

Touchscreen sensor-augmented pump (SAP) demonstrates less exposure to hypoglycemia and increased time in range compared to non-touchscreen SAPs.

Noel E. Schaffer, PhD*, Savannah McCoy, MBA*, Betsy Dokken, PhD*, Mikhail Stal, MS*, Eric Shearin*, Peter Chen, MS**, and Jonathan Navarrete**

*Tandem Diabetes Care, Inc. San Diego, CA 92121
**Algebraix Data, Encinitas, CA 92024

OVERVIEW

The first touchscreen insulin pump, the t:slim® Pump, demonstrated faster training times and reduced use-related errors for common pump tasks compared to the Medtronic Revel¹. The introduction of the first touchscreen SAP, the t:slim G4™ Insulin Pump, allowed for objective assessments of the impact of these new devices on glycemic control compared to published data from Medtronic MiniMed® SAPs².

PURPOSE AND METHODOLOGY

A retrospective study was conducted in which de-identified t:slim G4 Pump user data from the period of October 2015 – August 2016 was collected from the t:connect® Diabetes Management Application for analysis (n=3,046). These results were compared with similar data published from patients using MiniMed SAPs based on data collected from the CareLink® Therapy Management System. Both the Tandem and the Medtronic data sets utilized the same inclusion criteria:

- People with Type 1 and Type 2 diabetes using a SAP
- At least 6 months of use
- More than 15 days of CGM use during first 6 months

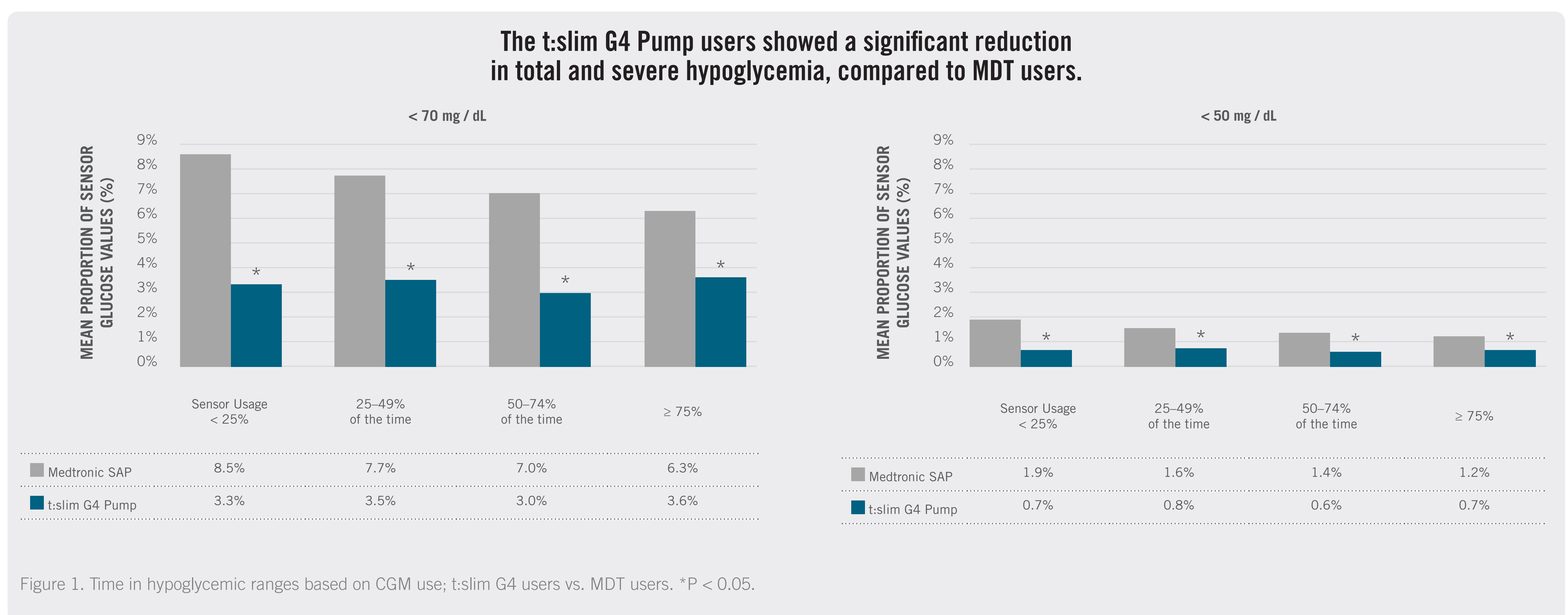
Notably, this retrospective data from both systems captures at-home use, representing how people actually use their devices and manage their diabetes outside of a controlled study environment.

RESULTS

An independent samples t-test (Welch's t-Test) was conducted to compare study participants from the published MiniMed sample of 7,916 (4,170 were using the low glucose suspend feature) to the 3,046 t:slim G4 Pump users. Both samples were analyzed by mean proportion of sensor glucose values (%) in each of six glucose ranges, and segmented into four groups based on sensor usage. There was found to be a statistically significant difference in favor of the Tandem pump for 17 of the 24 groups compared.

