Technology Update in Diabetes

Pumps, Sensors, and Progress Toward Closed Loop Systems

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Disclosures

Research and Grant Support to Employer: Abbott, Biodel, DexCom, Halozyme, Lilly, MannKind, Medtronic, Novo Nordisk, Sanofi, Valeritas

Consultant: Abbott, Halozyme, Medtronic, Novo Nordisk, Sanofi, Valeritas

Speaker’s Bureau: DexCom, Lilly, Medtronic, Novo Nordisk, Sanofi, Valeritas
Adapted from DCCT Research Group: NEJM 1993;329:977-986
Trade-off between: Reducing Long-term Complications & Minimizing Hypoglycemia

Patients used:

- Regular insulin/Intensive therapy via injections or insulin pump
- Self monitoring blood glucose (SMBG)

DCCT Results

Published 1993

Progression of Retinopathy (per 100 patient-years)

Rate of Severe Hypoglycemia (per 100 patient-years)

Percentage of A1C Level

DCCT Research Group, 1993
Risk of Death Over a Range of Average A1c

Adjusted log (HR) by Treatment Strategy
Relative to standard at A1c of 6%

Steady increase of risk from 6 to 9% A1c with intensive strategy

Intensive strategy

Standard strategy

Excess risk with intensive strategy vs standard occurred above A1c 7%

HR = hazard ratio

Riddle et al. Diabetes Care 2010
Hypoglycemia and Cardiovascular Events

- Tachycardia and high blood pressure
- Myocardial ischemia
  - Silent ischemia, angina, infarction
- Cardiac arrhythmias
  - Transiently prolonged corrected QT interval,
  - Increased QT dispersion
- Sudden death

Mean Glucose & In-Hospital Mortality in 16,871 Patients with AMI

(Reference: Mean BG 100-110 mg/dl)

2005 Blinded CGM Study

101 people with diabetes were placed on a blinded CGM and were told to do 10 finger stick blood tests a day; they averaged 9 tests per day

- < 30% of day was 90-130 mg/dL
- 30% of the day was >180 mg/dL
- two hours a day was <60 mg/dL

New technology is needed to help patients get to goal

The average type-1 patient has:

- Two symptomatic hypoglycemic events per week\(^1\)
- One or more episodes of severe, temporally disabling hypoglycemia per year
- Nocturnal hypoglycemia occurs ~ 8.5% of nights\(^2\)

\(^1\) The rate of seizure/coma in the DCCT was 26.7/100 patient years.
Indications for Basal Bolus Therapy (MDI or Insulin Pump)

All Type 1 DM patients
All Type 2 DM patients not at goal (>6.5 to 7%)
All Hospital patients not at goal (>140 mg/dL)
All Pregnancy patients not at goal
(Fasting >90 mg/dL; 1 hr PC >120 mg/dL)
Basal/Bolus Treatment Program with Rapid-acting and Long-acting Analogs

RAI: Rapid Acting Insulin (Aspart, Glulisine, Lispro)

Plasma insulin

Breakfast RAI
Lunch RAI
Dinner RAI

Glargine or Detemir

Time
Initiating SC Basal Bolus

- Starting total dose (TDD) = 0.5 x wgt. in kg
  
  \( Wt. \ is \ 100 \ kg; \ 0.5 \times 100 = 50 \ units \)

- Basal dose (basal analog) = 50% of TDD at HS
  
  \( 0.5 \times 50 = 25 \ units \ at \ HS \)

- Bolus doses (rapid analog) = 50% of TDD
  
  \( 0.5 \times 50 = 25 \text{ divided by } 3 \approx 8 \text{ units pc (tid)} \)

- Correction bolus = \( (BG - 100)/ CF \), where \( CF = 1700/\text{total daily dose}; \ CF = 30 \)
The pump delivers basal and bolus insulin precisely and can be easily customized as needed to meet individual requirements.
Current Durable Insulin Pumps

Photograph reproduced with permission of manufacturer.
Touch Screen Insulin Delivery System

- Durable light aluminum case
- Shatter-resistant glass
- Rechargeable battery
Combo system

• Offers an easy, quick* & discreet way to manage insulin pump therapy

• “smart meter”
Snap Pump with Insulin Cartridge

YOU HAVE THE RIGHT TO REVOLUTIONARY SOLUTIONS.
Snap Pump with Prefilled Insulin Cartridges

Uses prefilled 300 unit insulin cartridges that take seconds to drop in.

Automatically fills your tubing (autoprime) – saving you time.

