SUPPLEMENTARY INFORMATION TO "MENTOR CONTOUR PROFILE GEL IMPLANTS: CLINICAL OUTCOMES AT 10 YEARS"

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INTRODUCTION

Subject enrollment in the CPG/MS Continued Access (CA) Study was initiated after enrollment for the Core Study was complete. Initially, only Style MM (medium height, moderate profile, 321) implants were included in the CA Study; however, in 2005, the FDA approved the use of four additional styles of CPG/MS Breast Implants: medium height, moderate plus profile (Style MM+, 322); medium height, high profile (Style MH, 323); tall height, moderate plus profile (Style TM+, 332); and low height, moderate plus profile (Style LM+, 312; see Figure, Supplemental Digital Content 1). After FDA approval of Style MM Breast Implants in 2013, subjects in the CA Study with that style implant continued to be followed under the Post-Approval Continued Access (PACA) protocol and those implanted with the four additional styles continued to be followed under the Styles protocol.

METHODS

The PACA Study was a prospective, open-label, multi-center clinical study with 10-year follow-up, later reduced to 5 years (see Figure, Supplemental Digital Content 1). Estimated enrollment over a 6-month time frame was 360. Safety endpoints included incidence on a per-subject and per-device basis of all complications and time to occurrence of complications. Inclusion and exclusion criteria for this study were the same as that for the Core Study with the exception that subjects in the PACA Study were not excluded if they had implanted metal or metal devices, history of claustrophobia, or other conditions that would make an MRI scan prohibitive.

The Styles Study, initiated in 2013, was a prospective, open-label, multi-center clinical study designed to collect additional safety data on the four investigational styles of CPG/MS Breast Implants (see Figure, Supplemental Digital Content 1). Up to 500 new subjects and 1500 active subjects were to be rolled over from the CA Study to continue the 10-year follow-up under the Styles protocol. The Styles Study was later considered complete by the FDA and closed in 2014, therefore, while we report 9-year rates, few patients made it to 9-year follow-up which had the effect of inflating rates (Supplemental Digital Content 2). Primary safety endpoints and inclusion/ exclusion criteria were the same as in the PACA Study.

Additional safety endpoints in the Styles Study included number of subjects undergoing reoperations and additional surgical procedures, new incidence of rheumatic disease, and incidence of pregnancy and lactation complications.

RESULTS

In total, 3657 female subjects (n= 2387 primary augmentation, n=557 revision-augmentation, n=443 primary reconstruction, n=267 revision-reconstruction, n=2 unknown cohort designation, n=1 compassionate use subject) were enrolled in the CA Study. Of these, 1653 subjects were rolled over into the Styles Study; 2003 subjects remained in the PACA Study for accounting and follow-up (n=1365 primary augmentation, n=376 revision augmentation, n=167 primary reconstruction, n=95 revision-reconstruction, n=1 compassionate use; see Figure, Supplemental Digital Content 1). Supplemental Digital Content 2 provides KM estimated cumulative incidence rates at the subject level for the key complications of any reoperation, explantation with or without replacement, explanation with replacement with study device, Baker III/IV capsular contracture, and infection. Five primary augmentation subjects had a new diagnosis of breast cancer. No subject was diagnosed with anaplastic large cell lymphoma (ALCL). There were 10 suspected or confirmed rupture(s) reported in 8 subjects: 3 primary augmentation subjects (4 ruptures), 2 revision-augmentation subjects (3 ruptures), 1 primary reconstruction subject (1 rupture), and 2 revision-reconstruction subjects (2 ruptures).

