

Table 1: Summary of Breast-Q Domain Scores at Baseline, Year 1, and Year 2 Following Breast Reconstruction

BREAST-Q Domain	Cohorts SurgiMend, n=119 Control, n=868	Mean (SD) Score			Difference (95% CI)*	
		Baseline	Year 1	Year 2	Year 1	Year 2
BREAST-Q Physical Well-Being, Chest ⁺	SurgiMend	81.2 (15.6)	75.1 (17.2)	73.8 (20.1)	-2.4 (-0.9, 5.6)	1.5 (-2.4, 5.3)
	Control	80.5 (15.6)	72.7 (18.6)	72.3 (20.9)		
BREAST-Q Satisfaction with Breast ⁺	SurgiMend	62.2 (21.8)	59.8 (23.2)	62.8 (24.2)	-0.4 (-4.9, 4.2)	1.6 (-2.9, 6.1)
	Control	62.7 (21.2)	60.2 (20.3)	61.2 (26.8)		
BREAST-Q Psychosocial Well-Being ⁺	SurgiMend	71.6 (19.6)	71.1 (24.8)	70.4 (26.3)	3.8 (-0.8, 8.5)	1.0 (-3.8, 5.9)
	Control	71.4 (17.7)	67.3 (22.8)	69.4 (22.8)		
BREAST-Q Sexual Well-Being ⁺	SurgiMend	52.8 (20.7)	45.3 (31.3)	48.0 (27.1)	-2.7 (-8.6, 3.2)	-5.2 (11.8, 1.4)
	Control	56.8 (20.6)	48.0 (27.1)	49.5 (36.2)		
BREAST-Q Satisfaction with Outcome ⁺	SurgiMend		72.3 (n=75)	72.5 (n=50)		3.4 (-1.6, 8.3)
	Control		69.8 (n=504)	69.3 (n=333)		3.2 (-2.9, 9.3)
BREAST-Q Satisfaction with Nipple Reconstruction [@] How Nipple Looks [@]	SurgiMend				-0.1 (-0.7, 0.6)	0 (-0.5, 0.5)
	Control					
BREAST-Q Satisfaction with Nipple Reconstruction [@] How Natural Nipple Looks	SurgiMend				-0.1 (-0.7, 0.5)	0 (-0.6, 0.5)
	Control					

CONTROL, Control; SURGIMEND, SurgiMend.

* Difference = SurgiMend – Control.

+Note:

- missing data are imputed by the multiple imputation (MI) procedure where missing baseline covariates, missing physical well-being at pre-operative, post-operative 1 Week, 3 Month, 1 Year, 2 Year and missing satisfaction with breast at pre-operative, post-operative 1 Year, 2 Year are imputed simultaneously.

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- missing data are imputed by the MI procedure where missing baseline covariates, missing psychosocial and sexual well-being at pre-operative, post-operative 3 Month, 1 Year, 2 Year are imputed simultaneously.
- missing data are imputed by the MI procedure where missing baseline covariates, missing psychosocial and sexual well-being at pre-operative, post-operative 3 Month, 1 Year, 2 Year are imputed simultaneously.

@ The score ranged from 1 to 4. All subjects with missing values were excluded (I.e., this is complete case analysis).

Table 2: Summary of Continuous Change from Baseline in BREAST-Q Domain Scores

Breast-Q Domain	Mean (SD) Change from Baseline		Difference (95% CI)*
	SurgiMend (n=119)	Control (n=868)	
BREAST-Q Physical Well-Being, Chest †			
<i>Week 1</i>	-24.9 (16.1)	-24.2 (17.1)	-0.7 (-3.8, 2.4)
<i>Month 3</i>	-11.7 (17.5)	-13.6 (19.1)	1.9 (-1.5, 5.3)
<i>Year 1</i>	-6.1 (17.4)	-7.7 (20.0)	1.7 (-1.7, 5.0)
<i>Year 2</i>	-7.4 (21.3)	-8.2 (22.7)	0.7 (-3.3, 4.8)
BREAST-Q Satisfaction with Breast †			
<i>Year 1</i>	-2.3 (25.4)	-2.5 (27.4)	0.2 (-4.9, 5.2)
<i>Year 2</i>	0.7 (29.3)	-1.4 (33.0)	2.1 (-3.4, 7.7)
BREAST-Q Psychosocial Well-Being †			
<i>Month 3</i>	-7.5 (18.3)	-8.7 (20.3)	1.3 (-2.3, 4.8)
<i>Year 1</i>	-0.5 (23.0)	-4.1 (24.2)	3.6 (-0.8, 7.9)
<i>Year 2</i>	-1.2 (25.3)	-2.0 (24.4)	0.8 (-4.0, 5.5)
BREAST-Q Sexual Well-Being †			
<i>Month 3</i>	-14.4 (24.7)	-13.7 (24.7)	-0.8 (-5.5, 3.9)
<i>Year 1</i>	-7.5 (27.8)	-8.8 (26.8)	1.4 (-3.9, 6.6)
<i>Year 2</i>	-8.5 (33.2)	-7.3 (37.1)	-1.2 (-7.5, 5.2)

* Difference = SurgiMend - Control.

