

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.4

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (IMPLANT LEVEL) - FDA Item 4d
REVISION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	2	0	153	0.9745	0.0255	(0.0008,0.0501)
25	0	0	153	0.9745	0.0255	(0.0008,0.0501)
26	0	0	153	0.9745	0.0255	(0.0008,0.0501)
27	0	0	153	0.9745	0.0255	(0.0008,0.0501)
28	2	0	151	0.9618	0.0382	(0.0082,0.0682)
29	0	0	151	0.9618	0.0382	(0.0082,0.0682)
30	0	0	151	0.9618	0.0382	(0.0082,0.0682)
31	0	0	151	0.9618	0.0382	(0.0082,0.0682)
32	0	0	151	0.9618	0.0382	(0.0082,0.0682)
33	0	0	151	0.9618	0.0382	(0.0082,0.0682)
34	0	0	151	0.9618	0.0382	(0.0082,0.0682)
35	0	0	151	0.9618	0.0382	(0.0082,0.0682)
36	0	0	151	0.9618	0.0382	(0.0082,0.0682)

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_4.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

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Table 13.2.4

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (IMPLANT LEVEL) - FDA Item 4d
OVERALL IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	785	1.0000	0.0000	(0.0000,0.0000)
1	0	0	785	1.0000	0.0000	(0.0000,0.0000)
2	0	0	785	1.0000	0.0000	(0.0000,0.0000)
3	0	0	785	1.0000	0.0000	(0.0000,0.0000)
4	0	0	785	1.0000	0.0000	(0.0000,0.0000)
5	0	0	785	1.0000	0.0000	(0.0000,0.0000)
6	0	0	785	1.0000	0.0000	(0.0000,0.0000)
7	0	0	785	1.0000	0.0000	(0.0000,0.0000)
8	0	0	785	1.0000	0.0000	(0.0000,0.0000)
9	0	0	785	1.0000	0.0000	(0.0000,0.0000)
10	0	0	785	1.0000	0.0000	(0.0000,0.0000)
11	0	0	785	1.0000	0.0000	(0.0000,0.0000)
12	0	0	785	1.0000	0.0000	(0.0000,0.0000)
13	0	0	785	1.0000	0.0000	(0.0000,0.0000)
14	0	0	785	1.0000	0.0000	(0.0000,0.0000)
15	0	0	785	1.0000	0.0000	(0.0000,0.0000)
16	0	0	785	1.0000	0.0000	(0.0000,0.0000)
17	0	0	785	1.0000	0.0000	(0.0000,0.0000)
18	0	0	785	1.0000	0.0000	(0.0000,0.0000)
19	0	0	785	1.0000	0.0000	(0.0000,0.0000)
20	0	0	785	1.0000	0.0000	(0.0000,0.0000)
21	0	0	785	1.0000	0.0000	(0.0000,0.0000)
22	0	0	785	1.0000	0.0000	(0.0000,0.0000)
23	3	0	782	0.9962	0.0038	(0.0000,0.0081)

Program Name Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_4.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

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Table 13.2.4

TIME TO FIRST REPORT OF SILENT RUPTURE EXCLUDING IMPLANTS WHICH WERE EXPLANTED AND DETERMINED TO BE INTACT (IMPLANT LEVEL) - FDA Item 4d
OVERALL IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	2	0	780	0.9936	0.0064	(0.0008,0.0119)
25	1	0	779	0.9924	0.0076	(0.0016,0.0137)
26	0	0	779	0.9924	0.0076	(0.0016,0.0137)
27	0	0	779	0.9924	0.0076	(0.0016,0.0137)
28	2	0	777	0.9898	0.0102	(0.0032,0.0172)
29	0	0	777	0.9898	0.0102	(0.0032,0.0172)
30	0	0	777	0.9898	0.0102	(0.0032,0.0172)
31	0	0	777	0.9898	0.0102	(0.0032,0.0172)
32	0	0	777	0.9898	0.0102	(0.0032,0.0172)
33	0	0	777	0.9898	0.0102	(0.0032,0.0172)
34	0	0	777	0.9898	0.0102	(0.0032,0.0172)
35	0	0	777	0.9898	0.0102	(0.0032,0.0172)
36	0	0	777	0.9898	0.0102	(0.0032,0.0172)

Program Name: G:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_4.SAS

Creation Date, Time: 24AUG04 15.53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

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Table 13.2.5

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4e
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	202	1.0000	0.0000	(0.0000,0.0000)
1	0	0	202	1.0000	0.0000	(0.0000,0.0000)
2	0	0	202	1.0000	0.0000	(0.0000,0.0000)
3	0	0	202	1.0000	0.0000	(0.0000,0.0000)
4	0	0	202	1.0000	0.0000	(0.0000,0.0000)
5	0	0	202	1.0000	0.0000	(0.0000,0.0000)
6	0	0	202	1.0000	0.0000	(0.0000,0.0000)
7	0	0	202	1.0000	0.0000	(0.0000,0.0000)
8	0	0	202	1.0000	0.0000	(0.0000,0.0000)
9	0	0	202	1.0000	0.0000	(0.0000,0.0000)
10	0	0	202	1.0000	0.0000	(0.0000,0.0000)
11	0	0	202	1.0000	0.0000	(0.0000,0.0000)
12	0	0	202	1.0000	0.0000	(0.0000,0.0000)
13	0	0	202	1.0000	0.0000	(0.0000,0.0000)
14	0	0	202	1.0000	0.0000	(0.0000,0.0000)
15	0	0	202	1.0000	0.0000	(0.0000,0.0000)
16	0	0	202	1.0000	0.0000	(0.0000,0.0000)
17	0	0	202	1.0000	0.0000	(0.0000,0.0000)
18	0	0	202	1.0000	0.0000	(0.0000,0.0000)
19	0	0	202	1.0000	0.0000	(0.0000,0.0000)
20	0	0	202	1.0000	0.0000	(0.0000,0.0000)
21	0	0	202	1.0000	0.0000	(0.0000,0.0000)
22	0	0	202	1.0000	0.0000	(0.0000,0.0000)
23	0	0	202	1.0000	0.0000	(0.0000,0.0000)
24	0	0	202	1.0000	0.0000	(0.0000,0.0000)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_5.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

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Table 13.2.5

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4e
AUGMENTATION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	1	0	201	0.9950	0.0050	(0.0000,0.0146)
26	0	0	201	0.9950	0.0050	(0.0000,0.0146)
27	0	0	201	0.9950	0.0050	(0.0000,0.0146)
28	0	0	201	0.9950	0.0050	(0.0000,0.0146)
29	0	0	201	0.9950	0.0050	(0.0000,0.0146)
30	0	0	201	0.9950	0.0050	(0.0000,0.0146)
31	0	0	201	0.9950	0.0050	(0.0000,0.0146)
32	0	0	201	0.9950	0.0050	(0.0000,0.0146)
33	0	0	201	0.9950	0.0050	(0.0000,0.0146)
34	0	0	201	0.9950	0.0050	(0.0000,0.0146)
35	0	0	201	0.9950	0.0050	(0.0000,0.0146)
36	0	0	201	0.9950	0.0050	(0.0000,0.0146)

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(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
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Table 13.2.5

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4e
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	134	1.0000	0.0000	(0.0000,0.0000)
1	0	0	134	1.0000	0.0000	(0.0000,0.0000)
2	0	0	134	1.0000	0.0000	(0.0000,0.0000)
3	0	0	134	1.0000	0.0000	(0.0000,0.0000)
4	0	0	134	1.0000	0.0000	(0.0000,0.0000)
5	0	0	134	1.0000	0.0000	(0.0000,0.0000)
6	0	0	134	1.0000	0.0000	(0.0000,0.0000)
7	0	0	134	1.0000	0.0000	(0.0000,0.0000)
8	0	0	134	1.0000	0.0000	(0.0000,0.0000)
9	0	0	134	1.0000	0.0000	(0.0000,0.0000)
10	0	0	134	1.0000	0.0000	(0.0000,0.0000)
11	0	0	134	1.0000	0.0000	(0.0000,0.0000)
12	0	0	134	1.0000	0.0000	(0.0000,0.0000)
13	0	0	134	1.0000	0.0000	(0.0000,0.0000)
14	0	0	134	1.0000	0.0000	(0.0000,0.0000)
15	0	0	134	1.0000	0.0000	(0.0000,0.0000)
16	0	0	134	1.0000	0.0000	(0.0000,0.0000)
17	0	0	134	1.0000	0.0000	(0.0000,0.0000)
18	0	0	134	1.0000	0.0000	(0.0000,0.0000)
19	0	0	134	1.0000	0.0000	(0.0000,0.0000)
20	0	0	134	1.0000	0.0000	(0.0000,0.0000)
21	0	0	134	1.0000	0.0000	(0.0000,0.0000)
22	0	0	134	1.0000	0.0000	(0.0000,0.0000)
23	1	0	133	0.9925	0.0075	(0.0000,0.0220)
24	0	0	133	0.9925	0.0075	(0.0000,0.0220)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_5.SAS

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- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
 (1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
 (4) indeterminate for extracapsular silicone.

