



Sustainable Improvement in Quality of Blood Glucose Control in Users of mySugr's Integrated Diabetes Management Solution

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BACKGROUND

The mySugr app is the most widespread mobile health application in the diabetes industry, reaching 1.7M patients in over 60 countries. The positive impact of the application among users has previously been reported, indicating reduction of risk scores and improvement of blood glucose (BG) control in a number of user groups with Type 1 Diabetes¹⁻³. mySugr's Integrated Diabetes Management solution, the mySugr Bundle (Figure 1), introduces unlimited test strip delivery and Certified Diabetes Educator (CDE)-led coaching. In a previous retrospective study we looked at real world changes in BG in a US population of mySugr Bundle users⁴. In this follow up study we extended the observation period of intervention to further analyse the course of effect seen before.



Figure 1. The mySugr Bundle consists of the mySugr app, unlimited and usage-based resupply of teststrips and CDE-led glucose-centric coaching via in-app messaging interface.

METHODS

We analyzed changes in BG control (BG-mean, BG-SD, estimated A1c (eA1c)⁵, tests in range (TIR), tests above range) and frequency of testing. Participants monitored BG ≥ 3 times/day on average during the observation period. Data from the first 2 weeks after registration for the app (t_0), 0 to 8 weeks before (t_1), 0 to 8 weeks after (t_2) and 8 to 16 weeks after (t_3) initiation of Bundle usage were aggregated and statistically compared using paired two-sided t-tests ($p < 0.05$). Study participants were 61 users; 59% with type 1 diabetes, 32.8% with type 2 diabetes, 6.6% with LADA and 1.6% with an unreported diabetes type.

At baseline, BG-mean was 152.0 ± 39.3 mg/dl, BG-SD was 56.0 ± 23.7 mg/dl, eA1c was $6.9 \pm 1.4\%$, tests in range was $65 \pm 24\%$ and tests above range was $32 \pm 24\%$.

RESULTS

Significant improvements were observed in BG-mean (-11.8 mg/dl, Figure 2), BG-SD (-5.48 mg/dl), TIR ($+6.8\%$, Figure 3), tests above range (-7.2%) and eA1c (-0.41%)⁶ between t_0 and t_3 (Table 1). A significant improvement was also observed in monitoring frequency ($+21.4\%$) between t_1 and t_3 (Figure 4). Further, the participants were split into three equally-sized subgroups by their baseline eA1c (after registration). The above analysis was repeated for each subgroup.

Subgroup 1 ($n=20$) was defined by a baseline eA1c between 5.0% and 6.2%. At baseline, BG-mean was 115.5 ± 10.7 mg/dl, BG-SD was 36.3 ± 16.1 mg/dl and TIR was $87 \pm 12\%$.

Subgroup 2 ($n=20$) was defined by a baseline eA1c between 6.2% and 7.1%. At baseline, BG-mean was 142.8 ± 8.2 mg/dl, BG-SD was 56.8 ± 19.7 mg/dl and TIR was $71 \pm 11\%$.

Subgroup 3 ($n=21$) was defined by a baseline eA1c between 7.1% and 10.6%. Baseline BG-mean was 195.5 ± 32.6 mg/dl, BG-SD was 74.1 ± 18.3 mg/dl and TIR was $40 \pm 17\%$.

Subgroup analysis showed no significant changes for subgroups 1 and 2 over time. However, for subgroup 3 significant ($p < 0.01$) improvements in mean BG (-42.3 mg/dl), standard deviation (-14.7 mg/dl), tests in range ($+24\%$), tests above range (-25%) and eA1c (-1.48%) were observed from t_0 to t_3 (Table 2).

Table 1. Study participants were 61 users. All metrics show significant improvement when comparing t_3 to the baseline t_0 .

Value	t_0	t_3	$\Delta(t_0 \rightarrow t_3)$	$P(t_0 \rightarrow t_3)$
BG-mean (mg/dl)	152.0	140.2	-11.8	0.029
BG-SD (mg/dl)	56.0	50.5	-5.5	0.027
eA1c (%)	6.92	6.51	-0.41	0.029
Tests in range (%)	65.5	72.3	+6.8	0.040

Table 2. Subgroup 3 ($n=21$) was defined by a baseline eA1c between 7.1% and 10.6%. All metrics show significant improvement when comparing t_3 to the baseline t_0 . The amount of improvement (delta) is considerably higher for subgroup 3 compared to subgroups 1 and 2 where no significant changes were observed (data not shown).