† Missing data are imputed by the multiple imputation (MI) procedure, where missing baseline covariates; missing Physical Well-Being pre-reconstruction and at Week 1, Month 3, Year 1, and Year 2 after reconstruction; and missing Satisfaction with Breast pre-reconstruction and at Year 1 and Year 2 after reconstruction are imputed simultaneously

Table 3: Proportion of Subjects with Change from Baseline ≥ 4 in BREAST-Q Domain Scores

BREAST-Q Domain	SurgiMend (n=119)	Control (n=868)	Mean Difference (95% CI)*
BREAST-Q Physical Well-Being, Chest †	Propensity Score-adjusted Estimates		
<i>Year 1</i>	44.5%	39.1%	5.4% (-5.2%, 16.0%)
<i>Year 2</i>	42.7%	40.3%	2.4% (-9.0%, 13.9%)
BREAST-Q Satisfaction with Breast †			
<i>Year 1</i>	47.2%	46.7%	0.6% (-10.7%, 11.9%)
<i>Year 2</i>	52.1%	49.1%	3.0% (-8.5%, 14.5%)
BREAST-Q Psychosocial Well-Being †	Unadjusted Estimates		
<i>Month 3</i>	45.5%	41.9%	3.6% (-6.7%, 14.0%)
<i>Year 1</i>	61.3%	51.2%	10.1% (-0.5%, 20.7%)
<i>Year 2</i>	57.9%	55.5%	2.5% (-8.5%, 13.5%)
BREAST-Q Sexual Well-Being †			
<i>Month 3</i>	30.2%	33.6%	-3.4% (-13.0%, 6.2%)
<i>Year 1</i>	44.8%	42.4%	2.4% (-9.7%, 14.4%)
<i>Year 2</i>	40.5%	44.3%	-3.7% (-15.7%, 8.2%)
BREAST-Q Sum of Subject Response to Physical Well-Being and Satisfaction with Breast †			
<i>Year 1</i>	67.2%	67.9%	-0.7% (-10.5%, 9.2%)
<i>Year 2</i>	67.3%	68.1%	-0.8% (-11.4%, 9.9%)

* Difference = SurgiMend - Control.

† Missing data (SurgiMend, 58%; Control, 63%) are imputed by the multiple imputation (MI) procedure where missing baseline covariates; missing Physical Well-Being pre-reconstruction and at Week 1, Month 3, Year 1, and Year 2 after reconstruction; and missing Satisfaction with Breast pre-reconstruction and at Year 1 after reconstruction are imputed simultaneously.

‡ Missing data are imputed by the MI procedure, where missing baseline covariates and missing Psychosocial and Sexual Well-Being pre-reconstruction and at Month 3, Year 1, and Year 2 are imputed simultaneously.

Table 4: Summary of Continuous Change from Baseline in NPRS and MPQ Scores

Pain Measure	Mean Change from Baseline		Difference (95% CI) *
	SurgiMend (n=119)	Control (n=868)	
NPRS [†]			
<i>Week 1</i>	3.0	2.9	0.1 (-0.5, 0.5)
<i>Month 3</i>	0.6	1.1	-0.6 (-1.0, -0.1)
<i>Year 1</i>	0.3	0.4	-0.1 (-0.5, 0.3)
<i>Year 2</i>	0.6	0.5	0.1 (-0.4, 0.6)
MPQ [‡]			
<i>Week 1</i>	9.3 (n=77)	8.9 (n=622)	0.4 (-1.4, 2.3)
<i>Month 3</i>	1.9 (n=76)	3.0 (n=499)	-1.1 (-2.8, 0.5)
<i>Year 1</i>	-0.6 (n=58)	0.3 (n=403)	-0.8 (-2.2, 0.6)
<i>Year 2</i>	-0.9 (n=37)	-0.6 (n=272)	-0.2 (-2.0, 1.5)

MPQ, McGill Pain Questionnaire; NPRS, Numeric Pain Rating Scale.

