



Real World Experience with Bigfoot Unity: A 2-Year Retrospective Analysis

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Background

- The Bigfoot Unity System (System) is a smart pen cap system that incorporates data from the FreeStyle Libre 2 Sensor and provides clinician-directed dose recommendations.
- The objective was to analyze real world 2-year data for a large cohort using the System for multiple daily injections (MDI).

Methods

- De-identified data and a prespecified analysis plan was reviewed by a central institutional review board (IRB) and deemed exempt from IRB oversight.
- A retrospective analysis was performed for those using the System >50% of the time in the 90 days prior to the 24-month period (641-730 days). Outcomes for the cohort (N=310) are also reported for 3-month (0-90 days), 6-month (91-180 days) and 12-month (276-365 days) periods. Due to the retrospective nature, sample size was not based on statistical power.
- Selection criteria were 1) persons with diabetes completing training and initiating System use (Day 0), 2) at least 45 use-days and >45 CGM or BGM readings within the 24-month period, and 3) baseline

HbA1c from clinic records, prior to starting the System (within -120 to 0 days).

- The broad requirement of 45 use-days and >45 glucose readings in the 24-month period was to represent real-world use and avoid bias towards only highest System users. A use-day was defined as any day with a long- or rapid-acting insulin dose, glucose reading, or a CGM scan.
- Post-market surveillance data was derived from Medical Device Reports (MDRs) to the FDA.
- Given the limitation of having only baseline HbA1cs, estimated HbA1c (GMI) was used as a proxy to perform statistical comparisons of HbA1c data at baseline and GMI in the 24-month period of use. Differences between median baseline HbA1c and median estimated A1C (GMI) in the 24-month period was tested with the Wilcoxon signed rank test; a P-value <0.05 was considered statistically significant.

Results

- Mean age was 66.6 years and 88.1% had T2D.
- Using estimated HbA1c (GMI), improvement from baseline HbA1c was $1.3 \pm 1.8\%$ at 24 months and statistically significant (Figure 1 & Table 2; $p < 0.0001$). Similar improvement was observed at 3, 6 and 12 months (Figure 1).
- TIR was $63.0 \pm 22.2\%$ and $48.5 \pm 20.0\%$ for T2D and T1D subgroups, respectively; total time below range was $1.2 \pm 1.9\%$ and $2.6 \pm 2.6\%$, respectively (Table 1).
- During the 2-year period, the System was used, on average, for 91.6% of days with a long-acting insulin dose recorded on 66.4% of days (Table 1).
- Over 2 years of System use, long-acting and rapid-acting insulin therapy settings were changed an average of 2.9 and 1.9 times per user, respectively. Most therapy settings changes occurred early in System use (Figure 2).
- Comparing 14-days before vs after therapy settings changes, basal insulin increases improved TIR by 6.5%, while decreases reduced TBR by 1.0%. Bolus insulin increases improved TIR by 6.4%, while decreases reduced TBR by 0.5% (Table 2).
- Figure 3 shows change in glycemic outcomes within subgroups.
- Using post-market surveillance data, ten (10) MDRs were reported from 7 persons; these included 4 serious injury reports (severe hypoglycemia) and 6 malfunctions (with no adverse events). None of the severe hypoglycemia events were related to the device.

Table 2: Impact of Insulin Setting Changes

		Increase Insulin		Decrease Insulin	
		Long-acting	Rapid-acting	Long-acting	Rapid-acting
TIR (%)	Pre-Setting Change	45.3	44.8	70.4	67.4
	Post-Setting Change	51.8	51.2	68.8	67.5
	Difference	+6.5	+6.4	-1.6	+0.1
TBR (%)	Pre-Setting Change	0.4	0.7	3.2	2.6
	Post-Setting Change	0.7	1.0	2.1	2.2
	Difference	+0.3	+0.3	-1.0	-0.5