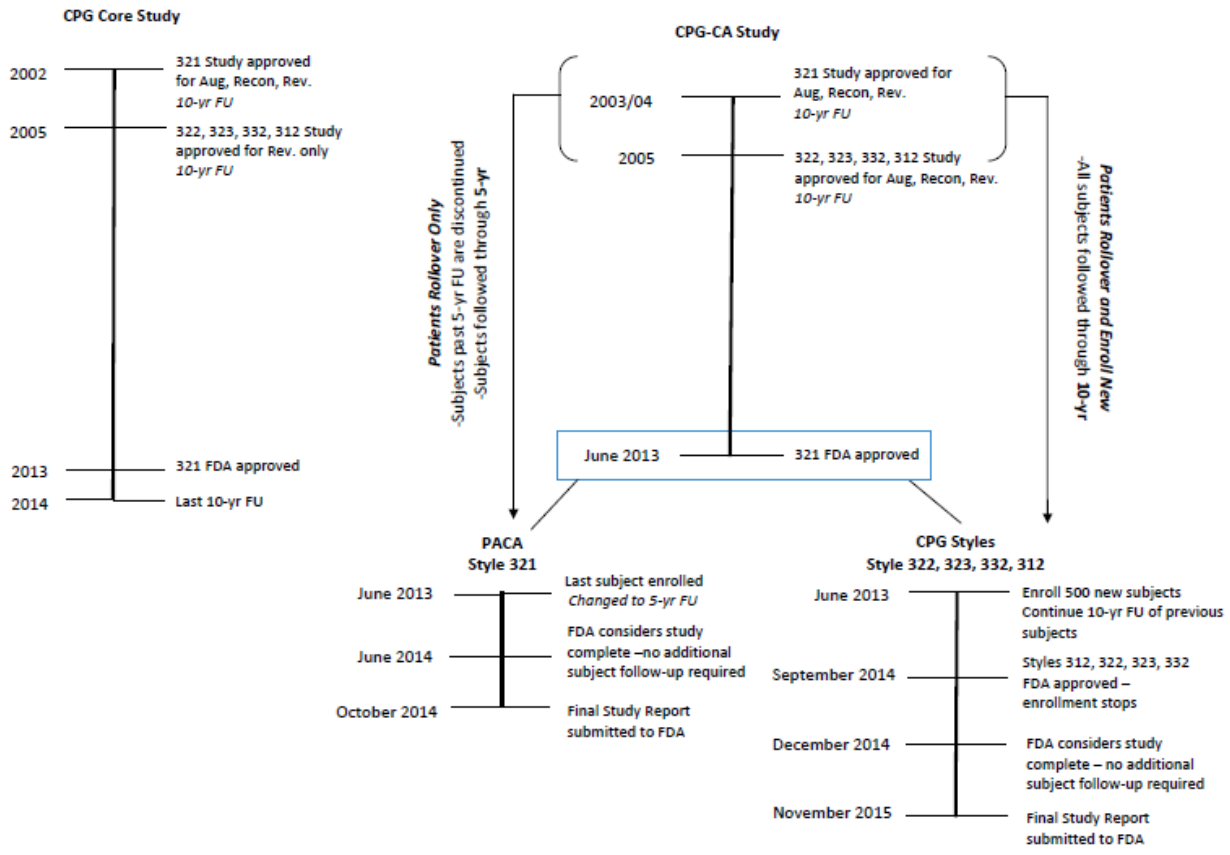
In total, 1891 female subjects were enrolled in the Styles Study (n=1132 primary augmentation, n=209 revision augmentation, n=369 primary reconstruction, n=181 revision-reconstruction; see Figure, Supplemental Digital Content 1). Supplemental Digital Content 2 provides safety outcomes reported in the Styles Study. Seven primary augmentation subjects and 2 primary reconstruction subjects had a new diagnosis of breast cancer. Overall, 1 late seroma, defined as a seroma that first presented clinically ≥1 year after the most recent breast surgery, was identified in one primary reconstruction subject. Another primary reconstruction subject was diagnosed with ALCL. Five subjects had suspected or confirmed rupture(s) (n=1 primary augmentation, n=1 revision-augmentation, n=3 primary reconstruction). Twelve subjects had a

new diagnosis of connective tissue, autoimmune, or rheumatic disease (n=6 primary augmentation, n=2 revision-augmentation, n=3 primary reconstruction, n=1 revision-reconstruction). Postoperatively, 74 subjects reported at least one pregnancy. Of the 34 subjects who reported that they attempted to breastfeed and answered the question, 29 (85.3%) subjects reported that they had adequate milk.

CONCLUSION

The results of these studies continue to demonstrate that CPG/MS Breast Implants are safe. Subjects in both studies exhibited 9-year complication rates similar to or lower than the rates in the Core Study.

CPG Study Flowchart.



KM Estimated 9-year cumulative incidence rates for key complications (patient level).

	Styles				PACA			
	Prim Aug (%)	Rev Aug (%)	Prim Recon (%)	Rev Recon (%)	Prim Aug (%)	Rev Aug (%)	Prim Recon (%)	Rev Recon (%)
Baker Grade III/IV Capsular Contracture	2.0	1.6	20.2	7.8	0.9	1.5	5.3	12.1
Infection	1.0	1.0	2.4	2.3	0.6	1.4	0.6	3.2
Explantation w/ or w/o replacement	5.0	23.6	30.9	19.2	5.6	13.1	13.0	37.3
Explantation w/ study device replacement	1.9	17.3	16.8	4.4	1.3	3.3	7.6	19.8
Any reoperation	8.8	28.9	41.8	33.9	11.3	21.0	25.5	48.7