Is 25% lighter than the leading pump.†

Never needs to have the battery changed or charged. Dispose post 300 units is used

Never requires an insulin reservoir to be filled
Infusion Sets

- Subcutaneous indwelling catheters
- Teflon cannula or steel needle
- Must be changed every 2-3 days
- Pump and tubing may be disconnected without removing insertion site
Crimped soft canulae
Pump infusion sets: perpendicular vs oblique

Perpendicular (Sof-set™, Quick-set™, Ultraflex™)
- Easier insertion
- Prone to kink

Oblique (Silhouette™, Tender™, Comfort™)
- More difficult insertion
- Less kinking
Patch Pump platform
Just two simple parts

Fully integrated two-part design
- Built-in FreeStyle® BG meter that automatically incorporates BG levels into suggested bolus calculations and history records
- Integrated infusion set, insulin reservoir, automated inserter, and batteries

Automated processes
- Cannula insertion
- Priming

Intuitive user interface
- Full text navigation
- Set-up wizard
- Easy to teach, easy to learn

Waterproof Pod
Simple Patch Pump for Type 2 DM

- Continuous preset basal insulin rate (20, 30 or 40 units/24 hrs)
- On-demand mealtime insulin via 2 unit clicks (Max 18 clicks/36 units)
- Uses only RAI
- Easy to fill, apply, use, and remove every 24 hours
- No electronics, batteries, infusion sets, or programming
- Fully disposable
Metabolic Advantages with CSII

Improved glycemic control

Better pharmacokinetic delivery of insulin
  – Less hypoglycemia than NPH based therapy
  – Less insulin required

Improved quality of life
Current Pump Therapy Indications

Need to normalize blood glucose (BG)

- A1C > 6.5% or 7%
- Glycemic excursions

Hypoglycemia or Hypoglycemia unawareness

Need for a flexible insulin regimen

Medicare requires: Fasting C-peptide to be ≤110% lower limit of normal
or ≤200% lower limit of normal if CrCl ≤50 ml/min with concurrent FPG ≤225 mg/dL;
or Beta Cell autoantibody positive (+ICA or +GAD antibodies)
US Pump Usage: Patients Using Insulin Pumps

*Industry estimates*
Insulin Therapy Segmentation (US) – 2008

>5.6 Million = 1.2 Million Type 1 (T1)
4.5 Million Type 2 (T2)

Insulin Therapy:

- **T1 Conventional**: 368,160 (48%)
- **T1 MDI**: 398,840 (52%)
- **T1 Pump Therapy**: 361,000
- **T2 Conventional**: 3,080,160 (69%)
- **T2 Pump Therapy**: 37,000
- **T2 MDI**: 1,383,840 (31%)

>31% Penetration in Type 1
<1% Penetration in Type 2

Source: Medtronic with 78% of the market
CSII
Factors Affecting A1C

Monitoring
- A1C = 8.3 - (0.21 x BG per day)

Bode et al. Diabetes Care 2002;25 439
Correlation between HbA$_{1c}$ levels and number of SMBG measurements

Mean ± 0.95 CI

$n = 12,725$

Factors Affecting A1C

Monitoring
- A1C = 8.3 - (0.21 x BG per day)

Recording 7.4% vs 7.8%

Diet practiced
- CHO: 7.2%
- Fixed: 7.5%
- WAG: 8.0%

Bode et al. Diabetes Care 2002;25 439
Monitor sends BG value to pump via radio waves:
No transcribing error
Enter carbohydrate intake into pump
“Bolus Wizard” calculates suggested dose
Bolus Calculator: Example

Estimation Details:
- Est total: 7.0 U
- Food intake: 60 gr
- BG: 200
- Food: 6.0 U
- Correction: 2.0 U
- Active ins: 1.0 U

Automatically calculates insulin bolus for the patient.
**CALCULATIONS FOR INSULIN PUMP DOSING**

**Method 1. Pre-Pump Total Daily Dose (TDD)**
- Pre-Pump TDD x .75

**Method 2. Patient weight**
- Wt: kg x .5 or lb x .23

**Pump TDD**

**BASAL RATE**
- (PumpTDD x .5)/24hr

**CARB RATIO (CR)**
- 450 / TDD

**Sensitivity Factor (ISF)/ Correction**
- 1700/Pump TDD

**Clinical Guidelines**
- Start with 1 basal rate, adjust according to glucose trends over 2-3 days
- Adjust to maintain stability in fasting state (between meals & during sleep)
- Add additional basals according to diurnal variations (dawn phenomena)

- Adjust based on lowfat meals with known carbohydrate content
- Acceptable 2-hr post-prandial rise is ~60mg/dL above pre-prandial BG
- Adjust carb. ratio in 10-20% increments based on post-prandial BG
- ALTERNATE METHODS
  - Carb Ratio: (6 x Wt in kg/ TDD) or (2.8 x wt in lbs/ TDD)
  - Fixed Meal Bolus = (TDD x .5)/ 3 equal meals (when not carb counting)

- Sensitivity Factor is correct if BG is within 30mg/dL of target range within 2 hours after correction
- Make adjustments in 10-20% increments if 2-hr post correction BGs are consistently above or below target.