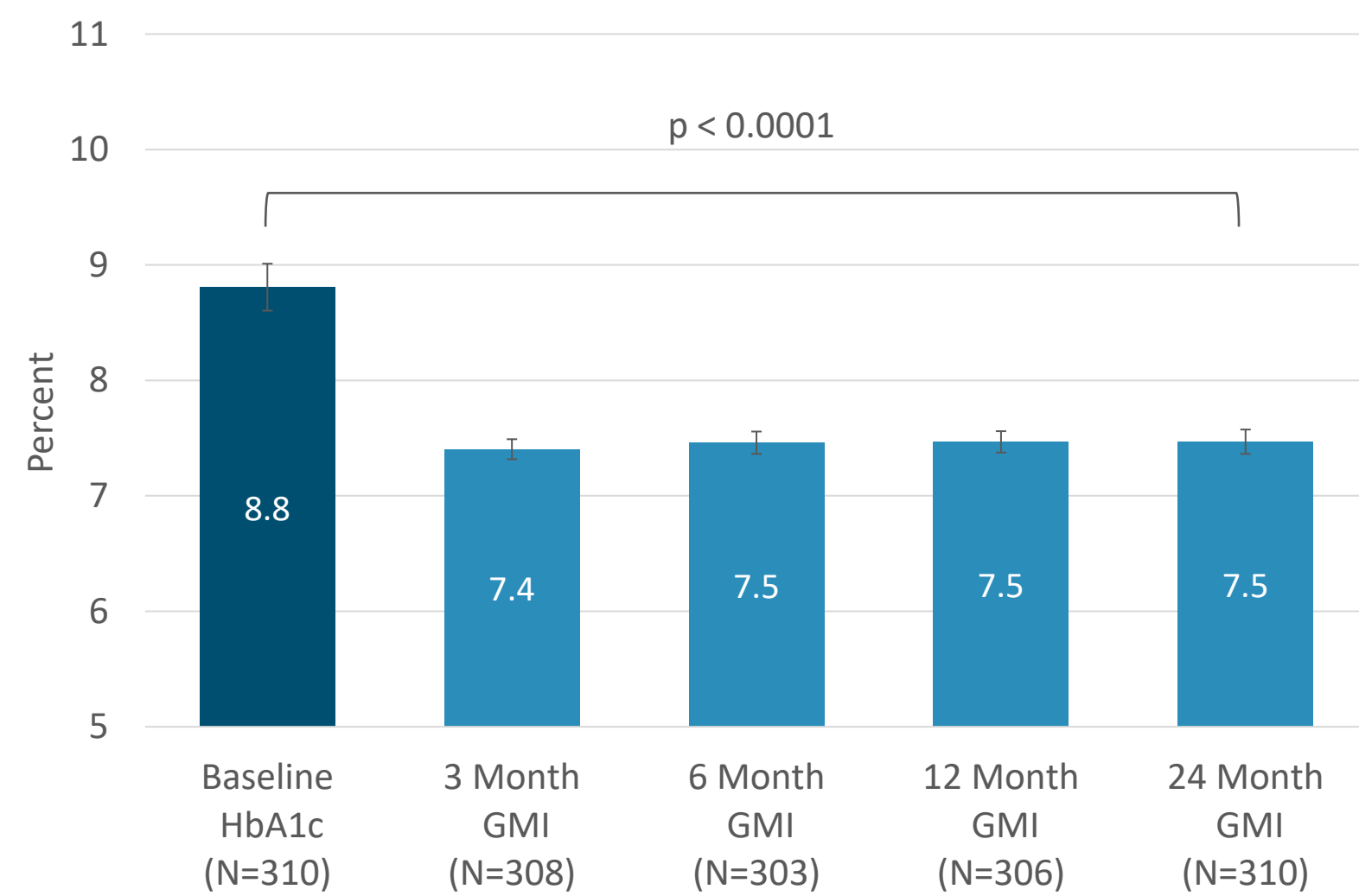


Figure 1: GMI compared with baseline A1C. Mean and 95% CI are shown for baseline HbA1c and GMI in the 3-, 6-, 12-, and 24-month analysis periods. The baseline HbA1c was compared to 24-month GMI using the Wilcoxon signed rank test.

