First Real-World Experience With Bigfoot Unity: A 6-Month Retrospective Analysis

Bantwal S. Baliga,[1] John B. Tillman,[2] Byron Olson,[2] Sarah Vaughan,[2] F. Naureen Sheikh,[2] and James K. Malone[2]

The Bigfoot Unity Diabetes Management System, a smart pen cap system cleared by the U.S. Food and Drug Administration in May 2021, incorporates continuous glucose monitoring data, real-time glycemic alerts, and clinician-directed dose recommendations. This study analyzed real-world clinical outcomes data for an initial cohort (*n* = 58, from 13 clinics) managing multiple daily injection insulin therapy using the pen cap system for 6 months. We examined glycemic control, including hypoglycemia events and interaction with and use of the pen cap system. In a cohort mainly consisting of adults with type 2 diabetes and an average age of 62 years, the results demonstrate close adherence to established glycemic targets, including a relatively short amount of time spent in the hypoglycemic range.

KEY POINTS

- Compared to the mean baseline A1C and using the glucose management indicator (GMI) as a proxy for A1C, there was an improvement in glycemic control of ∼1% with use of the Bigfoot Unity smart pen cap system. Individuals with higher baseline A1C, on average, had the largest decrease in GMI, while those with lower baseline A1C had smaller changes.
- The overall times spent with glucose <70 and <54 mg/dL, on average, were ∼1.4% and ∼0.2%, respectively in the sixth month of pen cap system use, which is below the recommended targets of <4% and <1%, respectively.
- This new diabetes management system may be a useful tool for clinicians and their patients managing multiple daily injection insulin therapy.

The worldwide prevalence of insulin-requiring diabetes is estimated at ∼200 million individuals and is increasing (1). In the United States alone, an estimated 10 million people require insulin (1–3). Living with diabetes is associated with physical, cognitive, and emotional burdens that may be more pronounced in traditional multiple daily injection (MDI) insulin therapy because of the complex, demanding, and often confusing self-care directives associated with this regimen (4–8).

At clinic visits, physicians often do not have enough glucose and dosing information available to make informed adjustments to the prescribed insulin dosing regimen. Although there have been significant advances in tools and technologies available to people with diabetes, these advances historically have focused on solutions for individuals using insulin pumps (7,9). Simple, intuitive, integrated smart pen systems are needed to help those managing diabetes with an MDI insulin regimen overcome the barriers of missed doses, inadequate insulin intensification, and dosing errors (10).

The Bigfoot Unity Diabetes Management System (Bigfoot Biomedical, Inc., Milpitas, CA) is a unique, interconnected diabetes management system designed to enable a holistic approach to address common barriers to MDI therapy. Bigfoot Unity is a smart pen cap system compatible with most commercially available, disposable pens for long- and rapid-acting insulin analogs. The system integrates with the commercially available FreeStyle Libre 2 continuous glucose monitoring (CGM) system (Abbott Diabetes Care, Alameda, CA) to incorporate CGM data and enable real-time glycemic alerts. The Bigfoot Unity mobile app is used to enter prescribed insulin doses from a health care professional (HCP), generate and display alerts and messaging about the user's glucose range, and store historical information, including glucose data and insulin dose timing. The

[1]East Alabama Endocrinology PC, Opelika, AL; [2]Bigfoot Biomedical, Inc., Milpitas, CA

Corresponding author: John B. Tillman, jtillman@bigfootbiomedical.com

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digital pen cap for rapid-acting insulin scans the CGM sensor and displays recommended meal and correction insulin doses based on HCP instructions and the current glucose value. The cap for long-acting insulin displays the recommended dose and time of last dose, and the app can alert users when a long-acting dose may have been missed. A connected blood glucose meter (Agamatrix, Salem, NH) provides flexibility for fingerstick blood glucose measurement when needed. Cloud-based services enable data to be passively shared from the mobile app to the Cloud for data analysis and sharing with an HCP through Bigfoot's Clinic Hub. Three-month real-world outcome data for individuals using the system were presented previously (11); here, we report 6-month outcome data.

Research Design and Methods

Study Design

We used de-identified data from the Bigfoot commercial database and a prespecified research analysis plan to perform a retrospective analysis. The prespecified research plan was reviewed by a central institutional review board (IRB) and deemed exempt from IRB oversight. Although Bigfoot Unity is indicated for individuals ≥12 years of age, no one <18 years of age was using it. All those who completed training and were active on the system for 6 months were included in this retrospective analysis except for those enrolled into the ongoing, prospective, Bigfoot Unity Real World Study (BURST; NCT05088265), who were excluded. A total of 75 individuals from 13 clinics met these criteria and were defined as the safety population.

