

**Data Comparisons Saline and Silicone PMA Data to Tebbetts Peer Reviewed and Published Data
Compiled December 5, 2006 by John B. Tebbetts, M.D. Revised January 1, 2008**

Sources:

**Mentor and Allergan Product Labelling PMA data from FDA website: <http://www.fda.gov/cdrh/breastimplants/labeling.html>,
last accessed December 5, 2006; FDA website updated November 17, 2006**

Chart updated August 6, 2008 with 410 5yr data from Allergan website

	Mentor Saline PMA (all saline) ⁶	Allergan Saline PMA⁶	Tebbetts Saline Style 468 Studies¹⁻⁴	Mentor Core Gel PMA^{7,8}	Allergan CoreGel PMA^{7,10}	Mentor CPG PMA⁹	Allergan Style 410 PMA¹¹	Allergan Style 410 Labeling¹²	Tebbetts Form Stable Gel Style 410 PMA series⁵
Date	Jan 2004	Nov 2004	Dec 2002	Nov 2006	Nov 2006	Dec 2007	Dec 2007	August 2008	Dec 2006
Patients	1264	901	1662	551	455	572	941 492 primary augs; 150 in MRI cohort	941 492 primary augs; 150 in MRI cohort	50 consecutive
Followup (years)	3 years (5 and 7 year FUs were 5% and 50%)	5 years (81% FU at 5 yrs)	up to 7 years, 83% FU	3 years 88% followup	4 years 82% followup	2 years	4 years 80% followup at 4 yrs	5 years 81% followup at 5 yrs	3 years 94% followup
References	SPS & Post approval study See ref #6	A95 and Post Approval Study See ref#7	See Refs #1-4	See ref #7,8	See ref#7,10	See ref #10	See ref #11 4 matrix cells FF,FM, MF, MM		See Ref # 5
Complications & Reoperations (%)									
	At 3 yrs	At 5 yrs	Up to 7 yrs	At 3 yrs	At 3 yrs	At 2 years	At 3 years	At 5 years	At 3 yrs
Reoperations all causes	13 20.2@7yrs	26 30%@7yrs	3	15.4	23.5	9.4	12.5	16.7% *17.7% of all reops were for size change	0
Capsular Contracture 3-4	9 10.1@7yrs	11@5yrs 16@7yrs	0.7	8.1	13.2	0.8	2.9	3.3	0

Rupture, Leakage, Deflation	3.3%@3yrs. 9.7%@5yrs 16.4% @7yrs ⁶	5.0%@3yrs 6.8 @5yrs 9.8@7yrs	0.8	0.5%@ 3yrs (MRI Cohort)	2.7%@3 yrs. (MRI Cohort) 5.5%@6yrs	0	1.4	4.3% in MRI cohort (? confirmed surgically)	0
Implant removal without replacement	14.2@7yrs ⁶	15@7yrs	0.3	2.3	2.3	0.9	0.7*	<1	0
	Mentor Saline PMA (all saline)⁶	Allergan Saline PMA⁶	Tebbetts Saline Style 468 Studies¹⁻⁴	Mentor Core Gel PMA^{7,8}	Allergan CoreGel PMA^{7,10}	Mentor CPG PMA⁹	Allergan Style 410 PMA¹¹		Tebbetts Form Stable Gel Style 410 PMA series⁵
Implant removal replacement any reason (size change, etc)	8	12	0.2	2.8	7.5	1.2	4.7	7.6	0
Implant malposition	2.2	9	0.1	NR	4.1	1.1 rotation; 1.4 position dissatisfaction	2.4	2.3	0
Breast pain	5	17	0	1.7	8.2	1.1	1.2	2.2	0
Visible Wrinkling	21	14	0	NR	<1	NR	0.5	<1	0
Asymmetry	7	12	0 reops	NR	3.2	NR	0.8	<1	0 reops
Nipple Paresthesia	5	10 (skin)	NR	2.2		2.8 nipple complications	NR	NR	NR
Implant palpability/visibility	2	12	0 visible	NR	<1	NR	NR	0-1	0
Loss nipple sensation	10	10	0	NR	NR	2.8 nipple complications	NR	NR	0

Hematoma	2	2	0.2	2.6	1.6	1.0	0.8	1.1	0
Seroma	NR	3	0.1	NR	1.3	NR	0.8	1.1	0
Infection	2	1	0.3	1.4	<1	0.7	1.3	1.7	0
Delayed wound healing	NR	1	0	NR	<1	NR	1.0	1.3	0
Implant extrusion	NR	NR	0	NR	<1	NR	NR	NR	0
Tissue/skin necrosis	NR	NR	0			NR	NR	0	
	Mentor Saline PMA (all saline)⁶	Allergan Saline PMA⁶	Tebbetts Saline Style 468 Studies¹⁻⁴	Mentor Core Gel PMA^{7,8}	Allergan CoreGel PMA^{7,10}	Mentor CPG PMA⁹	Allergan Style 410 PMA¹¹		Tebbetts Form Stable Gel Style 410 PMA series⁵
Sagging/Ptoisis	2% 3yr	28/901= 3.1%	0.1	2.3	1.4	NR	NR* See reasons for reops		0
Scarring Complications		7	0	6.7	3.7	2.5	NR* See reasons for reops		0
“Nipple Complications” (gel studies only)	-	-	-	10.4	7.9	2.8	NR		0
Reasons for Reops (%)	* Reported as “% Types Additional Surgical Treatment at 3 yrs”	* Reported as “% Types Additional Surgical Treatment at 5 yrs	% reops in 1664 pts. up to 7 year followup	3 years % of 109 reoperations	4 years % of 135 reoperations	2 years % of 54 reoperations, but 108 surgical procedures	3 years % of 72 reoperations	5 years % of 96 reoperations	3 years % reops

