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The translated Danish version of the Western Ontario Meniscal Evaluation Tool (WOMET) is reliable and responsive

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Authors' contributions: STS, HE and JBT conceived the study. JMC, SLH, HE, CMPM, LRM and JBT recruited patients, translated the WOMET and collected the data. JBT performed the analyses. JMC and JBT drafted the manuscript. All authors provided important intellectual feedback on the manuscript and approved the final version.

1 **The translated Danish version of the Western Ontario Meniscal**
2 **Evaluation Tool (WOMET) is reliable and responsive**

3

4 **ABSTRACT**

5 **Purpose** –The purpose of this study was to translate and cross-culturally adapt the Western Ontario
6 Meniscal Evaluation Tool (WOMET) for use in Denmark and evaluate its test-retest reliability and
7 comparative responsiveness.

8 **Methods** – Sixty patients (mean age 50 years (range 19-71 years), females 57%) with meniscal
9 injury scheduled for arthroscopic meniscal surgery at a small Danish hospital in the period from
10 September 2017 to February 2018 were included in this study. The WOMET was translated into
11 Danish using forward and backward translation. The WOMET was completed at baseline (pre-
12 surgery), at 3 and 6 months postoperatively. Additionally, reliability was assessed at 3 months and 3
13 months plus 1 week, for patients with a stable symptom state (Global Response Question) between
14 test and retest. Comparative responsiveness was assessed between the WOMET and the Knee injury
15 and Osteoarthritis Outcome Score (KOOS4 – aggregate score of 4 of the 5 KOOS subscales).

16 **Results** – The Danish version of WOMET showed excellent test-retest reliability, Intraclass
17 Correlation Coefficient of 0.88 (95% CI 0.84-0.92) for the total score. The Standard Error of
18 Measurement was 125 points and the Minimal Detectable Change was 347 points (i.e., 8% and 22%
19 of the total score, respectively). The WOMET was responsive with an effect size (ES) of 1.12 at 6
20 months after surgery, which was comparable to the KOOS4 (ES 1.10).

21 **Conclusion** - The Danish version of the WOMET is a reliable and responsive measure of health-
22 related quality of life in patients with meniscal pathology.

23

24 **Level of evidence:** Level II

25 **INTRODUCTION**

26 Meniscal knee injuries are common in the adult population [15], and are typically associated with
27 pain and functional limitations [16, 24].

28 A number of patient-reported outcome measures (PROM), such as the Knee injury and
29 Osteoarthritis Outcome Score (KOOS) [18], Lysholm Knee Scale [26], International Knee
30 Documentation Committee Subjective Knee Form (IKDC) [9] and Western Ontario and McMaster
31 Universities Osteoarthritis Index (WOMAC) [3] have been developed to evaluate patient-reported
32 symptoms, functional limitations and health-related quality of life (HRQoL) among patients with
33 knee pathologies. However, there is no consensus as to which PROM is the best instrument to
34 measure patient-reported outcomes for patients with meniscal tears.

35 The Western Ontario Meniscal Evaluation Tool (WOMET) was developed in 2007 by Kirkley et
36 al., specifically to evaluate meniscal injury symptoms, and therefore might be more responsive to
37 change over time than other generic knee PROMs [10]. For instance, the WOMET was more
38 responsive to measure the impact of meniscal pathology on knee-specific HRQoL compared with
39 the KOOS and WOMAC [21].

40 The psychometric properties of the WOMET have been investigated several times, including in
41 translational studies into Dutch, German, Chinese, Turkish and Persian, all finding it to be valid,
42 reliable and responsive [5, 6, 19, 28, 29].

43 No formally translated Danish version of the WOMET is available. Therefore, the scope of this
44 study was to translate and cross-culturally adapt the original English version of the WOMET to
45 Danish and evaluate its reliability and the responsiveness compared with the KOOS.

46

47 **MATERIALS AND METHODS**

48 **Study design**

49 Cross-cultural translation and adaptation of the original English WOMET questionnaire was
50 performed for use in Danish following the standardized and formalized forward and backward
51 translation procedure [2]. The translated Danish version was tested for face validity by semi-
52 structured interviews with patients scheduled for surgery for a meniscal tear. Subsequently, the
53 approved translated Danish version of the WOMET was evaluated for test-retest reliability (3
54 months and 3 months + 1 week post-surgery). To evaluate comparative responsiveness, the
55 WOMET and KOOS were completed at baseline (pre-surgery) and at 6 months post-surgery.
56 This study was exempted for notification to the Regional Ethics Committee according to Danish
57 law. The study was approved by the Danish Data Protection Agency.

