

## **Joslin Study of Common Sensing's Gocap w/ blinded G4 featured in Diabetes Care - big win for smart pen field! - March 27, 2019**

*N=75; Most adherent tertile (adhering to insulin prescription 85% of the time) had A1c ~0.9% lower than least adherent tertile (adhering to insulin prescription 49% of the time)*

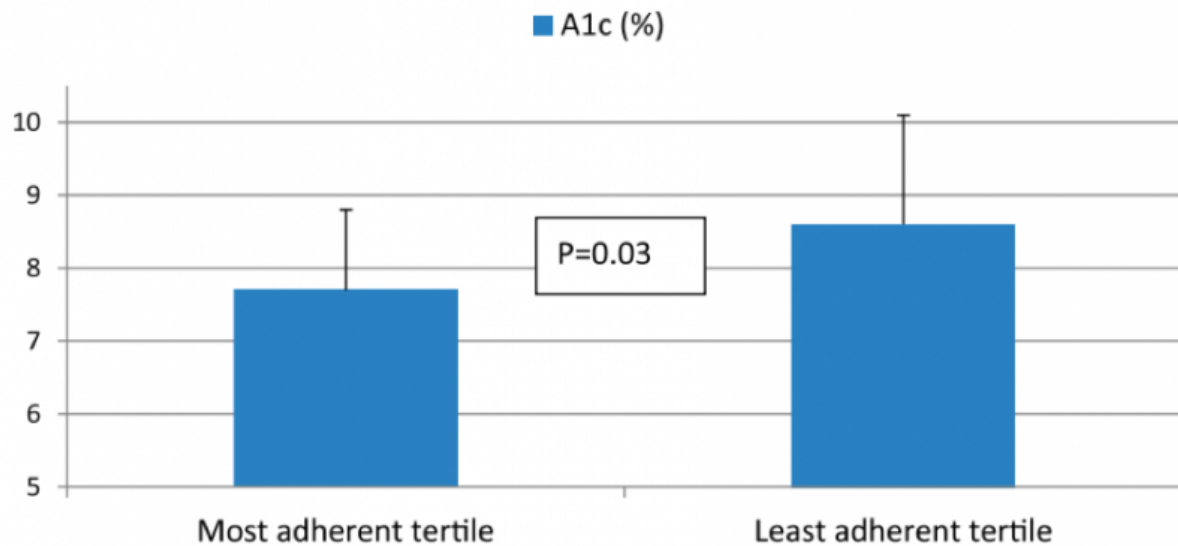
In a big milestone for smart pens, an observational study (n=75) of Common Sensing's Bluetooth-enabled insulin pen cap (Gocap) was featured in the [March edition of Diabetes Care](#). The study paired Gocap (on Lantus + Apidra pens) with blinded CGM (Dexcom G4 Software 505), and tracked the adherence and glycemic outcomes of people with diabetes on 2+ injections per day for one month. 42 younger patients (mean age 29 years; all type 1) and 33 older patients (mean age 73 years; ~1/2 type 1) were included in the cohort.

Over the study period, every participant deviated from prescribed insulin injection dose and/or timing at least once. Adherence to bolus insulin - defined as the participant completing a single dose each for breakfast, lunch, dinner, and overnight - was observed 76% of the time (i.e., 24% of bolus doses were considered missed or extra). Lack of adherence was detected in 36% of basal doses, indicating that they were missed or taken outside the one-hour window from the prescribed set time.

Not surprisingly, variability in adherence to dosing regimen partially explained variability in A1c. **For the tertile who was most adherent vs. least adherent (85% vs. 49% adherence to insulin prescriptions), mean A1cs almost differed by ~0.9% (7.7% vs. 8.6%; p=0.03).** The paper, unfortunately, doesn't report the differences in CGM metrics - time-in-range, hyperglycemia, hypoglycemia, or glycemic variability - between the two groups. It's also worth noting that there were nine real-time CGM users in the most-adherent tertile vs. just three in the least-adherent tertile, which could certainly explain the differences in A1c.

Though not a true outcomes study, this paper represents an important step toward greater recognition of the potential for dose capture to make invisible insulin injection data finally visible to HCPs. This potential is even greater when considering that, in the Joslin study: (i) participants were blinded to their dosing data; (ii) participants did not meet with HCPs to discuss any of the insulin dose/CGM results; and (iii) there was no decision support provided. The rubber will really meet the road, in terms of outcomes, when patients can learn, with the help of professionals and software, how they could be taking their insulin more effectively (and when they are doing a great job!).

## Glycemic Control by Tertile of Adherence



- **This paper seems like an extension from a preliminary poster from the same group, with the same protocol, presented at [ADA 2017](#).** We were pleased, in that poster, to see three CGM plots overlaid with insulin dose data. At [ATTD](#), Novo Nordisk's booth featured a display of the AGP overlaid with dose data - we expect something like this display will become standard as connected dose capture devices grow in prevalence over the next few years!
  - **In one [ADA 2018 poster](#) from the UVA, Stanford, Mt. Sinai group using NFC-enabled Novo Nordisk pens,** over one in four meals were associated with either a late or missed meal bolus, with 13% of total meals accompanied by a late bolus, and 14% of meals with no bolus whatsoever. Baseline A1c wasn't provided, but there was a significant positive correlation between the number of missed meal boluses and A1c (there was no such correlation between late boluses and A1c).
- **As of [DTM 2018](#), the Gocap remained in limited supply direct from the company.** To our knowledge, Common Sensing has not said when it intends to scale the pen cap to broader audiences.
- **In other news, [Insulclock's dose capture device](#) was featured in a [DTT paper](#) published last week.** The paper overviews the device's dose detection accuracy (relative errors of 3%-7% across different dosages).

-- by Brian Levine and Kelly Close