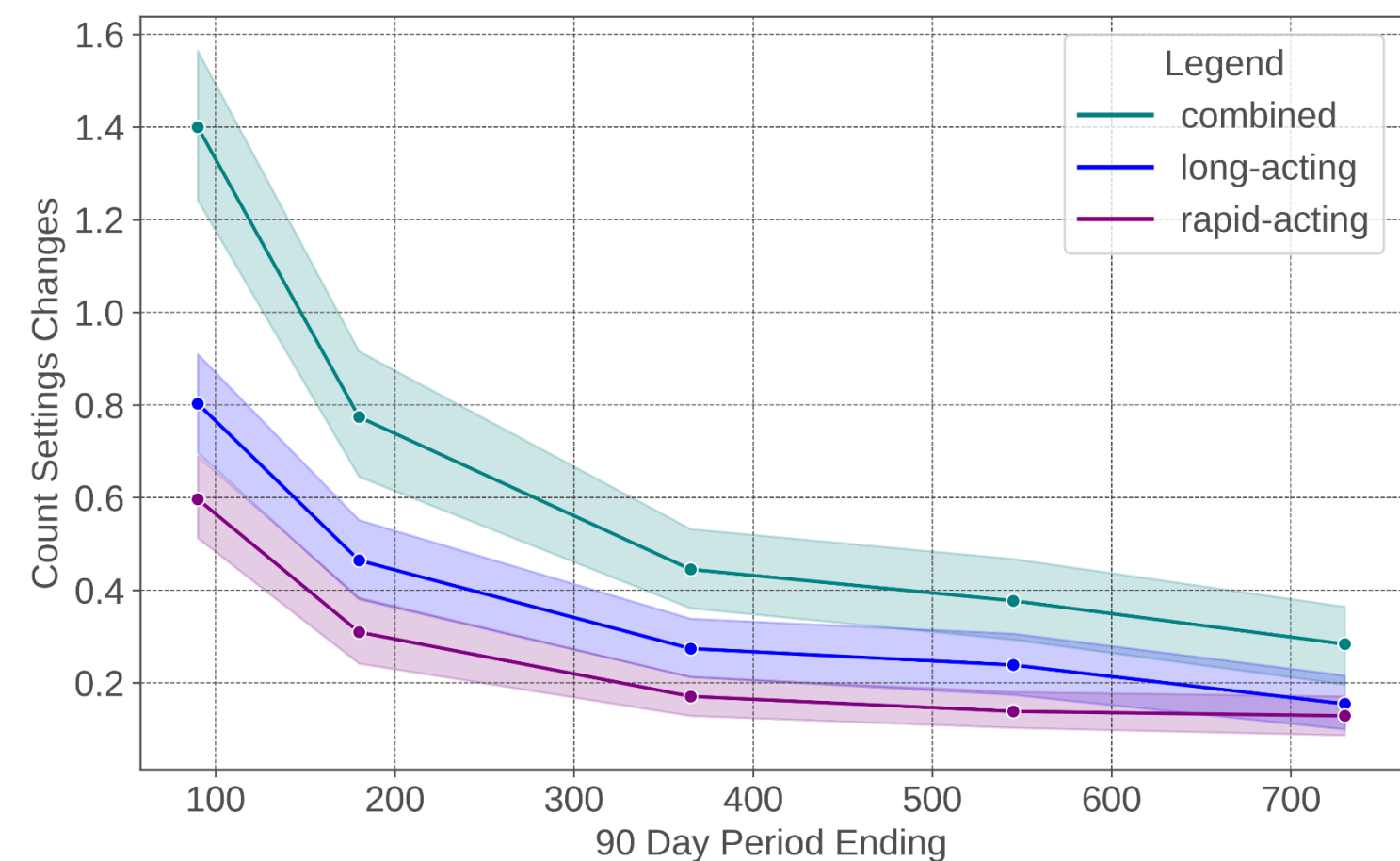


Figure 2: Insulin Settings Changes Over Time. Mean and 95% CI are shown for the total number of insulin settings changes (green line) and those specific for long-acting insulin (blue line) and rapid-acting insulin (red line) over the 2-year analysis period.

