Diabetes Technology

3rd Annual Sweet Science Conference

Myrtle Beach, SC

March 14, 2020

B. Adam Dennis, MD

- No conflicts to disclose
- Some products discussed are not FDA approved for all pediatric patients

Question

- **A 14 year old male patient calls you because his sugar is 478 mg/dL. He was diagnosed with Type 1 Diabetes four years ago and currently uses an insulin pump. His last A1c in clinic was 7.6%. He cannot figure out why his sugar is high and won't come down because he feels he is doing everything as usual. He feels fine with no symptoms.**

- **What is the most likely issue?**
- **What is the intervention?**
- **What might happen without the intervention?**

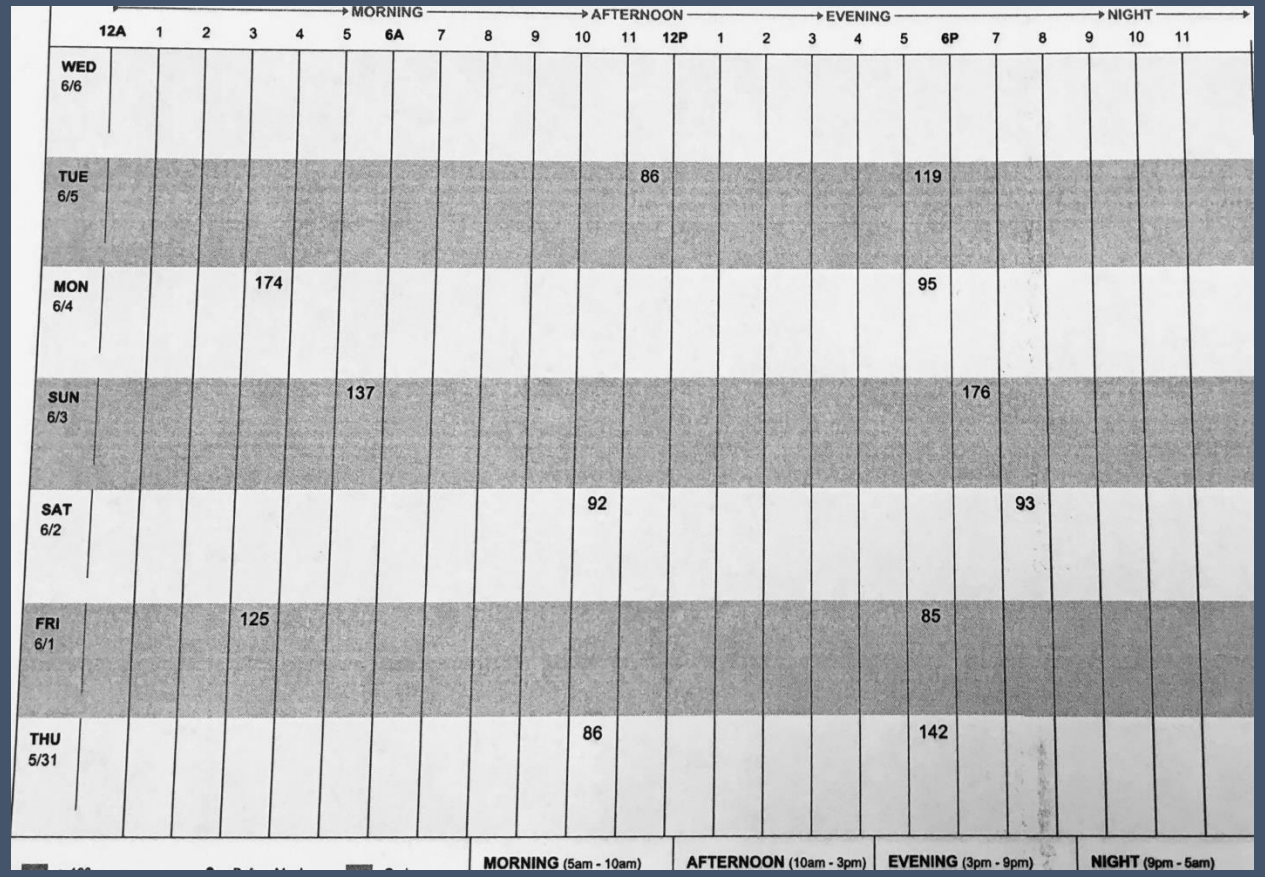
Diabetes Technology Timeline

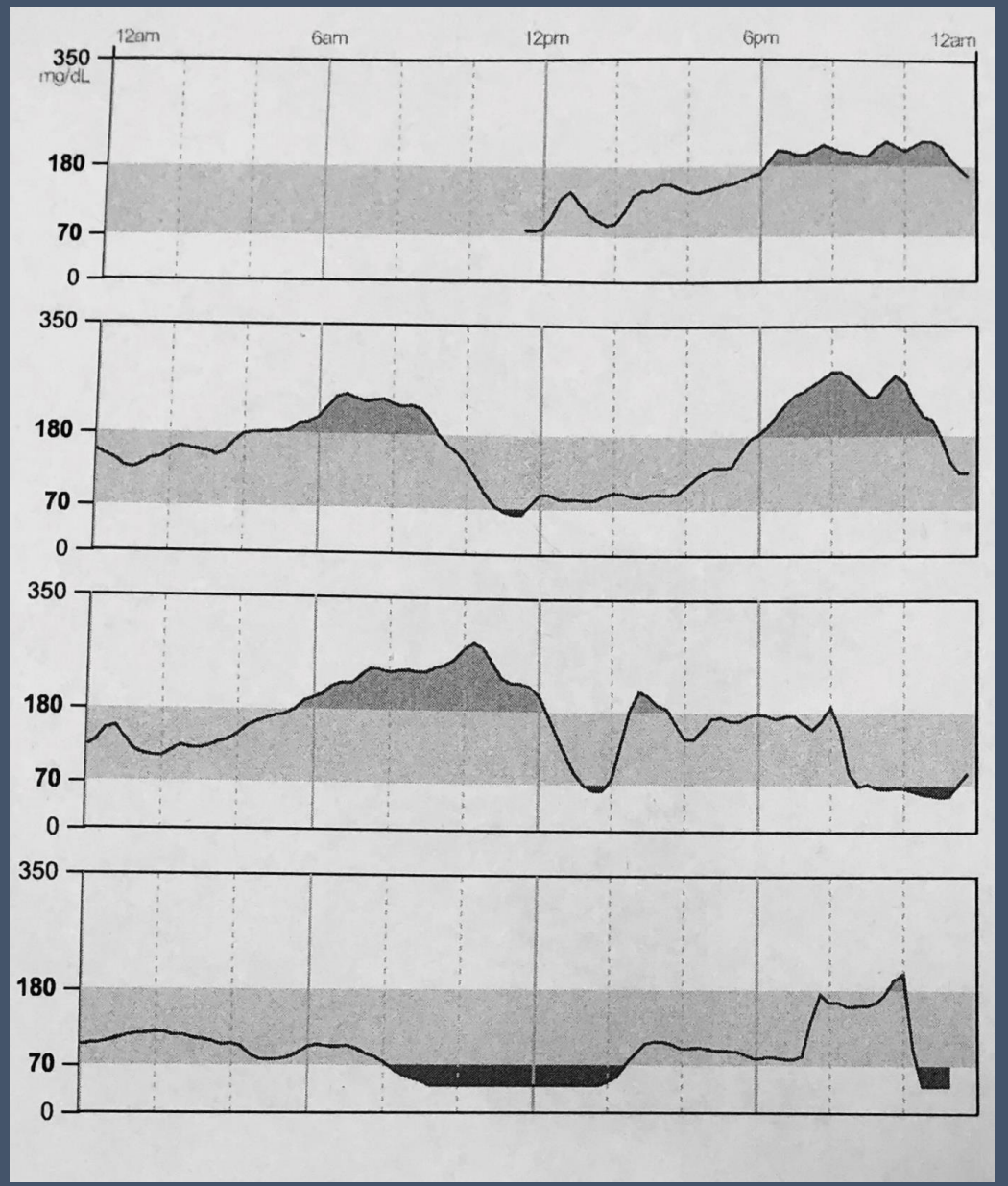
- **1920's:**
  - **Insulin**
- **1970's:**
  - **first pumps**
- **1980's:**
  - **Insulin pens**
  - **recombinant human insulin**
- **1990's:**
  - **Insulin pumps become readily available**
  - **Rapid acting insulin**
- **2000's:**
  - **Long acting insulins**
  - **Sensors**
- **Now:**
  - **Commercial integrated pump/sensor products**
  - **Smart phone app integration**

What's new in Diabetes Technology?