58

59 **Translation and cross-cultural adaptation of the WOMET**

60 The translation followed the procedure below:

- 61 1: Forward translation of the original English version of the WOMET into Danish was
62 independently performed by two native Danish individuals with proficient skills in English. One
63 was a healthcare professional.
- 64 2: The two forward translations were reviewed and discrepancies were addressed and handled by
65 consensus between the two forward translators. The two forward translations were then reconciled
66 into one single preliminary Danish version.
- 67 2: The preliminary Danish version was then backward translated into English by two individuals
68 proficient in Danish, but with English as first language (one being a healthcare professional).
- 69 3: The Danish version of WOMET was evaluated for comprehensibility (linguistic content and
70 understanding) in patients with meniscal injury scheduled for surgery at a Danish university
71 hospital (not otherwise involved in the study) using semi-structured cognitive debriefing interviews.
- 72 This process was repeated until theoretical data saturation was reached (i.e. no new information was

73 retrieved by adding further participants).

74 4: The final Danish version of WOMET was translated into English and sent to the corresponding
75 author of the original English WOMET for approval.

76

77 **Psychometric testing of the Danish version of the WOMET**

78 **Patients**

79 To evaluate reliability and responsiveness, patients with meniscal injuries from a sports surgery
80 facility at a small Danish hospital were recruited by nurses trained in the study procedures at the
81 time they were assigned for knee arthroscopy for MRI-verified meniscal pathology. Written
82 informed consent was obtained after thorough information about the study.

83 Eligible patients were men and women who met the following inclusion criteria: (1) 18 years or
84 older, (2) knee symptoms compatible with a meniscal tear (i.e. knee pain and joint line tenderness),
85 positive clinical tests (McMurray and Thessaly), (3) MRI-verified meniscal pathology, (4) assigned
86 for knee arthroscopy. Only patients with severe ligamentous instability of the knee were excluded
87 (e.g. ACL rupture).

88

89 **Patient-reported outcome measures**

90 *The Western Ontario Meniscal Evaluation Tool (WOMET)*

91 The WOMET is a disease-specific tool to evaluate HRQoL in patients with meniscal pathology [10,
92 25]. The WOMET has 16 items, representing three domains. The physical domain has 9 items;
93 sports, recreation, the work and lifestyle domain has 4 items; and the emotion domain has 3 items.
94 Each item is scored on a visual analogue scale from 0 (no symptoms) to 100 (extreme symptoms).
95 The best or least symptomatic overall score is zero and the worst or most symptomatic overall score
96 is 1600. The score can also be converted to a percent of maximum score, to allow comparison to

97 other PROMs (i.e. scoring on a 0-100 scale), where 0 represents the worst score and 100 the best
98 score. The English WOMET has been tested and found valid in patients with meniscal pathology
99 [1] and has been used as an outcome in several studies on patients with meniscal tears [8, 20, 23].
100

101 **The Knee injury and Osteoarthritis Outcome Score (KOOS)**

102 For evaluation of comparative responsiveness, patients also completed the KOOS score. The KOOS
103 score is designed to evaluate knee pain, function and symptoms in the continuum from knee injury
104 to knee osteoarthritis (including patients with meniscal tears). The KOOS consists of 5 domains:
105 pain, symptoms, activities of daily living (ADL) function, sports and recreational function
106 (Sport/Rec) and quality of life (QOL). Each domain is scored in a 5-point Likert scale, which is
107 converted to a 0-100 score (0 indicating extreme knee problems and 100 indicating no knee
108 problems) [17, 18]. In previous randomized controlled trials on patients with anterior cruciate
109 ligament (ACL) injuries and meniscal tears, the KOOS4 [7, 11], which is an average of 4 of the 5
110 KOOS subscales (excluding the ADL subscale due to a ceiling effect in younger populations) has
111 been used as the primary outcome. Therefore, we assessed the comparative responsiveness of the
112 Danish version of the WOMET with the KOOS4 score.

