

Appendix M. Consistency of Knee Pain and Function Outcomes Used for Models With Other Measure of Knee Pain and Function

APPENDIX M

Consistency of knee pain and function outcomes used for models with other measure of knee pain and function

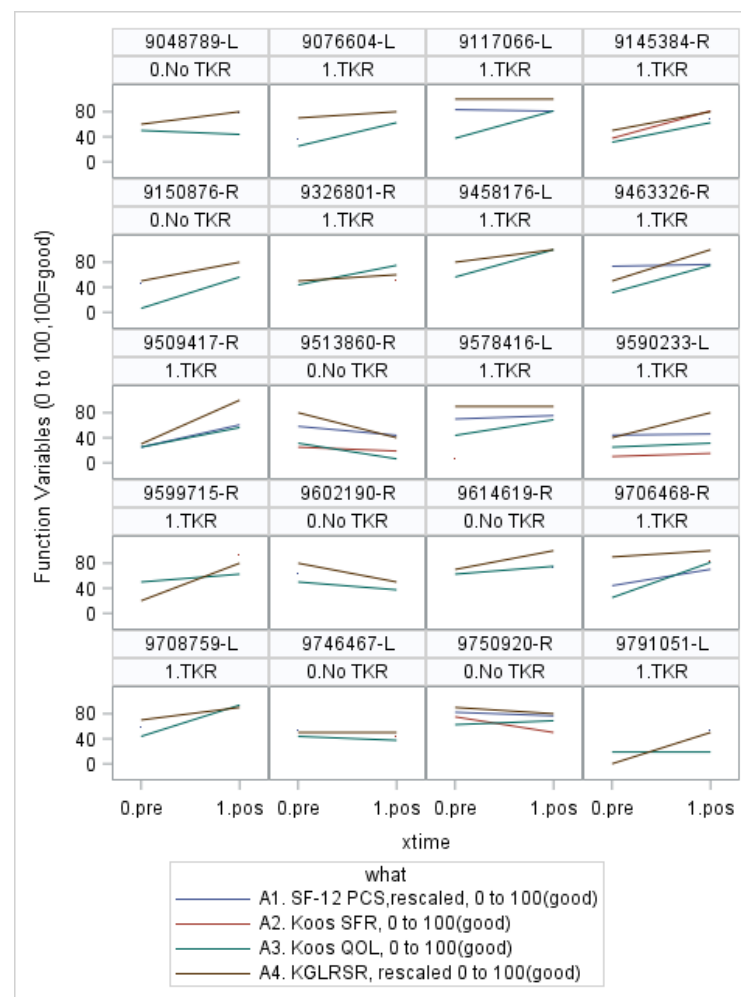
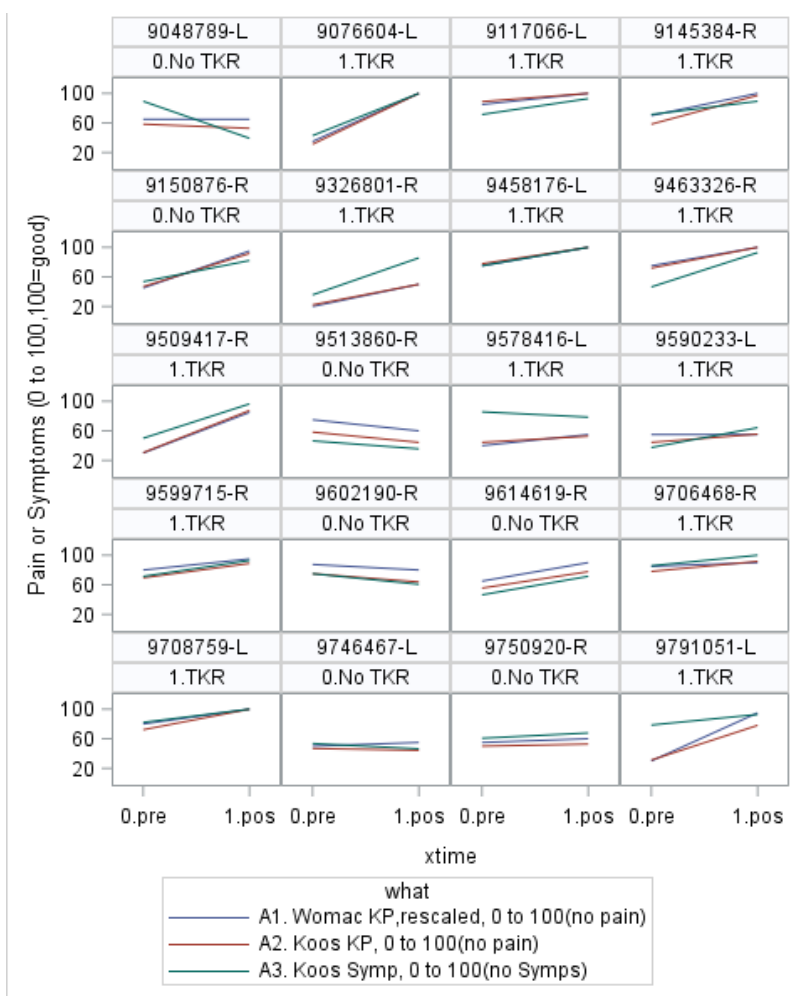
The team felt it important to evaluate other outcomes to look for consistency of effect. These were exploratory analyses done after the models for pain and function were finalized. The evaluations were done using the OAI database.