**Clinical considerations on Pump TDD**
- Average values from Method 1 & 2
- Hypo patients -> start at lower value
- Hyper, elevated A1C or pregnant-> start at higher value
Bolus Calculator Set Up Screen

Wizard: On
Carb Units: Grams
Carb Ratios: 10
BG Units: mg/dl
Sensitivity: 40
BG Target: 90-100
Active Insulin Time: 5 hours
If on Smart Pumps and not at Goal

Post meal too high
  Lower CIR (Carb to Insulin Ratio)
All BGs too high
  Lower target and / or change CF (ISF)
Fasting or pre meal too high
  Increase basal
Case 1: Type 1 DM on pump at goal

28-year-old male with type 1 DM since age 17
On pump since age 22
No complaints; No assisted hypoglycemia
A1C 6.7%
Current insulin: 62 +/- 8 units/day (0.6 units/kg) with 59% basal; 41% Bolus
SMBG 3.9/day; mean BG 155 +/- 118 mg/dL
<table>
<thead>
<tr>
<th>Glucose Measurements</th>
<th>Bolus Events</th>
<th>Fill Events</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>50 Readings</strong></td>
<td><strong>Sensor Duration (h:mm)</strong></td>
<td><strong>Manual Boluses</strong></td>
</tr>
<tr>
<td>Tuesday 3/29/2011</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Wednesday 3/30/2011</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Thursday 3/31/2011</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Friday 4/1/2011</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Saturday 4/2/2011</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Sunday 4/3/2011</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Monday 4/4/2011</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Tuesday 4/5/2011</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Wednesday 4/6/2011</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Thursday 4/7/2011</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Friday 4/8/2011</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Saturday 4/9/2011</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Sunday 4/10/2011</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Monday 4/11/2011</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td><strong>Summary</strong></td>
<td>3.6/day</td>
<td>0.0/day</td>
</tr>
</tbody>
</table>

Data Sources: Paradigm Revel - 723 (049166)
### Device Settings Snapshot

**Tuesday 4/12/2011 3:19 PM**

#### Basal
- **Maximum Basal Rate**: 2.00 U/hr
- **Temp Basal Type**: Percent of Basal

#### Standard (active)
- **24-Hour Total**: 37.200 U

#### Pattern A
- **24-Hour Total**: --

#### Pattern B
- **24-Hour Total**: --

#### Bolus
- **Maximum Bolus**: 25.0 U
- **Dual/Square (Variable)**: Off
- **Blood Glucose Reminder**: Off
- **Easy (Audio) Bolus**: Off
- **Entry (Step)**: 0.10 U
- **Missed Bolus Reminder**: Off

#### Carbohydrate Ratio (g/L)
- **TIME** | **Ratio**
  - 0:00 | 8.0

#### Insulin Sensitivity (mg/dL per U)
- **TIME** | **Sensitivity**
  - 0:00 | 25

#### Blood Glucose Target (mg/dL)
- **TIME** | **Low** | **High**
  - 0:00 | 100 | 100

#### Notes

#### Sensor
- **Sensor**: Off
- **Transmitter ID**: ------
- **BG Units**: mg/dL

#### Glucose Alerts
- **Off**
- **TIME**: 0:00
- **Low (mg/dL)**: 80
- **High (mg/dL)**: 240

#### Utilities
- **Alert Type**: Vibrate
- **Low Reservoir Warning**: Insulin Units
Readings Below Target | 17 | 33%
Sensor Avg (mg/dL) | -- | --
Avg AUC > 140 (mg/dL) | -- | --
Avg AUC < 70 (mg/dL) | -- | --

Avg Daily Carbs (g) | 175 ± 63
Carbs/Bolus Insulin (g/U) | 6.8

Avg Total Daily Insulin (U) | 62.3 ± 8.2
Avg Daily Basal (U) | 36.8 | 59%
Avg Daily Bolus (U) | 25.5 | 41%

Dinner: 4:00 PM - 10:00 PM
Meals Analyzed: 11

Avg Carbs | 78g
Avg Insulin | 10.4U
Avg Carbs/Insulin | 7.5g/U

<table>
<thead>
<tr>
<th></th>
<th>3</th>
<th>5</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>188</td>
<td>151</td>
<td>181</td>
<td></td>
</tr>
</tbody>
</table>
Do Smart Pumps Enable Others To Go To CSII?

