SUPPLEMENTARY DATA

Evaluation of Long-Term Treatment Effect in an Intervention Trial in Type 1 Diabetes: Differences after Stimulation with Glucagon or a Mixed-Meal

Pearson's Correlations between GST and MMTT measurements in the DiaPep277® and Placebo patients.

Pearson's correlations between the absolute C-peptide AUC values at specific time points as obtained using the GST and the MMTT methods were performed separately on patients treated with DiaPep277® or placebo in the Subgroup population.

In the placebo group, the correlation coefficients (r) for C-peptide AUC values obtained by the GST and MMTT methods at individual time points were 0.73, 0.81, and 0.86 at baseline, month 12, and month 24, respectively (Figures S1A, B, C). In DiaPep277®-treated patients, the corresponding correlation coefficients were r = 0.77, 0.80, and 0.92 at baseline, month 12, and month 24, respectively (Figures S2 A, B, C)
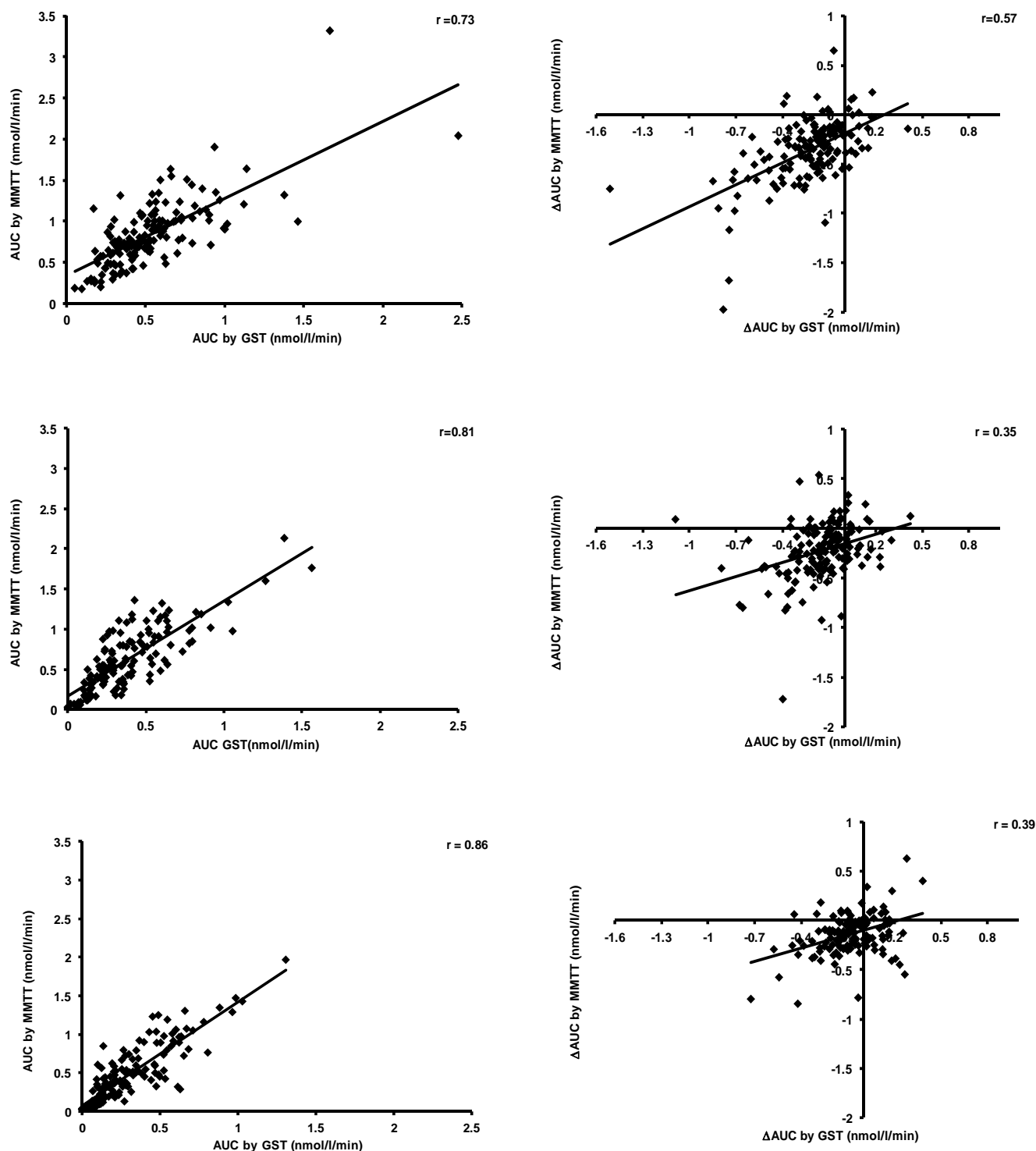
Correlations between the two stimulated C-peptide measurement methods were also obtained across time periods (ΔAUC). The correlations in the placebo group were: r= 0.57 across the whole study period (baseline–month 24); r = 0.35 during the first year of the study (baseline–month 12); and r = 0.39 during the second year (month 12–month 24) (Supplemental Figure S1D, E, F). In the DiaPep277® group, the corresponding correlations were: r= 0.59 across the whole study period (baseline–month 24); r= 0.42 during the first year of the study (baseline–month12); and r = 0.49 during the second year (month 12–month 24) (Supplemental Figure S2 D, E, F).