Considering all of the native 15-minute-interval CGM data available from the sensor within the defined analysis periods, at least 50% of the CGM data were required within the first 2 weeks and in the sixth month of system use to be included in the analysis of glycemic and system use parameters. Using these criteria, a clinical outcomes analysis cohort (n = 58 from 13 clinics) with insulin-requiring diabetes managed with an MDI insulin regimen with use of the pen cap system for at least 180 days was identified for this analysis. Baseline A1C values from before initiation of the system (n = 51 from 12 clinics) were obtained from clinic medical records. The allowable window for baseline A1C data inclusion was −180 to +14 days from the start of pen cap use. Available A1C values from after system initiation were also obtained from clinic medical records. Thirty of the 58 individuals in the clinical outcomes analysis cohort had at least one post-initiation A1C value.

Analysis Periods

The final cutoff date for this retrospective analysis was 16 June 2022. The initial system glucose value was used to indicate the system start (day 0). The first 14 days of system use were considered the initial period for CGM metrics analysis. The 3- and 6-month end points were defined as 61–90 and 150–180 days, respectively, after system initiation.

Glycemic and System-Use Parameters

Prespecified outcomes to analyze were glucose management indicator (GMI) calculated as described by Bergenstal et al. (12), percent time in range (TIR; 70–180 mg/dL), percent times below range (<70, 54–69, and <54 mg/dL), percent times above range (>180, 181–250, and >250 mg/dL), sensor data availability (from sensor scans), mean sensor glucose, coefficient of variation, mean sensor scans, dose events, and other system interactions. For system interactions, a patient engagement proxy was prespecified as the total interactions with the system per day, combining the following data parameters captured in the commercial Cloud database: visits to the app's History or Home screen, visits to the Cap Meal screen or Meal+Correction screen, sensor scans, dose events, settings changes, and acknowledgment of low glucose, very low glucose, or long-acting dose alerts. Similarly, as a proxy for physician engagement, the average number of HCP visits per patient per week to view ambulatory glucose profile reports (accessed through Bigfoot's Clinic Hub) are reported for each time period. Prespecified subgroup analyses included those with baseline A1C ≥8% versus <8% and those with and without previous CGM experience.

As a proxy of pre- and postprandial glucose, we analyzed insulin dose events without any intervening doses within ± 2 hours. In this analysis, only doses with a valid glucose reading (e.g., from a sensor scan) occurring 10 minutes before the recorded dose were included. The valid glucose reading event allows a determination of whether a clinician-directed correction was recommended by the system at the time of the dose based on the glucose value at the time of scanning. This feature allows for aggregate analysis according to doses taken when glucose was above the target range (when a clinician-directed correction dose would be recommended by the system) versus those doses taken when glucose was in range (when a correction dose would not be recommended).

Safety Assessments

For assessing hypoglycemia, the mean numbers of unique low and very low glucose events occurring per week within each analysis period were summarized. A low glucose event was defined as glucose <70 mg/dL with subsequent recovery to >80 mg/dL. A very low glucose event was defined as glucose <55 mg/dL with subsequent recovery to >65 mg/dL. Hypoglycemia events were also summarized for the nocturnal period, defined as midnight (2400 hours) to 6:00 a.m. (0600 hours) the next day.

Post-market surveillance data were reviewed for adverse events occurring in the 75-person safety population of commercial users.

Statistical Analysis

Because this was an observational, retrospective analysis, the sample size was not based on statistical power. Analyses were prespecified to combine type 1 and type 2 diabetes, but times in ranges and GMI were tested for poolability using bootstrapping because of the small sample size of individuals with type 1 diabetes. For each metric, 1,000 random samples of size $n = 9$ (the size of the sample with type 1 diabetes) were drawn. The 2.5th and 97.5th percentiles of the bootstrapped means were used to determine whether the true mean fell within this range.

There were no attempts to account for missing data in the analyses. Depending on the distribution, repeated-measures ANOVA or Freidman tests were conducted on glycemic and system-use parameters and hypoglycemia events to assess whether there were any significant differences across time periods (2 weeks and third and sixth months). Similar methods were used to identify significant differences between baseline A1C and GMI (estimated A1C) across time periods. If the ANOVA or Freidman tests were found to be significant, subsequent paired *t* tests or Wilcoxon signed rank tests were used to test for differences between periods. All *P* values were two-sided and were not adjusted for multiple tests. A *P* value <0.05 was considered statistically significant. Analyses were conducted using Python software.