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TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4e
RECONSTRUCTION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	0	133	0.9925	0.0075	(0.0000,0.0220)
26	0	0	133	0.9925	0.0075	(0.0000,0.0220)
27	0	0	133	0.9925	0.0075	(0.0000,0.0220)
28	0	0	133	0.9925	0.0075	(0.0000,0.0220)
29	0	0	133	0.9925	0.0075	(0.0000,0.0220)
30	0	0	133	0.9925	0.0075	(0.0000,0.0220)
31	0	0	133	0.9925	0.0075	(0.0000,0.0220)
32	0	0	133	0.9925	0.0075	(0.0000,0.0220)
33	0	0	133	0.9925	0.0075	(0.0000,0.0220)
34	0	0	133	0.9925	0.0075	(0.0000,0.0220)
35	0	0	133	0.9925	0.0075	(0.0000,0.0220)
36	0	0	133	0.9925	0.0075	(0.0000,0.0220)

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Creation Date, Time: 24AUG04 15.53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
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TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4e
REVISION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	84	1.0000	0.0000	(0.0000,0.0000)
1	0	0	84	1.0000	0.0000	(0.0000,0.0000)
2	0	0	84	1.0000	0.0000	(0.0000,0.0000)
3	0	0	84	1.0000	0.0000	(0.0000,0.0000)
4	0	0	84	1.0000	0.0000	(0.0000,0.0000)
5	0	0	84	1.0000	0.0000	(0.0000,0.0000)
6	0	0	84	1.0000	0.0000	(0.0000,0.0000)
7	0	0	84	1.0000	0.0000	(0.0000,0.0000)
8	0	0	84	1.0000	0.0000	(0.0000,0.0000)
9	0	0	84	1.0000	0.0000	(0.0000,0.0000)
10	0	0	84	1.0000	0.0000	(0.0000,0.0000)
11	0	0	84	1.0000	0.0000	(0.0000,0.0000)
12	0	0	84	1.0000	0.0000	(0.0000,0.0000)
13	0	0	84	1.0000	0.0000	(0.0000,0.0000)
14	0	0	84	1.0000	0.0000	(0.0000,0.0000)
15	0	0	84	1.0000	0.0000	(0.0000,0.0000)
16	0	0	84	1.0000	0.0000	(0.0000,0.0000)
17	0	0	84	1.0000	0.0000	(0.0000,0.0000)
18	0	0	84	1.0000	0.0000	(0.0000,0.0000)
19	1	0	83	0.9881	0.0119	(0.0000,0.0351)
20	0	0	83	0.9881	0.0119	(0.0000,0.0351)
21	0	0	83	0.9881	0.0119	(0.0000,0.0351)
22	0	0	83	0.9881	0.0119	(0.0000,0.0351)
23	1	0	82	0.9762	0.0238	(0.0000,0.0564)
24	2	0	80	0.9524	0.0476	(0.0021,0.0932)

Program Name: O:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_5.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

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Table 13.2.5

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4e
REVISION PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	0	0	80	0.9524	0.0476	(0.0021,0.0932)
26	0	0	80	0.9524	0.0476	(0.0021,0.0932)
27	0	0	80	0.9524	0.0476	(0.0021,0.0932)
28	1	0	79	0.9405	0.0595	(0.0089,0.1101)
29	0	0	79	0.9405	0.0595	(0.0089,0.1101)
30	0	0	79	0.9405	0.0595	(0.0089,0.1101)
31	0	0	79	0.9405	0.0595	(0.0089,0.1101)
32	0	0	79	0.9405	0.0595	(0.0089,0.1101)
33	0	0	79	0.9405	0.0595	(0.0089,0.1101)
34	0	0	79	0.9405	0.0595	(0.0089,0.1101)
35	0	0	79	0.9405	0.0595	(0.0089,0.1101)
36	0	0	79	0.9405	0.0595	(0.0089,0.1101)

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(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
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TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4e
OVERALL PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	420	1.0000	0.0000	(0.0000,0.0000)
1	0	0	420	1.0000	0.0000	(0.0000,0.0000)
2	0	0	420	1.0000	0.0000	(0.0000,0.0000)
3	0	0	420	1.0000	0.0000	(0.0000,0.0000)
4	0	0	420	1.0000	0.0000	(0.0000,0.0000)
5	0	0	420	1.0000	0.0000	(0.0000,0.0000)
6	0	0	420	1.0000	0.0000	(0.0000,0.0000)
7	0	0	420	1.0000	0.0000	(0.0000,0.0000)
8	0	0	420	1.0000	0.0000	(0.0000,0.0000)
9	0	0	420	1.0000	0.0000	(0.0000,0.0000)
10	0	0	420	1.0000	0.0000	(0.0000,0.0000)
11	0	0	420	1.0000	0.0000	(0.0000,0.0000)
12	0	0	420	1.0000	0.0000	(0.0000,0.0000)
13	0	0	420	1.0000	0.0000	(0.0000,0.0000)
14	0	0	420	1.0000	0.0000	(0.0000,0.0000)
15	0	0	420	1.0000	0.0000	(0.0000,0.0000)
16	0	0	420	1.0000	0.0000	(0.0000,0.0000)
17	0	0	420	1.0000	0.0000	(0.0000,0.0000)
18	0	0	420	1.0000	0.0000	(0.0000,0.0000)
19	1	0	419	0.9976	0.0024	(0.0000,0.0070)
20	0	0	419	0.9976	0.0024	(0.0000,0.0070)
21	0	0	419	0.9976	0.0024	(0.0000,0.0070)
22	0	0	419	0.9976	0.0024	(0.0000,0.0070)
23	2	0	417	0.9929	0.0071	(0.0000,0.0152)
24	2	0	415	0.9881	0.0119	(0.0015,0.0223)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_5.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
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Table 13.2.5

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (PATIENT LEVEL) - FDA Item 4e
OVERALL PATIENTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
25	1	0	414	0.9857	0.0143	(0.0029,0.0256)
26	0	0	414	0.9857	0.0143	(0.0029,0.0256)
27	0	0	414	0.9857	0.0143	(0.0029,0.0256)
28	1	0	413	0.9833	0.0167	(0.0044,0.0289)
29	0	0	413	0.9833	0.0167	(0.0044,0.0289)
30	0	0	413	0.9833	0.0167	(0.0044,0.0289)
31	0	0	413	0.9833	0.0167	(0.0044,0.0289)
32	0	0	413	0.9833	0.0167	(0.0044,0.0289)
33	0	0	413	0.9833	0.0167	(0.0044,0.0289)
34	0	0	413	0.9833	0.0167	(0.0044,0.0289)
35	0	0	413	0.9833	0.0167	(0.0044,0.0289)
36	0	0	413	0.9833	0.0167	(0.0044,0.0289)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_5.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.6

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4e
AUGMENTATION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	417	1.0000	0.0000	(0.0000,0.0000)
1	0	0	417	1.0000	0.0000	(0.0000,0.0000)
2	0	0	417	1.0000	0.0000	(0.0000,0.0000)
3	0	0	417	1.0000	0.0000	(0.0000,0.0000)
4	0	0	417	1.0000	0.0000	(0.0000,0.0000)
5	0	0	417	1.0000	0.0000	(0.0000,0.0000)
6	0	0	417	1.0000	0.0000	(0.0000,0.0000)
7	0	0	417	1.0000	0.0000	(0.0000,0.0000)
8	0	0	417	1.0000	0.0000	(0.0000,0.0000)
9	0	0	417	1.0000	0.0000	(0.0000,0.0000)
10	0	0	417	1.0000	0.0000	(0.0000,0.0000)
11	0	0	417	1.0000	0.0000	(0.0000,0.0000)
12	0	0	417	1.0000	0.0000	(0.0000,0.0000)
13	0	0	417	1.0000	0.0000	(0.0000,0.0000)
14	0	0	417	1.0000	0.0000	(0.0000,0.0000)
15	0	0	417	1.0000	0.0000	(0.0000,0.0000)
16	0	0	417	1.0000	0.0000	(0.0000,0.0000)
17	0	0	417	1.0000	0.0000	(0.0000,0.0000)
18	0	0	417	1.0000	0.0000	(0.0000,0.0000)
19	0	0	417	1.0000	0.0000	(0.0000,0.0000)
20	0	0	417	1.0000	0.0000	(0.0000,0.0000)
21	0	0	417	1.0000	0.0000	(0.0000,0.0000)
22	0	0	417	1.0000	0.0000	(0.0000,0.0000)
23	0	0	417	1.0000	0.0000	(0.0000,0.0000)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_6.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.6

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4e
AUGMENTATION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	0	0	417	1.0000	0.0000	(0.0000,0.0000)
25	1	0	416	0.9976	0.0024	(0.0000,0.0071)
26	0	0	416	0.9976	0.0024	(0.0000,0.0071)
27	0	0	416	0.9976	0.0024	(0.0000,0.0071)
28	0	0	416	0.9976	0.0024	(0.0000,0.0071)
29	0	0	416	0.9976	0.0024	(0.0000,0.0071)
30	0	0	416	0.9976	0.0024	(0.0000,0.0071)
31	0	0	416	0.9976	0.0024	(0.0000,0.0071)
32	0	0	416	0.9976	0.0024	(0.0000,0.0071)
33	0	0	416	0.9976	0.0024	(0.0000,0.0071)
34	0	0	416	0.9976	0.0024	(0.0000,0.0071)
35	0	0	416	0.9976	0.0024	(0.0000,0.0071)
36	0	0	416	0.9976	0.0024	(0.0000,0.0071)

Program Name Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_6.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.6

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4e
RECONSTRUCTION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	211	1.0000	0.0000	(0.0000,0.0000)
1	0	0	211	1.0000	0.0000	(0.0000,0.0000)
2	0	0	211	1.0000	0.0000	(0.0000,0.0000)
3	0	0	211	1.0000	0.0000	(0.0000,0.0000)
4	0	0	211	1.0000	0.0000	(0.0000,0.0000)
5	0	0	211	1.0000	0.0000	(0.0000,0.0000)
6	0	0	211	1.0000	0.0000	(0.0000,0.0000)
7	0	0	211	1.0000	0.0000	(0.0000,0.0000)
8	0	0	211	1.0000	0.0000	(0.0000,0.0000)
9	0	0	211	1.0000	0.0000	(0.0000,0.0000)
10	0	0	211	1.0000	0.0000	(0.0000,0.0000)
11	0	0	211	1.0000	0.0000	(0.0000,0.0000)
12	0	0	211	1.0000	0.0000	(0.0000,0.0000)
13	0	0	211	1.0000	0.0000	(0.0000,0.0000)
14	0	0	211	1.0000	0.0000	(0.0000,0.0000)
15	0	0	211	1.0000	0.0000	(0.0000,0.0000)
16	0	0	211	1.0000	0.0000	(0.0000,0.0000)
17	0	0	211	1.0000	0.0000	(0.0000,0.0000)
18	0	0	211	1.0000	0.0000	(0.0000,0.0000)
19	0	0	211	1.0000	0.0000	(0.0000,0.0000)
20	0	0	211	1.0000	0.0000	(0.0000,0.0000)
21	0	0	211	1.0000	0.0000	(0.0000,0.0000)
22	0	0	211	1.0000	0.0000	(0.0000,0.0000)
23	1	0	210	0.9953	0.0047	(0.0000,0.0140)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_6.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following.
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.6