* Difference =SurgiMend – Control.

[†] The NPRS score ranges from 0 to 10; higher scores indicate worse pain. Missing data are imputed by the multiple imputation procedure, where missing baseline covariates and missing Physical Well-Being and missing NPRS pre-reconstruction and at Week 1, Month 3, Year 1, and Year 2 are imputed simultaneously.

[‡] The MPQ consists of 15 Items, with its total score ranging from 0 to 45; higher scores indicate worse pain. If the number of missing Items of MPQ is less than 8, then the missing item was imputed by the mean of the observed items; otherwise, the subject is considered as missing and excluded from the analyses.

Table 5: Summary of Change from Baseline in PROMIS Domain Scores

PROMIS Domain	Subjects, n		Mean Change from Baseline		Difference (95% CI) *
	SurgiMend	Control	SurgiMend	Control	
PROMIS-Physical Function					
<i>Month 3</i>	96	590	2.6	3.3	-0.7 (-1.9, 0.4)
<i>Year 1</i>	75	511	1.0	1.6	-0.5 (-1.7, 0.6)
<i>Year 2</i>	49	324	1.4	0.7	0.7 (-0.2, 1.6)
PROMIS-Anxiety					
<i>Month 3</i>	96	589	-8.6	-7.4	-1.2 (-3.1, 0.8)
<i>Year 1</i>	75	497	-9.2	-8.7	-0.5 (-3.0, 2.0)
<i>Year 2</i>	49	324	-8.9	-9.1	0.2 (-2.9, 3.4)
PROMIS-Depression					
<i>Month 3</i>	96	587	-0.2	-1.3	1.1 (-0.6, 2.7)
<i>Year 1</i>	75	497	-1.6	-2.3	0.7 (-1.4, 2.8)
<i>Year 2</i>	49	324	-1.8	-3.4	1.6 (-1.2, 4.4)

PROMIS Domain	Subjects, n		Mean Change from Baseline		Difference (95% CI) *
	SurgiMend	Control	SurgiMend	Control	
PROMIS-Fatigue					
<i>Month 3</i>	96	511	1.1	2.7	-1.6 (-3.5, 0.3)
<i>Year 1</i>	73	476	-1.7	-0.2	-1.5 (-3.5, 0.5)
<i>Year 2</i>	48	314	-0.7	-1.2	0.5 (-2.0, 3.0)
PROMIS-Sleep					
<i>Month 3</i>	96	586	0.5	-0.1	0.6 (-0.4, 1.6)
<i>Year 1</i>	75	495	0.9	-0.1	1.0 (-0.2, 2.2)
<i>Year 2</i>	49	325	0.9	0	0.9 (-0.5, 2.3)
PROMIS-Social Functioning					
<i>Month 3</i>	96	585	-1.7	-3.6	1.9 (-0.4, 4.2)
<i>Year 1</i>	75	492	1.1	0.3	0.8 (-1.9, 3.5)
<i>Year 2</i>	49	325	0.9	1.2	-0.3 (-3.6, 3.0)
PROMIS-Pain					
<i>Month 3</i>	96	584	2.9	4.7	-1.8 (-3.8, 0.2)
<i>Year 1</i>	75	492	0.8	2.1	-1.3 (-2.9, 0.4)
<i>Year 2</i>	49	324	1.6	0.2	1.5 (-0.9, 3.8)

Table 6: Summary of Continuous Change from Baseline in EORTC Functional Scale Scores*

EORTC Functional Scales	Subjects, n		Mean Change from Baseline		Difference (95% CI) †
	SurgiMend	Control	SurgiMend	Control	
Body Image					
<i>Month 3</i>	92	582	-12.3	-15.5	3.2 (-2.9, 9.4)
<i>Year 1</i>	72	485	-7.4	-8.6	1.4 (-5.9, 8.8)
<i>Year 2</i>	46	320	-5.7	-5.8	0.1 (-8.7, 8.9)
Sexual Functioning					
<i>Month 3</i>	94	576	3.5	4.8	-1.3 (-5.6, 3.1)
<i>Year 1</i>	73	488	-0.7	1.4	-2.1 (-7.9, 3.7)
<i>Year 2</i>	48	319	-2.4	1.9	-4.3 (-11.9, 3.3)
Sexual Enjoyment					
<i>Month 3</i>	59	322	9.6	10.5	-0.9 (-8.7, 7.0)
<i>Year 1</i>	38	273	3.5	4.9	-1.4 (-11.4, 8.6)
<i>Year 2</i>	30	184	7.8	3.8	4.0 (-7.3, 15.3)
Future Perspective					
<i>Month 3</i>	91	574	13.9	11.1	2.8 (-3.7, 9.2)
<i>Year 1</i>	68	478	15.2	14.3	0.9 (-8.1, 9.9)
<i>Year 2</i>	44	316	16.7	15.2	1.5 (-9.6, 12.5)