Results

Patient Characteristics

Within the clinical outcomes analysis cohort ($n = 58$), the mean age was 62.0 years (range 23–88 years) and 49 of the 58 individuals (84.5%) had type 2 diabetes. The mean duration of diabetes was 17.2 years. Most individuals (76.4%) had used CGM previously, while nearly all were new to using smart pens (96.4%) and diabetes apps (92.7%) (Table 1). The mean A1C before system use was 8.4 ± 1.8% in 51 individuals; the mean timing of the baseline A1C was 48.4 ± 33.9 days before system start.

TABLE 1 Patient Characteristics ($n = 58$)

Parameter	Value
Age, years	62.0 ± 14.2
Type 2 diabetes	49 (84.5)
Correction insulin use at start	53 (91.4)
Fixed-meal dose at start	35 (60.3)
Meal dose setup	
Breakfast, lunch, dinner	40 (69.0)
Small, medium, large	13 (22.4)
Three carbohydrate amounts	4 (6.9)
Estimated total daily dose, units	81.5 ± 46.4
Diabetes duration, years	17.2 ± 10.1
Prior CGM use*	42 (76.4)
New to smart pens*	53 (96.4)
New to diabetes apps*	51 (92.7)
Prior pump use*	3 (5.6)

Data are mean ± SD or *n* (%). *Some parameters had missing data: estimated total daily dose ($n = 57$); diabetes duration ($n = 50$); prior CGM, smart pen, and diabetes app use ($n = 55$); and prior pump use ($n = 54$).

Post-Initiation A1C

Fifty-eight post-initiation A1C values were available for 30 individuals. The mean timing of these A1C tests was 184.3 ± 101.6 days after system start. These A1C values were compared with the associated GMI values calculated for the 30-day period just before the A1C collection date. For this subset of the cohort, the mean error in the difference was 0.13 ± 0.58%, which was not statistically significant ($P = 0.42$) and suggested that GMI is a reasonable proxy for A1C metrics for this population.

Glycemic Outcomes

Mean GMI values in the first 2 weeks (days 1–14), the third month (days 61–90), and the sixth month (days 151–180) of use were 7.1 ± 0.8% ($n = 58$), 7.4 ± 0.9% ($n = 57$), and 7.3 ± 0.8% ($n = 58$), respectively (Table 2). Given the limited post-initiation A1C values, we used GMI as a proxy for A1C to perform pairwise comparisons in 50 individuals with data available from baseline through 6 months of use. The estimated improvement in glycemic control using

TABLE 2 CGM Parameters (n = 58)

Parameter	2 Weeks	Third Month*	Sixth Month
CGM data availability, %	83.0 ± 9.9	76.4 ± 17.1	79.0 ± 11.7
Coefficient of variation, %	30.1 ± 7.2	30.9 ± 6.3	30.0 ± 6.6
Glucose, mg/dL	160.4 ± 32.7†	170.7 ± 38.0	166.2 ± 31.8
GMI, %	7.1 ± 0.8†	7.4 ± 0.9	7.3 ± 0.8
Percent times in ranges, mg/dL			
70–180	67.3 ± 20.2†	61.8 ± 20.8	64.2 ± 20.3
>180	30.8 ± 20.6†	36.6 ± 21.7	34.3 ± 20.6
181–250	22.7 ± 11.9	24.8 ± 11.3	24.7 ± 11.4
>250	8.1 ± 12.6†	11.8 ± 15.5	9.6 ± 12.4
<70	1.9 ± 3.1	1.6 ± 2.7	1.4 ± 2.4
54–69	1.7 ± 2.6	1.5 ± 2.4	1.3 ± 2.1
<54	0.2 ± 0.6	0.2 ± 0.3	0.2 ± 0.4

Data are mean ± SD. *One person did not have >50% of CGM data for analysis in the third month; data reflects n = 57. †Friedman test and subsequent pairwise comparisons showed a statistically significant difference of the first 2 weeks compared with the third and sixth months (P <0.05); no other variables were found to be statistically significant using statistics appropriate to the distribution.

GMI at 2 weeks and in the third and sixth months was 1.2 ± 1.5, 1.1 ± 1.7, and 1.1 ± 1.6%, respectively, and was statistically significant compared with baseline A1C ($P < 0.05$) (Figure 1*A*). In a subset analysis of those with baseline A1C ≥8% (n = 29), the mean baseline A1C was 9.4 ± 1.7%, and GMI in the sixth month was 7.5 ± 0.8%; this change was statistically significant (Figure 1*B*). In the subgroup with starting A1C <8% (n = 22), the mean A1C was 7.0 ± 0.7%, and GMI in the sixth month was 6.9 ± 0.5%; this change was not statistically significant (Figure 1*B*).