Table 1: Glycemic Outcomes and System Use Parameters in 2-Year Period

	Total (N=310)	T2D (N=273)	T1D (N=37)
Change of estimated A1C (GMI) from baseline A1C, mean (SD)	-1.3 (1.8) ^a	-1.4 (1.8) ^a	-0.7 (1.8)
Glucose Management Indicator (GMI), mean (SD)	7.5 (0.9)	7.4 (0.9)	8.0 (1.0)
Average glucose, mean (SD)	173.9 (39.6)	171.1 (38.4)	194.6 (42.8)
Coefficient of variation, mean (SD)	31.6 (6.7)	30.8 (6.5)	37.0 (6.3)
Percent Sensor time in ranges:			
70-180 mg/dL, mean (SD)	61.3 (22.4)	63.0 (22.2)	48.5 (20.0)
>180 mg/dL, mean (SD)	37.3 (22.6)	35.7 (22.5)	48.9 (20.5)
>250 mg/dL, mean (SD)	13.8 (16.2)	12.5 (15.4)	23.9 (18.5)
<70 mg/dL, mean (SD)	1.4 (2.1)	1.2 (1.9)	2.6 (2.6)
<54 mg/dL, mean (SD)	0.2 (0.4)	0.1 (0.3)	0.5 (0.7)
Percent of days of System use, mean (SD) ^b	91.6 (13.7)	91.9 (13.4)	89.8 (15.4)
Percent of days with a long-acting insulin dose, mean (SD) ^b	66.4 (33.0)	65.9 (33.0)	70.2 (33.0)
Percent of days with ≥2 rapid-acting insulin dose, mean (SD) ^b	56.7 (32.1)	55.6 (31.9)	64.7 (33.2)
Glucose readings/day, mean (SD)	61.1 (21.2)	60.6 (21.2)	64.7 (21.1)

^aIndicates statistically significant difference of 2-year period result from baseline ($p < 0.0001$).

^bParameter is expressed as a percentage, using the 90-day analysis period as the denominator.