113

114 **Study procedure**

115 Patients recruited for assessment of test-retest reliability and responsiveness of the Danish version
116 of the WOMET received an online questionnaire, which also included the KOOS questionnaire and
117 questions on baseline characteristics such as age, sex, height, weight, presentation and duration of
118 symptoms and earlier surgery. Surgery was performed maximally 2 weeks after the baseline
119 questionnaire was filled out. The WOMET and KOOS were completed again at 3 months, at 3
120 months + 1 week (for test-retest reliability) and finally again at 6 months (for responsiveness). To

121 reduce loss to follow up, patients were contacted by email and text message (SMS) in the case of
122 initial non-response, once weekly for 4 weeks.

123 To evaluate symptom stability between test and retest assessments (i.e. 3 months and 3 months + 1
124 week), a Global Response Assessment (GRA) question was used as an external anchor at the 3
125 months + 1 week assessment time point. The GRA question used was: “Compared with last time
126 you answered this questionnaire, how are your knee symptoms now?”, with the response options
127 being “worse”, “largely unchanged” and “better”. Only patients who responded “largely
128 unchanged” were included in the reliability analysis.

129

130 **Statistical analysis**

131 Baseline characteristics are summarized as mean with standard deviation (SD) or numbers and
132 percentages as appropriate.

133 It is generally recommended to include a minimum of 50 subjects in reliability studies [13]. We
134 aimed to include 75 patients to take into account missing data and potential change in symptoms
135 between test and retest. As WOMET scores at test and retest were not normally distributed, we
136 assessed systematic differences between the two time points using Wilcoxon signed rank test. We
137 also performed a paired t-test between the two time points (i.e. test and retest) to facilitate
138 comparison with previous studies. Relative reliability was assessed by calculating the Intraclass
139 Correlation Coefficient (ICC) based on variance components obtained using a linear mixed model
140 approach with time (i.e. test and retest) as fixed effect and ID (person) as random effect. ICC above
141 0.80 was considered as excellent reliability [12]. Absolute reliability was expressed as the Standard
142 Error of Measurement (SEM) calculated as: $SEM = SD \text{ of the mean difference (SDdiff)} / \sqrt{2}$ and the
143 Minimal Detectable Change (MDC) was calculated as $SEM \times 1.96 \times \sqrt{2}$. Furthermore, SEM and
144 MDC are presented as absolute values and percentages of maximal scores. To provide a visual

145 presentation of the absolute reliability, a Bland-Altman Plot was generated, and inspected for
146 systematic bias and funnel effects [4].

147 Floor and ceiling effects indicate a limited content validity and are considered when more than 15%
148 of patients score either the highest or lowest scores possible. Therefore, the proportion of patients
149 reaching maximum (1600 points) or minimum scores (0 points) was assessed [27].

150 Comparative responsiveness was investigated by comparing the standardized response mean (SRM)
151 as a measure of the effect size (ES) from baseline to 6 months post-surgery between the WOMET
152 and KOOS4 scores. WOMET scores were converted to percentage values as recommended to
153 enable comparison with the KOOS4 [10]. Effect size was calculated as mean change score from
154 baseline to 6 months post-surgery, divided by the SD of change scores. A graphical comparison
155 between WOMET and KOOS4 using all time points (i.e. baseline, 3 months and 6 months) was also
156 performed. The correlation between WOMET and KOOS4 scores was investigated by Pearson's
157 correlation. A correlation higher than 0.80 was considered a strong correlation [27]. No specific
158 sample size calculation was performed for the evaluation of responsiveness, as this was a secondary
159 aim of the study. All statistical analyses were performed using STATA 15.0 software, with a
160 significance level set at $p < 0.05$.

161

162

163 **RESULTS**

164 **Translation and cross-cultural adaptation**

165 No major language difficulties were seen in the forward and backward translations of the WOMET.
166 Five meniscal injury patients participated in the cognitive debriefing interviews which did not
167 reveal any difficulties in understanding or completing the questionnaire items of the Danish version
168 of WOMET. The backward translated version was accepted without comment by the corresponding
169 author of the original WOMET.

170

171 **Patients**

172 A total of 81 patients scheduled for arthroscopic meniscal surgery were invited to participate, of
173 whom 76 completed the baseline questionnaire. Ultimately, 55 and 60 patients contributed to the
174 reliability and responsiveness analyses, respectively (Figure 1). (See Table 1 for baseline
175 characteristics of the included patients).