To better understand subgroups with the greatest changes in glycemic control, a change plot for GMI in the sixth month, based on 1-point increments of baseline A1C values, was created (Figure 1*C*). Those with higher baseline A1C, on average, had the largest decrease in GMI, while those with lower baseline A1C had smaller changes. The lowest starting baseline A1C subgroups (baseline A1C in the 5 or 6% range), on average, had minimal change or slight increases in GMI.

Within a subgroup of users who had used CGM previously (n = 36), mean baseline A1C was 8.2 ± 1.6%, and GMI in the sixth month was 7.3 ± 0.7%, while improvement was greater in the small group of users who were considered CGM naive (n = 12). These individuals had a mean baseline A1C of 9.0 ± 2.3% and a GMI in the sixth month of 7.1 ± 0.9%.

Sensor use, mean glucose, coefficient of variation, and times in, above, and below range were evaluated (Table 2).

For example, TIR (70–180 mg/dL) in the first 2 weeks, third month, and sixth month of use was 67.3 ± 20.2, 61.8 ± 20.8, and 64.2 ± 20.3%, respectively. For TIR and several other related variables such as average glucose, GMI, and time above range (TAR), the first 2-week period was statistically significantly different from the third- and sixth-month periods (Table 2). Time below range (TBR; <70 mg/dL) was 1.9 ± 3.1, 1.6 ± 2.7, and 1.4 ± 2.4 in the first 2 weeks, third month, and sixth month of use, respectively, and these values were not statistically significantly different across analysis periods (Table 2).

Poolability testing demonstrated that TIR, times above range, and GMI were poolable between the type 1 and type 2 diabetes subgroups. However, TBR was not considered poolable between these subgroups. Therefore, Figure 2 shows a stacked bar chart for times in ranges by type of diabetes in the sixth month of use; total TBR was 4.0 ± 4.7 and 1.0 ± 1.3% for the type 1 and type 2 diabetes subgroups, respectively.

The average number of rapid-acting doses per day was 3.1 ± 1.3, 2.7 ± 1.0, and 2.6 ± 1.1 in the first 2 weeks, third month, and sixth month of use, respectively, and was statistically significantly different in the first 2 weeks of use (Table 3). The average number of long-acting doses per week was 7.2 ± 3.0, 6.7 ± 2.5, and 6.7 ± 2.2 in the first 2 weeks, third month, and sixth month of use, respectively, and was not statistically significantly different across time periods. When a long-acting dose alert was issued (average of 1.1 alerts/person/week), >70% of the time, the alert was followed by a long-acting dose within 2 hours (Table 3).