EORTC Functional Scales	Subjects, n		Mean Change from Baseline		Difference (95% CI) †
	SurgiMend	Control	SurgiMend	Control	
Systemic therapy side effects					
<i>Month 3</i>	95	590	5.8	12.9	-7.1 (-11.6, 2.7)
<i>Year 1</i>	75	496	0.7	1.8	-1.1 (-5.1, 3.0)
<i>Year 2</i>	48	324	4.9	1.3	3.5 (-0.4, 7.4)
Breast Symptoms					
<i>Month 3</i>	95	589	7.2	5.8	1.4 (-2.8, 5.6)
<i>Year 1</i>	74	495	0.5	-0.2	0.7 (-2.6, 4.0)
<i>Year 2</i>	49	324	0.1	-3.2	3.4 (-0.7, 7.4)
Arm Symptoms					
<i>Month 3</i>	95	587	8.2	9.2	-1.0 (-5.5, 3.5)
<i>Year 1</i>	74	494	5.2	7.4	-2.3 (-6.7, 2.2)
<i>Year 2</i>	49	321	5.4	3.4	2.1 (-3.2, 7.3)
Upset by hair loss					
<i>Month 3</i>	24	103	-5.6	8.7	-14.3 (-35.7, 7.1)
<i>Year 1</i>	16	80	-14.6	-5.0	-9.6 (-35.6, 16.5)
<i>Year 2</i>	0	0.8	0	0.8	-0.8 (-36.2, 34.7)

EORTC, European Organization for Research and Treatment of Cancer.

* The scale ranged from 0 to 100. Values are unadjusted estimates. All subjects with missing values were excluded (i.e., this is completer case analysis). If the number of missing items of the scale is greater than the half of the total number of items, then the subject is excluded from the analysis.

† Difference = SurgiMend - Control.

Table 7: Brief Fatigue Inventory (BFI) – Change from Baseline

	Unadjusted Estimates		
	SurgiMend	Control	Difference (SurgiMend - Control) 95%CI
Month 3	(n=97) 0.4	(n=596) 0.8	-0.3 (-0.8,0.2)
Year 1	(n=76) -0.2	(n=502) 0.1	-0.4 (-0.9,0.2)
Year 2	(n=50) 0.4	(n=327) -0.1	0.4 (-0.2, 1.1)

Note: BFI has 9 items with its total score ranged from 0 to 10. If the number of missing items is less than 5, then the missing item was imputed by the mean of the observed items. Otherwise, the subject is considered as missing and excluded from the analyses.

Table 8: Anxiety and Depression (PHQ-9) – Change from Baseline

	Unadjusted Estimates		
	SurgiMend	Control	Difference (SurgiMend - Control) 95%CI
Month 3	(n=97) 0.6	(n=590) 0.2	0.4 (-0.6, 1.4)
Year 1	(n=77) -1.4	(n=508) -1.3	-0.1 (-1.0, 0.8)
Year 2	(n=50) -1.2	(n=325) -1.5	0.4 (-1.2, 1.9)

Note: PHQ-9 has 9 Items, ranged from 0 to 27. If the number of missing items is less than 5, then the missing item was imputed by the mean of the observed items. Otherwise, the subject is considered as missing and excluded from the analyses.

Table 9: GAD-7 Scale for Anxiety and Depression – Change from Baseline

	Unadjusted Estimates		
	SurgiMend	Control	Difference (SurgiMend - Control) 95%CI
Month 3	(n=97) -1.4	(n=588) -1.8	0.5 (-0.4, 1.3)
Year 1	(n=77) -1.6	(n=509) -2.3	0.7 (-0.3, 1.6)
Year 2	(n=50) -1.9	(n=324) -2.3	0.4 (-1.1, 1.9)

Note: GAD-7 has 7 items, ranged from 0 to 21. If the number of missing items is less than 4, then the missing item was imputed by the mean of the observed items. Otherwise, the subject is considered as missing and excluded from the analyses.

Imputation was used for Numeric Pain Rating Scale and Breast Q: Satisfaction with Breasts/Psycho-social Well-being/Sexual Well-being/Physical Well-being. For all other secondary endpoints, if there were missing items, missing item was imputed as indicated in the footnotes of each tables.