176

177 **Reliability and Responsiveness**

178 No signs of ceiling or floor effects of the Danish version of the WOMET were observed. Generally,
179 no systematic difference was observed between the total WOMET scores at test and retest, although
180 slightly different scores between test and retest were indicated for the ‘emotion’ domain (Table 2).
181 Test-retest reliability was excellent, with an ICC of 0.88 (95% CI 0.84-0.92) for the total WOMET
182 score. The ICC scores were similar for all three domains. The SEM and MDC for the total WOMET
183 score was 125 and 347 points, respectively (corresponding to 8% and 22% of the maximum total
184 score, respectively) (Table 2). Visual inspection of the Bland-Altman Plot confirmed the impression
185 of good reliability and did not indicate a systematic bias or funnel effect (Figure 2).

186 Among the 60 patients with a full dataset, the mean WOMET total score improved from 871 (95%
187 CI 801-941) at baseline to 519 (95% CI 428-611) at 3 months and 481 (95% CI 397-564) at 6
188 months, and the mean change from baseline to 6 months was 390 (95% CI 301-480).
189 The mean WOMET percentage score and KOOS4 demonstrated comparable scores at all time
190 points (Figure 3). Similarly, the ES of the change from baseline to 6 months were almost identical,
191 1.12 for WOMET and 1.10 for KOOS4, and a strong correlation was observed between the
192 WOMET and KOOS4 scores ($r=0.85$, $p<0.0001$) (Supplementary Figure 1).
193

194 **DISCUSSION**

195 The English version of the WOMET was successfully translated and cross-culturally adapted for
196 use in a Danish patient population with knee meniscal injury. The WOMET was translated into
197 Danish according to international guidelines by bilingual individuals, and with no major difficulties
198 experienced during the translation and adaptation procedure with patients.

199 The test-retest reliability of the Danish WOMET was excellent, with an ICC of 0.88 for the total
200 score and with all sub-domains showing ICC values exceeding 0.80. This is similar to what has
201 been reported for the original English version of the WOMET total score (ICC=0.83), and what has
202 been reported for the German (ICC=0.90), Chinese (ICC=0.93), Dutch (ICC=0.78), Turkish
203 (ICC=0.87) and Persian (ICC=0.73) versions [5, 6, 10, 19, 28, 29].

204

205 The SEM of the total WOMET score was found to be 125 points or 8% of the total score and the
206 MDC was 347 points corresponding to 22% of the total score. These results are similar to that
207 which was found for the Dutch [29] version of the WOMET, reporting an SEM and MDC of 7%
208 and 21% of the total score, respectively. In the assessment of reliability of the Finnish [22] version
209 of the WOMET, the width of the 95% confidence interval for the 'limits of agreement' of the total
210 score was 20%, which corresponds well with the MDC found in this study. Clinicians should be
211 cautious if using the WOMET for individual patients, as a change of 22% or 347 points,
212 corresponding to the MDC, is needed to identify true changes larger than measurement error. For
213 other translated versions of the WOMET (German, Turkish and Persian), much lower SEM values
214 have been reported. However, sufficient data are not reported in these studies to further clarify the
215 reason for the questionably low SEM values. A strength of the current study was the inclusion of a
216 GRA question at the retest, to ensure that patients had not changed their symptom state compared

217 with the first test session. This led to exclusion of 7 out of 62 patients, highlighting that it cannot be
218 assumed that symptoms are the same, even with a small time period between test and retest.
219 Substantial improvements (i.e. reduced scores) were found in the WOMET total scores from
220 baseline which were assessed prior to surgery and at the 6 months follow up indicating that the
221 Danish version of the WOMET score was able to detect symptom change over time in this
222 population. The large effect size (1.12) observed for the WOMET score from before surgery to the
223 6 months follow up was comparable to what have been observed for the original English version of
224 the WOMET and other translated versions [5, 10, 19, 28, 29]. The responsiveness of the WOMET
225 and the KOOS4 score was found to be comparable with similar ES and changes in scores over time,
226 which suggest that both questionnaires are equally good at assessing changes in outcome after
227 meniscal surgery.

228
229 Some limitations apply to this study. All patients for the test-retest reliability and responsiveness
230 analyses were recruited from a single centre, which may affect generalizability. Nevertheless,
231 patients in this study had a very similar mean age and age range, compared with a larger cohort of
232 Danish meniscal injury patients [24], supporting the use of this tool in the Danish patient
233 population. It was not investigated if the paper version and the electronic version could potentially
234 yield different outcomes in the same group of participants. However, evidence seems to suggest that
235 electronic completion is equivalent to paper completion [14]. Furthermore, using an electronic
236 version resulted in no missing data, nor any incorrectly completed items, which can often be
237 observed when using the paper version of the WOMET. Only five patients participated in the
238 cognitive debriefing interviews to assess their understanding of the translated version of the
239 WOMET. This is substantially lower than recommended, however saturation of information was
240 achieved. Finally, only the MDC was investigated in the current study and thus, the MIC, indicating

241 the smallest change score that is important or meaningful to patients, cannot be extracted from this
242 study.