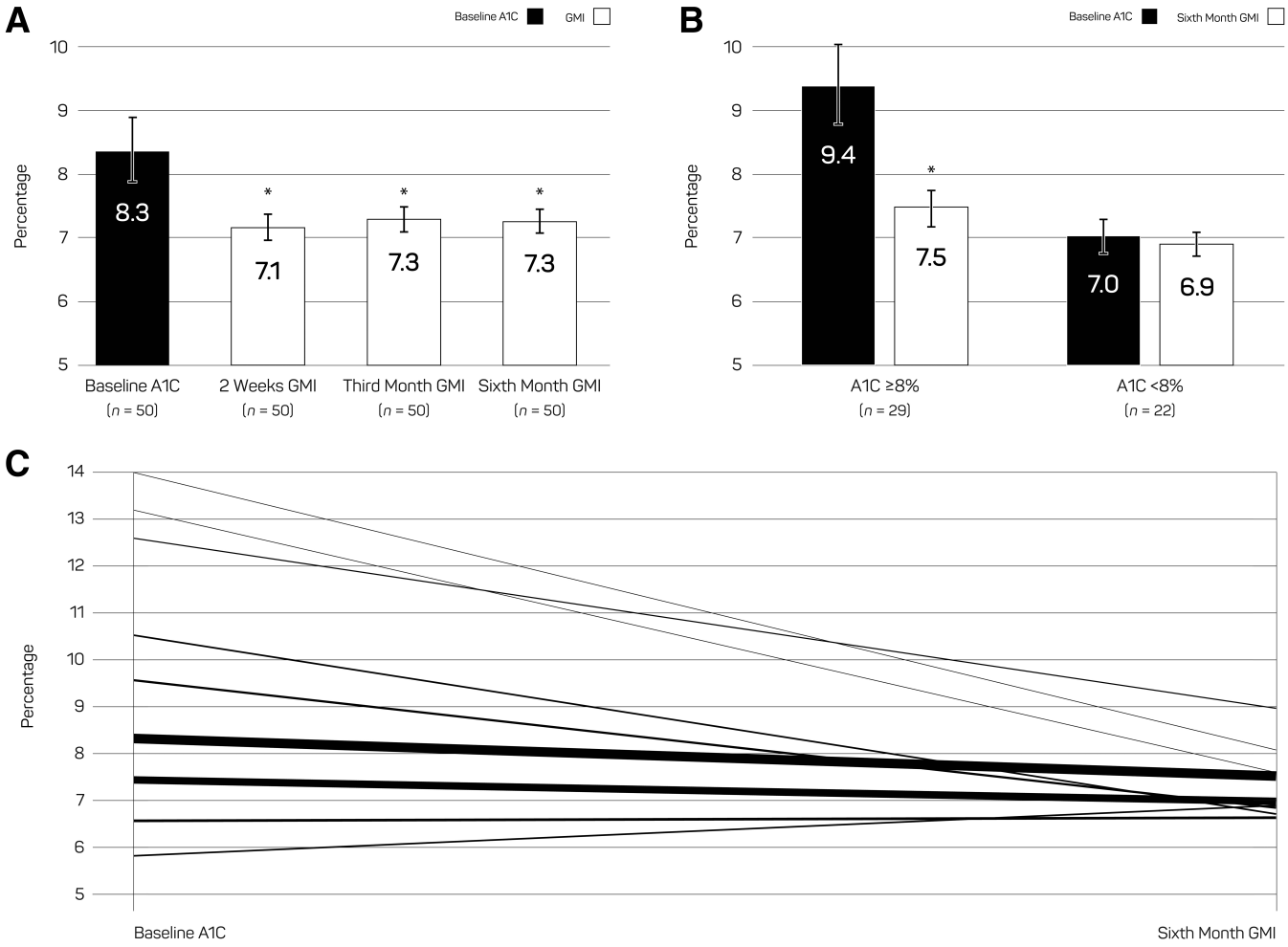

FIGURE 1 GMI compared with baseline A1C. *A*: Pairwise comparisons of baseline A1C and GMI in the first 2 weeks, third month, and sixth month of use for the cohort with data available for each period ($n = 50$). *B*: Comparison of baseline A1C and GMI in the sixth month of use for baseline A1C subgroups (≥8% vs. <8%). For *A* and *B*, data represent mean and 95% CI; *GMI is significantly different ($P < 0.05$) from baseline A1C using the Wilcoxon signed rank test. *C*: Change plot for baseline A1C to GMI in the sixth month. Lines reflect subgroups for various starting A1C levels based on 1-point increments. Data reflect those in the cohort with both parameters ($n = 51$). Line thickness reflects number of individuals in each A1C level.

As a proxy for pre- and postprandial glucose, we analyzed pre- and post-dose average glucose when a correction dose was recommended versus when no correction dose was recommended. In the sixth month of use, mean 2-hour postprandial glucose was 173.9 ± 36.3 and 159.8 ± 34.3 mg/dL, respectively (Figure 3*B*).

Within the full cohort of 58, total system use was 38.3 person-years, 38,471 insulin doses were tracked, and a total of 9.3×10^6 CGM sensor readings were captured.

Safety Data

To assess hypoglycemia beyond TBR, we analyzed unique hypoglycemic events throughout the day and nocturnally. For example, at night, the average number of low glucose events (<70 mg/dL) was 1.3 ± 1.6, 0.8 ± 1.4, and 0.8 ± 1.0 in the first 2 weeks, third month, and sixth month of use, respectively, and was statistically significantly different in the first 2 weeks of use (Table 4).

In reviewing complaint data for the safety population active on the system for 6 months ($n = 75$), two adverse events were identified; one user had a hyperglycemia event of unknown severity, and one user had a cardiac event that resulted in death (but had not used the system for 2 days before the event). In both cases, investigation indicated the system was working as intended (i.e., functioning and issuing alerts per system settings) in the time frame of the event. Neither adverse event occurred within the cohort meeting the CGM analysis criteria ($n = 58$).