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4e
RECONSTRUCTION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	0	0	210	0.9953	0.0047	(0.0000,0.0140)
25	0	0	210	0.9953	0.0047	(0.0000,0.0140)
26	0	0	210	0.9953	0.0047	(0.0000,0.0140)
27	0	0	210	0.9953	0.0047	(0.0000,0.0140)
28	0	0	210	0.9953	0.0047	(0.0000,0.0140)
29	0	0	210	0.9953	0.0047	(0.0000,0.0140)
30	0	0	210	0.9953	0.0047	(0.0000,0.0140)
31	0	0	210	0.9953	0.0047	(0.0000,0.0140)
32	0	0	210	0.9953	0.0047	(0.0000,0.0140)
33	0	0	210	0.9953	0.0047	(0.0000,0.0140)
34	0	0	210	0.9953	0.0047	(0.0000,0.0140)
35	0	0	210	0.9953	0.0047	(0.0000,0.0140)
36	0	0	210	0.9953	0.0047	(0.0000,0.0140)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_6.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.6

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4e
REVISION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	157	1.0000	0.0000	(0.0000,0.0000)
1	0	0	157	1.0000	0.0000	(0.0000,0.0000)
2	0	0	157	1.0000	0.0000	(0.0000,0.0000)
3	0	0	157	1.0000	0.0000	(0.0000,0.0000)
4	0	0	157	1.0000	0.0000	(0.0000,0.0000)
5	0	0	157	1.0000	0.0000	(0.0000,0.0000)
6	0	0	157	1.0000	0.0000	(0.0000,0.0000)
7	0	0	157	1.0000	0.0000	(0.0000,0.0000)
8	0	0	157	1.0000	0.0000	(0.0000,0.0000)
9	0	0	157	1.0000	0.0000	(0.0000,0.0000)
10	0	0	157	1.0000	0.0000	(0.0000,0.0000)
11	0	0	157	1.0000	0.0000	(0.0000,0.0000)
12	0	0	157	1.0000	0.0000	(0.0000,0.0000)
13	0	0	157	1.0000	0.0000	(0.0000,0.0000)
14	0	0	157	1.0000	0.0000	(0.0000,0.0000)
15	0	0	157	1.0000	0.0000	(0.0000,0.0000)
16	0	0	157	1.0000	0.0000	(0.0000,0.0000)
17	0	0	157	1.0000	0.0000	(0.0000,0.0000)
18	0	0	157	1.0000	0.0000	(0.0000,0.0000)
19	2	0	155	0.9873	0.0127	(0.0000,0.0303)
20	0	0	155	0.9873	0.0127	(0.0000,0.0303)
21	0	0	155	0.9873	0.0127	(0.0000,0.0303)
22	0	0	155	0.9873	0.0127	(0.0000,0.0303)
23	2	0	153	0.9745	0.0255	(0.0008,0.0501)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_6.SAS

Creation Date, Time: 24AUG04 15:53

- (a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.6

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4e
REVISION IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	2	0	151	0.9618	0.0382	(0.0082,0.0682)
25	0	0	151	0.9618	0.0382	(0.0082,0.0682)
26	0	0	151	0.9618	0.0382	(0.0082,0.0682)
27	0	0	151	0.9618	0.0382	(0.0082,0.0682)
28	2	0	149	0.9490	0.0510	(0.0166,0.0854)
29	0	0	149	0.9490	0.0510	(0.0166,0.0854)
30	0	0	149	0.9490	0.0510	(0.0166,0.0854)
31	0	0	149	0.9490	0.0510	(0.0166,0.0854)
32	0	0	149	0.9490	0.0510	(0.0166,0.0854)
33	0	0	149	0.9490	0.0510	(0.0166,0.0854)
34	0	0	149	0.9490	0.0510	(0.0166,0.0854)
35	0	0	149	0.9490	0.0510	(0.0166,0.0854)
36	0	0	149	0.9490	0.0510	(0.0166,0.0854)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_6.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.6

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4e
OVERALL IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
0	0	0	785	1.0000	0.0000	(0.0000,0.0000)
1	0	0	785	1.0000	0.0000	(0.0000,0.0000)
2	0	0	785	1.0000	0.0000	(0.0000,0.0000)
3	0	0	785	1.0000	0.0000	(0.0000,0.0000)
4	0	0	785	1.0000	0.0000	(0.0000,0.0000)
5	0	0	785	1.0000	0.0000	(0.0000,0.0000)
6	0	0	785	1.0000	0.0000	(0.0000,0.0000)
7	0	0	785	1.0000	0.0000	(0.0000,0.0000)
8	0	0	785	1.0000	0.0000	(0.0000,0.0000)
9	0	0	785	1.0000	0.0000	(0.0000,0.0000)
10	0	0	785	1.0000	0.0000	(0.0000,0.0000)
11	0	0	785	1.0000	0.0000	(0.0000,0.0000)
12	0	0	785	1.0000	0.0000	(0.0000,0.0000)
13	0	0	785	1.0000	0.0000	(0.0000,0.0000)
14	0	0	785	1.0000	0.0000	(0.0000,0.0000)
15	0	0	785	1.0000	0.0000	(0.0000,0.0000)
16	0	0	785	1.0000	0.0000	(0.0000,0.0000)
17	0	0	785	1.0000	0.0000	(0.0000,0.0000)
18	0	0	785	1.0000	0.0000	(0.0000,0.0000)
19	2	0	783	0.9975	0.0025	(0.0000,0.0061)
20	0	0	783	0.9975	0.0025	(0.0000,0.0061)
21	0	0	783	0.9975	0.0025	(0.0000,0.0061)
22	0	0	783	0.9975	0.0025	(0.0000,0.0061)
23	3	0	780	0.9936	0.0064	(0.0008,0.0119)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_6.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.2.6

TIME TO FIRST REPORT OF RUPTURE OR SILENT RUPTURE (IMPLANT LEVEL) - FDA Item 4e
OVERALL IMPLANTS

Months Following Procedure	Number With Event (a)	Number Lost to Follow-up	Number Remaining	Estimated Proportion Without Event	Estimated Proportion With Event	95% CI for Proportion With Event
24	2	0	778	0.9911	0.0089	(0.0023,0.0155)
25	1	0	777	0.9898	0.0102	(0.0032,0.0172)
26	0	0	777	0.9898	0.0102	(0.0032,0.0172)
27	0	0	777	0.9898	0.0102	(0.0032,0.0172)
28	2	0	775	0.9873	0.0127	(0.0049,0.0206)
29	0	0	775	0.9873	0.0127	(0.0049,0.0206)
30	0	0	775	0.9873	0.0127	(0.0049,0.0206)
31	0	0	775	0.9873	0.0127	(0.0049,0.0206)
32	0	0	775	0.9873	0.0127	(0.0049,0.0206)
33	0	0	775	0.9873	0.0127	(0.0049,0.0206)
34	0	0	775	0.9873	0.0127	(0.0049,0.0206)
35	0	0	775	0.9873	0.0127	(0.0049,0.0206)
36	0	0	775	0.9873	0.0127	(0.0049,0.0206)

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_2_6.SAS

Creation Date, Time: 24AUG04 15:53

(a) Silent rupture defined as occurring if either the local radiologist or the central MRI reader indicated any of the following:
(1) evidence of rupture, (2) evidence of extracapsular silicone, (3) indeterminate for rupture, or
(4) indeterminate for extracapsular silicone.

Note: Implant counts exclude events where breast side = N/A.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.3.1

PATIENT ACCOUNTING FOR MRI SUBSTUDY PATIENTS - FDA Item 5a
AUGMENTATION PATIENTS

	1 Year Visit	2 Year Visit
All Patients (theoretically due) (a)	202	202
Deaths	0	0
Discontinuations due to Explantation (b)	0	0
Expected Due (c)	202	202
Missed Follow-up Visit	44	20
Number of Patients Included in Data Listings (Actual Included)	158	182
% Follow-up	78	90
Exclusion from Analyses (d)	0	1
Number of Patients Included in Summary Tables	158	181

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_3_1.SAS

Creation Date, Time: 26AUG04 13:48

- (a) Patients who would have been examined according to implant date and follow-up schedules.
 (b) For unilateral patients, the device must be removed and not replaced by a study device for the patient to be discontinued.
 For bilateral patients, both devices must be removed and neither replaced by a study device for the patient to be discontinued.
 (c) Patients theoretically due minus deaths and removals without replacement.
 (d) Includes patients not having MRI in the visit year only after explanation of original study device.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.3.1

PATIENT ACCOUNTING FOR MRI SUBSTUDY PATIENTS - FDA Item 5a
RECONSTRUCTION PATIENTS

	1 Year Visit	2 Year Visit
All Patients (theoretically due) (a)	134	134
Deaths	0	1
Discontinuations due to Explantation (b)	0	1
Expected Due (c)	134	132
Missed Follow-up Visit	32	15
Number of Patients Included in Data Listings (Actual Included)	102	117
% Follow-up	76	89
Exclusion from Analyses (d)	6	7
Number of Patients Included in Summary Tables	96	110

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_3_1.SAS

Creation Date, Time: 26AUG04 13:48

- (a) Patients who would have been examined according to implant date and follow-up schedules.
- (b) For unilateral patients, the device must be removed and not replaced by a study device for the patient to be discontinued.
For bilateral patients, both devices must be removed and neither replaced by a study device for the patient to be discontinued.
- (c) Patients theoretically due minus deaths and removals without replacement.
- (d) Includes patients not having MRI in the visit year only after explanation of original study device.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.3.1

PATIENT ACCOUNTING FOR MRI SUBSTUDY PATIENTS - FDA Item 5a
REVISION PATIENTS

	1 Year Visit	2 Year Visit
All Patients (theoretically due) (a)	84	84
Deaths	0	0
Discontinuations due to Explantation (b)	0	0
Expected Due (c)	84	84
Missed Follow-up Visit	18	11
Number of Patients Included in Data Listings (Actual Included)	66	73
% Follow-up	79	87
Exclusion from Analyses (d)	2	3
Number of Patients Included in Summary Tables	64	70

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_3_1.SAS

Creation Date, Time: 26AUG04 13:48

- (a) Patients who would have been examined according to implant date and follow-up schedules.
- (b) For unilateral patients, the device must be removed and not replaced by a study device for the patient to be discontinued.
For bilateral patients, both devices must be removed and neither replaced by a study device for the patient to be discontinued.
- (c) Patients theoretically due minus deaths and removals without replacement.
- (d) Includes patients not having MRI in the visit year only after explanation of original study device.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 13.3.1