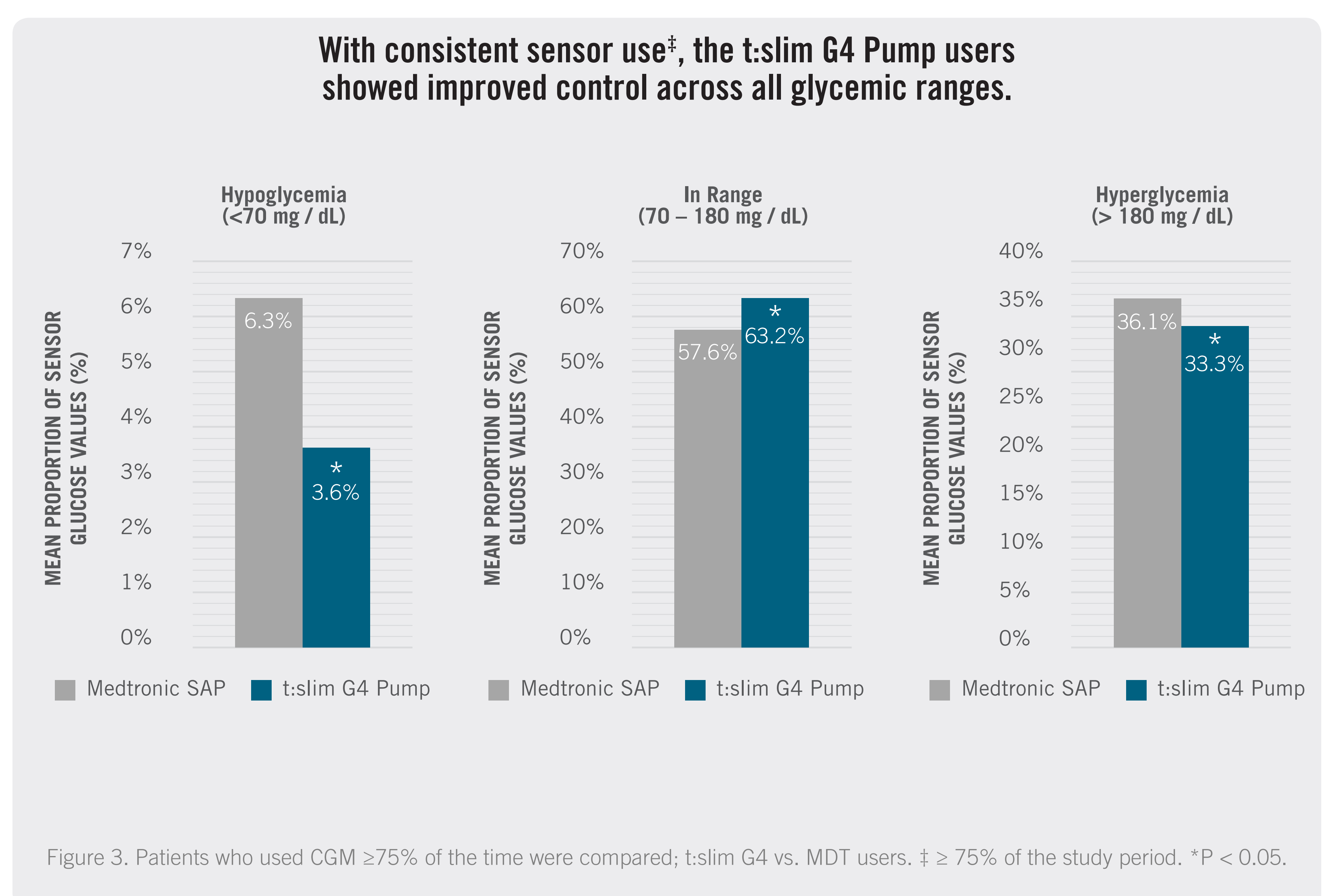
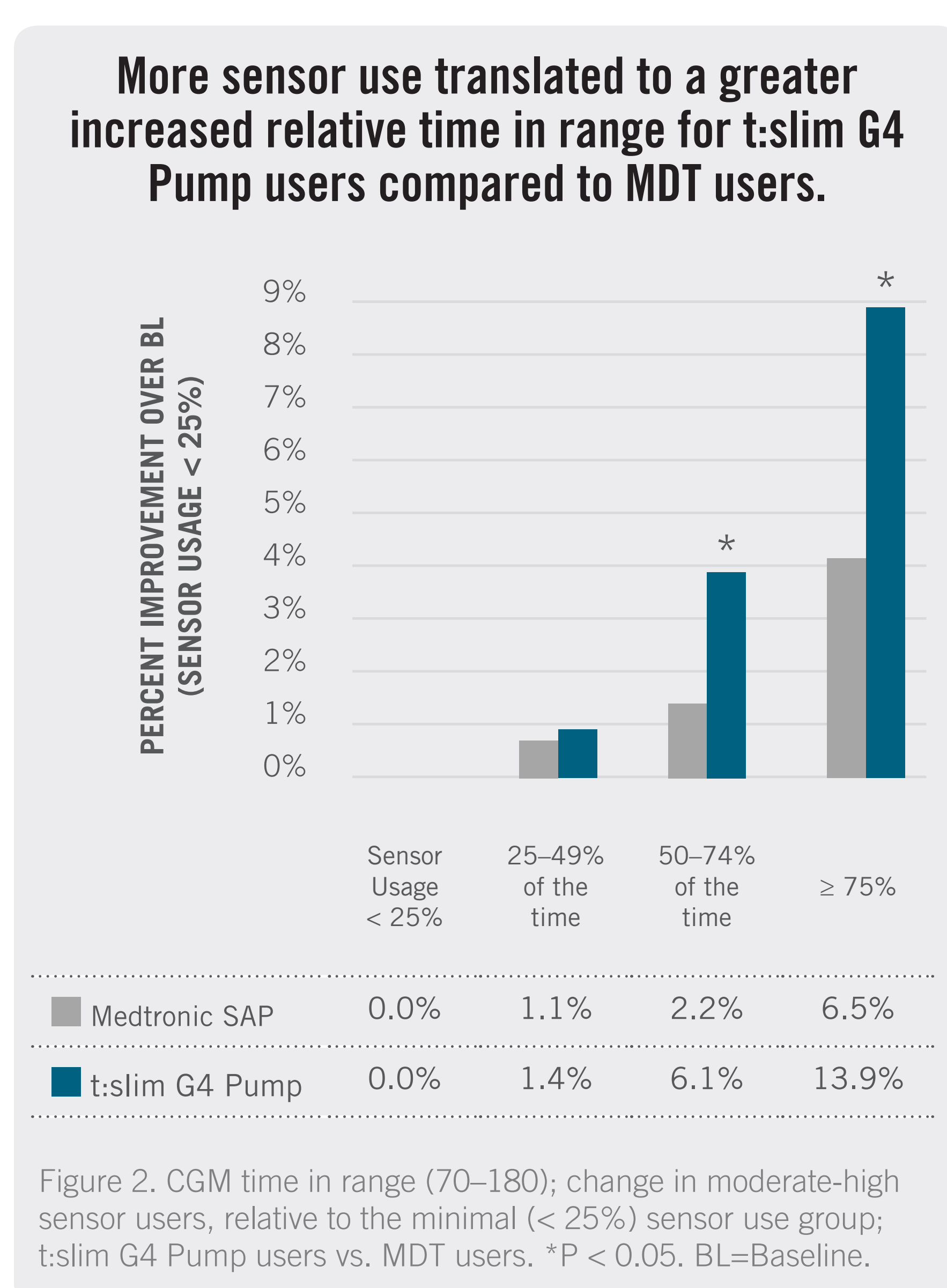
Reduced Hypoglycemia