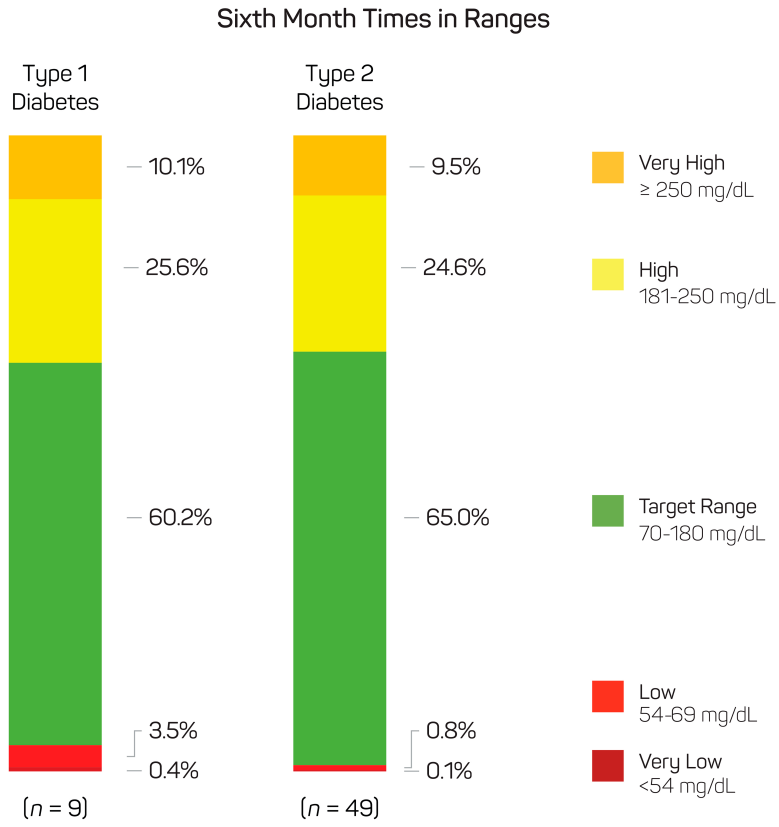

FIGURE 2 Stacked bar chart for times in ranges for type 1 and type 2 diabetes subgroups. TIR, TAR, and TBR are shown by diabetes type for the sixth month of system use. Data represent the mean percentage within each range.

Discussion

Bigfoot Unity is a relatively new and unique, U.S. Food and Drug Administration–cleared (13), interconnected smart pen cap diabetes management system. It incorporates CGM data, HCP-directed dose recommendations for long- and rapid-acting insulin analog pens, real-time alerts for low glucose, and reminders for dosing long-acting insulin. System data are collected passively to the Cloud for HCP review.

In this cohort of early adopters for whom 6-month use data were analyzed retrospectively, 76.4% had used CGM previously, but 96.4 and 92.7% were new to using smart pens and diabetes apps, respectively. Compared with baseline A1C (8.4%), we observed a similar change in GMI (7.3%) in the subsequent system-use time periods analyzed, indicating an approximate 1% improvement. A similar improvement (0.9%) was observed in the subset who had used CGM previously, with greater observed improvement (1.9%) in the small subset who were new to using CGM. Consistent with the observations of other studies (14), the magnitude of the observed difference was larger (~2% observed here) in a subset with suboptimal glycemic control (baseline A1C ≥8%).

Considering the mean age of the cohort of 62.0 years, mean TIR and GMI results (64.2 and 7.3%, respectively, at 6 months) demonstrate close adherence to established glycemic targets (15–17). A low number of nocturnal hypoglycemia events (mean 0.8 events/person/week in the sixth month) were observed, and the relatively short time spent in the low and very low hypoglycemia ranges overall (mean 1.4% of time <70 mg/dL and 0.2% of time <54 mg/dL in the sixth month) were below established clinical recommendations of 4 and 1%, respectively (15–17). Other parameters such as the mean percentage of sensor use time and mean coefficient of variation (79.0 and 30.0, respectively, in the sixth month) were also within established guidelines (15–17).

Established American Diabetes Association clinical guidelines for nonpregnant adults with diabetes also recommend maintaining 2-hour postprandial glucose <180 mg/dL (17). In our 6-month analysis, on average, 2-hour postprandial glucose fell within this range when the system displayed an HCP-recommended correction dose (173.9 mg/dL) and when no correction was suggested (159.8 mg/dL). These data support the importance of the system displaying clinician-directed meal doses and correction dose recommendations when appropriate.

TABLE 3 System-Use Parameters (n = 58)

Parameter	2 Weeks	Third Month	Sixth Month
CGM scans/day*	9.0 ± 5.1†	6.4 ± 3.9	6.3 ± 4.2
Rapid-acting insulin doses/person/day	3.1 ± 1.3‡	2.7 ± 1.0	2.6 ± 1.1
Long-acting insulin doses/person/week	7.2 ± 3.0	6.7 ± 2.5	6.7 ± 2.2
Long-acting insulin dose alerts/person/week	1.1 ± 0.8	1.0 ± 0.8	1.1 ± 1.0
Long-acting insulin alerts followed by dose within 2 hours, %§	73.8 ± 33.9	74.0 ± 28.8	71.6 ± 32.4
Individuals with insulin dose adjustments, n (%)	10 (17.2)	14 (24.1)	10 (17.2)
HCP engagement interactions/patient/week	2.1 ± 2.3	2.4 ± 1.8	2.6 ± 2.1
Patient engagement interactions/person/day	22.1 ± 9.8†	14.5 ± 8.3	14.0 ± 7.2

