Use of Fuzzy Logic (FL) Controller in a Closed Loop Artificial Pancreas

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Introduction

Fuzzy Logic (FL) provides a novel approach to controlling an insulin pump as part of a closed-loop artificial pancreas. A key attribute is the straight forward incorporation of a physician's knowledge into controller commands. Our team has been developing a FL controller since 2002. We received FDA approval for human trials in January 2011. The controller uses only the patients total daily insulin and the three previous 5-minute CGM readings.

Objective

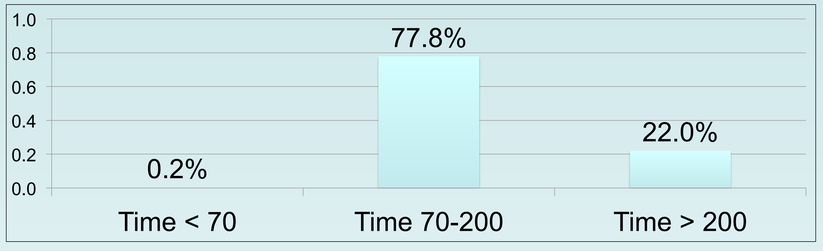
To evaluate the effectiveness of a fully automated system using a FL controller in a 24-hour clinical research center setting. We sought to determine whether this system could (1) correct an elevated blood glucose, (2) control the fasting state and diurnal variation, (3) control the glycemic response to a small meal (30 gms CHO), and (4) control the glycemic response to a larger meal (60 gms CHO).

Methods

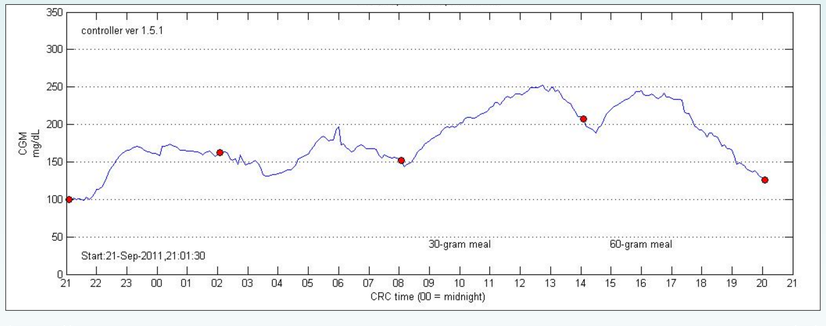
A FL controller was used to calculate insulin dosing to adult type 1 patients. The Artificial Pancreas System (APS) developed by UC Santa Barbara and Sansum Diabetes Research Institute was used to merge the FL controller, OmniPod pump and Dexcom Seven Plus CGMS. The controller was initialized using only the patient's total daily insulin. The study began at 8 pm after giving the patient only 75% of their usual insulin dose for dinner. There were four periods of six hours corresponding to each of the 4 objectives. There were no pre-meal priming boluses, meal announcements, nurse or physician data entry, dosing or intervention.

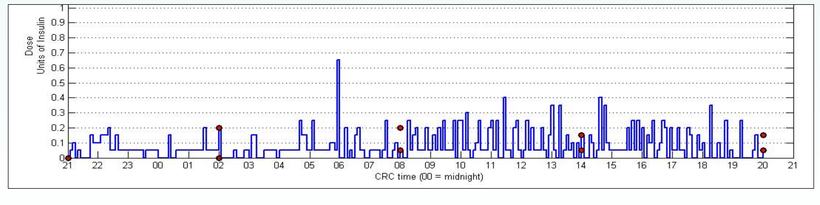
Results

ID	PF	Avg BG	Max BG	Min BG	Time > 200	Time < 70	Time 70 - 200
102	4	176	303	90	28%	0%	72%
103	4	156	304	66	18%	1%	81%
Avg PF4	4	166	303	78	23%	.5%	76.5%
106	5	206	288	125	50%	0%	50%
107	5	151	273	80	18%	0%	82%
108	5	181	252	99	31%	0%	69%
109	5	165	313	72	27%	0%	73%
Avg PF5	5	176	282	94	32%	0%	69%
Avg All	**all**	**172**	**291**	**87**	**28%**	**0%**	**72%**



BG & Dose History (Typ. Patient)





Results

Six patients have completed the study. Two patients did not complete the study due to hypoglycemia related to incorrect controller initialization data. The average blood sugar value over a 24 hour period was 172 mg/dL (plasma-calibrated). The average blood sugar values for the four six hour periods are:

- Correction of elevated glucose: 172 mg/dL
- Fasting and diurnal variation: 128 mg/dL
- 30 gram meal: 183 mg/dL
- 60 gram meal: 205 mg/dL.

Average LBGI and HBGI values were 0.24 and 8.44 respectively.

Conclusion

These preliminary data indicate that a FL controller in the CRC setting can provide an effective method of automating the regulation of blood sugar of a sedentary patient given meals using only the patient's total daily insulin and CGMS data.

Future Research

Our next study will use a slightly modified version of the FL controller and will include exercise & fatty meals. Concurrent with that clinical work, modifications to the controller will be explored and studied.

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