Deflation/Rupture (Suspected rupture in gels)	24 (calculated), NR	18% of 293 reops	0.8	1/109= 0.91	6.135= 2.2	0	0.7% \times 492/72 = 4.7% ???	4/96= 4.1% (gel fracture or suspected rupture, ? confirmed surgically?)	0
Removal with replacement (size or shape change)	32	34 15% "Pt choice of 293 reops)	0.2	16/109= 14.6%	7/135= 5.1%	13%	16.7% at 3 yrs; 17.9% at 4 yrs	*17.7% at 5 years; most common cause reop	0
Capsular contracture	22	19	0.7	40/109= 36.7%	39/135= 28.8%	4.5/54= 8.1%	6.9% at 3 yrs;	7/96=7.3	0
Scarring/Wound Revision	19	9	0	NR	NR	NR	12.5% ??	*12/96= 12.5%	0
Implant malposition/ reposition implant	8	5	0.2	2/109= 1.8%	21/135= 15.5%	NR	18.1%	*14/96= 14.5%	0
	Mentor Saline PMA (all saline) ⁶	Allergan Saline PMA⁶	Tebbetts Saline Style 468 Studies¹⁻⁴	Mentor Core Gel PMA⁸	Allergan CoreGel PMA⁹	Mentor CPG PMA⁹	Allergan Style 410 PMA¹¹		Tebbetts Form Stable Gel Style 410 PMA series⁵
Saline adjustment	8	11	0	NA	NA	NA	NA	NA	NA
Mastopexy/Ptoxis	6	6	0	4/109= 3.6%	19/135= 14.0%	NR	8.3%	9/96	0
Implant removal without replacement	3	2	0.3	NR	NR	0.9 \times 551/54= 9.1%	0.7% \times 492/72= 4.7%	0	0
Biopsy/Cyst removal	2	5	0	6/109= 5.5%	12/135= 8.8%	NR	5.6%	6/96= 6%	0
Nipple related	<1	<1	0	NR	1/135= 0.74%	NR	NR	NR	0

Hematoma/Seroma	See above	See above	See above	12/109= 11.0%	9/135= 6.6%	1/54= 1.8%	12.5%	9/96= 9.3%	0

Mentor 5 and 7 year saline followup were 5% and 50% respectively, so the 3 year data is more reliable.

References:

- (1) Tebbetts, J.B.: "Patient acceptance of adequately filled breast implants", *Plastic and Reconstructive Surgery*, 106(1):139-47, July 2000.
- (2) Tebbetts, J.B.: "Dual Plane (DP) Breast Augmentation: Optimizing Implant-Soft Tissue Relationships in a Wide Range of Breast Types", *Plastic and Reconstructive Surgery*, 107: 1255, April 2001.
- (3) Tebbetts, J.B.: "Achieving a Predictable 24 Hour Return to Normal Activities After Breast Augmentation Part I: Refining Practices Using Motion and Time Study Principles", *Plastic and Reconstructive Surgery*:109:273-290, January 2002.
- (4) Tebbetts, J.B.: "Achieving a Predictable 24 Hour Return to Normal Activities After Breast Augmentation Part II: Patient Preparation, Refined Surgical Techniques and Instrumentation", *Plastic and Reconstructive Surgery*:109:293-305, January, 2002.
- (5) Tebbetts, J.B. Achieving a zero percent reoperation rate at 3 Years in a 50 consecutive case augmentation mammoplasty PMA study. *Plast Reconstr Surg.* 118 (6), 1453-57, Nov 2006.
- (6) U.S. Food and Drug Administration. Product labeling for Mentor saline implants. http://www.mentorcorp.com/pdf/pids/saline_spectrum_ppi.pdf, accessed February 27, 2008.
- (7) U.S. Food and Drug Administration. Product labeling for Allergan core studies of saline implants. http://allergan.com/assets/pdf/M712-04_Saline_DFU.pdf, accessed February 27, 2008.
- (8) The Mentor core study on silicone MemoryGel breast implants. *Plast. Reconstr. Surg.* 120 (Suppl. 1): 19S, 2007.
- (9) The Mentor study on contour profile gel silicone MemoryGel breast implants. *Plast. Reconstr. Surg.* 120 (Suppl. 1): 33S, 2007.
- (10) Inamed silicone breast implant core study results at 6 years. *Plast. Reconstr. Surg.* 120 (Suppl. 1): 8S, 2007.
- (11) Style 410 highly cohesive silicone breast implant core study results at 3 years. *Plast. Reconstr. Surg.* 120 (Suppl. 1): 40S, 2007.
- (12) Important information for women about breast augmentation with Natrelle™ silicone-filled breast implants. http://www.allergan.com/assets/pdf/11174_Aug_Labeling_7308.pdf