Data are mean ± SD or n (%). *n = 57 for third month. †ANOVA and subsequent pairwise comparisons showed a statistically significant difference for the first 2 weeks compared with the third and sixth months (P <0.05). ‡Friedman test and subsequent pairwise comparisons showed a statistically significant difference for the first 2 weeks compared with the third and sixth months (P <0.05); no other variables were found to be statistically significant using statistics appropriate to the distribution. §n = 46 for 2 weeks and n = 48 for the third and sixth months, reflecting those who received an alert.

We evaluated several parameters pertaining to patient engagement with the system. For an overall proxy of engagement, we estimated an average 14 interactions with the system per day, including sensor scans, dosing, and app and cap interactions, in the third and sixth months. Engagement was statistically greater in the first 2 weeks of use (Table 3), which may be partially the result of interaction during training on the system and enthusiasm or interactions needed to learn to use a new management tool. Nonetheless, this observation may be related to the observation of statistically greater TIR (and lower GMI) in the first 2 weeks compared with the third and sixth months (Table 2). Sensor scan data were consistent with other studies evaluating use of FreeStyle Libre CGM sensors (18). Given that the system is intended for once-daily, long-acting insulin dosing, the finding that the average number of long-acting doses per week was 6.7 in the third and sixth months of use is encouraging. The average of 1.1 long-acting dose alerts per person per week is relatively low; data showing that ~73% of such alerts were followed by a dose taken within 2 hours of the alert demonstrate good engagement with the system with regard to taking long-acting insulin. For meal doses, the system does not capture data regarding times users are eating,

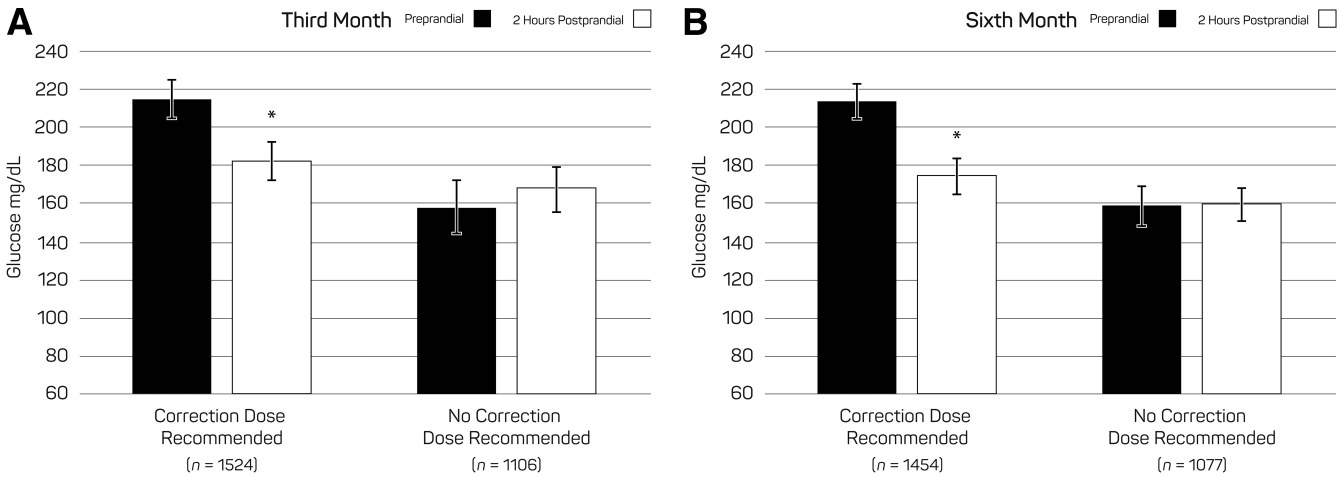

FIGURE 3 Preprandial and postprandial glucose. Preprandial and postprandial average glucose are shown for the third month of use when the system displayed an HCP-recommended correction dose versus when no correction was suggested (*A*). Similar preprandial and postprandial average glucose data are shown for the sixth month (*B*). In both *A* and *B*, data represent mean and 95% CI. *Difference in postprandial glucose from the preprandial glucose is statistically significant (P <0.05) using the paired t test.