- **Interoperable Insulin Pump (2/14/19)**
- **Implantable Continuous Glucose Monitoring System (6/6/19)**
- **New glucagon formulations**
  - **6/24/19: Baqsimi intranasal glucagon**
  - **7/24/19: Gvoke prefilled pen**
- **iLet (insulin + glucagon closed loop system) gets breakthrough device recognition from FDA (12/10/19)**

Glucose Sensors


MORNING
AFTERNOON
EVENING
NIGHT
12A 1 2 3 4 5 6A 7 8 9 10 11 12P 1 2 3 4 5 6P 7 8 9 10 11
WED 6/6
TUE 6/5
86
119
MON 6/4
174
95
SUN 6/3
137
176
SAT 6/2
92
93
FRI 6/1
125
85
THU 5/31
86
142
MORNING (5am - 10am)
AFTERNOON (10am - 3pm)
EVENING (3pm - 9pm)
NIGHT (9pm - 5am)


12am
6am
12pm
6pm
12am
350
mg/dL
180
70
0

Continuous Glucose Sensors

Libre
Change sensor every 14 days

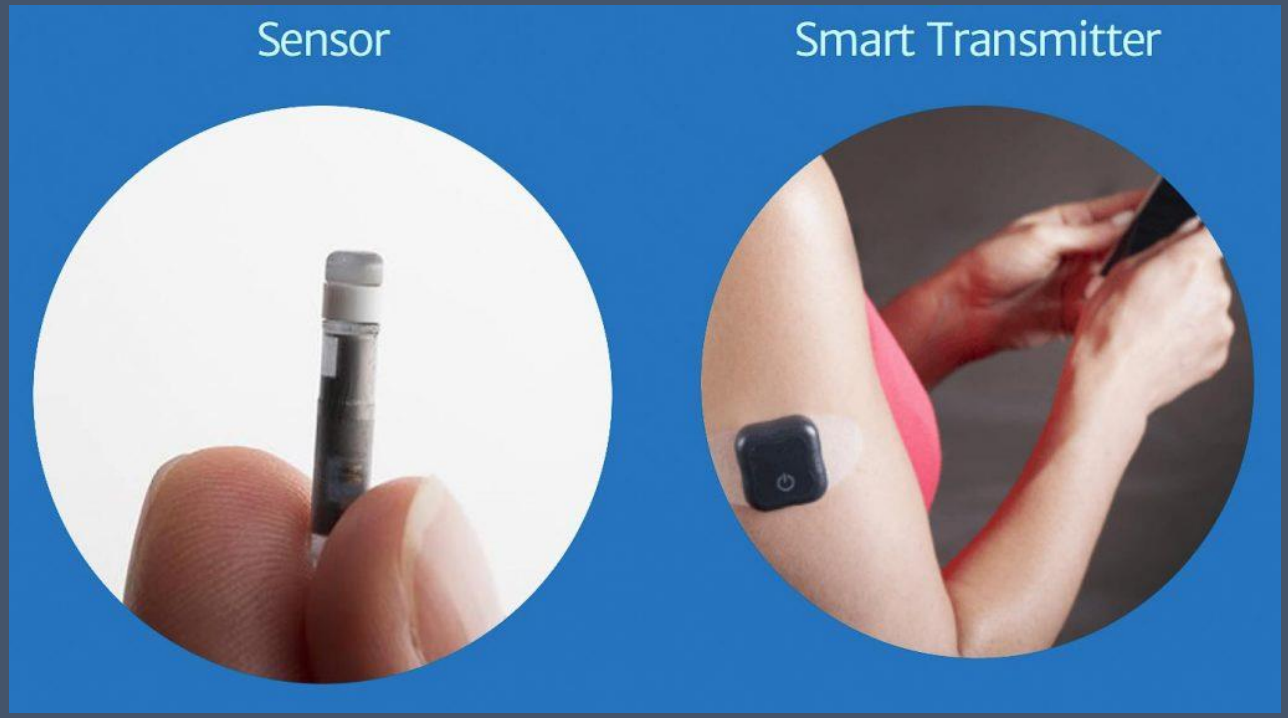
Dexcom
Change sensor every 10 days

Medtronic
Guardain Sensor 3

Eversense
Change Implant every 3 months
Reattach patch daily

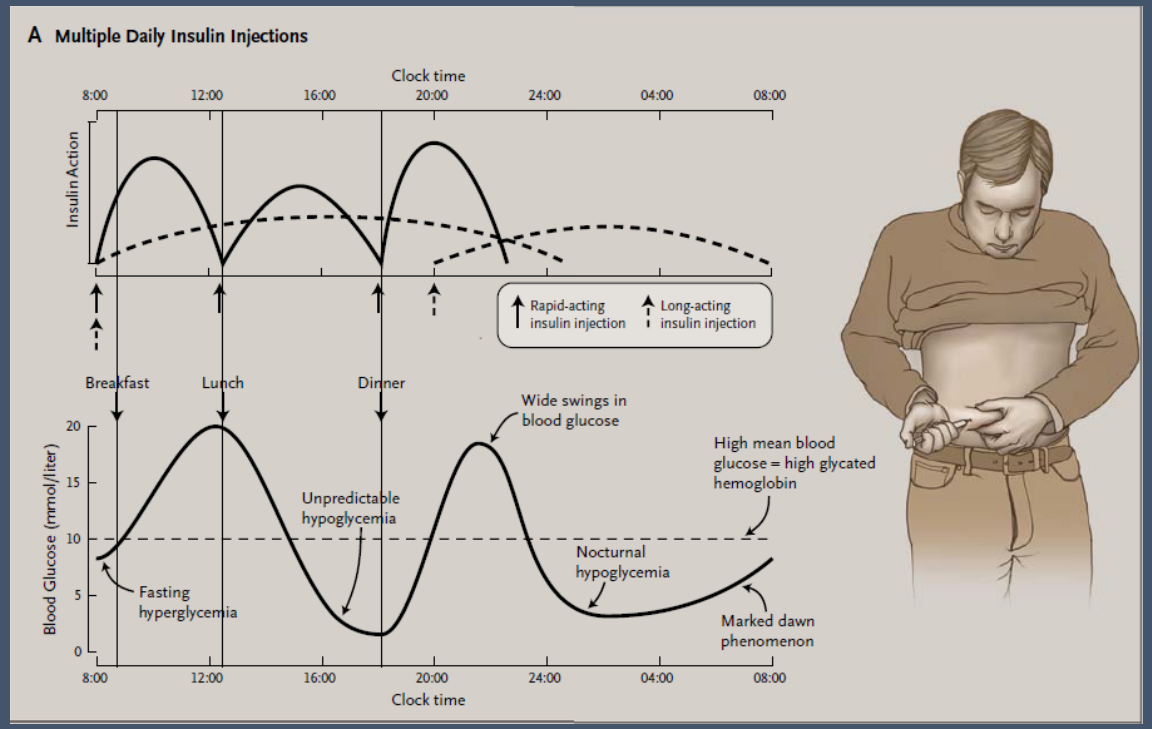
Is Implantable CGM the Future?

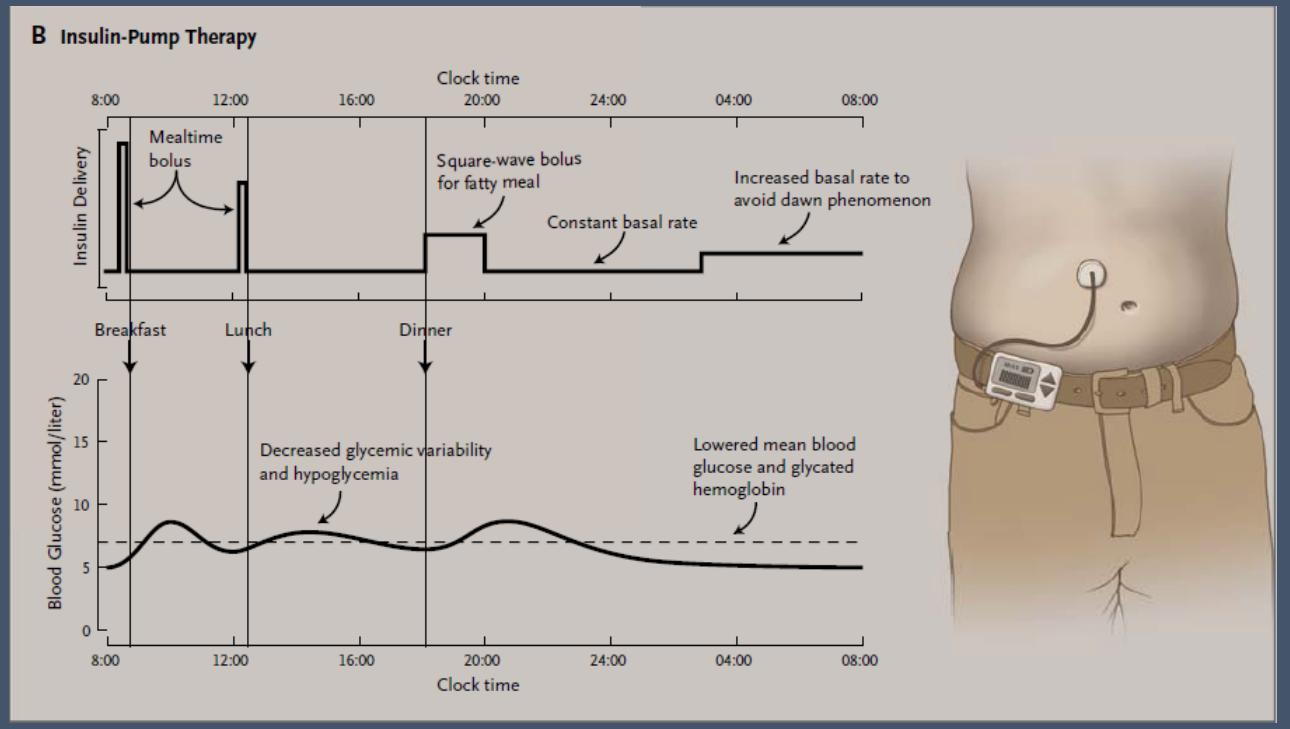
- **Advantages: Accuracy, physical stability, ease of use.**
- **Disadvantages: Currently replaced every 3 months, requires meter calibration, tetracycline antibiotic interaction**