For pain, the study outcome was WOMAC knee pain. For the consistency of effect evaluation, we also looked at KOOS knee pain, and KOOS symptom scales.

For function, the study outcome was SF-12 physical function score. For the consistency of effect evaluation, we also looked at the KOOS function, sports, recreation (FSR) scale, the KOOS quality of life (QOL) scale, and the KGLRS scale. The KGLRS is another quality of life index that asks responders to 'consider all the ways that knee pain and knee arthritis affect you' rated on a 10 point scale of how they 'are doing' ranging from very good to very poor. For the purposes of these evaluations, all of these scales/instruments were re-scaled to 0 to 100 where a low value indicated poorer function and/or higher pain and high values indicated good function and/or lower pain.

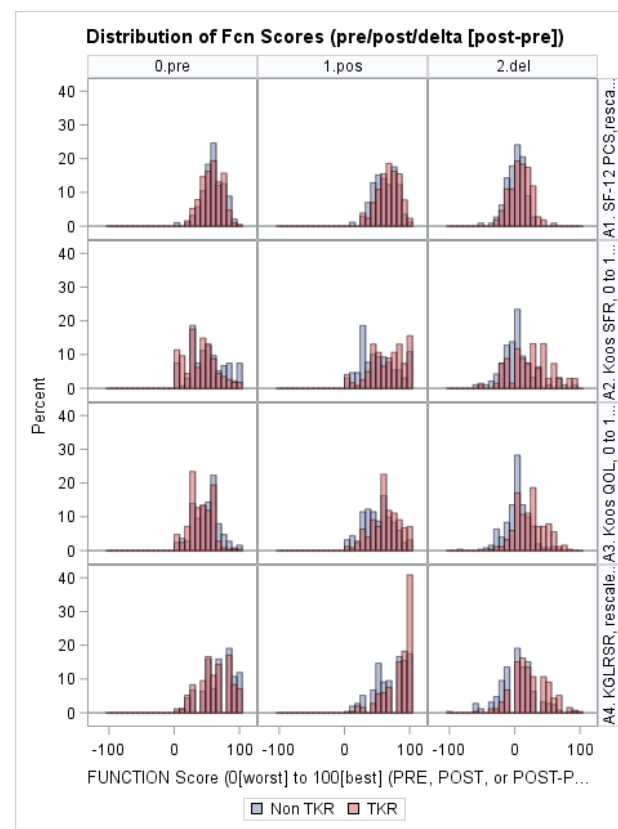
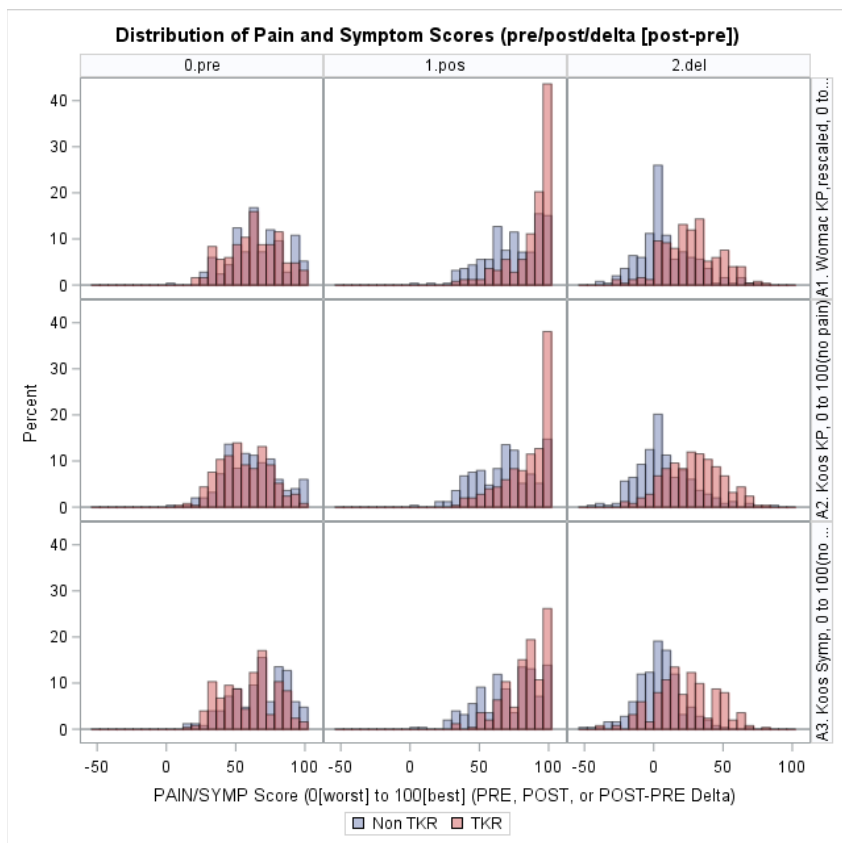
The results of these exploratory analyses suggest that the WOMAC knee pain tracks well with other measures of knee pain and symptoms, and in particular, KOOS knee pain. The SF-12 physical function score, while positively correlated, does not track as strongly with other knee-related quality of life and function variables. These results are somewhat to be expected in that while there may be overlap in physical function and knee-related function they are not the same thing. Our stakeholders suggest both overall and knee-related function are important and we have come to believe future work to develop predictions of the more specific knee-related function would be useful to both patient and clinical stakeholders.