TABLE 4 Hypoglycemia (n = 58)

Parameter	2 Weeks	Third Month	Sixth Month
Low glucose events/person/week	4.9 ± 4.9*	2.9 ± 4.4	2.8 ± 3.0
Nocturnal low glucose events/person/week	1.3 ± 1.6*	0.8 ± 1.4	0.8 ± 1.0
Very low glucose events/person/week	1.2 ± 2.3	0.8 ± 1.5	0.7 ± 1.1
Nocturnal very low glucose events/person/week	0.3 ± 0.6	0.2 ± 0.5	0.2 ± 0.4

Data are mean ± SD. *Friedman test and subsequent pairwise comparisons showed a statistically significant difference of the first 2 weeks compared with the third and sixth months (P <0.05); no other variables were found to be statistically significant using statistics appropriate to the distribution.

but given other studies' findings that most people using an MDI insulin regimen take three rapid-acting injections per day (19), our findings of an average of 2.7 and 2.6 rapid-acting doses per day in the third and sixth months, respectively, suggest minimal missed meal doses. Importantly, the system use data along with glycemic outcomes support minimal missed insulin doses overall in this cohort of people using an MDI regimen.

One benefit of connected systems are their ability to support telehealth and population health management; this is particularly relevant given the coronavirus disease 2019 (COVID-19) pandemic (20–23). Although there is increasing discussion regarding the likely future importance of connected insulin pen systems and the need for standards for data integration (10,23), there is currently a paucity of published clinical data (24–27). Therefore, although relatively small, this study is an important contribution to the available literature.

Limitations of this report include the retrospective nature of the analysis, small sample size, lack of a control group, and self-reported adverse event data. For example, the lack of a control group of people not using the system limits interpretation of system-specific effects on glycemic control.

An additional limitation is that, because of the retrospective nature of the study, A1C values were limited at baseline (available for 51 of 58 individuals) and even more so after system initiation (58 values available for only 30 of 58 individuals). This lack of A1C data may have been related to reduced clinic visits and A1C monitoring during the COVID-19 pandemic (21,22). Nonetheless, our analysis of available A1C data with a corresponding GMI suggests a strong correlation and average error of 0.13%, which is lower than the 0.3% A1C threshold often considered to be clinically meaningful. These findings reinforce other literature demonstrating the strong correlation between A1C and GMI and support using GMI as a proxy of A1C (12,28), although there are reports of potential mismatches between A1C and GMI (29).

Finally, we combined data from individuals with type 1 or type 2 diabetes, as the overall data were deemed poolable both statistically and based on clinical judgment. The type 1 diabetes subgroup was very small (n = 9), which limits interpretation, but there may be a difference in time spent with glucose <70 mg/dL between individuals with type 1 and those with type 2 diabetes (4.0 vs 1.0%); these findings are consistent with other studies in similar MDI populations (19,30).

The prospective BURST study and other studies will be needed to further investigate the clinical effectiveness and safety data of the Bigfoot Unity system.

Conclusion

We report here the first real-world data from individuals with insulin-requiring diabetes using the Bigfoot Unity system for 6 months within an MDI therapy regimen. These data indicate that, for this cohort consisting primarily of older adults with type 2 diabetes who were on MDI therapy with suboptimal glycemic control, using the system has the potential for rapid and durable improvement in glycemic control. Most individuals in this cohort were not new to using CGM but were new to using smart pens and support apps, suggesting that HCP-directed meal and correction dose recommendations and patient engagement with the system may contribute to the reduction we found from a mean baseline A1C of 8.4 ± 1.8% to a mean GMI of 7.3 ± 0.8% after 6 months of system use.

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DUALITY OF INTEREST

B.S.B. has received consulting fees and is on a paid speakers bureau for Bigfoot Biomedical, Inc. J.B.T., B.O., S.V., and J.K.M. are employees of Bigfoot Biomedical, Inc. F.N.S. is a former employee of Bigfoot Biomedical, Inc.

AUTHOR CONTRIBUTIONS

B.S.B. contributed to the study conceptualization and resources and participated in the investigation, data curation, and writing, reviewing, and editing of the manuscript. J.B.T. contributed to the conceptualization and methodology and participated in data curation and visualization and writing of the manuscript. B.O. contributed to the conceptualization and methodology and participated in data curation and visualization, formal data analysis, and writing, reviewing, and editing of the manuscript. S.V. contributed to the methodology and participated in data curation, software management, formal data analysis, and writing, reviewing, and editing of the manuscript. F.N.S. contributed to the conceptualization and methodology, was responsible for project administration and supervision, and participated in the writing, reviewing, and editing of the manuscript. J.K.M. contributed to the conceptualization and methodology, was responsible for project administration and supervision, and participated in writing, reviewing, and editing of the manuscript. J.K.M. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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