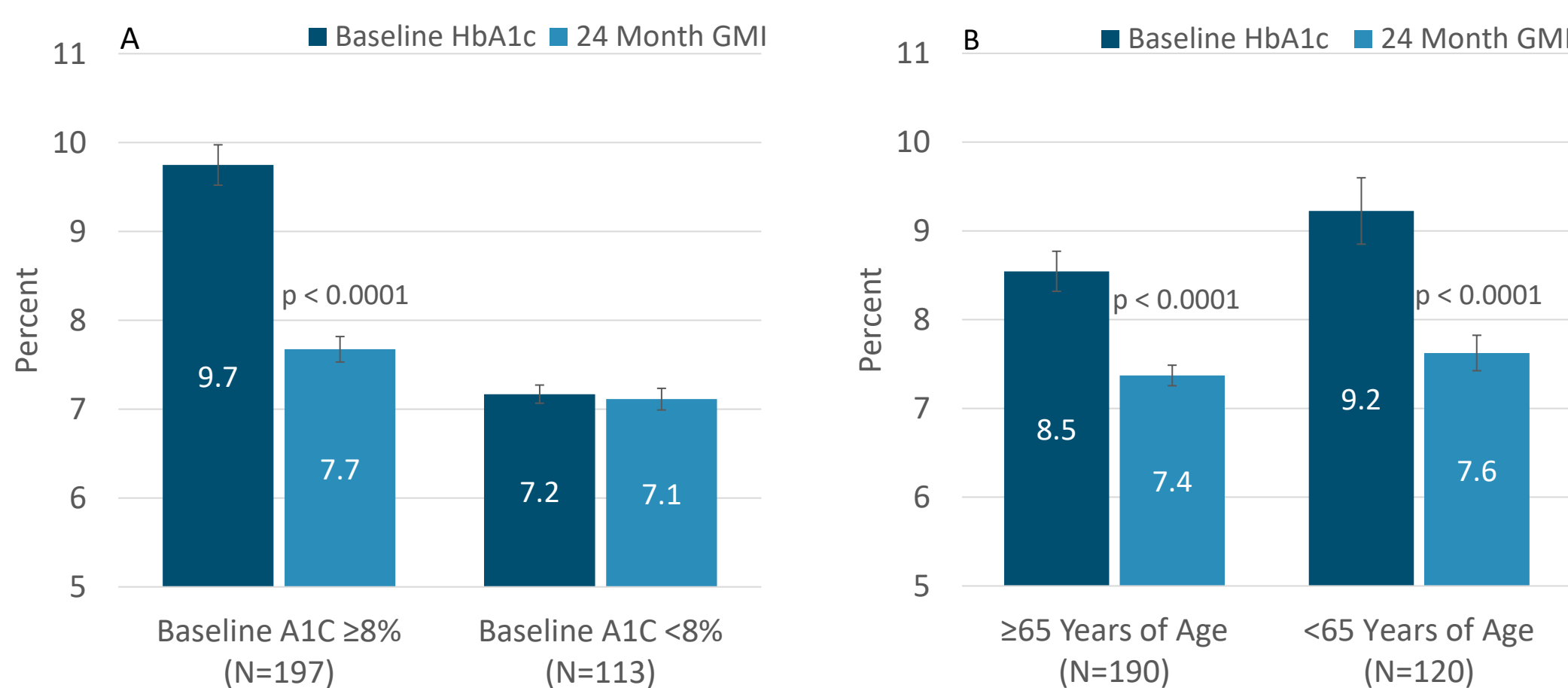


Figure 3: GMI compared with baseline A1C in subgroups. Mean and 95% CI are shown for baseline HbA1c and GMI in the 2-year analysis period. Baseline HbA1c was compared to GMI using the Wilcoxon signed rank test.

Discussion

- Across the cohort, using GMI as a proxy of HbA1c, ~1.3% improvement was observed at 3 months and sustained through 24 months. Results demonstrate improvement towards established glycemic targets.¹⁻³ Improvement was larger for those with baseline HbA1c ≥8%; both older and younger subgroups had significant improvement.
- Most therapy settings changes occurred early in System use, when most glycemic improvement was observed (i.e., within the first 3 months). Therapy settings changes were relatively infrequent over the 2-year period, especially after the initial 3 months. This may reflect the common occurrence of clinical inertia.
- On average, those with settings changes to decrease insulin were close to TIR goals but had higher TBR (>2.5%), resulting in improved TBR (~2%) with only slight changes in TIR. Those with settings changes to increase insulin started further from TIR goals with TBR <1%, resulting in clinically significant improvement in TIR without substantial increases in TBR (overall ≤1%).
- Maintenance of improved glycemia from 3 through 24 months was achieved despite possible missed injections which may impact ability to meet glycemic targets.^{4,5}
- The rate of severe hypoglycemia and DKA events was relatively low but may be underestimated due to the retrospective nature of the study using post-market surveillance.
- Limitations of this analysis include the retrospective design and lack of a control group. HbA1cs during System use were not available, but strong correlation between A1C and GMI support using GMI as a proxy of A1C.^{6,7}

Conclusions

- For this cohort, consisting primarily of older adults with T2D above goal, using the System resulted in durable improvement in glycemia from 3-24 months. The magnitude of improvement was larger in a subset further from established goals (e.g., baseline HbA1c ≥8%).
- Observed sustained glycemic improvement up to 24 months using the System is encouraging. More frequent insulin therapy settings changes and engagement for missed doses may help achieve results closer to established glycemic targets of HbA1c/GMI of 7%.¹⁻³

References

- Battelino T, et al. Diabetes Care 2019;42(8):1593-603.
- American Diabetes Association. Diabetes Care. 2023;46(Suppl 1):S97-S110.
- American Diabetes Association. Diabetes Care. 2023;46(Suppl 1):S216-S229.
- Randlov J, Poulsen JU. J Diabetes Sci Technol. 2008;2(2):229-235
- Burdick J, et al. Pediatrics. 2004;113(3 Pt 1):e221-4.
- Bergental RM et al. Diabetes Care. 2018;41(11):2275-80.
- Al Hayek AA, et al. Diabetes Therapy. 2022;13(5):953-67.

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