I. SUBJECT PLOTS: For illustrative purposes we are showing baseline (pre) and 1-year follow-up (pos) raw (knee) pain and function scores for a random sample of subjects. The header for each panel in each figure tells if the subject got a total knee replacement (TKR). If the different scales are all capturing the same information, the lines within each panel should be overlapping. The panel on the left shows the different pain scales (WOMAC knee pain (KP), KOOS KP, and KOOS Symptom). The panel on the right shows the different function scales (SF-12 physical component score, KOOS SFR, KOOS QOL, KGLRS). In general, the lines were reasonably parallel and going in the same direction, although there was variability.

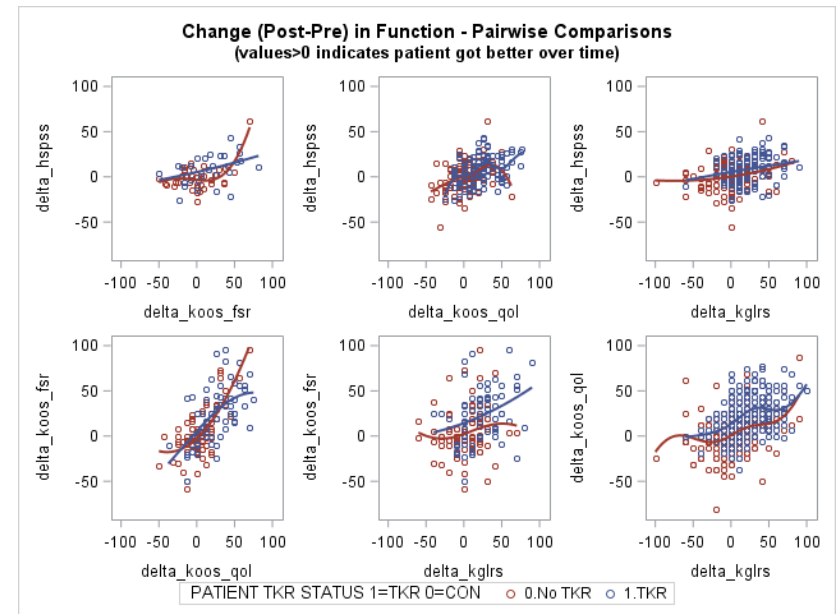
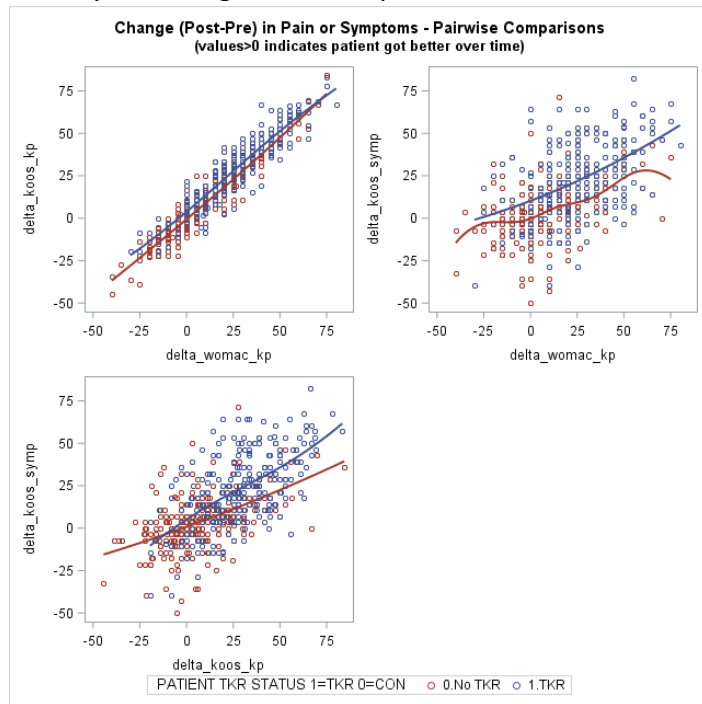


II. DISTRIBUTIONS: The distribution of scores at baseline (PRE), at the approximate 1-year follow-up (POS), and the POS minus PRE change from baseline delta (DEL) were plotted for each scale. Different colors were used to show the distributions for both the group of subjects that got TKR (red) and did not get TKR (blue). The results for distributions of the 3 pain scores are on the left panel, and of the 4 function scores on the right panel.

Consistency of the scores would best be illustrated by finding similarities of the distributions between ROWs of the figures, while there still may be differences between columns. This is shown clearly for the plot of pain scores on the left. For the PRE, the distributions are reasonably symmetric