PATIENT ACCOUNTING FOR MRI SUBSTUDY PATIENTS - FDA Item 5a
OVERALL PATIENTS

	1 Year Visit	2 Year Visit
All Patients (theoretically due) (a)	420	420
Deaths	0	1
Discontinuations due to Explantation (b)	0	1
Expected Due (c)	420	418
Missed Follow-up Visit	94	46
Number of Patients Included in Data Listings (Actual Included)	326	372
% Follow-up	78	89
Exclusion from Analyses (d)	8	11
Number of Patients Included in Summary Tables	318	361

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T13_3_1.SAS

Creation Date, Time: 26AUG04 13:48

- (a) Patients who would have been examined according to implant date and follow-up schedules.
- (b) For unilateral patients, the device must be removed and not replaced by a study device for the patient to be discontinued.
For bilateral patients, both devices must be removed and neither replaced by a study device for the patient to be discontinued.
- (c) Patients theoretically due minus deaths and removals without replacement.
- (d) Includes patients not having MRI in the visit year only after explanation of original study device.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 13.3.2

IMPLANT ACCOUNTING FOR MRI SUBSTUDY PATIENTS - FDA Item 5a
AUGMENTATION IMPLANTS

	1 Year Visit	2 Year Visit
All Implants (theoretically due) (a)	417	417
Deaths	0	0
Discontinuations due to Explantation	0	0
Expected Due (b)	417	417
Missed Follow-up Visit	93	43
Number of Implants Included in Data Listings (Actual Included)	324	374
% Follow-up (excludes "Not theoretically due but had MRI")	78	90
Exclusion from Analyses (c)	1	4
Number of Implants Included in Summary Tables	323	370

(a) Implants who would have been examined according to implant date and follow-up schedules.

(b) Implants theoretically due minus deaths and removals without replacement.

(c) Includes implants not having MRI in the visit year only after explanation of original study device.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 13.3.2

IMPLANT ACCOUNTING FOR MRI SUBSTUDY PATIENTS - FDA Item 5a
RECONSTRUCTION IMPLANTS

	1 Year Visit	2 Year Visit
All Implants (theoretically due) (a)	211	211
Deaths	0	2
Discontinuations due to Explantation	0	1
Expected Due (b)	211	208
Missed Follow-up Visit	47	23
Number of Implants Included in Data Listings (Actual Included)	164	185
% Follow-up (excludes "Not theoretically due but had MRI")	78	89
Exclusion from Analyses (c)	10	11
Number of Implants Included in Summary Tables	154	174

(a) Implants who would have been examined according to implant date and follow-up schedules.

(b) Implants theoretically due minus deaths and removals without replacement.

(c) Includes implants not having MRI in the visit year only after explanation of original study device.

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Table 13.3.2

IMPLANT ACCOUNTING FOR MRI SUBSTUDY PATIENTS - FDA Item 5a
REVISION IMPLANTS

	1 Year Visit	2 Year Visit
All Implants (theoretically due) (a)	157	157
Deaths	0	0
Discontinuations due to Explantation	0	0
Expected Due (b)	157	157
Missed Follow-up Visit	32	21
Number of Implants Included in Data Listings (Actual Included)	125	136
% Follow-up (excludes "Not theoretically due but had MRI")	80	87
Exclusion from Analyses (c)	7	10
Number of Implants Included in Summary Tables	118	126

(a) Implants who would have been examined according to implant date and follow-up schedules.

(b) Implants theoretically due minus deaths and removals without replacement.

(c) Includes implants not having MRI in the visit year only after explanation of original study device.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 13.3.2

IMPLANT ACCOUNTING FOR MRI SUBSTUDY PATIENTS - FDA Item 5a
OVERALL IMPLANTS

	1 Year Visit	2 Year Visit
All Implants (theoretically due) (a)	785	785
Deaths	0	2
Discontinuations due to Explantation	0	1
Expected Due (b)	785	782
Missed Follow-up Visit	172	87
Number of Implants Included in Data Listings (Actual Included)	613	695
% Follow-up (excludes "Not theoretically due but had MRI")	78	89
Exclusion from Analyses (c)	18	25
Number of Implants Included in Summary Tables	595	670

(a) Implants who would have been examined according to implant date and follow-up schedules.

(b) Implants theoretically due minus deaths and removals without replacement.

(c) Includes implants not having MRI in the visit year only after explanation of original study device.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 14.1

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT I
AUGMENTATION PATIENTS

Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
Preoperative	85.2	85.00	86.00	6.44	68.0	113.0	543
6 Months	92.1	91.00	91.00	6.65	76.0	120.0	493
1 Year	92.3	91.00	88.00	7.13	61.0	126.0	507
2 Years	92.8	92.00	89.00	7.46	61.0	121.0	500
3 Years	92.6	92.00	88.00	7.49	75.0	126.0	391

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T14_1.SAS

Creation Date, Time: 16JUL04 13:33

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 14.1

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT I
OVERALL RECONSTRUCTION

Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
Preoperative	92.3	91.00	89.00	10.73	41.0	131.0	206
6 Months	96.6	96.00	88.00	9.73	78.0	131.0	205
1 Year	97.0	95.00	94.00	10.02	78.0	134.0	196
2 Years	96.7	95.50	98.00	9.18	81.0	135.0	178
3 Years	92.6	95.00	85.00	19.08	17.0	127.0	118

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T14_1.SAS

Creation Date, Time: 16JUL04 13.33

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 14.1

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT 1
DELAYED POST-MASTECTOMY

Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
Preoperative	94.1	95.00	89.00	11.04	41.0	129.0	79
6 Months	97.8	98.00	98.00	9.75	78.0	129.0	83
1 Year	98.2	97.00	94.00	9.67	78.0	129.0	75
2 Years	97.7	97.00	99.00	8.81	83.0	127.0	69
3 Years	93.1	97.00	85.00	22.35	21.0	127.0	40

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T14_1.SAS

Creation Date, Time: 16JUL04 13:33

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 14.1

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT 1
IMMEDIATE POST-MASTECTOMY

Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
Preoperative	95.2	94.00	94.00	11.97	75.0	131.0	57
6 Months	97.3	96.00	88.00	11.59	79.0	131.0	58
1 Year	97.4	95.00	84.00	12.29	80.0	134.0	57
2 Years	98.2	97.00	89.00	11.80	81.0	135.0	52
3 Years	91.9	96.00	87.00	25.01	17.0	125.0	35

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T14_1.SAS

Creation Date, Time: 16JUL04 13:33

Note 1. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

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Table 14.1

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT I
REVISION PATIENTS

Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
Preoperative	90.3	90.00	86.00	6.93	69.0	120.0	194
6 Months	93.5	93.00	93.00	7.46	78.0	124.0	174
1 Year	93.0	92.00	90.00	6.94	78.0	116.0	175
2 Years	93.3	92.00	87.00	7.49	78.0	123.0	169
3 Years	92.8	92.00	90.00	9.93	82.0	120.0	135

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Note 1. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision

Table 14.1

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT I
OVERALL

Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
Preoperative	87.8	87.00	86.00	8.28	41.0	131.0	943
6 Months	93.4	92.00	93.00	7.85	76.0	131.0	872
1 Year	93.5	93.00	94.00	8.05	61.0	134.0	878
2 Years	93.7	93.00	90.00	8.01	61.0	135.0	847
3 Years	92.7	92.00	88.00	10.99	17.0	127.0	644

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T14_1.SAS

Creation Date, Time: 16JUL04 13:33

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit.

Note 2: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

Table 14.2

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT II
AUGMENTATION PATIENTS

0

Change from Preop Assessment (cm)							
Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
6 Months	6.8	7.00	6.00	4.15	-7.0	28.0	485
1 Year	7.1	7.00	7.00	4.62	-25.0	29.0	500
2 Years	7.5	8.00	9.00	5.16	-25.0	28.0	493
3 Years	7.4	7.00	6.00	5.22	-6.0	35.0	384
Overall Mean Change (a) (Standard Deviation)		7.12 (4.40)					
p-value (b)	<0.0001						
p-value (c)	<0.0001						
p-value (d)	<0.0001						

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

Note 2: Immediate post-mastectomy patients are excluded from all analyses involving Overall Reconstruction Patients and Overall Patients.

Note 3: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

(a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(b) From Wilcoxon Signed Rank Test on overall mean change.

(c,d) From Wilcoxon Signed Rank Test on change from preoperative assessment to Year 2,3 visit.

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Creation Date, Time: 16JUL04 13.33

Table 14.2

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT II
OVERALL RECONSTRUCTION

0

Change from Preop Assessment (cm)							
Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
6 Months	3.9	3.00	0.00	6.85	-13.0	59.0	179
1 Year	4.4	4.00	2.00	7.22	-14.0	57.0	174
2 Years	3.8	3.00	6.00	7.31	-14.0	58.0	153
3 Years	1.4	3.00	5.00	14.46	-72.0	57.0	101
Overall Mean Change (a) (Standard Deviation)	3.26 (8.28)						
p-value (b)	<0.0001						
p-value (c)	<0.0001						
p-value (d)	<0.0001						

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

Note 2: Immediate post-mastectomy patients are excluded from all analyses involving Overall Reconstruction Patients and Overall Patients.

Note 3: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

(a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(b) From Wilcoxon Signed Rank Test on overall mean change.

(c,d) From Wilcoxon Signed Rank Test on change from preoperative assessment to Year 2,3 visit.

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Table 14.2

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT II
DELAYED POST-MASTECTOMY

0

Change from Preop Assessment (cm)							
Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
6 Months	3.2	1.00	0.00	8.69	-5.0	59.0	68
1 Year	3.3	2.00	-2.00	9.12	-14.0	57.0	61
2 Years	3.4	1.00	-1.00	9.05	-6.0	58.0	53
3 Years	-0.6	1.00	-2.00	21.06	-72.0	57.0	30
Overall Mean Change (a) (Standard Deviation)		1.90 (10.82)					
p-value (b)		0.0028					
p-value (c)		0.0016					
p-value (d)		0.3768					

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

Note 2: Immediate post-mastectomy patients are excluded from all analyses involving Overall Reconstruction Patients and Overall Patients.