YES

All patients with diabetes not at goal are candidates for Insulin Pump Therapy

- Type 1 any age
- Type 2
- Diabetes in Pregnancy
If A1C is Not to Goal

Must look at:

- SMBG frequency and recording
- Diet practiced
  - Do they know what they are eating?
  - Do they bolus for all food and snacks?
- Infusion site areas
  - Are they in areas of lipohypertrophy?
- Other factors:
  - Bolus % <50% TDD
  - Fear of low BG
  - Overtreatment of low BG
Limitations of SMBG

Traditional glucose monitoring looks at only one point in time.

It doesn’t tell you where you’ve really been, or where you’re going.
Cgm Provides Patient with Live Bio-Feedback

What action should a patient take?

80 mg/dL
What action should be taken now?

- In 30 minutes, what might patient’s glucose be?
- What if patient is about to go to sleep or drive?

Seeing How Glucose is Trending

- 1 arrow indicates glucose has been changing 1 to 2 mg/dL/min
- 2 arrows indicate glucose has been changing >2 mg/dL/min.
CGM Provides Important Live Biofeedback

How might a patient react differently, to this?

Sensor data provides information that allows patients to make more informed decisions.

- 1 arrow indicates glucose has been changing 1 to 2 mg/dL/min.
- 2 arrows indicate glucose has been changing >2 mg/dL/min.

80 mg/dL
Continuous Monitoring Systems

CGMS® iPro™ Recorder

DexCom G4 Platinum

Paradigm or Guardian REAL-Time
Interstitial Glucose Readings
Issues with Lag Time

- Occurs with all subcutaneous sensors
- Will delay alarm for hypoglycemia
- Will affect calibration of sensor
  - Calibration should not be done when glucose values are changing rapidly
CGM

Professional
Owned by Professional (HCP, CDE, Clinic, Hospital)
Can be Masked or Real-time
Reimbursement for Technical fee (95250) and Interpretation (95251)
Covered by most insurers including CMS

Personal
Owned by the Patient
Real-time only
Reimbursement for the Interpretation (95251)
Covered by most insurers but not CMS
Indications for CGM

Patient is not at goal
- A1C above target
- Labile BG values
- Hypoglycemia
- Lifestyle or Employment reasons

Pharmaceutical Research (Masked)
Case 1: Type 2 DM not at goal

64 year-old female with type 2 DM since age 37, 1984
On insulin since 1994; pump since 2000
Gastric bypass 2006; BMI 48 to 29
Current insulin: 26 units/day (0.35 units/kg) with 69% basal; 31% Bolus
SMBG 1.5/day; mean BG 149 +/- 97 mg/dL
A1C 7.9%
### Patient PG: Case 1; Type 2 DM on pump

**Logbook | Trend | Standard Day | Standard Week | Summary**

**Standard Day from: October 12, 2010 to November 11, 2010**

**Blood Sugar Value (mg/dL)**

<table>
<thead>
<tr>
<th>Time of Day</th>
<th>Morning 12:00 AM - 8:00 AM</th>
<th>Midday 8:00 AM - 4:00 PM</th>
<th>Evening 4:00 PM - 12:00 AM</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Readings</td>
<td>No Mark 28</td>
<td>No Mark 8</td>
<td>No Mark 10</td>
</tr>
<tr>
<td>Average Reading</td>
<td>107</td>
<td>156</td>
<td>264</td>
</tr>
<tr>
<td>Std. Deviation</td>
<td>24</td>
<td>57</td>
<td>152</td>
</tr>
<tr>
<td>Above Target(%)</td>
<td>96.4</td>
<td>37.5</td>
<td>70</td>
</tr>
<tr>
<td>Target(%)</td>
<td>62.5</td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Below Target(%)</td>
<td>3.6</td>
<td></td>
<td>20</td>
</tr>
</tbody>
</table>
Patient PG: Case 1; Type 2 DM on pump

Summary of Readings from: October 12, 2010 to November 11, 2010

**DATA SUMMARY**

- No. of Readings: 46
- Min. (mg/dL): 60
- Max. (mg/dL): 530
- Control Readings: 1
- Deleted Readings: 0
- Avg. Tests Per Day: 1.5
- Days Covered: 31
- Days Without Tests: 4
- HbA1c Reading: 0