243

244 **CONCLUSION**

245 The English version of the WOMET was successfully translated and culturally adapted into Danish.

246 The Danish version of the WOMET showed excellent reliability and had comparable

247 responsiveness to the KOOS in detecting change in symptom state following meniscal surgery.

248 Caution should be exercised if using the WOMET for assessing change in individual patients as

249 large changes are needed to rule out measurement variation.

250

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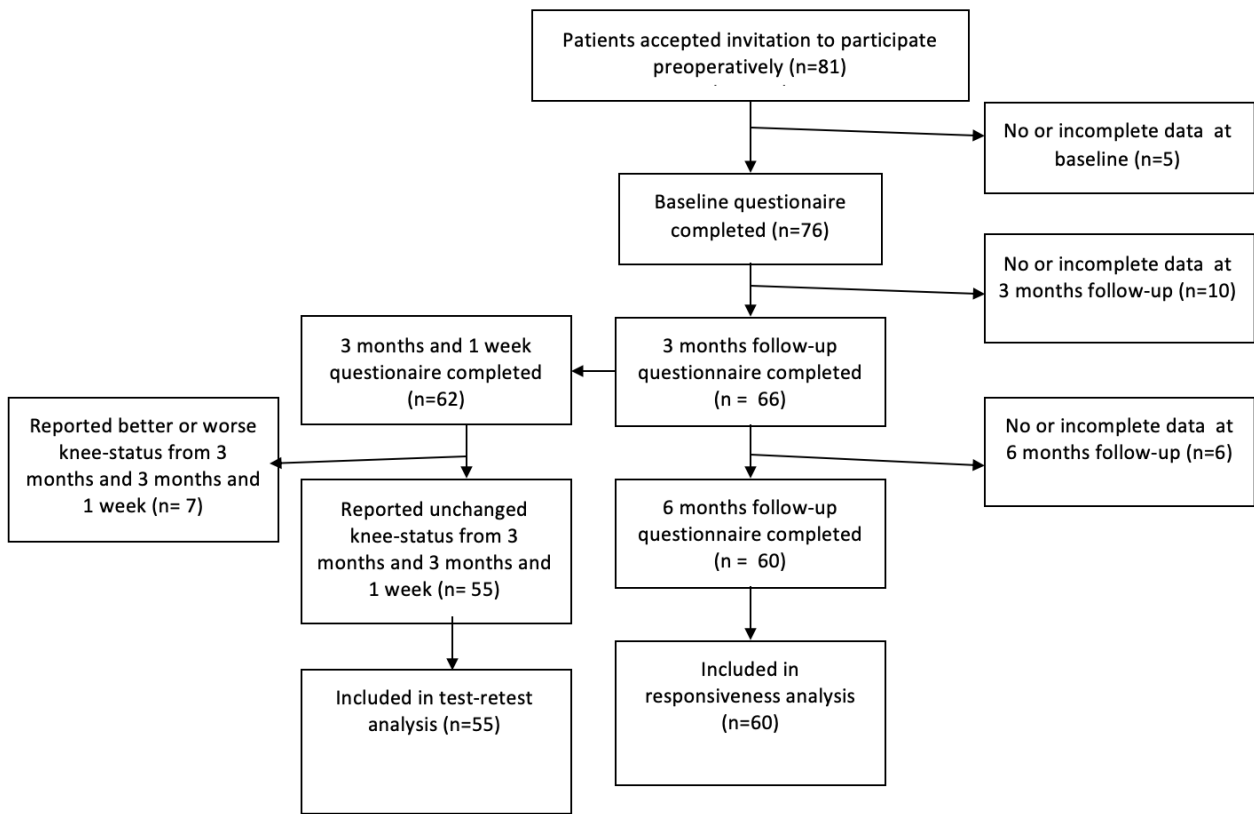
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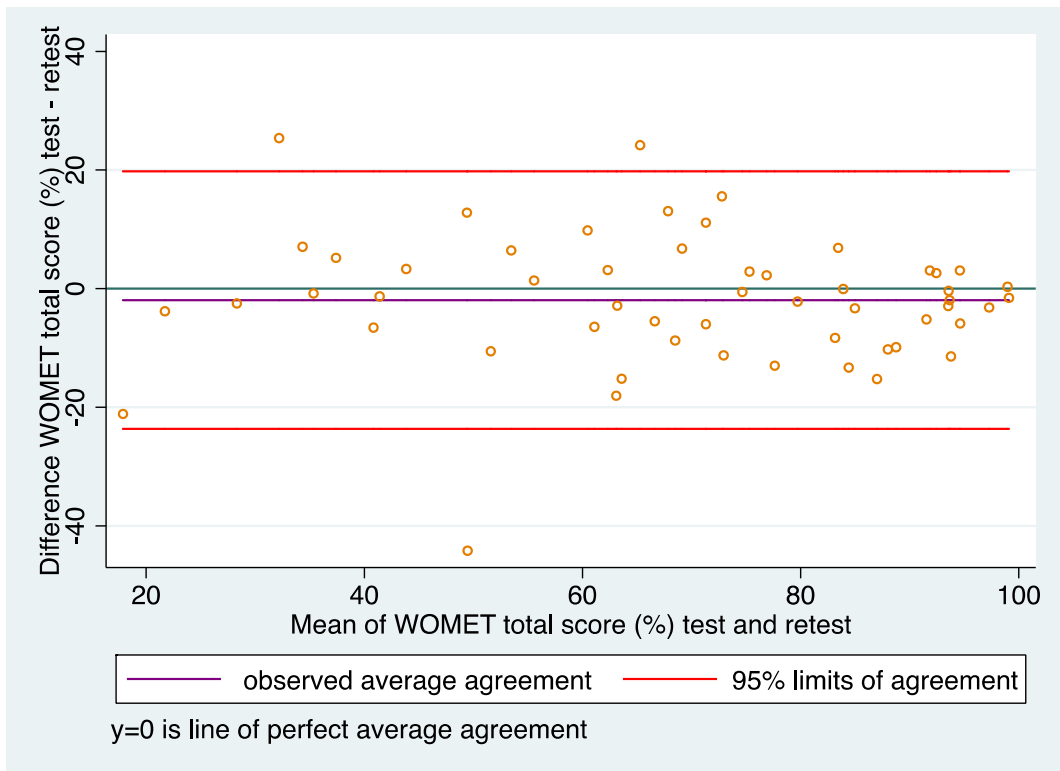
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341

