Real-time Detection of Infusion Set Failures in a Closed-Loop Artificial Pancreas

Daniel P. Howsmon[1], Nihat Baysal[1], Bruce A. Buckingham[2], Gregory P. Forlenza[3], Trang T. Ly[2], David M. Maahs[2], Tatiana Marcal[2], Lindsey Towers[3], Sunil Deshpande[4], Ravi Gondhalekar[4], Francis J. Doyle III[4], Eyal Dassau[4], Juergen Hahn[1,5], B. Wayne Bequette[1]

[1] Department of Chemical & Biological Engineering, Rensselaer Polytechnic Institute, Troy, NY, USA
[2] Lucile Packard Children's Hospital, Stanford University, Palo Alto, CA, USA
[3] Barbara Davis Center, University of Colorado Denver, Aurora, CO, USA
[4] John A. Paulson School of Engineering and Applied Sciences, Harvard University, Cambridge, MA, USA
[5] Department of Biomedical Engineering, Rensselaer Polytechnic Institute, Troy, NY, USA

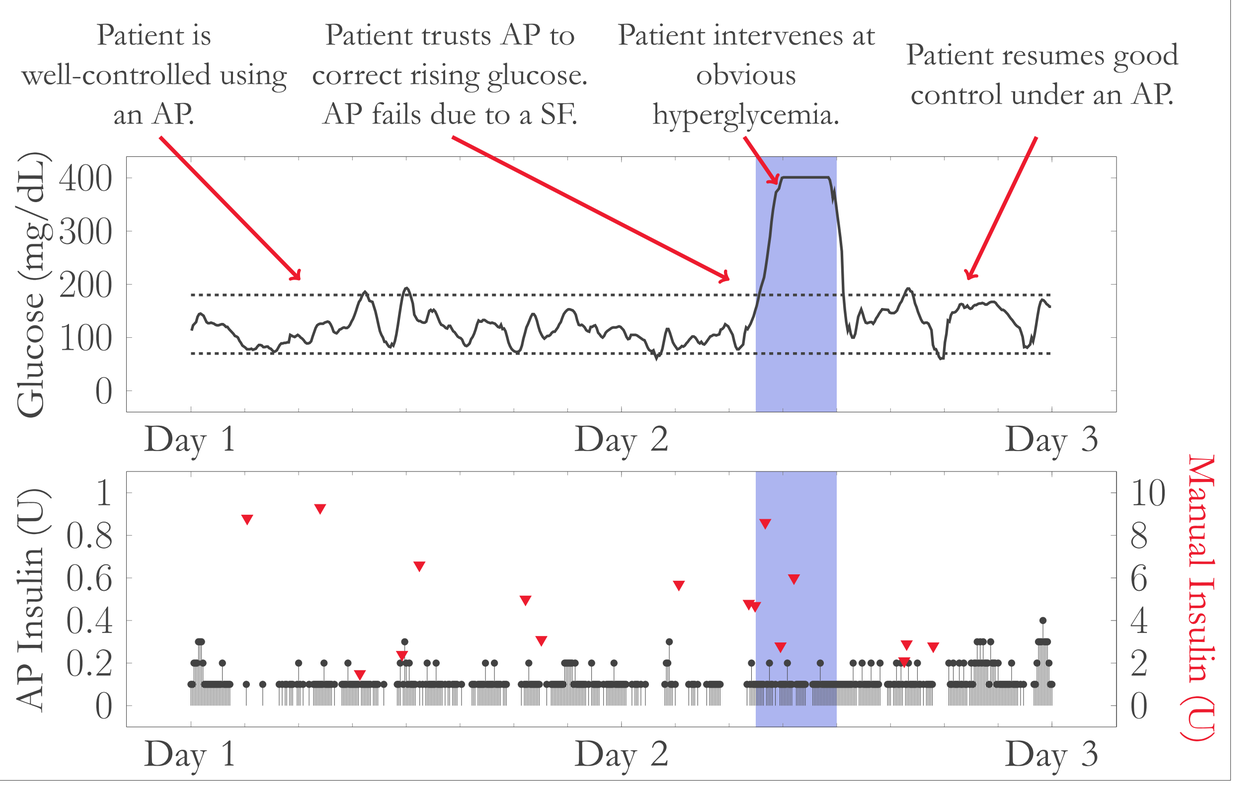
See the following related poster for additional study information:
ATTD7-0151: Zone-MPC Performance

Background

As evidence emerges that artificial pancreas systems may improve clinical outcomes for patients with type 1 diabetes and decrease the burden of disease management, there is the risk that

decrease in burden could cause patients to be less observant of when devices stop functioning appropriately.