**DATA ANALYSIS**

<table>
<thead>
<tr>
<th>No. of Readings</th>
<th>Average</th>
<th>Std. Deviation</th>
<th>Above Target(%)</th>
<th>Target(%)</th>
<th>Below Target(%)</th>
<th>Min. (mg/dL)</th>
<th>Max. (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Mark</td>
<td>46</td>
<td>150</td>
<td>98</td>
<td>21.7</td>
<td>71.7</td>
<td>6.5</td>
<td>60</td>
</tr>
<tr>
<td>Before Meal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After Meal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Ordered a Professional CGM on Case 1
Patient PG: Case 1; Type 2 DM on pump

Daily Sensor Overlay

Sensor Data (mg/dL)

<table>
<thead>
<tr>
<th>Date</th>
<th>Thursday Jan 26</th>
<th>Friday Jan 27</th>
<th>Saturday Jan 28</th>
<th>Sunday Jan 29</th>
<th>Monday Jan 30</th>
<th>Tuesday Jan 31</th>
<th>Wednesday Feb 1</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td># Sensor Values</td>
<td>78</td>
<td>288</td>
<td>280</td>
<td>288</td>
<td>288</td>
<td>207</td>
<td>0</td>
<td>1,429</td>
</tr>
<tr>
<td>Highest</td>
<td>253</td>
<td>259</td>
<td>380</td>
<td>319</td>
<td>305</td>
<td>256</td>
<td>N/A</td>
<td>380</td>
</tr>
<tr>
<td>Lowest</td>
<td>72</td>
<td>112</td>
<td>106</td>
<td>70</td>
<td>75</td>
<td>44</td>
<td>N/A</td>
<td>44</td>
</tr>
<tr>
<td>Average</td>
<td>173</td>
<td>170</td>
<td>200</td>
<td>191</td>
<td>147</td>
<td>145</td>
<td>N/A</td>
<td>172</td>
</tr>
<tr>
<td>Standard Dev.</td>
<td>46</td>
<td>36</td>
<td>71</td>
<td>72</td>
<td>49</td>
<td>41</td>
<td>N/A</td>
<td>60</td>
</tr>
<tr>
<td>MAD %</td>
<td>16.1</td>
<td>10.7</td>
<td>7.8</td>
<td>4.6</td>
<td>25.9</td>
<td>2.5</td>
<td>N/A</td>
<td>11.9</td>
</tr>
<tr>
<td>Correlation</td>
<td>N/A</td>
<td>N/A</td>
<td>1.00</td>
<td>0.99</td>
<td>0.78</td>
<td>N/A</td>
<td>N/A</td>
<td>0.91</td>
</tr>
</tbody>
</table>
Patient PG: Case 1; Type 2 DM on pump

Meal Sensor Overlay

Overlay by Meal Event (mg/dL)

Breakfast

Lunch

Dinner

<table>
<thead>
<tr>
<th>Sleeping 3:00 AM - 6:00 AM</th>
<th>Before Breakfast</th>
<th>After Breakfast</th>
<th>Before Lunch</th>
<th>After Lunch</th>
<th>Before Dinner</th>
<th>After Dinner</th>
<th>Evening 11:00 PM - 3:00 AM</th>
<th>All Time Periods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>100 - 150</td>
<td>70 - 130</td>
<td>100 - 160</td>
<td>70 - 130</td>
<td>100 - 160</td>
<td>70 - 130</td>
<td>100 - 160</td>
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<td>Highest</td>
<td>174</td>
<td>170</td>
<td>319</td>
<td>267</td>
<td>288</td>
<td>238</td>
<td>380</td>
<td>380</td>
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<tr>
<td>Lowest</td>
<td>70</td>
<td>76</td>
<td>75</td>
<td>114</td>
<td>71</td>
<td>44</td>
<td>96</td>
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<tr>
<td>Average</td>
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<td>189</td>
<td>173</td>
<td>176</td>
<td>224</td>
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<tr>
<td>Standard Dev.</td>
<td>25</td>
<td>29</td>
<td>61</td>
<td>46</td>
<td>37</td>
<td>41</td>
<td>80</td>
<td>38</td>
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<tr>
<td># of Readings</td>
<td>180</td>
<td>60</td>
<td>120</td>
<td>60</td>
<td>120</td>
<td>46</td>
<td>96</td>
<td>240</td>
</tr>
</tbody>
</table>
Patient PG: Case 1; Type 2 DM on pump
Night Time Sensor Overlay

Night Time Sensor Data (mg/dL)

Thu Jan 26  Fri Jan 27  Sat Jan 28  Sun Jan 29  Mon Jan 30  Tue Jan 31  Wed Feb 1  Average