and centered near a value of 60. For POS, the scores are higher (better) and skewed to the right, especially for the TKR (red) subjects. The delta scores for all (3) pain measures are symmetric, but one can see more separation between the TKR and non-TKR (red and blue respectively) subjects with the TKR subjects having greater improvements captured by all three scales.



III. CORRELATION: We next wanted to look at consistency of scores at the subject level using simple bivariate scatter plots. If scores for any two scales were the same, one would expect the points on the scatter plot to all fall along a diagonal line on the plot. The corresponding correlation coefficient would be 1.0. Again, the panel on the left shows the 3 bivariate scatter plots for the 3 pain scores, and the panel on the right shows the 6 bivariate plots for the 4 function scores. The red dots and red smoothed line are the data for the subjects with TKR, and the blue dots and blue smoothed line are for the subjects who did not have TKR. All correlations were positive, and nearly all having associated p-value <0.05.



Spearman Rank Correlations	delta_womac_kp	delta_koos_kp	delta_koos_symp
delta_womac_kp	1	0.93198	0.42873
delta_koos_kp	0.91335	1	0.48809
delta_koos_symp	0.45438	0.55676	1

RED IS TKR BLUE IS NON TKR

Spearman Correlation Coefficients	delta_hspss	delta_koos_fsr	delta_koos_qol	delta_kglrs
delta_hspss	1	0.20176	0.337	0.20543
delta_koos_fsr	0.44029	1	0.5341	0.20293
delta_koos_qol	0.38043	0.60577	1	0.41407
delta_kglrs	0.2341	0.37076	0.3929	1

