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

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1 **Title page**

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

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26 **Abstract**

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

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

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

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

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

47

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

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

117 - *Populations*

118 Three populations were used to evaluate the questionnaire. Two convenience samples,
119 composed of easily queryable women in the investigators' entourage, were set up with 56
120 women in the first sample (No.1) and 52 women in the second (No. 2). Sample No. 1 tested
121 understanding of the issues (acceptability) and the reliability of the questionnaire through a
122 test-retest and the construct validity of the bladder section of the FPFQ. The issues deemed
123 difficult to understand by sample No.1 were reformulated and then re-tested by sample
124 No.2. Inclusion criteria for these samples were voluntary adult women in the authors'
125 entourage (regardless of age or occupation) or an adult women consulting for reasons other
126 than PFD. Women likely to benefit from PFD treatment or intervention were excluded, as
127 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.

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

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

162 *Construct validity* – Data from the FPFQ were compared with reference data collected for
163 inclusion in sample No. 1 and 71 3PN women at the Nîmes CHU. Longitudinal follow-up of
164 3PN women allowed the change measured by the FPFQ questionnaire to be compared to
165 those recorded by the reference measurements between the different assessments.
166 Calculation of correlations from score differences allows data to be matched. Four statistical
167 correlation levels were established: strong $r > 0.5$; moderate $r = 0.36$ to 0.5 ; poor $r = 0.35$ to
168 0.2 ; absent $r < 0.2$ (20). To assess association strength, the Pearson and Spearman
169 correlation coefficient was used.

170 Construct validity is far more robust if the investigators establish prior hypotheses about
171 probable correlations between the test questionnaire and the reference measurements
172 (14). Seventy-five prior assumptions (using 4 levels of correlation defined in the previous
173 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 undergo 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 ± 0.1 with a minimum of 0.3 [95% CI 0.1-0.4] and a maximum of 0.8 [95% CI

212 0.6-1.0]. The intraclass correlation coefficient was greater than or equal to 0.7 for the
213 overall score and each sub-domain (Table I). On average, the change in the FPFQ total score
214 and subscores was less than 10% between the two assessments (Table I). The Bland-Altman
215 test was able to identify a lower response concordance among the most symptomatic
216 women with a marked increase in the difference in overall score in women with a score
217 higher than 6 out of 40 (Figure 1).

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

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

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

230 *Responsiveness* - 3PN women showed a significant ($p < .0001$) decline in bladder symptoms
231 between late pregnancy and two months postpartum (SMR = 0.83); increased sexual
232 symptoms between late pregnancy and two months postpartum (RMS = -0.30; $p = 0.001$)
233 with a significant decrease at 12 months postpartum (SMR = 0.44; $p < 0.0001$). Bowel
234 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

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

264 The questionnaire showed stable results over time, during the test-retest, with an
265 acceptable intraclass correlation coefficient in all sections of the FPFQ. Average difference
266 did not exceed 10% between the two assessments. Our hypothesis is that a variation of less
267 than 10% is not clinically significant as the smallest significant variation in quality of life was
268 estimated at 15% for other surveys on the same subject (8). Despite high response
269 consistency during the test-retest, weighted kappa coefficients were poor for certain issues.
270 This result is explained by a low prevalence of certain responses because overall, sample No.
271 1 was not particularly symptomatic. The kappa coefficient is very sensitive to frequency of
272 response and the extreme modalities of certain questions were never indicated (24).
273 Response consistency was lower among the most symptomatic women according to the
274 Bland-Altman test. This result can be explained by the fact that bladder and bowel
275 symptoms are closely related to lifestyle and therefore likely to change over a short period
276 of time in the absence of medical or surgical intervention.

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

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

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

294 **Conclusion**

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

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308

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362 for pelvic organ prolapse. *Am J Obstet Gynecol* 2006;194:1492-8.
- 363

364 **Tables and figures**

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

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

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

375

376

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

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

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

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

386

387

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

390

391

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

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395

396 Figure 2: Evolution of scores and sub-scores obtained in the FPFQ, the ICIQ-UI-SF, Contilife, the PFDI-
397 20 and PFIQ-7 during longitudinal monitoring of 3PN patients recruited at Nîmes CHU (n = 71).

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

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

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