Value	t_0	t_3	$\Delta(t_0 \rightarrow t_3)$	$P(t_0 \rightarrow t_3)$
BG-mean (mg/dl)	195.5	153.1	-42.3	< 0.001
BG-SD (mg/dl)	74.1	59.3	-14.7	0.004
eA1c (%)	8.44	6.96	-1.48	< 0.001
Tests in range (%)	39.9	64.3	+24.4	< 0.001

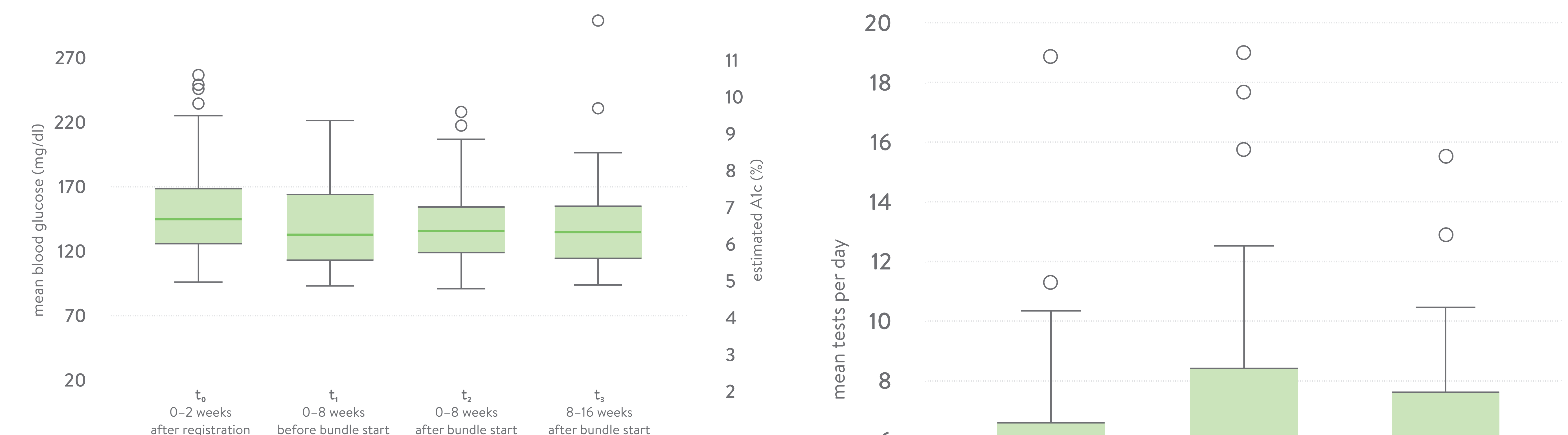


Figure 2. Variability of mean BG within the sample ($n=61$) and across the four time periods. A significant reduction of mean BG occurs compared to the baseline t_0 .