The graph shows the nocturnal sensor data for the patient over a period from Thursday, January 26, to Wednesday, February 1. The data is color-coded for each day, with a green shaded area indicating the target range for glucose levels. The data points are plotted from 11:00 p.m. to 6:00 a.m., with an average value indicated at the bottom.
Case 2: Type 1 DM on pump not at goal

Recommendations:

1. Bolus for each meal
   - Start with 4 to 6 units and increase as needed to keep next BG <120 mg/dL or post meal <180 mg/dL

2. Increase SMBG to 4/day
Short-term, Episodic, Real-Time Continuous Glucose Monitoring (RT-CGM) Improves Short-Term and Legacy Glycemic Control in Patients with Type 2 Diabetes

Study population:

- Type 2 diabetes with an A1C of $\geq 7.0\%$.
- N=50 real-time CGM group; N=50 SMBG/control group.
- No subjects were on meal-time/prandial insulin.

# Selected Characteristics of Study Subjects

N=100; 50 per group

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>SMBG Group</th>
<th>RT-CGM Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age [mean (SD)]</td>
<td>60.0 (11.9)</td>
<td>55.5 (9.6)</td>
</tr>
<tr>
<td>Male [n (%)]</td>
<td>22 (44.0)</td>
<td>33 (66.0)</td>
</tr>
<tr>
<td>Baseline A1c [mean (SD)]</td>
<td>8.2 (1.1)</td>
<td>8.4 (1.3)</td>
</tr>
</tbody>
</table>

Mean A1c Change From Baseline (RT-CGM vs. SMBG)

Figure 2. Mean A1c Change-from-Baseline, by Treatment Group

\[ \Delta = 0.51\% \times \frac{1}{\text{Time}^2} \]

\[ \Delta = 1.16\% \times \frac{1}{\text{Time}^2} \]

Conclusion of CGM in Type 2 DM

Intermittent use of real-time CGM in the type 2, non-intensive insulin treated diabetes patients showed a significantly greater reduction in A1C than SMBG alone and was sustained for 1 year (p=0.05).

More regular use of real time CGM (>48 out of 56 days) led to greater reductions in A1C.

Study suggests that real time CGM is a powerful behavior modification tool.

- Real time CGM increases glycemic awareness and promotes lifestyle changes and medication adherence.

JDRF Study HbA1c Change in ≥ 7.0% Cohort with CGM Use ≥ 6 days/week in Month 12

<table>
<thead>
<tr>
<th>Age</th>
<th>Change in A₁c (%)</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 25</td>
<td></td>
<td>34</td>
</tr>
<tr>
<td>Age 15-24</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Age 8-14</td>
<td></td>
<td>15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age Group</th>
<th>0-26wks</th>
<th>0-52wks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 25</td>
<td>-0.5</td>
<td>-0.5</td>
</tr>
<tr>
<td>Age 15-24</td>
<td>-0.5</td>
<td>-0.7</td>
</tr>
<tr>
<td>Age 8-14</td>
<td></td>
<td>-0.8</td>
</tr>
</tbody>
</table>

Note: Data represents the change in HbA1c (%) for different age groups with CGM use ≥ 6 days/week in Month 12.
JDRF $A_1c < 7\%$ Cohort: Change in the frequency of sensor glucose levels $< 70 \text{ mg/dL}$

- **Baseline**
  - RT-CGM: 91 minutes/day
  - Control: 96 minutes/day
  - $p = 0.002$

- **26 Wks**
  - RT-CGM: 54 minutes/day
  - Control: 91 minutes/day
  - $p = 0.43$
Severe hypoglycemia

≥ 7.0% HbA1c  < 7.0% HbA1c
STAR 3: Randomized, controlled SAPT vs MDI

1-year study 6-month continuation phase

- 485 type 1 adults and children
- 30 sites
- Published 2010

Two Arms:
- MDI + meter + CareLink (control)
- Pump + CGM + CareLink

- Pump + CGM improves $A_1c$ 1.21%
- Pump + CGM improves $A_1c$ 1.0% compared to MDI + meter
- No increase in hypoglycemia

6 month study
- 115 subjects, $A_{1c} \geq 8.0$
  - 69 adults
  - 46 children
- On MDI + meter
  - $\geq 3$ meter readings / day
- 8 French centers
- Published 2009

Two Arms:
- Pump + meter
- Pump + CGM (CGM group instructed to wear sensors 70% of the time (5 d/wk)

RealTrend: Randomized, controlled SAPT vs Pump

- Pump improves $A_{1c} > 0.5\%$ compared to MDI
- Pump + CGM improves $A_{1c} 1.2\%$ compared to MDI + meter