Right is an example of an infusion set failure (SF) that occurred under closed-loop as well as the patient's thought process in detecting and addressing this fault.



Methods

SF Detection Algorithm

The SF detection algorithm was developed previously [1]. Briefly, patient-specific baselines of glucose control and insulin requirements are adapted over time via averages on sliding windows. These baselines are compared to current values and alarms occur when thresholds are exceeded.

Zone Model Predictive Control (Zone-MPC)

Zone-MPC [2] is an AP algorithm that controls to a desired zone, rather than to a single setpoint.

Study Design

RCT with cross-over:

SAP (Patient Detection) vs. Zone-MPC + SF det. (Algorithm + Patient Detection)

SFs were determined by
(i) failed correction doses
(ii) ketones > 0.6
(iii) insulin leaking at insertion
(iv) pump-occlusion alarms

Primary Clinical Outcome

The SF detection algorithm attempts to reduce SF-associated hyperglycemia. Therefore, the primary clinical outcome sought to reduce

the time > 250 mg/dL in the 4 hours prior to a SF detection

between Zone-MPC + SF detection and SAP arms.

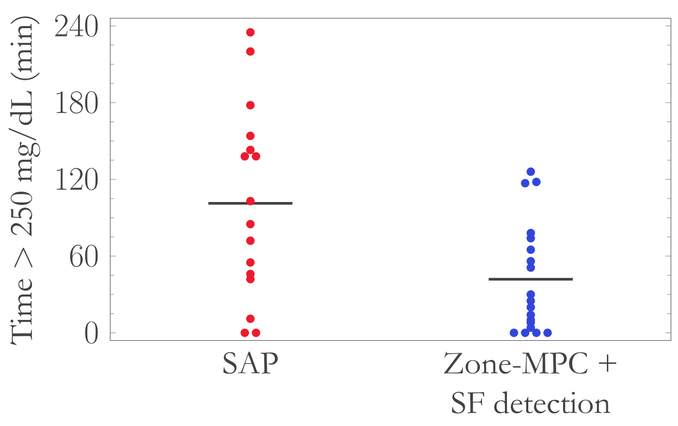
Patient Demographics

Subjects:	19
Sex:	11 F, 8 M
Age (years):	28.0 ± 10.8
Years with T1D:	12.7 ± 7.1
Insulin (U/day):	56.3 ± 18.4
Weight (kg):	86.1 ± 22.8
Insulin/BW (U/day/kg):	0.65 ± 0.22

Reported as mean ± SD

Results

Primary Clinical Outcome



Mean time > 250 mg/dL:
101 vs. 43 minutes ($p < 0.01$)

Classification of Failures

	SAP	Zone-MPC + SF det.
Failure to Correct	11	16
Insulin Leaking at Site	3	1
Infection	1	1
Pump-Occlusion	0	1
Unknown	1	0
Total	16	19

Total number of SFs not statistically significant between intervention groups (Chi-square test of independence, $p = 0.49$)

Algorithm Performance

The SF detection algorithm attained

88% Sensitivity — **0.22** FP/day

(72% sensitivity and 0.28 FP/day predicted from previous analysis.)

This is the first study in the literature that investigates **online** detection of SFs.

Discussion

False positives: Fewer FPs than indicated by previous retrospective analysis. Likely reducible further by announcing meals.

False negatives: 3 SFs remained undetected. One overzealous patient had already experienced three SFs in the seven day period, making her quicker to act than the algorithm. The other two developed very slowly and simulations indicate that they can be easily detected by increasing the length of the long window.

Future Work: The main contribution of this work is in evaluating the derived features for the detection of SFs. Other classification techniques (e.g., discriminant analysis) that incorporate these features could further improve performance.

Conclusion

As patient burden is reduced by each generation of advanced diabetes technology, fault detection algorithms will help ensure that patients are alerted when they need to manually intervene.

References

1. Howsmon DP *et al.* Continuous glucose monitoring enables detection of Losses in Infusion Set Actuation (LISAs). Sensors. 2017;17(1):161.
2. Gondhalekar R *et al.* Periodic zone-MPC with asymmetric costs for outpatient-ready safety of an artificial pancreas to treat type 1 diabetes. Automatica. 2016;71:237–46.