Insulin Pumps

Multiple Daily Injections vs. Insulin Pump





NEJM 366;17. April 26, 2012.

Who needs an Insulin Pump?
Diabetes Control and Complications Trial
(began enrollment in 1983)

measurement greater than 65 mg per deciliter (3.6 mmol per liter), and hemoglobin A_{1c} (glycosylated hemoglobin), measured monthly, within the normal range (less than 6.05 percent). The patients initially chose either multiple injections or pump therapy and could subsequently change to the other method if their glycemic goals were not achieved or if such was their preference. The patients in

Insulin Pumps

Do I have Everything?!

- **Tube Pump: Pump is attached to child**
- **Tubeless Pump: Need to keep track of controlling device**
- **Tip: If something falls off an you aren't 100% confident, don't throw it away.**

Original Omnipod vs. Dash

Original Omnipod

Pod

+

PDM

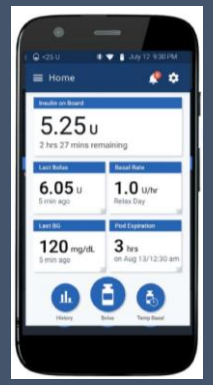
+/-

Meter

Omnipod Dash

Pod

+



PDM

+

Meter

+/-

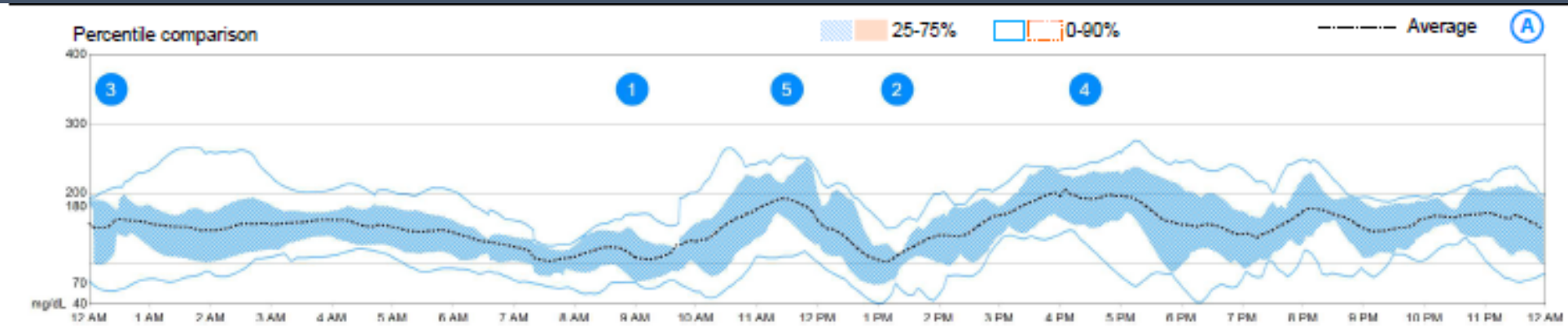
Phone (display only)

Integrated Pumps/Sensors

Medtronic 670G and Tandem Control-IQ

Limitations of Integrated Pump/Sensor Technology

- ***Minimum*** **requirement that patient wear a fully functioning pump *and* glucose sensor at all times.**
- **Is not an "artificial pancreas"**
- **Potential for patient to spend more time with technological trouble shooting**