EURYTHMICS: Investigator-initiated, randomized, controlled

6 Month Study
- 83 adults type 1: Age 18-65 years
  - Using MDI (multiple daily injections)
  - HbA$_{1c} \geq 8.2\%$
- Multicenter: 8 European centers
  - 8 European countries

Two Arms:
- Stay on MDI + meter (control)
- Pump + CGM (Paradigm REAL-Time)
  - No specified CGM usage frequency

• Pump + CGM improves A$_{1c}$ 1.2% compared to MDI + meter
• No increase in hypoglycemia

Abstract, EASD 2010 to be published 2011.
Severe Hypoglycemia and A1C: DCCT\textsuperscript{15} (1993), JDRF\textsuperscript{2} (2008), and STAR 3\textsuperscript{16} (2010) Studies

- DCCT (intensive therapy): 62 per 100 pt-yrs, A1C (6.5 yr): 9.0% $\rightarrow$ 7.2%
- JDRF CGM (adults): 43.4 per 100 pt-yrs; A1C (6 mo): 7.5% $\rightarrow$ 7.1%

Adapted from Figure 5B of: DCCT. \textit{N Engl J Med.} 1993;329:977-986.
Severe Hypoglycemia and A1C:
DCCT\textsuperscript{15} (1993), JDRF\textsuperscript{2} (2008), and STAR 3\textsuperscript{16} (2010) Studies

- **DCCT (intensive therapy):**
  - 62 per 100 pt-yrs,
  - A1C(6.5 yr): 9.0% → 7.2%

- **JDRF CGM (adults, 1 subject excluded):**
  - 20.0 per 100 pt-yrs;
  - A1C (6 mo): 7.5% → 7.1%

- **STAR 3 SAP (all ages):**
  - 13.3 per 100 pt-yrs;
  - A1C (1 yr): 8.3% → 7.5%

- **STAR 3 MDI (all ages):**
  - 13.5 per 100 pt-yrs;
  - A1C (1 yr): 8.3% → 8.1%

Adapted from Figure 5B of: DCCT. *N Engl J Med*. 1993;329:977-986.
CGM Concepts and Guidelines

1. Empower patients to use trending
Preventing Hypoglycemia with CGM:

Hypoglycemia avoided
Cgm Concepts and Guidelines

1. Empower patients to use trending
2. Look for patterns in foods commonly eaten
How CGM Provides Information Missed By SMBG

Delayed increase after rapid analog wears off

High Fat Meal

Insulin Boluses
CGM Concepts and Guidelines

1. Empower patients to use trending
2. Look for patterns in foods commonly eaten
3. Be patient: avoid over treatment of both highs and lows
Welcome to the Glucose Roller Coaster…

Correction dose given, no breakfast

Hypoglycemia overtreated with 3 chocolate bars

Marked hyperglycemia after overtreatment of hypoglycemia, followed by stacking insulin boluses, leading to more hypoglycemia

Insulin given
CGM Concepts and Guidelines

1. Empower patients to use trending
2. Look for patterns in foods commonly eaten
3. Be patient: avoid over treatment of both highs and lows
4. Calibration is key: get a high quality fingerstick
How important is a clean fingerstick...

SMBG reading 182 mg/dl

SMBG 2 minutes later 48 mg/dl
CGM Concepts and Guidelines

1. Empower patients to use trending
2. Look for patterns in foods commonly eaten
3. Be patient: avoid over treatment of both highs and lows
4. Calibration is key: get a high quality fingerstick
5. Alarms should mean something
Normal Bolus w/ BW; followed by low in late meal period may indicate Basals are too high.
CGM Concepts and Guidelines

1. Empower patients to use trending
2. Look for patterns in foods commonly eaten
3. Be patient: avoid over treatment of both highs and lows
4. Calibration is key: get a high quality fingerstick
5. Alarms should mean something
6. Timing is everything: bolus 20 minutes ahead to lower post prandial hyperglycemia
Ultimate Goal