Bland-Altman plots were used to assess homogeneity of error variation over the range of subject values. The difference between the percent change in AUC by MMTT and that by GST was plotted against the average percent change of the two methods for each subject (Bland JM and Altman DG. Statistical methods for assessing agreement between two methods of clinical measurements. Lancet 8476: 307-10, 1986) (Supplemental Figure S3).
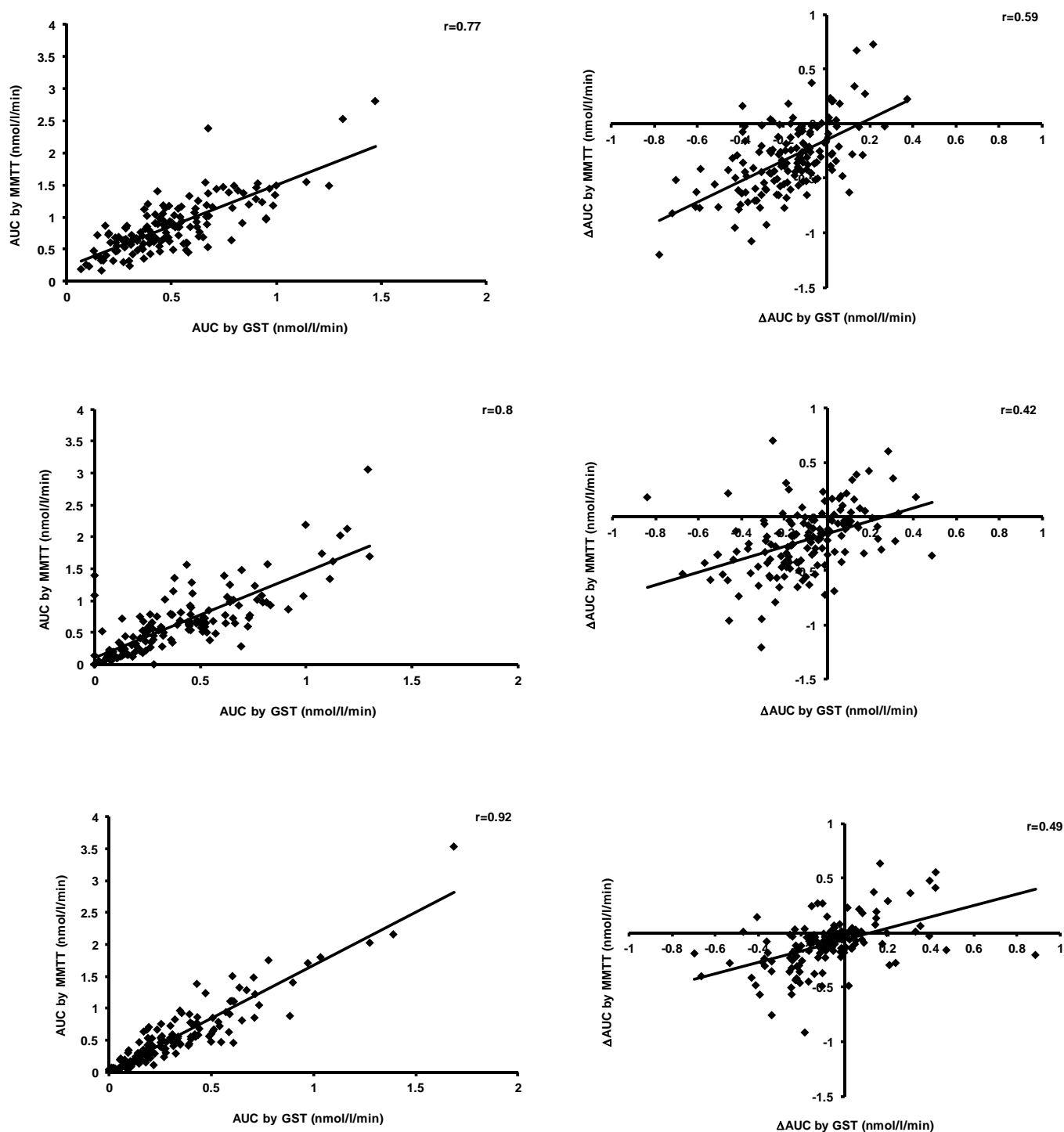
The Kappa coefficient agreement is 0.53.

SUPPLEMENTARY DATA

Supplementary Figure 1. Placebo-treated patients in the Subgroup Population. Correlations between the GST and MMTT methods for obtaining the area under the curve (AUC) for stimulated C-peptide secretion at: (A) baseline; (B) month 12; and (C) month 24. Correlations between the GST and MMTT methods for obtaining changes in the AUC values (ΔAUC): (D) from baseline to month 24; (E) from baseline to month 12; (F) from month 12 to month 24. Each data point represents a single patient.

SUPPLEMENTARY DATA

Supplementary Figure 2. DiaPep277®-treated patients in Subgroup Population.Correlations between the GST and MMTT methods for obtaining the area under the curve (AUC) for stimulated C-peptide secretion at: (A) baseline; (B) month 12; and (C) month 24 . Correlations between the GST and MMTT methods for obtaining changes in the AUC values (ΔAUC): (D) from baseline to month 24; (E) from baseline to month 12; (F) from month 12 to month 24. Each data point represents a single patient.

SUPPLEMENTARY DATA

Supplementary Figure 3. Bland-Altman Plot: Average and difference of AUC Relative Change (%) GST and MMTT.