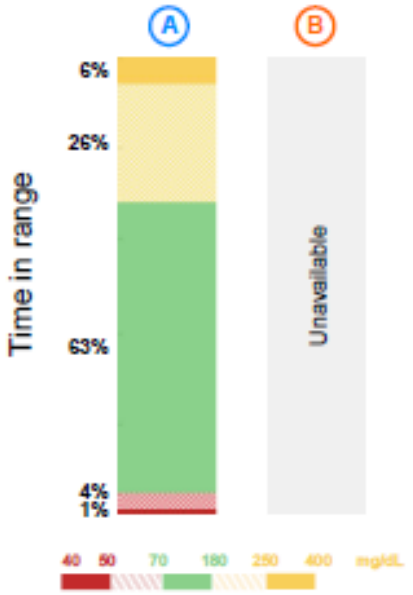
Carb Ratio (g/U)					
A	13.0	14.0	13.0	14.0	14.0
B					

Hypoglycemic patterns (4)**

1	7:20 AM- 10:35 AM (4 occurrences)	
2	12:33 PM- 2:04 PM (3 occurrences)	
3	12:05 AM- 12:40 AM (1 occurrences)	

Hyperglycemic patterns (2)

4	3:20 PM- 5:30 PM
5	11:05 AM- 11:55 AM



** Only highest priority shown.

Auto Mode Exits	A	B
No Calibration	• 1	–
High SG Auto Mode Exit	0	–
Auto Mode max delivery	• 1	–
Auto Mode min delivery	0	–
BG required for Auto Mode	0	–
Sensor Algorithm Underread	• • • 3	–
Sensor Updating	0	–
No SG values	0	–
Sensor Expired	• 1	–
Auto Mode disabled by user	0	–
Alarms	0	–
Pump Suspend by user	0	–
Auto Mode Warm Up	0	–
Unidentified	0	–

Statistics	A	B
Auto Mode (per week)	63% (4d 09h)	–
Manual Mode (per week)	37% (2d 15h)	–
Sensor Wear (per week)	63% (4d 09h)	–
Average SG ± SD	152 ± 55 mg/dL	–
Average BG	148 ± 67 mg/dL	–
BG / Calibration (per day)	7.7 / 2.1	–
Total daily dose (per day)	35 units	–
Bolus amount (per day)	15U (43%)	–
Auto Basal / Basal amount (per day)	20U (57%)	–
Set Change	Every 6.0 days	–
Reservoir Change	Every 6.0 days	–
Meal (per day)	4.2	–
Carbs entered (per day)	173 ± 57 g	–
Active Insulin time	2:45 hrs	–