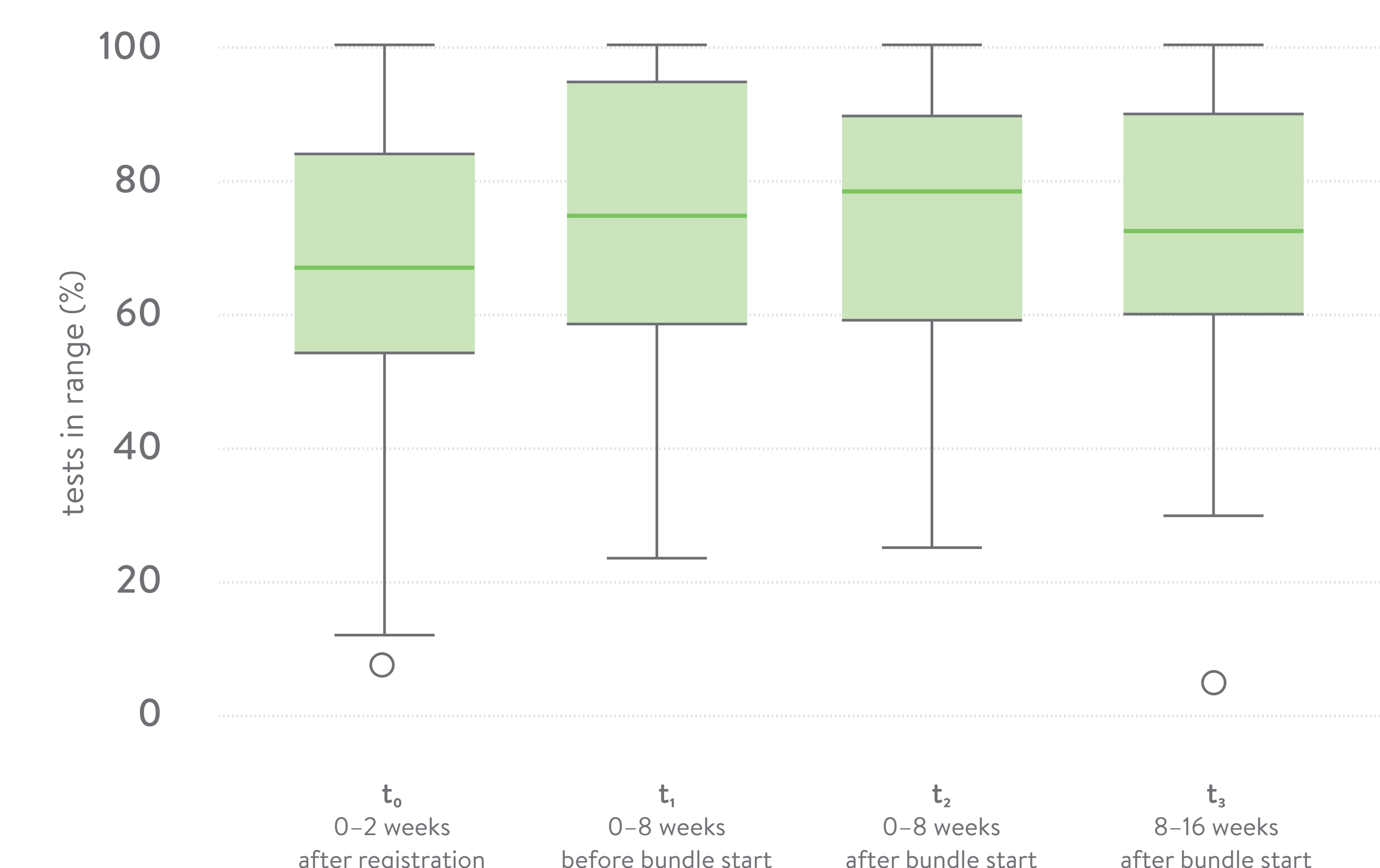


Figure 3. Variability of the percentage of tests in range within the sample ($n=61$) and across the four time periods. A significant increase of tests in range occurs compared to the baseline t_0 .

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¹ Hompesch M, Kalcher K, and Dehong F, "High Risk Population Using Mobile Logging Application Shows Significant Reduction in LBG1", Diabetes, vol. 66, no. suppl 1, p. 952-P, 2017

² Hompesch M, Kalcher K, Dehong F, and Morrow L, "Significant Improvement of Blood Glucose Control in a High Risk Population of Type 1 Diabetes Using a Mobile Health App – A Retrospective Observational Study", DTT, vol. 64, no. suppl 1, p. 2337, 2017.

³ Hompesch M, Hergesheimer L, Kalcher K, Boubela R, and Dehong F, "Retrospective analysis of Impact on SMBG and Glycemic Control of Mobile Health (mHealth)-Application for Diabetes Management," JDST, vol. 11, no. 2, p. 346-437 (A31), 2017.

⁴ Hompesch M, Scheiner G, Schuster L, Kober J. "Clinically relevant improvement in quality of blood glucose control in well controlled users of mySugr's mobile diabetes management tool". Presented at the Diabetes Technology Meeting. November 8-10, 2018, Bethesda, Maryland, USA.

⁵ Kahn R, Fonseca V, "Translating the A1C assay". Diabetes Care. 2008;31(8):1704-1707. doi:10.2337/dc08-0878.

⁶ An indicated clinically relevant change in eA1c defined as $\geq 0.3\%$ according to EMA guidelines; European Medicines Agency, Guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus, CPMP/EWP/1., May. European Medicines Agency, 2012.