RED ARE TKR RESULTS BLUE ARE NON-TKR

IV. AGREEMENT: The last evaluation we did was categorize the change from baseline to follow-up as an improvement of over 8 points, worsening of over 8 points, or a change of no more than +/- 8 points. This was done for each subject for each scale. Again, bivariate tables were constructed looking at agreement for the change categories. The choice of a change of 8 points on a 100-point scale was based on the KOOS User's Guide 1.1 Updated August 2012 (<http://www.koos.nu/>) which notes "The Minimal Important Change (MIC) is currently suggested to be 8-10" with an acknowledgment that there are limitations to this suggestion. We evaluated "agreement" with a kappa statistic. A Kappa of 1 indicates perfect agreement. The results of these analyses are displayed below. For the pain scales, the WOMAC knee pain (KP) and KOOS KP had the highest Kappa (consistent with the largest correlation seen in part III). Kappa's were lower for the function scales than pain scales. The SF-12 agreeing more with the KOOS than KGLRS. Among the function measures, the kappa was highest for the 2 KOOS scales (KOOS FSR and KOOS QOL). These results are shown on the following page.

A. AGREEMENT: Pain Scales

Agreement on Knee Pain /Symptom Measures 1 of 3:		KOOS KP			Kappa: Womac KP vs. Koos KP				
		Improve >8 pts	+/- 8 pts	Worsen >8 pts	Statistic	Value	ASE	95% Confidence Limits	
WOMAC KP					Simple Kappa	0.707	0.0297	0.6488	0.7652
Improve>8 pts		295	24	1	Weighted Kappa	0.7722	0.0243	0.7245	0.8199
+/- 8 pts		23	81	17					
Worse >8 pts		0	11	47					
Agreement on Knee Pain /Symptom Measures 2 of 3:		KOOS SYMP			Kappa: Womac KP vs. Koos Symptom				
		Improve >8 pts	+/- 8 pts	Worsen >8 pts	Statistic	Value	ASE	95% Confidence Limits	
WOMAC KP					Simple Kappa	0.3041	0.0343	0.2368	0.3714
Improve>8 pts		225	77	19	Weighted Kappa	0.3493	0.0348	0.2811	0.4174
+/- 8 pts		33	66	23					
Worse >8 pts		13	29	16					
Agreement on Knee Pain /Symptom Measures 3 of 3:		KOOS SYMP			Kappa: Koos KP vs. Koos Symptom				
		Improve >8 pts	+/- 8 pts	Worsen >8 pts	Statistic	Value	ASE	95% Confidence Limits	
KOOS KP:					Simple Kappa	0.3382	0.0344	0.2706	0.4057
Improve>8 pts		228	76	14	Weighted Kappa	0.4074	0.0343	0.3403	0.4746
+/- 8 pts		33	63	20					
Worse >8 pts		9	33	23					

B. AGREEMENT: Function Scales

Agreement on Function 1 of 6:		koosFSR3			Kappa: SF-12 PCS vs. KOOS FSR				
hspss3 (SF12)	Improve >8 pts	+/- 8 pts	Worsen >8 pts	Statistic	Value	ASE	95% Confidence Limits		
Improve>8 pts	19	1	8	Simple Kappa	0.1429	0.0806	-0.0152	0.3009	
+/- 8 pts	9	8	11	Weighted Kappa	0.1832	0.0874	0.012	0.3545	
Worse >8 pts	3	9	4						
Agreement on Function 2 of 6:		koosqol3			Kappa: SF-12 PCS vs. KOOS QOL				
hspss3 (SF12)	Improve >8 pts	+/- 8 pts	Worsen >8 pts	Statistic	Value	ASE	95% Confidence Limits		
Improve>8 pts	66	21	7	Simple Kappa	0.2071	0.0511	0.1069	0.3073	
+/- 8 pts	38	30	12	Weighted Kappa	0.2747	0.0521	0.1726	0.3768	
Worse >8 pts	12	20	15						
Agreement on Function 3 of 6:		kgllrs3			Kappa: SF-12 PCS vs. KGLRS				
hspss3 (SF12)	Improve >8 pts	+/- 8 pts	Worsen >8 pts	Statistic	Value	ASE	95% Confidence Limits		
Improve>8 pts	64	12	18	Simple Kappa	0.1457	0.0476	0.0525	0.2389	
+/- 8 pts	38	20	22	Weighted Kappa	0.1693	0.0534	0.0645	0.274	
Worse >8 pts	20	11	16						

