Nîmes CHU (n = 71).

\*The PFDI-20 and PFIQ-7 sub-scores are out of 100 points (UDI-6 CRADI-8 POPDI-6, UIQ-7 CRAIQ-7 POPIQ-7), the ICIQ-UI-SF is out of 21 points. These scores were reduced 10 to facilitate comparison with FPFQ subscores.

\*\*Contilife is given a score out of 10 points and is inversely proportional to the FPFQ Bladder subscore. The graph shows the difference between the maximum score (10) and the score obtained by the subject.

\*\*\*The PFDI-20 and PFIQ -7 are scored out of 300 points. These scores were reduced 40 to facilitate comparison with the total FPFQ score.