

Bridging Clinical Trials and Real-Life: The Impact of a Bolus Calculator App on Glycemic Control



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Background

State-of-the-art diabetes self-management includes software tools like Bolus Calculators to aid in therapeutic decisions. While clinical trials prove safety of such devices, they can’t always mimic real-life. Our previous work established an innovative “**evidence generation continuum**” including human factors engineering, real-world data, and patient-reported outcomes.

This study assesses glycemic control changes after 3 months of continuous Bolus Calculator use, considering baseline glycemia and customization of default settings.

Results

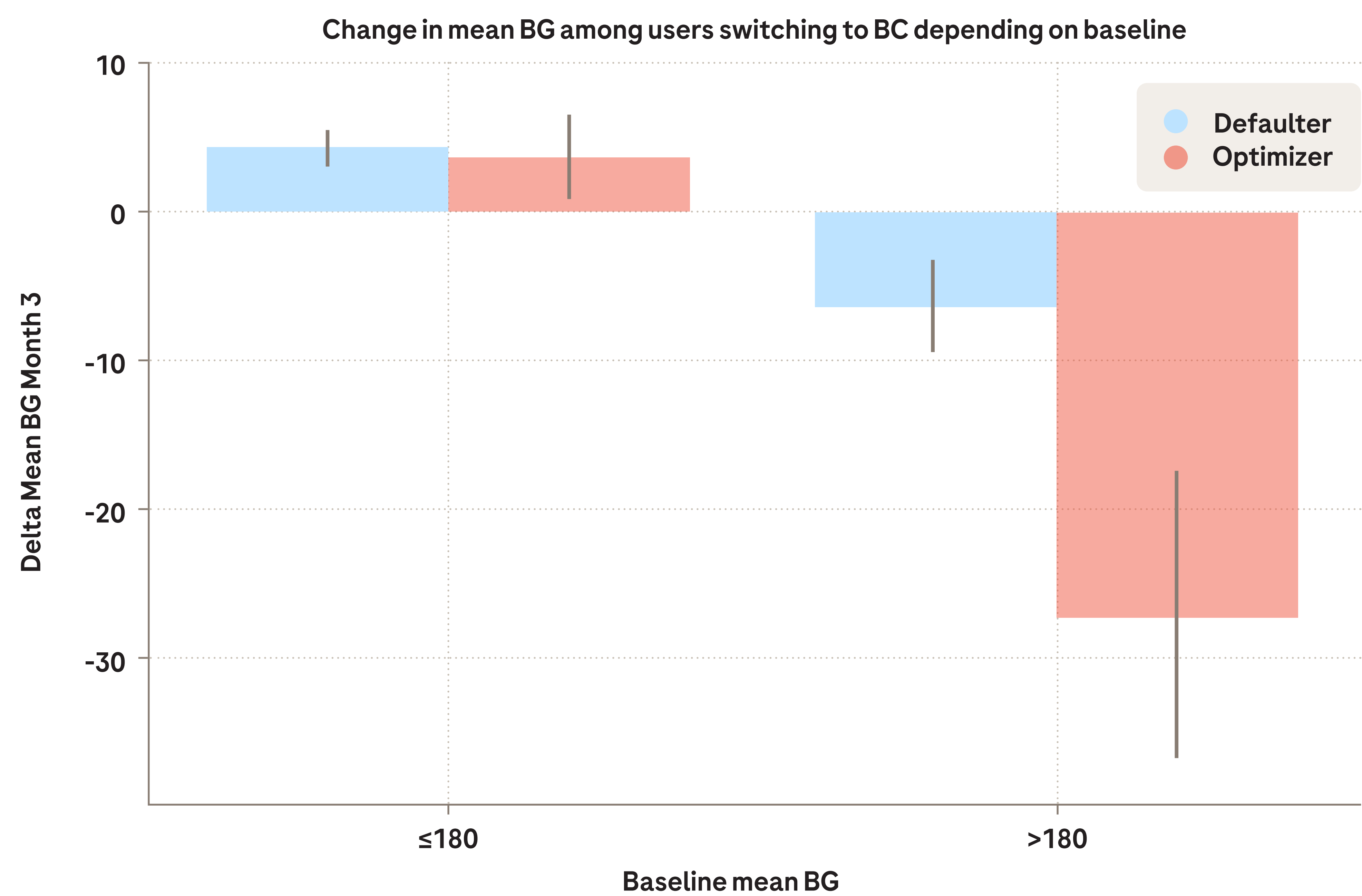
The entire cohort showed stable mean BG values (Eichinger et al., 2024). Users with baseline BG >180 mg/dl experienced a statistically significant ($p<0.01$) and clinically relevant decrease in mean BG by 10.4 mg/dl after three months. Changes for users with initial BG ≤ 180 mg/dl were not clinically relevant (+3.9 mg/dl ($p<0.01$)).

Moreover, users **above 180 mg/dl baseline mean BG who adjusted the settings** according to their therapy needs (“Optimizers”) **reduced their mean BG by 27.4 (± 4.7) mg/dl and CV above 36% by 4.27%** ($p<0.001$), respectively.

Methods

A statistical analysis of real-world data evaluated the safety and effectiveness of the mySugr® Bolus Calculator. Data from users (N=3436) transitioning from a legacy device to the current version, were collected. Follow-up analyses focused on a subgroup of highly engaged users (n=2076) and examined changes in monthly mean blood glucose (BG) and glycemic variability (CV) from one month before use, to 3 months after. Changes were stratified by baseline mean BG ($\leq /> 180$ mg/dl), and customization of Bolus Calculator settings (n=1701 “Defaulters” who did not change their settings, n=375 ‘Optimisers’ who customised their Bolus Calculator settings).

Changes in mean BG



Take-away

Bolus Calculator results can be significantly improved if the settings are customised according to the users needs.

References:
Eichinger, V., de Klepper, M., Zivkovic, J., Malenczyk, K., Theodorou, D., Heinemann, L., & Silbermann, S. (2024). Systematic Improvement of a Bolus Calculator That Is on the Market: A User-Centric Approach. Journal of diabetes science and technology, 19322968241266204. Advance online publication. <https://doi.org/10.1177/19322968241266204>