Note 3: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

(a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(b) From Wilcoxon Signed Rank Test on overall mean change.

(c,d) From Wilcoxon Signed Rank Test on change from preoperative assessment to Year 2,3 visit.

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Table 14.2

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT II
IMMEDIATE POST-MASTECTOMY

Change from Preop Assessment (cm)							
Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
6 Months	1.6	1.50	0.00	4.51	-9.0	14.0	50
1 Year	1.9	1.00	0.00	5.39	-9.0	16.0	49
2 Years	1.0	1.00	2.00	5.70	-14.0	16.0	45
3 Years	-1.7	0.00	-4.00	14.44	-70.0	12.0	30
Overall Mean Change (a) (Standard Deviation)		1.28 (6.05)					
p-value (b)	----						
p-value (c)	----						
p-value (d)	----						

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

Note 2: Immediate post-mastectomy patients are excluded from all analyses involving Overall Reconstruction Patients and Overall Patients.

Note 3: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

(a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages

(b) From Wilcoxon Signed Rank Test on overall mean change.

(c,d) From Wilcoxon Signed Rank Test on change from preoperative assessment to Year 2,3 visit.

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Table 14.2

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT II
REVISION PATIENTS

0

Change from Preop Assessment (cm)							
Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
6 Months	2.9	2.00	0.00	4.81	-10.0	23.0	169
1 Year	2.6	2.00	2.00	4.77	-12.0	18.0	170
2 Years	2.8	2.00	0.00	5.09	-13.0	20.0	164
3 Years	1.9	2.00	1.00	8.78	-60.0	19.0	132
Overall Mean Change (a) (Standard Deviation)		2.82 (5.07)					
p-value (b)	<0.0001						
p-value (c)	<0.0001						
p-value (d)	<0.0001						

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

Note 2: Immediate post-mastectomy patients are excluded from all analyses involving Overall Reconstruction Patients and Overall Patients.

Note 3: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

(a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(b) From Wilcoxon Signed Rank Test on overall mean change.

(c,d) From Wilcoxon Signed Rank Test on change from preoperative assessment to Year 2,3 visit.

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Table 14.2

CIRCUMFERENTIAL CHEST SIZE ASSESSMENT II
OVERALL

0

Change from Preop Assessment (cm)							
Type of Visit	Mean	Median	Mode	Standard Deviation	Minimum	Maximum	n
6 Months	5.4	5.00	0.00	5.27	-13.0	59.0	833
1 Year	5.6	6.00	7.00	5.59	-25.0	57.0	844
2 Years	5.8	6.00	6.00	5.98	-25.0	58.0	810
3 Years	5.2	6.00	6.00	8.67	-72.0	57.0	617
Overall Mean Change (a) (Standard Deviation)	5.40 (5.94)						
p-value (b)	<0.0001						
p-value (c)	<0.0001						
p-value (d)	<0.0001						

Note 1: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

Note 2: Immediate post-mastectomy patients are excluded from all analyses involving Overall Reconstruction Patients and Overall Patients.

Note 3: If the measurements recorded for right and left breast were different for a particular visit, the patient's measurement recorded for the right breast was used for analyses at that visit.

(a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(b) From Wilcoxon Signed Rank Test on overall mean change.

(c,d) From Wilcoxon Signed Rank Test on change from preoperative assessment to Year 2,3 visit.

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Creation Date, Time: 16JUL04 13:33

Table 15.1

BRA-CUP SIZE ASSESSMENT
AUGMENTATION PATIENTS

Size change from Preop Assessment (a)

Type of Visit	Decrease				No Change	Increase				Total n (%)
	>=4 steps n (%)	3 steps n (%)	2 steps n (%)	1 step n (%)	n (%)	1 step n (%)	2 steps n (%)	3 steps n (%)	>=4 steps n (%)	
6 Months	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)	6 (1.3)	165 (36.2)	236 (51.8)	48 (10.5)	0 (0.0)	456 (100.0)
1 Year	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	13 (2.7)	161 (33.4)	258 (53.5)	50 (10.4)	0 (0.0)	482 (100.0)
2 Year	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	9 (1.9)	172 (36.7)	237 (50.5)	51 (10.9)	0 (0.0)	469 (100.0)
3 Year	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	11 (3.0)	126 (34.1)	185 (50.0)	48 (13.0)	0 (0.0)	370 (100.0)

Overall Average Number of Steps of Increase (b)
(Standard Deviation) 1.71 (0.65)

p-value (c) <0.0001

p-value (d) <0.0001

p-value (e) <0.0001

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) A one-step increase(decrease) is, for example, from AA to A or from B to C (from A to aa or from C to B); a two-step increase(decrease) is from B to D or from AA to B(from D to B or from B to AA), etc. In the event that the bra cup size was recorded as a range, the smaller size was used for calculation(e.g., if B-C was recorded in the CRF, then B was used for calculation); pluses and minuses (e.g. in A+ or C-) were ignored in the calculation.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the average across patients of these average.
- (c) From Wilcoxon Signed Rank Test on overall average number of steps of increase.
- (d,e) From Wilcoxon Signed Rank Test on change from Preoperative Assessment to Year 2,3 visit.

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Table 15.2

BRA-CUP ASSESSMENT: CHANGE OVER TIME
AUGMENTATION PATIENTS

Post-op Visit		Preop Assessment							Total
		AA	A	B	C	D	E	Missing	
6 Months	AA	0	0	0	0	0	0	0	0
	A	0	0	0	0	0	0	0	0
	B	2	28	4	0	0	0	0	34
	C	6	143	104	2	1	0	0	256
	D	0	42	91	33	0	0	0	166
	E	0	0	0	0	0	0	0	0
	Missing	0	3	11	8	2	0	1	25
	Total	8	216	210	43	3	0	1	481
1 Year	AA	0	0	0	0	0	0	0	0
	A	0	0	0	0	0	0	0	0
	B	3	33	5	0	0	0	0	41
	C	5	144	99	7	0	0	0	255
	D	0	45	111	29	1	0	0	186
	E	0	0	0	0	0	0	0	0
	Missing	0	8	10	9	2	0	0	29
	Total	8	230	225	45	3	0	0	511

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis
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Table 15.2

BRA-CUP ASSESSMENT, CHANGE OVER TIME
AUGMENTATION PATIENTS

Post-op Visit		Preop Assessment							Total
		AA	A	B	C	D	E	Missing	
2 Year	AA	0	0	0	0	0	0	0	0
	A	0	0	0	0	0	0	0	0
	B	3	39	4	0	0	0	0	46
	C	6	132	100	3	0	0	0	241
	D	0	45	102	33	2	0	0	182
	E	0	0	0	0	0	0	0	0
	Missing	0	4	18	9	1	0	1	33
	Total	9	220	224	45	3	0	1	502
3 Year	AA	0	0	0	0	0	0	0	0
	A	0	0	0	0	0	0	0	0
	B	2	29	5	0	0	0	0	36
	C	7	103	78	5	0	0	0	193
	D	0	41	79	19	1	0	0	140
	E	0	0	0	1	0	0	0	1
	Missing	0	5	13	8	1	0	0	27
	Total	9	178	175	33	2	0	0	397

Table 16.1

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
AUGMENTATION PATIENTS

Type of Visit	Total Score (a)					n
	mean	median	standard deviation	minimum	maximum	
Preop	376.43	379.00	30.64	263.00	437.00	476
1 Year	378.20	380.00	29.98	285.00	440.00	441
2 Year	377.63	381.00	31.22	243.00	443.00	442

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	1.93	1.00	22.82	-86.00	96.00	391
2 Year	2.16	2.00	24.03	-106.0	87.00	395

Overall Mean Change (b) (Standard Deviation)	1.88 (21.90)
p-value (c)	0.0621

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score, the precise wording of each question can be found in Listing 11. Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.1

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
OVERALL RECONSTRUCTION

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	373.73	377.00	28.75	276.00	439.00	200
1 Year	372.90	375.50	33.19	240.00	438.00	184
2 Year	373.98	374.50	29.82	262.00	439.00	170

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-0.96	-0.50	20.40	-92.00	60.00	154
2 Year	-1.22	-1.00	22.17	-62.00	87.00	139

Overall Mean Change (b) (Standard Deviation)	-1.09 (18.78)
p-value (c)	0.3699

Note. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11. Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.1

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
DELAYED POST-MASTECTOMY

Total Score (a)						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
Preop	372.40	373.00	24.55	296.00	414.00	83
1 Year	367.54	371.50	32.93	240.00	428.00	76
2 Year	367.16	367.50	29.02	262.00	438.00	70
Change from Preop Assessment						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
1 Year	-3.93	-5.00	22.68	-92.00	60.00	61
2 Year	-7.00	-7.00	20.40	-62.00	38.00	54
Overall Mean Change (b) (Standard Deviation)		-4.73 (19.56)				
p-value (c)		0.0143				

Note. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11. Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.1

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
IMMEDIATE POST-MASTECTOMY

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	373.22	379.00	30.63	276.00	435.00	58
1 Year	371.14	378.00	32.39	299.00	430.00	51
2 Year	372.96	373.00	30.66	294.00	433.00	49

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-1.07	0.00	17.78	-44.00	52.00	43
2 Year	0.12	-1.00	22.22	-47.00	87.00	43

Overall Mean Change (b) (Standard Deviation)	-1.07 (17.62)
p-value (c)	----

Note. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11. Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.1

TENNESSEE SELF-CONCEPT SCALE. TOTAL SCORE
REVISION PATIENTS

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	385.36	388.00	27.07	294.00	436.00	175
1 Year	378.32	378.00	26.26	308.00	437.00	161
2 Year	377.12	379.00	27.71	312.00	445.00	147

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-5.18	-4.00	20.70	-75.00	76.00	138
2 Year	-8.10	-5.00	20.53	-72.00	41.00	129

Overall Mean Change (b) (Standard Deviation)	-6.61 (19.96)
p-value (c)	0.0000

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11. Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.1

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
OVERALL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	377.63	380.00	29.75	263.00	439.00	851
1 Year	376.98	379.00	30.11	240.00	440.00	786
2 Year	376.71	379.00	30.26	243.00	445.00	759

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-0.16	0.00	22.02	-92.00	96.00	683
2 Year	-0.55	0.00	23.31	-106.0	87.00	663