342 **Figure 1:** Study Flowchart for reliability and responsiveness studies

343



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Figure 2: Bland-Altman plot of the reliability of the Danish version of the WOMET score. The

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green horizontal line intersecting $y=0$ indicates perfect agreement, whereas the purple line

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represents the observed mean difference. The closer the purple line is to the green line, the less

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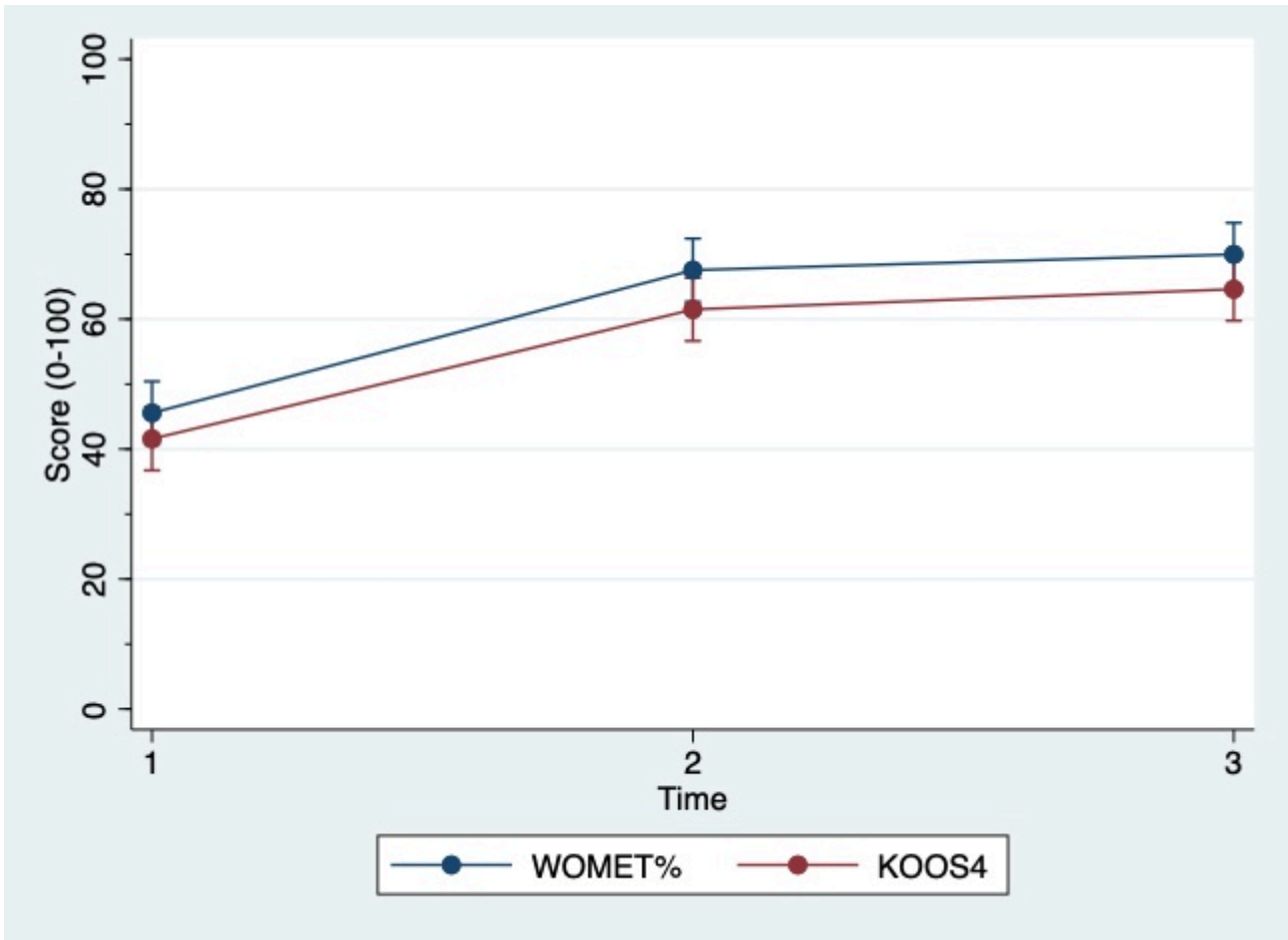
disagreement between measurements at test and retest. This distance was tested for systematic bias

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using a paired t-test. Red lines indicate upper and lower limits of agreements (95% LOA), $n=55$.

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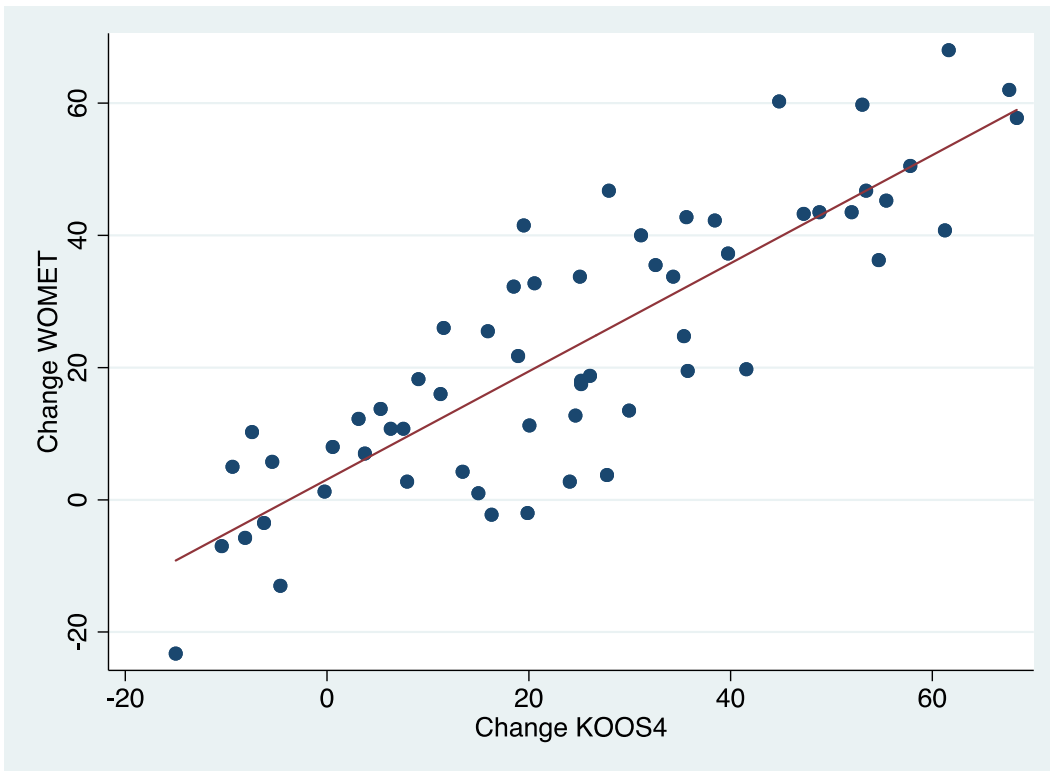
354 **Figure 3:** Comparison of WOMET% and KOOS4 scores at 1) baseline (preoperatively), 2) 3