B. AGREEMENT: Function Scales (continued)

Agreement on Function 2 of 6:		koosqol3			Kappa				
koosFSR3		Improve> 8 pts	+/- 8 pts	Worsen> 8 pts	Kappa: KOOS FSR vs. KOOS QOL				
					Statistic	Value	ASE	95% Confidence Limits	
Improve>8 pts		61	13	3	Simple Kappa	0.4164	0.0571	0.3046	0.5282
+/- 8 pts		10	28	6	Weighted Kappa	0.4606	0.0601	0.3429	0.5783
Worse >8 pts		7	20	14					
Agreement on Function 2 of 6:		kglrs3			Kappa: KOOS FSR vs. KGLRS				
koosFSR3		Improve> 8 pts	+/- 8 pts	Worsen> 8 pts	Statistic	Value	ASE	95% Confidence Limits	
Improve>8 pts		56	11	10	Simple Kappa	0.2382	0.0577	0.1251	0.3513
+/- 8 pts		14	13	17	Weighted Kappa	0.2754	0.063	0.1519	0.3989
Worse >8 pts		17	8	16					
Agreement on Function 3 of 6:		kglrs3			Kappa: KOOSQOL vs. KGLRS				
koosqol3		Improve> 8 pts	+/- 8 pts	Worsen> 8 pts	Statistic	Value	ASE	95% Confidence Limits	
Improve>8 pts		207	36	27	Simple Kappa	0.2352	0.0318	0.1728	0.2975
+/- 8 pts		68	34	61	Weighted Kappa	0.317	0.034	0.2504	0.3835
Worse >8 pts		21	16	33					

V. Summary of Scales


Pain /Function Variables [0=bad, more pain, 0=good, less pain]	PATIENT TKR STATUS 1=TKR 0=CON					
	No TKR			Yes TKR		
	Mean	Median	N	Mean	Median	N
baseline womac knee pain	6.9	7	250	7.6	8	251
baseline womac pain_reverse scale	65.6	65	250	62	60	251
baseline koos knee pain	61.2	61.1	249	56.1	55.6	251
baseline koos symptom	67.5	67.9	251	59.9	63.4	252
1-year womac knee pain	5.3	5	252	2.4	1	252
1-year womac knee pain_reverse scale	73.4	75	252	88.2	95	252
1-year koos knee pain	68.2	69.4	251	84.9	90.6	252
1-year koos symptom	71.5	75	252	83	85.7	252

Function Vars [0=bad, 0=good]	PATIENT TKR STATUS 1=TKR 0=CON					
	No TKR			Yes TKR		
	Mean	Median	N	Mean	Median	N
baseline SF-12 PCS _stretched scale to 0-100	59.3	59	191	57.5	58.1	191
baseline Koos FSR (Func/Sports/Rec)	49.2	50	134	38.1	40	114
baseline Koos QOL (Quality of Life)	48.5	50	251	39.9	37.5	252
baseline KGLRS _ x10,reversed to 0-100	65.9	70	251	60.8	60	252
1-year SF-12 PCS _stretched scale to 0-100	61.9	61.8	171	67.6	69.2	129
1-year Koos FSR (Func/Sports/Rec)	51.1	50	129	64.9	66.7	122
1-year Koos QOL (Quality of Life)	51.5	50	252	62.6	62.5	252
1-year KGLRS _ x10,reversed to 0-100	69.2	70	252	83	90	252

VI. Screenshots of components of KOOS and KGLRS Scales from OAI database

KOOS Knee Pain

XKOOSKP (Screenshot from Enrollment workbook)




KOOS PAIN

2 Still thinking about your right knee during the last 7 days, how much pain have you had during these other activities?
(Examiner Note: Read response options. REQUIRED - Show Card #1.) KOO SKPR

a. Twisting/pivoting on your knee? KPRKN1
<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Extreme <input type="radio"/> Don't know <input type="radio"/> Refused <input type="radio"/> Don't do 0 1 2 3 4 .D .R .X
b. Straightening knee fully? KPRKN2
<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Extreme <input type="radio"/> Don't know <input type="radio"/> Refused 0 1 2 3 4 .D .R
c. Bending knee fully? KPRKN3
<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Extreme <input type="radio"/> Don't know <input type="radio"/> Refused 0 1 2 3 4 .D .R

KOOS Function, Sports, Recreational Activities

XKOOSFSR (Screenshot from Enrollment workbook)