Closed-Loop Pump + Sensor

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 31, 2019 VOL. 381 NO. 18

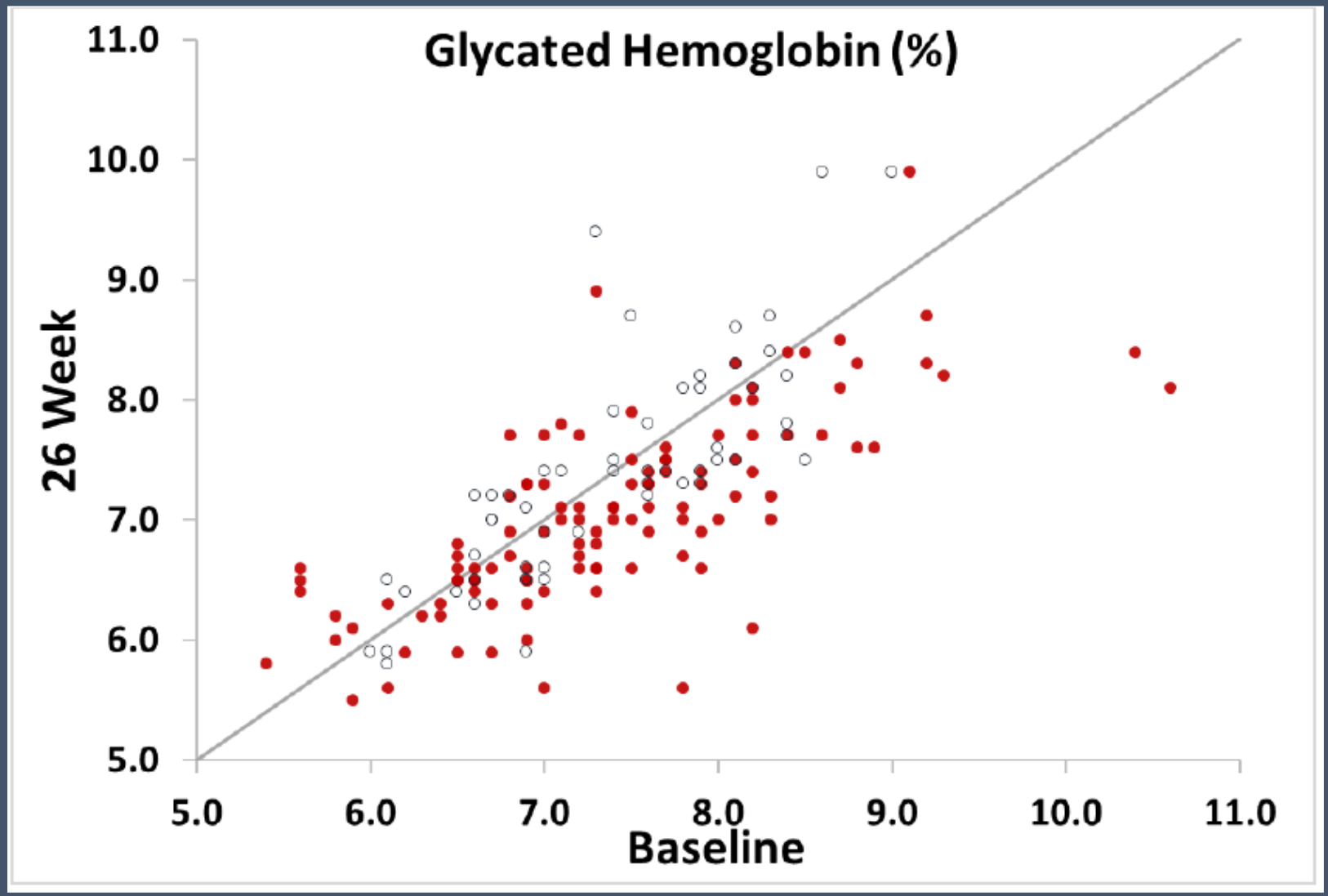
Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes

S.A. Brown, B.P. Kovatchev, D. Raghinaru, J.W. Lum, B.A. Buckingham, Y.C. Kudva, L.M. Laffel, C.J. Levy, J.E. Pinsker, R.P. Wadwa, E. Dassau, F.J. Doyle III, S.M. Anderson, M.M. Church, V. Dadlani, L. Ekhlaspour, G.P. Forlenza, E. Isganaitis, D.W. Lam, C. Kollman, and R.W. Beck, for the iDCL Trial Research Group*

- **Significantly more time in range in the closed-loop group**
- **Not perfect: Average A1c reduction of 0.3%, with 7% of patients in closed-loop group seeing increase in their A1c**
- **Same technology limits apply: DKA occurred in a closed-loop participant due to bad site**

NEJM 2019; 381:1707-17.