Overall Mean Change (b) (Standard Deviation)	-0.56 (21.06)
p-value (c)	0.4256

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score, the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
AUGMENTATION PATIENTS - SUBMUSCULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	375.30	378.00	30.29	263.00	432.00	197
1 Year	377.55	382.00	30.49	285.00	431.00	175
2 Year	377.67	382.50	33.00	243.00	441.00	178

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	3.17	2.50	25.21	-86.00	96.00	156
2 Year	4.04	5.00	26.44	-106.0	87.00	158

Overall Mean Change (b) (Standard Deviation)	3.36 (24.53)
p-value (c)	0.0248

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T16_2.SAS

Creation Date, Time: 21JUL04 10:33

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
AUGMENTATION PATIENTS - SUBGLANDULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	378.42	383.00	30.99	297.00	437.00	158
1 Year	380.89	383.00	29.44	298.00	440.00	153
2 Year	378.30	379.50	29.24	310.00	437.00	152

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	1.38	1.00	21.20	-83.00	58.00	133
2 Year	0.35	0.00	23.80	-56.00	83.00	133

Overall Mean Change (b) (Standard Deviation)	0.91 (20.47)
p-value (c)	0.6895

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
AUGMENTATION PATIENTS - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	375.67	377.00	30.89	303.00	437.00	121
1 Year	375.54	377.00	29.89	306.00	440.00	113
2 Year	376.66	379.00	31.17	295.00	443.00	112

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	0.76	0.50	21.08	-45.00	93.00	102
2 Year	1.61	2.00	20.20	-49.00	70.00	104

Overall Mean Change (b) (Standard Deviation)	0.81 (19.15)
p-value (c)	0.7249

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T16_2.SAS

Creation Date, Time: 21JUL04 10:33

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
OVERALL RECONSTRUCTION - SUBMUSCULAR

Type of Visit	Total Score (a)					n
	mean	median	standard deviation	minimum	maximum	
Preop	373.79	377.00	27.40	276.00	435.00	124
1 Year	370.67	374.00	32.83	240.00	435.00	110
2 Year	370.35	372.50	29.59	262.00	438.00	110

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-2.13	-2.00	22.08	-92.00	60.00	88
2 Year	-3.37	-2.00	22.77	-62.00	87.00	89

Overall Mean Change (b) (Standard Deviation)	-2.53 (20.32)
p-value (c)	0.1472

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE. TOTAL SCORE
OVERALL RECONSTRUCTION - SUBGLANDULAR

Type of Visit	Total Score (a)					n
	mean	median	standard deviation	minimum	maximum	
Preop	352.67	345.00	33.70	284.00	422.00	18
1 Year	360.12	353.00	35.55	285.00	427.00	17
2 Year	364.64	361.50	25.84	329.00	421.00	14

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	4.31	5.50	25.19	-36.00	57.00	16
2 Year	6.83	2.50	24.10	-26.00	67.00	12

Overall Mean Change (b) (Standard Deviation)	4.50 (19.93)
p-value (c)	0.2583

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.
Higher scores indicate improvement in self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
OVERALL RECONSTRUCTION - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	385.39	388.50	24.29	333.00	439.00	44
1 Year	384.87	384.50	28.20	308.00	438.00	46
2 Year	386.56	385.00	28.33	334.00	439.00	39

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-1.11	-2.00	15.89	-33.00	44.00	38
2 Year	2.23	1.00	20.72	-55.00	39.00	31

Overall Mean Change (b) (Standard Deviation)	0.69 (15.80)
p-value (c)	1.0000

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score, the precise wording of each question can be found in Listing 11.
Higher scores indicate improvement in self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
DELAYED POST-MASTECTOMY - SUBMUSCULAR

Type of Visit	Total Score (a)					n
	mean	median	standard deviation	minimum	maximum	
Preop	373.44	374.00	24.36	296.00	414.00	62
1 Year	369.50	372.50	34.05	240.00	428.00	60
2 Year	367.79	372.00	30.27	262.00	438.00	57

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-3.37	-4.00	24.71	-92.00	60.00	46
2 Year	-7.60	-5.00	21.44	-62.00	38.00	43

Overall Mean Change (b) (Standard Deviation)	-4.58 (21 54)
p-value (c)	0.0684

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
DELAYED POST-MASTECTOMY - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	376.92	380.50	24.23	345.00	410.00	12
1 Year	361.90	367.00	21.44	330.00	398.00	10
2 Year	359.80	353.00	22.90	334.00	408.00	10

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-10.75	-14.50	15.29	-33.00	17.00	8
2 Year	-6.13	-11.50	14.95	-21.00	20.00	8

Overall Mean Change (b) (Standard Deviation)	-7.40 (12.35)
p-value (c)	0.1055

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
IMMEDIATE POST-MASTECTOMY - SUBMUSCULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	372.43	377.00	30.80	276.00	435.00	49
1 Year	369.52	374.00	32.20	299.00	425.00	42
2 Year	371.37	371.00	29.82	294.00	433.00	43

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-1.65	-1.00	19.15	-44.00	52.00	34
2 Year	0.11	-1.00	22.75	-47.00	87.00	37

Overall Mean Change (b) (Standard Deviation)	-1.31 (18.68)
p-value (c)	----

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score, the precise wording of each question can be found in Listing 11. Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
IMMEDIATE POST-MASTECTOMY - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	383.83	386.50	12.67	362.00	395.00	6
1 Year	386.83	384.50	10.61	378.00	407.00	6
2 Year	387.25	387.00	20.60	363.00	412.00	4

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	3.00	3.00	13.70	-16.00	21.00	6
2 Year	4.25	2.00	23.60	-18.00	31.00	4

Overall Mean Change (b) (Standard Deviation)	3.17 (12.99)
p-value (c)	----

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11. Higher scores indicate improvement in self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE. TOTAL SCORE
REVISION PATIENTS - SUBMUSCULAR

Type of Visit	Total Score (a)					n
	mean	median	standard deviation	minimum	maximum	
Preop	382.94	385.00	27.92	294.00	436.00	94
1 Year	373.41	374.00	25.22	318.00	437.00	87
2 Year	373.20	370.50	26.49	321.00	445.00	82

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-7.08	-6.00	21.44	-75.00	76.00	72
2 Year	-9.83	-6.00	19.39	-72.00	23.00	71

Overall Mean Change (b) (Standard Deviation)	-8.01 (20.50)
p-value (c)	0.0000

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
REVISION PATIENTS - SUBGLANDULAR

Type of Visit	Total Score (a)					n
	mean	median	standard deviation	minimum	maximum	
Preop	387.61	390.50	26.52	317.00	432.00	54
1 Year	385.79	390.50	25.36	330.00	430.00	52
2 Year	383.70	386.50	28.31	315.00	429.00	44

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-1.49	-1.00	17.45	-35.00	39.00	47
2 Year	-4.69	-4.00	15.88	-38.00	28.00	39

Overall Mean Change (b) (Standard Deviation)	-2.74 (14.65)
p-value (c)	0.2293

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11. Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
REVISION PATIENTS - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	389.30	389.00	25.18	346.00	428.00	27
1 Year	381.38	375.00	29.11	308.00	425.00	21
2 Year	379.10	380.00	30.32	312.00	424.00	20

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-7.11	-5.00	24.81	-50.00	28.00	19
2 Year	-8.63	-7.00	31.07	-63.00	41.00	19

Overall Mean Change (b) (Standard Deviation)	-9.46 (25.89)
p-value (c)	0.0769

Note. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
OVERALL - SUBMUSCULAR

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	376.58	379.00	29.06	263.00	436.00	415
1 Year	374.55	377.00	30.15	240.00	437.00	372
2 Year	374.51	377.50	30.75	243.00	445.00	370

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-0.64	-0.50	23.84	-92.00	96.00	316
2 Year	-1.13	-1.50	24.60	-106.0	87.00	318

Overall Mean Change (b) (Standard Deviation)	-0.96 (22.89)
p-value (c)	0.3960

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
OVERALL - SUBGLANDULAR

Type of Visit	Total Score (a)					n
	mean	median	standard deviation	minimum	maximum	
Preop	378.57	384.00	31.26	284.00	437.00	230
1 Year	380.45	383.00	29.58	285.00	440.00	222
2 Year	378.52	381.00	29.03	310.00	437.00	210

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	0.93	1.00	20.68	-83.00	58.00	196
2 Year	-0.29	-0.50	22.44	-56.00	83.00	184

Overall Mean Change (b) (Standard Deviation)	0.34 (19.25)
p-value (c)	0.9651

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

(a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11.

Higher scores indicate improvement in self-esteem.

(b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.

(c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 16.2

TENNESSEE SELF-CONCEPT SCALE: TOTAL SCORE
OVERALL - SUBPECTORAL

Type of Visit	Total Score (a)					
	mean	median	standard deviation	minimum	maximum	n
Preop	379.81	381.50	29.15	303.00	439.00	192
1 Year	378.61	379.00	29.50	306.00	440.00	180
2 Year	379.20	381.00	30.55	295.00	443.00	171

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-0.62	0.00	20.48	-50.00	93.00	159
2 Year	0.47	1.50	22.01	-63.00	70.00	154

Overall Mean Change (b) (Standard Deviation)	-0.68 (19.78)
p-value (c)	0.7006

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) The Total Score is calculated as Q1+Q2+Q4+Q5+Q7+Q8+Q10+Q11+Q13+Q14+Q18+Q21+Q24+Q27+Q30+Q35+Q36+Q38+Q39+Q41+Q42+Q44+Q45+Q47+Q48+Q52+Q55+Q58+Q61+Q64+Q69+Q70+Q72+Q73+Q75+Q76+Q78+Q79+Q81+Q82+Q85+Q88+Q91+Q94+Q97-Q3-Q6-Q9-Q12-Q15-Q19-Q20-Q22-Q23-Q25-Q26-Q28-Q29-Q31-Q32-Q37-Q40-Q43-Q46-Q49-Q53-Q54-Q56-Q57-Q59-Q60-Q62-Q63-Q65-Q66-Q71-Q74-Q77-Q80-Q83-Q86-Q87-Q89-Q90-Q92-Q93-Q95-Q96-Q98-Q99+270. The results include only patients who had responses for all these questions used to derive the total score; the precise wording of each question can be found in Listing 11. Higher scores indicate improvement in self-esteem.
- (b) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (c) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.1