The t:slim G4 Pump users showed reduced time in each of the hypoglycemic ranges. The effect size is large and persists regardless of the frequency of sensor usage.



Increased Time In Range

Among subjects using the sensor greater than 25% of the time, the data showed increased time in range among t:slim G4 Pump users relative to Medtronic SAP users. The effect size is moderate and improves with increased sensor usage.



DISCUSSION AND CONCLUSIONS

Retrospective analysis of user data from the t:connect Application and similar data published from CareLink shows the t:slim G4 pump demonstrates a significant clinical advantage when compared with Medtronic SAPs, including reduced hypoglycemia, increased time in range, and improved glycemic control.

These results, particularly related to hypoglycemia, are unexpected since over half of the Medtronic users reported by Battelino et al.² were actively using the low glucose suspend (LGS) feature. LGS suspends insulin delivery if blood glucose falls below a preset threshold and would be expected to decrease hypoglycemia. Based on earlier data demonstrating a greater ease-of-use and lower rate of error¹, the current results may be related to the usability benefits introduced by the touchscreen, suggesting that the intuitive user interface of the Tandem t:slim G4 Pump translates into better outcomes in everyday life. Future research is needed to determine causation.

1. Schaffer, N. E., Parks, L. J., Verhoef, E. T., Bailey, T. S., Schorr, A. B., Davis, T., Halford, J., Sulik, B. Usability and training differences between two personal insulin pumps. *J Diabetes Sci Technol*, March 2015 vol.9 no. 2 221-230. 2. Battelino T, Liabat S, Veeze HJ, Castañeda J, Arrieta A, Cohen O. Routine use of continuous glucose monitoring in 10 501 people with diabetes mellitus. *Diabet Med*. 2015;32:1568–1574.