KOOS FUNCTION, SPORTS AND RECREATIONAL ACTIVITIES

23 The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the last 7 days due to either of your knees.
(Examiner Note: Read response options. REQUIRED - Show Card #13.) KOO SFSR

a. Squatting KOOSFX1
<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Extreme <input checked="" type="radio"/> Don't do <input type="radio"/> Don't know <input type="radio"/> Refused 0 1 2 3 4 .X .D .R
b. Running KOOSFX2
<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Extreme <input checked="" type="radio"/> Don't do <input type="radio"/> Don't know <input type="radio"/> Refused 0 1 2 3 4 .X .D .R
c. Jumping KOOSFX3
<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Extreme <input checked="" type="radio"/> Don't do <input type="radio"/> Don't know <input type="radio"/> Refused 0 1 2 3 4 .X .D .R
d. Twisting/pivoting on your injured knee KOOSFX4
<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Extreme <input checked="" type="radio"/> Don't do <input type="radio"/> Don't know <input type="radio"/> Refused 0 1 2 3 4 .X .D .R
e. Kneeling KOOSFX5
<input type="radio"/> None <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Extreme <input checked="" type="radio"/> Don't do <input type="radio"/> Don't know <input type="radio"/> Refused 0 1 2 3 4 .X .D .R


VII. Screenshots of components of KOOS and KGLRS Scales from OAI database (continued)

KOOS SYMPTOMS

KOOS QOL and KGLRS

XKOOSYM (Screenshot from Enrollment workbook)

XKOOSQOL , XKGLRS (Screenshot from Enrollment workbook)

 **KOOS SYMPTOMS**

Still thinking about your right knee, these questions are about other symptoms you have had during the last 7 days.

6 Do you have swelling in your right knee?
(Examiner Note: Read response options. REQUIRED - Show Card #5.) **KSXRK**

0 Never 1 Rarely 2 Sometimes 3 Often 4 Always .D Don't know .R Refused

7 Do you feel grinding, hear clicking or any other type of noise when your right knee moves?
(Examiner Note: Read response options. REQUIRED - Show Card #5.) **KSXRK**

0 Never 1 Rarely 2 Sometimes 3 Often 4 Always .D Don't know .R Refused

8 Does your right knee catch or hang up when moving?
(Examiner Note: Read response options. REQUIRED - Show Card #5.) **KSXRK**


0 Never 1 Rarely 2 Sometimes 3 Often 4 Always .D Don't know .R Refused

9 Can you straighten your right knee fully?
(Examiner Note: Read response options. REQUIRED - Show Card #6.) **KSXRK**

0 Always 1 Often 2 Sometimes 3 Rarely 4 Never .D Don't know .R Refused

10 Can you bend your right knee fully?
(Examiner Note: Read response options. REQUIRED - Show Card #6.) **KSXRK**

0 Always 1 Often 2 Sometimes 3 Rarely 4 Never .D Don't know .R Refused

 **KOOS QUALITY OF LIFE**

24 How often are you aware of problems with your knee(s)?
(Examiner Note: Read response options. REQUIRED - Show Card #14.) **KOOSQOL**

0 Never 1 Monthly 2 Weekly 3 Daily 4 Constantly .D Don't know .R Refused **KQOL1**

25 Have you modified your lifestyle to avoid potentially damaging activities to your knee(s)?
(Examiner Note: Read response options. REQUIRED - Show Card #15.) **KQOL2**

0 Not at all 1 Mildly 2 Moderately 3 Severely 4 Totally .D Don't know .R Refused

26 How much are you troubled with lack of confidence in your knee(s)?
(Examiner Note: Read response options. REQUIRED - Show Card #16.) **KQOL3**

0 Not at all 1 Mildly 2 Moderately 3 Severely 4 Extremely .D Don't know .R Refused

27 In general, how much difficulty do you have with your knee(s)?
(Examiner Note: Read response options. REQUIRED - Show Card #17.) **KQOL4**

0 None 1 Mild 2 Moderate 3 Severe 4 Extreme .D Don't know .R Refused

28 Considering all the ways that knee pain and knee arthritis affect you, if at all, how are you doing today? Please point to the number on this card that best describes how you are doing. "0" means "Very Good" and "10" means "Very Poor."
(Examiner Note: REQUIRED. Show Card #18.) **KGLRS**

0	1	2	3	4	5	6	7	8	9	10
○	○	○	○	○	○	○	○	○	○	○
0	1	2	3	4	5	6	7	8	9	10
Very Good										Very Poor