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE
OVERALL RECONSTRUCTION

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	54.00	56.06	6.99	24.07	64.44	247
1 Year	53.39	55.45	7.74	18.77	66.97	216
2 Year	53.63	55.71	7.43	13.60	66.38	191

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.82	-0.25	7.96	-28.76	22.69	214
2 Year	-0.34	-0.01	8.36	-39.03	25.25	190

Overall Mean Change (a) (Standard Deviation)	-0.99 (7.97)
p-value (b)	0.1447

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Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.1

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE
DELAYED POST-MASTECTOMY

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	52.25	54.72	6.77	27.07	61.99	104
1 Year	51.64	53.53	8.08	22.38	63.15	86
2 Year	53.04	55.32	7.79	13.60	66.38	76

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.81	-1.15	8.78	-28.76	19.16	85
2 Year	0.98	0.81	8.57	-39.03	19.78	75

Overall Mean Change (a) (Standard Deviation)	-0.51 (8.65)
p-value (b)	0.6747

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_1.SAS

Creation Date, Time: 21JUL04 10:35

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.1

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE
IMMEDIATE POST-MASTECTOMY

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	52.90	55.49	7.33	32.45	64.44	70
1 Year	52.29	54.69	8.26	18.77	66.97	66
2 Year	51.46	53.94	8.18	26.10	60.60	57

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.33	0.03	8.55	-23.46	22.69	65
2 Year	-0.79	-0.27	10.21	-29.62	25.25	57

Overall Mean Change (a) (Standard Deviation)	-1.05 (8.92)
p-value (b)	----

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_1.SAS

Creation Date, Time: 21JUL04 10:35

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.1

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE
REVISION PATIENTS

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	56.36	57.57	5.24	36.11	71.49	204
1 Year	54.86	57.28	7.60	25.05	70.65	179
2 Year	54.32	56.98	7.74	25.93	67.09	172

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-1.48	-0.48	6.58	-24.72	18.24	179
2 Year	-2.15	-0.93	7.20	-32.48	16.88	172

Overall Mean Change (a) (Standard Deviation)	-1.82 (5.88)
p-value (b)	<0.0001

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_1.SAS

Creation Date, Time: 21JUL04 10.35

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.1

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE
OVERALL

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	56.61	57.93	5.30	24.07	73.13	997
1 Year	55.86	57.84	6.63	18.77	72.89	892
2 Year	55.30	57.33	7.08	13.60	73.40	855

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.80	-0.22	6.28	-28.76	22.69	887
2 Year	-1.38	-0.45	7.17	-39.03	25.25	850

Overall Mean Change (a) (Standard Deviation)	-1.19 (6.16)
p-value (b)	<0.0001

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_1.SAS

Creation Date, Time: 21JUL04 10:35

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.2

SF-36 HEALTH SURVEY SCALE. MENTAL COMPONENT SUMMARY SCALE
AUGMENTATION PATIENTS

Type of Visit	Total Score					
	mean	median	standard deviation	minimum	maximum	n
Preop	53.80	55.90	6.83	12.98	69.15	546
1 Year	53.18	55.44	7.68	10.99	68.74	497
2 Year	52.67	55.35	8.50	8.17	63.75	492

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-0.72	-0.48	7.46	-34.92	25.26	494
2 Year	-1.48	-0.52	8.56	-49.70	39.18	488

Overall Mean Change (a) (Standard Deviation)	-1.08 (7.19)
p-value (b)	< 0.0001

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_2.SAS

Creation Date, Time: 21JUL04 10:35

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.2

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE
OVERALL RECONSTRUCTION

Total Score						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
Preop	52.44	54.97	7.98	16.62	66.38	247
1 Year	53.25	55.65	8.43	9.78	65.05	216
2 Year	53.38	55.47	8.08	13.66	67.67	191
Change from Preop Assessment						
Type of Visit	mean	median	standard deviation	minimum	maximum	n
1 Year	0.75	0.41	8.34	-34.67	30.97	214
2 Year	0.86	0.55	8.36	-26.01	35.43	190
Overall Mean Change (a) (Standard Deviation)	0.94 (7.90)					
p-value (b)	0.8771					

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_2.SAS

Creation Date, Time: 21JUL04 10:35

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.2

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE
DELAYED POST-MASTECTOMY

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	53.06	54.89	7.52	22.82	62.25	104
1 Year	53.40	55.58	8.23	9.78	63.08	86
2 Year	53.16	55.43	7.59	24.55	62.15	76

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.03	0.41	8.25	-24.80	29.41	85
2 Year	0.17	0.67	7.08	-25.03	25.00	75

Overall Mean Change (a) (Standard Deviation)	0.29 (7.22)
p-value (b)	0.7765

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_2.SAS

Creation Date, Time: 21JUL04 10.35

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.2

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE
IMMEDIATE POST-MASTECTOMY

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	50.28	53.16	8.53	26.68	62.28	70
1 Year	52.83	55.84	9.47	17.81	65.05	66
2 Year	53.52	54.99	8.28	13.73	67.67	57

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	2.32	1.40	9.37	-21.94	30.97	65
2 Year	2.51	1.68	9.50	-26.01	26.02	57

Overall Mean Change (a) (Standard Deviation)	2.87 (8.93)
p-value (b)	----

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_2.SAS

Creation Date, Time: 21JUL04 10:35

Note. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.2

SF-36 HEALTH SURVEY SCALE. MENTAL COMPONENT SUMMARY SCALE
REVISION PATIENTS

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	54.79	56.22	5.80	15.51	65.68	204
1 Year	52.24	55.35	8.78	9.89	64.86	179
2 Year	52.47	55.04	8.46	14.44	63.82	172

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-2.46	-0.77	7.79	-41.04	13.42	179
2 Year	-2.12	-1.15	6.77	-28.39	12.42	172

Overall Mean Change (a) (Standard Deviation)	-2.51 (6.97)
p-value (b)	< 0.0001

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_2.SAS

Creation Date, Time: 21JUL04 10.35

Note. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.2

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE
OVERALL

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	53.67	55.89	6.98	12.98	69.15	997
1 Year	53.01	55.46	8.10	9.78	68.74	892
2 Year	52.79	55.35	8.40	8.17	67.67	855

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.72	-0.23	7.81	-41.04	30.97	887
2 Year	-1.08	-0.51	8.25	-49.70	39.18	850

Overall Mean Change (a) (Standard Deviation)	-0.88 (7.41)
p-value (b)	< 0.0001

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_2.SAS

Creation Date, Time: 21JUL04 10:35

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
AUGMENTATION PATIENTS - SUBMUSCULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	57.76	58.37	3.77	39.45	67.69	227
1 Year	57.53	58.41	4.84	27.84	69.51	204
2 Year	56.06	57.87	5.89	26.49	64.69	205
Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.20	-0.24	5.24	-24.00	18.18	203
2 Year	-1.66	-0.50	6.17	-32.70	18.84	203
Overall Mean Change (a) (Standard Deviation)		-1.04 (5.18)				
p-value (b)		0.0019				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
AUGMENTATION PATIENTS - SUBGLANDULAR

Type of Visit	Total Score					
	mean	median	standard deviation	minimum	maximum	n
Preop	57.64	58.22	3.80	35.66	66.04	184
1 Year	57.55	58.72	4.66	37.43	72.89	168
2 Year	57.20	58.38	5.93	19.47	71.33	167

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-0.07	0.00	4.78	-15.80	18.81	167
2 Year	-0.39	0.06	6.37	-35.62	22.24	166

Overall Mean Change (a) (Standard Deviation)	-0.12 (4.95)
p-value (b)	0.5495

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE - PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
OVERALL RECONSTRUCTION - SUBMUSCULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	52.74	54.91	7.04	32.45	64.44	156
1 Year	52.38	54.71	7.89	18.77	66.97	135
2 Year	52.56	55.02	7.89	13.60	66.38	124

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.19	-0.51	8.50	-24.19	22.69	134
2 Year	0.36	0.45	9.18	-39.03	25.25	123

Overall Mean Change (a) (Standard Deviation)	-0.40 (8.67)
p-value (b)	0.8092

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
OVERALL RECONSTRUCTION - SUBGLANDULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	56.04	58.36	8.05	24.07	64.43	21
1 Year	56.98	58.08	4.36	43.66	62.96	18
2 Year	54.29	55.73	5.59	41.15	62.85	17
Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.42	0.43	4.55	-15.24	5.60	18
2 Year	-3.43	-3.15	6.54	-17.75	4.04	17
Overall Mean Change (a) (Standard Deviation)		-1.83 (4.96)				
p-value (b)		0.2305				

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
OVERALL RECONSTRUCTION - SUBPECTORAL

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	56.88	58.53	5.92	27.07	63.63	57
1 Year	55.37	57.65	7.19	30.79	65.36	50
2 Year	56.03	57.51	6.48	26.10	62.06	43

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-2.23	-0.22	6.80	-26.19	8.27	50
2 Year	-1.35	-0.54	6.78	-29.62	14.51	43

Overall Mean Change (a) (Standard Deviation)	-2.00 (6.27)
p-value (b)	0.0813

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

Note. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
DELAYED POST-MASTECTOMY - SUBMUSCULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	52.29	54.71	6.67	34.01	61.99	79
1 Year	52.47	54.05	7.51	22.38	61.75	67
2 Year	52.99	55.45	8.26	13.60	66.38	63

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	0.17	-0.51	8.32	-24.19	19.16	66
2 Year	1.24	1.66	9.00	-39.03	19.78	62

Overall Mean Change (a) (Standard Deviation)	0.12 (8.54)
p-value (b)	0.7937

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08.39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
DELAYED POST-MASTECTOMY - SUBPECTORAL

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	52.39	55.01	8.60	27.07	61.46	16
1 Year	49.22	51.75	9.01	30.79	63.15	11
2 Year	53.38	55.06	5.29	39.91	58.34	10
Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-4.24	-2.78	8.40	-16.75	8.27	11
2 Year	-0.22	-0.82	7.16	-9.70	12.80	10
Overall Mean Change (a) (Standard Deviation)		-2.03 (6.93)				
p-value (b)		0.3054				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time. 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
IMMEDIATE POST-MASTECTOMY - SUBMUSCULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	52.49	55.34	7.72	32.45	64.44	61
1 Year	51.46	54.22	8.68	18.77	66.97	56
2 Year	51.37	53.65	7.73	29.16	60.60	50
Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.65	-0.72	9.14	-23.46	22.69	56
2 Year	-0.36	0.03	10.03	-26.48	25.25	50
Overall Mean Change (a) (Standard Deviation)		-1.15 (9.40)				
p-value (b)		----				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
IMMEDIATE POST-MASTECTOMY - SUBPECTORAL

