

Appendix IV: Summary of Propensity Score Stratification in the SurgiMend Study

In the SurgiMend study, study subjects were stratified into 5 strata according to the propensity score quintiles of the SurgiMend subjects, so that each stratum had roughly equal number of SurgiMend subjects (Table 1).

Table 1. Number of Subjects from the SurgiMend and Control Groups Within Each Propensity Score Stratum

Group	Propensity score stratum					Total
	1	2	3	4	5	
SurgiMend	23	24	24	24	24	119
Control	404	198	122	93	51	868

To assess the overlap in propensity scores between the two study groups within each stratum, the boxplots of propensity score distribution per stratum for each study group are presented in Figure 1. It shows acceptable overlap in propensity score distribution between the two study groups in each stratum.

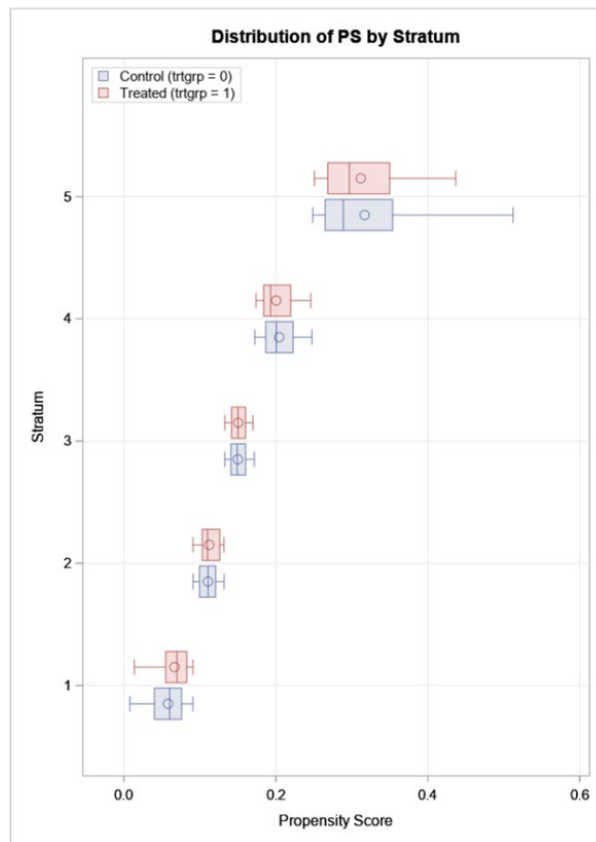


Figure 1. Overlap of propensity scores between the SurgiMend and control groups within each propensity score stratum

To further assess baseline covariate balance between the two study groups after the propensity score stratification, the standardized mean differences for each identified covariate between the SurgiMend and control groups, before and after propensity score stratification, are presented in Figure 2. After the propensity score stratification, the standardized mean differences are less than 0.1 for all controlled baseline characteristics, indicating acceptable covariate balance between the two study groups.

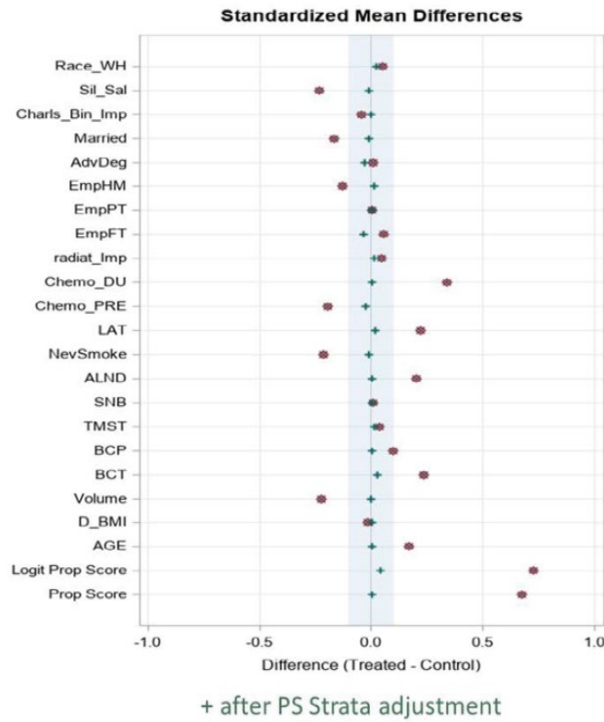


Figure 2. Standardized mean difference for each covariate between the SurgiMend and control groups before (*) and after (+) propensity score stratification

The above propensity score stratification was agreed to by the sponsor and FDA prior to the execution of the SAP. Consequently, the clinical outcomes were unblinded and analyzed.