

Appendix Table: Additional Secondary Quality of Life Measures by Intention to Treat

		<u>PCI</u>	<u>MED</u>	<u>Difference between PCI and MED (95% CI)</u>
SF role function - emotional				
Baseline	N	432	432	
	median	100 (67, 100)	100 (33, 100)	
	mean	76.62±37.94	71.76±40.55	4.86 (-0.38, 10.11)
4 months	N	409	411	
	median	100 (33, 100)	100 (67, 100)	
	mean	75.26±37.74	76.16±37.65	-0.89 (-6.06, 4.28)
12 months	N	399	396	
	median	100 (67,100)	100 (67,100)	
	mean	78.99±36.29	79.12±36.00	-0.14 (-5.17, 4.90)
24 months	N	379	375	
	median	100 (67,100)	100 (67,100)	
	mean	82.41±33.35	79.69±36.48	2.72 (-2.28, 7.72)
SF role function - physical				
Baseline	N	429	427	
	median	50 (0,100)	75 (0,100)	
	mean	54.74±43.08	56.03±44.21	-1.29 (-7.15, 4.57)
4 months	N	407	408	
	median	75 (0,100)	75 (25,100)	
	mean	58.85±42.28	59.38±40.94	-0.53 (-6.25, 5.19)
12 months	N	400	396	
	median	100 (25,100)	100 (25,100)	
	mean	68.90±39.04	69.34±40.73	-0.44 (-5.99, 5.11)
24 months	N	380	381	
	median	100 (25,100)	100 (50,100)	
	mean	68.82±40.09	70.19±38.58	-1.37 (-6.97, 4.23)
SF general health				
Baseline	N	443	443	
	median	57 (50,62)	57 (50,65)	
	mean	56.25±11.06	56.86±11.25	-0.62 (-2.09, 0.85)
4 months	N	410	416	
	median	57 (50,62)	57 (50,62)	
	mean	55.49±9.67	55.41±10.51	0.08 (-1.30, 1.46)

12 months	N	409	404	
	median	57 (47,62)	57 (50,62)	
	mean	54.75±10.26	55.52±9.49	-0.77 (-2.13, 0.59)
24 months	N	383	384	
	median	57 (50,62)	57 (50,62)	
	mean	54.86±9.54	55.60±10.17	-0.74 (-2.14, 0.66)
SF vitality				
Baseline	N	442	446	
	median	60 (40,75)	58 (40,75)	
	mean	56.83±23.66	55.92±24.09	0.92 (-2.23, 4.06)
4 months	N	414	420	
	median	60 (45,80)	60 (45,80)	
	mean	59.45±23.38	58.19±23.23	1.27 (-1.90, 4.43)
12 months	N	408	406	
	median	60 (45,80)	65 (45,80)	
	mean	59.73±21.37	60.30±23.05	-0.57 (-3.63, 2.49)
24 months	N	386	387	
	median	63 (50,80)	65 (45,80)	
	mean	60.79±21.65	60.10±22.86	0.70 (-2.45, 3.84)
SF social functioning				
Baseline	N	446	450	
	median	81 (50,100)	88 (50,100)	
	mean	74.13±27.37	74.25±28.40	-0.12 (-3.78, 3.54)
4 months	N	416	420	
	median	94 (63,100)	88 (63,100)	
	mean	81.07±24.31	79.85±25.35	1.22 (-2.15, 4.59)
12 months	N	410	406	
	median	100 (75,100)	100 (75,100)	
	mean	84.60±21.28	83.53±23.39	1.08 (-2.00, 4.15)
24 months	N	388	389	
	median	100 (75,100)	100 (75,100)	
	mean	84.66±21.68	83.23±22.82	1.44 (-1.70, 4.57)
SF pain index				
Baseline	N	447	449	
	median	62 (41,84)	62 (41,84)	
	mean	61.74±26.85	60.55±28.30	1.19 (-2.42, 4.81)
4 months	N	414	420	
	median	74 (61,100)	74 (61,100)	
	mean	73.58±24.60	73.88±24.36	-0.29 (-3.62, 3.03)
12 months	N	409	406	
	median	74 (52,100)	74 (61,100)	
	mean	73.59±24.39	74.04±24.85	-0.46 (-3.84, 2.93)
24 months	N	388	390	

	median	74 (52,100)	74 (61,100)	
	mean	72.72±24.94	74.59±24.94	-1.87 (-5.38, 1.64)

Bed days

Baseline	N	422	428	
	mean	1.45±4.26	1.76±5.17	-0.31 (-0.95, 0.33)
4 months	N	397	402	
	mean	0.83±3.24	0.95±3.60	-0.12 (-0.60, 0.35)
12 months	N	387	391	
	mean	0.78±3.59	0.92±4.21	-0.14 (-0.69, 0.42)
24 months	N	365	368	
	mean	0.98±4.24	0.76±3.51	0.22 (-0.34, 0.79)

Disability days

Baseline	N	422	424	
	mean	5.59±10.28	5.62±10.46	-0.03 (-1.42, 1.38)
4 months	N	394	394	
	mean	5.07±11.03	4.81±10.99	0.26 (-1.28, 1.80)
12 months	N	383	388	
	mean	2.68±7.50	2.95±8.35	-0.27 (-1.39, 0.85)
24 months	N	363	360	
	mean	2.18±6.48	3.45±9.67	-1.27 (-2.47, 0.07)

0-100 rating scale

Baseline	N	435	439	
	median	80 (60,90)	76 (60,90)	
	mean	73.85±20.40	72.83±20.96	1.02 (-1.72, 3.77)
4 months	N	405	406	
	median	80 (70,90)	80 (67,90)	
	mean	76.97±17.57	76.06±19.83	0.91 (-1.67, 3.49)
12 months	N	399	402	
	median	80 (70,90)	80 (70,90)	
	mean	78.08±17.35	77.94±18.23	0.14 (-2.33, 2.61)
24 months	N	373	380	
	median	80 (70,90)	80 (70,90)	
	mean	77.99±17.51	77.53±18.57	0.46 (-2.12, 3.05)

Time Trade-Off

Baseline	N	413	410	
	median	0.9 (0.6,1.0)	1.0 (0.7,1.0)	
	mean	0.72±0.37	0.75±0.36	-0.03 (-0.08,0.02)
4 months	N	378	385	
	median	1.0 (0.9,1.0)	1.0 (0.8,1.0)	
	mean	0.85±0.28	0.79±0.33	0.06 (0.01,0.10)
12 months	N	378	368	
	median	1.0 (0.9,1.0)	1.0 (0.9,1.0)	

	mean	0.85±0.30	0.84±0.30	0.00 (-0.04,0.05)
24 months	N	361	359	
	median	1.0 (0.9,1.0)	1.0 (0.9,1.0)	
	mean	0.87±0.27	0.84±0.31	0.03 (-0.01,0.08)

Working full or part time

Baseline	N	447	442	
	% yes	50.3	51.6	-1.25 (-0.08,0.05)
4 months	N	418	424	
	% yes	43.8	45.8	-1.97 (-0.09,0.05)
12 months	N	407	411	
	% yes	44.0	46.7	-2.73 (-0.10,0.04)
24 months	N	389	386	
	% yes	41.9	46.6	-4.73 (-0.12,0.02)

Continuous variables shown as medians (25th to 75th percentiles) and means with standard deviations. Categorical variables are shown as percentages.

95% confidence intervals on treatment differences calculated as PCI minus MED.
 Comparisons with bolded values were statistically significant at a p≤ 0.05 level.