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	56.21	55.72	2.54	53.22	60.33	7
1 Year	57.48	56.63	1.44	56.35	59.89	7
2 Year	49.71	55.27	13.31	26.10	57.36	5
Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	1.27	0.98	2.41	-1.30	4.18	7
2 Year	-7.18	-2.00	12.61	-29.62	-0.30	5
Overall Mean Change (a) (Standard Deviation)		-1.59 (5.32)				
p-value (b)		----				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

Note. Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
REVISION PATIENTS - SUBMUSCULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	55.42	57.32	6.16	36.11	64.36	112
1 Year	53.89	57.00	7.89	29.97	64.73	95
2 Year	53.79	56.90	7.52	32.31	63.66	97

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-1.42	-0.50	7.15	-24.72	18.24	95
2 Year	-1.97	-0.63	6.92	-25.22	16.88	97

Overall Mean Change (a) (Standard Deviation)	-1.70 (6.16)
p-value (b)	0.0017

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
REVISION PATIENTS - SUBGLANDULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	57.33	57.92	3.81	49.35	71.49	62
1 Year	55.55	57.00	7.88	25.05	70.65	57
2 Year	54.49	56.77	8.88	25.93	67.09	52

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-1.69	-0.25	6.10	-24.29	7.96	57
2 Year	-2.97	-1.33	8.26	-32.48	11.12	52

Overall Mean Change (a) (Standard Deviation)	-2.37 (5.90)
p-value (b)	0.0114

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
REVISION PATIENTS - SUBPECTORAL

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	57.62	58.07	2.74	50.43	63.42	29
1 Year	56.75	57.57	5.38	34.11	62.97	26
2 Year	55.94	57.78	5.56	40.55	65.72	22

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-1.11	-0.13	5.62	-21.77	9.25	26
2 Year	-1.06	-0.65	5.80	-16.83	8.88	22

Overall Mean Change (a) (Standard Deviation)	-1.10 (4.87)
p-value (b)	0.3842

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08.39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
OVERALL PATIENTS - SUBMUSCULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	55.65	57.48	5.94	32.45	67.69	495
1 Year	55.13	57.27	7.01	18.77	69.51	434
2 Year	54.53	56.68	7.06	13.60	66.38	426

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.47	-0.36	6.82	-24.72	22.69	432
2 Year	-1.14	-0.31	7.37	-39.03	25.25	423

Overall Mean Change (a) (Standard Deviation)	-0.99 (6.67)
p-value (b)	0.0003

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

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- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
OVERALL PATIENTS - SUBGLANDULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	57.45	58.22	4.28	24.07	71.49	267
1 Year	57.04	58.42	5.60	25.05	72.89	243
2 Year	56.39	57.92	6.76	19.47	71.33	236
Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.48	-0.03	5.13	-24.29	18.81	242
2 Year	-1.18	-0.21	6.92	-35.62	22.24	235
Overall Mean Change (a) (Standard Deviation)		-0.76 (5.25)				
p-value (b)		0.0378				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.3

SF-36 HEALTH SURVEY SCALE: PHYSICAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
OVERALL PATIENTS - SUBPECTORAL

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	57.93	58.86	4.36	27.07	73.13	221
1 Year	56.29	58.29	6.47	30.79	72.75	201
2 Year	55.60	57.71	7.42	26.10	73.40	185

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-1.81	-0.20	5.98	-26.19	9.25	200
2 Year	-2.26	-0.79	7.09	-29.62	16.86	184

Overall Mean Change (a) (Standard Deviation)	-2.07 (5.68)
p-value (b)	<0.0001

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_3.SAS

Creation Date, Time: 23JUL04 08.39

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- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.4

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
AUGMENTATION PATIENTS - SUBMUSCULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	53.69	55.46	6.31	18.57	61.99	227
1 Year	52.68	54.94	7.89	19.94	62.14	204
2 Year	53.50	55.60	7.78	10.61	62.51	205

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-1.00	-0.42	7.73	-31.28	24.98	203
2 Year	-0.10	0.12	7.38	-46.42	24.68	203

Overall Mean Change (a) (Standard Deviation)	-0.54 (6.34)
p-value (b)	0.1675

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_4.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.4

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
AUGMENTATION PATIENTS - SUBGLANDULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	54.20	56.13	6.71	15.70	66.25	184
1 Year	53.83	55.95	7.55	18.41	68.74	168
2 Year	51.82	54.92	9.27	8.17	61.99	167

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.51	-0.51	6.93	-34.92	25.26	167
2 Year	-2.77	-1.19	9.76	-49.70	39.18	166

Overall Mean Change (a) (Standard Deviation)	-1.87 (7.81)
p-value (b)	0.0002

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_4.SAS

Creation Date, Time: 23JUL04 08:39

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- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.4

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
AUGMENTATION PATIENTS - SUBPECTORAL

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	53.44	55.90	7.80	12.98	69.15	135
1 Year	53.11	55.40	7.50	10.99	62.45	125
2 Year	52.44	54.91	8.51	11.51	63.75	120

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.56	-0.43	7.76	-26.98	25.10	124
2 Year	-1.98	-1.07	8.38	-46.73	20.12	119

Overall Mean Change (a) (Standard Deviation)	-0.89 (7.58)
p-value (b)	0.0307

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Creation Date, Time: 23JUL04 08:39

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- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.4

SF-36 HEALTH SURVEY SCALE. MENTAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
OVERALL RECONSTRUCTION - SUBMUSCULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	51.93	54.42	7.93	22.82	62.25	156
1 Year	53.39	56.04	9.14	9.78	65.05	135
2 Year	52.90	55.26	8.82	13.66	67.67	124

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	1.39	0.96	8.93	-24.80	30.97	134
2 Year	0.70	0.82	8.67	-26.01	26.02	123

Overall Mean Change (a) (Standard Deviation)	1.35 (8.02)
p-value (b)	0.7562

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_4.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.4

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
OVERALL RECONSTRUCTION - SUBGLANDULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	52.38	54.30	10.08	16.62	66.38	21
1 Year	50.98	55.18	10.99	21.84	58.59	18
2 Year	54.50	55.59	5.56	41.66	64.77	17

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.71	0.55	9.11	-34.67	8.52	18
2 Year	2.90	0.20	10.04	-7.40	35.43	17

Overall Mean Change (a) (Standard Deviation)	0.40 (10.33)
p-value (b)	0.4524

Program Name. Q:\MENTOR\COREGEL\3YEAR\TABLES\117_4.SAS

Creation Date, Time: 23JUL04 08.39

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- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.4

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
OVERALL RECONSTRUCTION - SUBPECTORAL

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	53.87	56.45	6.87	29.91	61.99	57
1 Year	53.68	55.43	5.66	35.55	61.77	50
2 Year	53.99	55.62	7.13	20.52	62.15	43

Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	-0.63	-0.75	6.67	-15.05	18.46	50
2 Year	0.70	0.57	7.30	-23.65	25.00	43

Overall Mean Change (a) (Standard Deviation)	-0.09 (6.89)
p-value (b)	0.4092

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_4.SAS

Creation Date, Time: 23JUL04 08:39

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- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.4

SF-36 HEALTH SURVEY SCALE. MENTAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
DELAYED POST-MASTECTOMY - SUBMUSCULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	53.19	54.73	7.03	22.82	62.25	79
1 Year	53.86	56.44	8.93	9.78	63.08	67
2 Year	52.80	55.42	8.07	24.55	62.09	63
Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	0.29	0.64	8.34	-24.80	29.41	66
2 Year	-0.44	0.39	6.71	-25.03	15.93	62
Overall Mean Change (a) (Standard Deviation)		0.12 (6.75)				
p-value (b)		0.6151				

Program Name: Q:\MENTOR\COREGEL\3YEAR\TABLES\T17_4.SAS

Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.4

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
DELAYED POST-MASTECTOMY - SUBPECTORAL

Type of Visit	Total Score					
	mean	median	standard deviation	minimum	maximum	n
Preop	54.42	57.64	8.03	29.91	60.46	16
1 Year	51.99	53.77	4.81	45.41	58.94	11
2 Year	55.29	55.26	4.29	47.65	62.15	10

Type of Visit	Change from Preop Assessment					
	mean	median	standard deviation	minimum	maximum	n
1 Year	-4.02	-4.48	7.52	-15.05	11.32	11
2 Year	3.51	2.02	9.10	-9.39	25.00	10

Overall Mean Change (a) (Standard Deviation)	-0.21 (9.73)
p-value (b)	0.4143

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Creation Date, Time: 23JUL04 08:39

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- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.

Table 17.4

SF-36 HEALTH SURVEY SCALE: MENTAL COMPONENT SUMMARY SCALE BY DEVICE PLACEMENT
IMMEDIATE POST-MASTECTOMY - SUBMUSCULAR

Type of Visit	Total Score					n
	mean	median	standard deviation	minimum	maximum	
Preop	49.70	52.58	8.78	26.68	61.99	61
1 Year	52.40	55.84	10.12	17.81	65.05	56
2 Year	53.31	55.00	8.71	13.73	67.67	50
Type of Visit	Change from Preop Assessment					n
	mean	median	standard deviation	minimum	maximum	
1 Year	2.43	1.56	9.88	-21.94	30.97	56
2 Year	2.80	2.71	10.08	-26.01	26.02	50
Overall Mean Change (a) (Standard Deviation)		3.13 (9.48)				
p-value (b)		----				

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Creation Date, Time: 23JUL04 08:39

Note: Patients who returned for a particular visit outside of the pre-established visit windows are excluded from analyses of that specific visit and are excluded from analyses of the overall mean change.

- (a) Obtained by calculating, for each patient, the average change from preop assessment across all postop assessments and then calculating the mean across patients of these averages.
- (b) From Wilcoxon Signed Rank Test on overall mean change. Immediate post-mastectomy patients are excluded from the calculation of p-value for the Overall Reconstruction Patients and Overall Patients.