355 months and 3) 6 months postoperatively. Values are mean scores with 95% CI, n=60.

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360 **Supplementary figure 1:** Relationship between change in WOMET% score and KOOS4 scores
361 from baseline to 6 months follow up ($r=0.85$, $p<0.0001$).

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Table 1: Patient characteristics at baseline.

Variables	Responsiveness analysis (n=60)	Reliability analysis (Test-retest sub-group) (n=55)
Age, years (SD)	50 (11)	50 (11)
Female, no. (%)	34 (57)	28 (51)
BMI, kg/m ² (SD)	27.6 (5)	27.6 (5)
Duration of symptoms, no. (%)		
0-3 months	6 (10%)	5 (9%)
4-6 months	19 (32%)	17 (31%)
7-12 months	16 (27%)	14 (25%)
13-24 months	11 (18%)	11 (20%)
>24 months	8 (13%)	8 (15%)
Symptom onset, no. (%)		
Slowly evolved over time	26 (43%)	25 (45%)
Semi-traumatic*	22 (37%)	19 (35%)
Traumatic**	12 (20%)	11 (20%)
Mechanical symptoms***, no. (%)		
Never	31 (52%)	31 (56%)
Monthly	10 (17%)	8 (15%)
Weekly	3 (5%)	2 (4%)
Several times a week	10 (17%)	10 (17%)
Daily	6 (10%)	4 (7%)
Earlier surgery same knee, no. (%)		
Yes	14 (23%)	13 (24%)
No	46 (77%)	42 (76%)
Earlier surgery opposite knee, no. (%)		
Yes	17 (28%)	16 (29%)
No	43 (72%)	39 (71%)

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no.: Number, BMI: Body Mass Index, SD: Standard Deviation

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*As a result of a specific incident (i.e. kneeling, sliding and/or twisting of the knee)

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**As a result of a violent incident (i.e. during sports, a crash, collision or the like)

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***The sensation of catching or locking of the knee.

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378 *Table 2, Test-retest scores for the reliability analysis sub-group, n=55.*

	Test	Retest	Difference Test retest (95% CI)	p-value	ICC (95% CI)	SEM	MDC 95%
WOMET % score (0-100%)							
Mean (SD)	68 (22)	70 (2)	2.0 (-1.0; 4.9)	n.s.*	0.88 (0.84-0.92)	8%	22%
Median (IQR)	74 (56-84)	73 (55-91)		n.s.**			
WOMET total score (0-1600)							
Mean (SD)	512 (355)	480 (364)	31 (-17; 79)	n.s.*	0.88 (0.84-0.92)	125	347
Median (IQR)	410 (258-707)	434 (142-722)		n.s.**			
Physical symptoms (0-900)							
Mean (SD)	203 (191)	190 (187)	12 (-15; 39)	n.s.*	0.86 (0.81-0.91)	71	197
Median (IQR)	151 (60-288)	118 (41-280)		n.s.**			
Sports/recreation/work/lifestyle (0-400)							
Mean (SD)	174 (116)	168 (117)	6 (-10; 22)	n.s.*	0.87 (0.82-0.91)	42	117
Median (IQR)	179 (83-285)	152 (56-289)		n.s.**			
Emotions (0-300)							
Mean (SD)	135 (81)	123 (91)	13 (-1; 26)	n.s.*	0.83 (0.78-0.89)	35	97
Median (IQR)	126 (76-207)	130 (40-202)		0.020**			

379 *P-value from paired t-test

380 **P-value from Wilcoxon Signed Rank test