Closed-Loop Pump + Sensor



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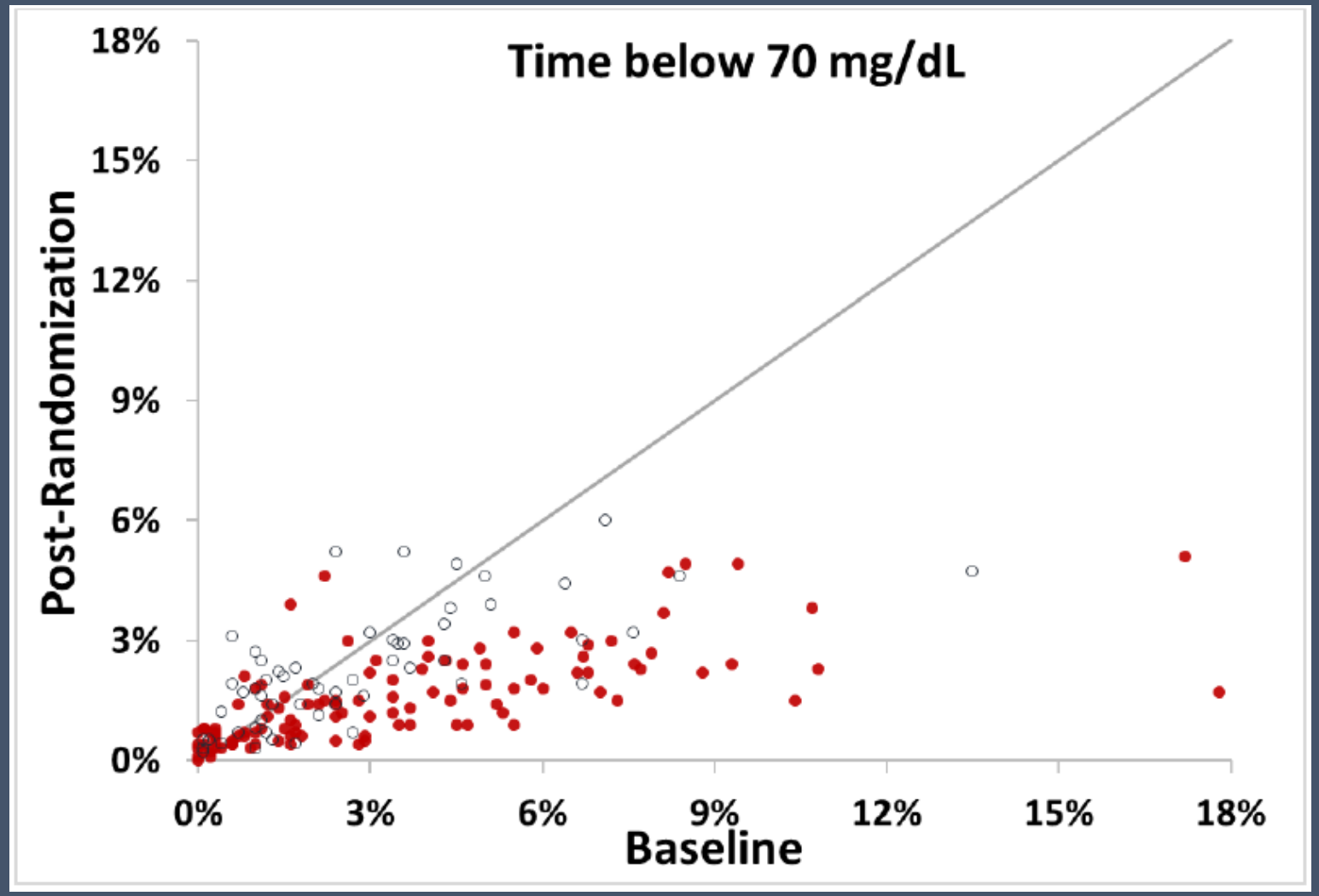
Closed-Loop Pump + Sensor



NEJM 2019; 381:1707-17.

More Flexible Device Interaction in the Future?

- **Alternate controller enabled (ACE) insulin pump: Ability to interact with different devices that meet FDA "special controls" standards**

FDA authorizes first interoperable insulin pump intended to allow patients to customize treatment through their individual diabetes management devices

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For Immediate Release: February 14, 2019

Do-it-yourself Artificial Pancreas?

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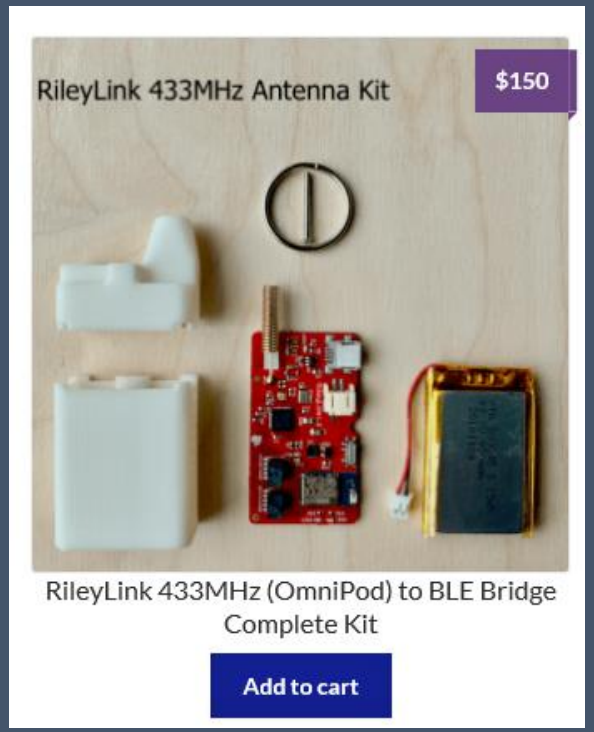

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FDA Warning About Unapproved Devices

FDA Warns People with Diabetes and Health Care Providers Against the Use of Devices for Diabetes Management Not Authorized for Sale in the United States: FDA Safety Communication

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