A closed-loop system
### Pipeline Overview: Closed Loop

<table>
<thead>
<tr>
<th>Past</th>
<th>Present</th>
<th>2013-2014</th>
<th>Future</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PUMPING</strong>&lt;br&gt;THINKING</td>
<td><strong>SENSING</strong>&lt;br&gt;COMMUNICATING</td>
<td><strong>ACTING</strong></td>
<td><strong>AUTOMATING</strong></td>
</tr>
<tr>
<td><strong>Phase I:</strong> Building the Foundation</td>
<td><strong>Phase II:</strong> The First Big Step</td>
<td><strong>Phase III:</strong> The Next Big Step</td>
<td><strong>Phase IV:</strong> Closing the Loop</td>
</tr>
<tr>
<td>- Standard pump &lt;br&gt;- Data/pump integration &lt;br&gt;- Sensor technology &lt;br&gt;- Bolus Wizard</td>
<td>- Pump &amp; Sensor combined &lt;br&gt;- REAL-Time data integration &lt;br&gt;- Improved algorithms &lt;br&gt;- Enhanced data management</td>
<td>- Semi-automated insulin dosing &lt;br&gt;- Threshold suspend if low &lt;br&gt;- Enhanced data management &lt;br&gt;- Optimized sensor performance</td>
<td>- Predictive LGS algorithm &lt;br&gt;- Treat-to-Range &lt;br&gt;- Overnight closed loop &lt;br&gt;- Fully-automated delivery</td>
</tr>
</tbody>
</table>
First Commercial Step in the Artificial Pancreas

Threshold Suspend
Example of Threshold Suspend Cycle

Automatically suspends insulin delivery if sensor glucose reaches the user-set limit

- **Insulin Suspends for 2 hours / Resumes for 4 hours**

- **Suspend time maximum = 2 hrs**

- **Basal insulin infusion will resume even if glucose is below Thresh Suspend limit**

Glucose (mg/dL)

- 180
- 160
- 140
- 120
- 100
- 80
- 60

- 40
- 20
- 0

12 AM 3 AM 6 AM

- **Basal Insulin**

- **2 Hour Suspend**

- **Time**

- **Basal Insulin**
Threshold Suspend in CareLink® Professional

Daily Detail Report

Threshold Suspend

Manual Suspend
(Not represented in above report)
Threshold Suspend: Two Hour Suspension

- Patient did not respond to TS alarm
- Basal suspended for two hours, then automatically resumed
Threshold Suspend: Insulin Restarted

Patient:
- Cleared the alarm
- Tested BG
- Resumed insulin delivery immediately
Threshold Suspend: Insulin Restarted after One Hour

Patient:
- Cleared alarm and kept the basal rate suspended.
- Confirmed low with a fingerstick.
- Resumed basal delivery after approximately one hour.
<table>
<thead>
<tr>
<th>Therapy Management Dashboard</th>
</tr>
</thead>
</table>

### Pump Use

<table>
<thead>
<tr>
<th></th>
<th>Per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin TDD</td>
<td>44.0 ± 4.2U</td>
</tr>
<tr>
<td>Basal/Bolus Ratio</td>
<td>42 / 58</td>
</tr>
<tr>
<td>Manual Boluses</td>
<td>0.0U (0.0 boluses)</td>
</tr>
<tr>
<td>Bolus Wizard</td>
<td>25.7U (4.6 boluses)</td>
</tr>
<tr>
<td>Food</td>
<td>23.8U (3.9 boluses)</td>
</tr>
<tr>
<td>Correction</td>
<td>4.3U (3.9 boluses)</td>
</tr>
<tr>
<td>Override (+)</td>
<td>0.2U (0.1 boluses)</td>
</tr>
<tr>
<td>Override (-)</td>
<td>-1.4U (0.3 boluses)</td>
</tr>
</tbody>
</table>

### Suspended Duration

- **1h 22m per day**

### Threshold Events

- **2.3 per day**

### Time

- **1h 14m per day**

### Res./Site Change

- **Every 4.7 / 3.5 days**

### Sensor Use

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg SG</td>
<td>127 ± 45 mg/dL</td>
</tr>
<tr>
<td>Wear Duration</td>
<td>6d 20h per week</td>
</tr>
<tr>
<td>Low SG Alarms</td>
<td>20.5 per day</td>
</tr>
<tr>
<td>High SG Alarms</td>
<td>5.1 per day</td>
</tr>
</tbody>
</table>

**Only highest priority shown.**
## CareLink® Sample Report
### Adherence Report

<table>
<thead>
<tr>
<th>Glucose Measurements</th>
<th>Bolus Events</th>
<th>Fill Events</th>
<th>Suspend Duration (h:mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BG Readings</strong></td>
<td>Manual Boluses</td>
<td>Rewind</td>
<td><strong>Cannula Fills</strong></td>
</tr>
<tr>
<td><strong>Sensor Duration (h:mm)</strong></td>
<td>Bolus Wizard Events</td>
<td>Cannula Amount (U)</td>
<td></td>
</tr>
<tr>
<td><strong>With Food</strong></td>
<td>With Correction</td>
<td>Overridden</td>
<td></td>
</tr>
<tr>
<td><strong>Overridden</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Day</th>
<th>BG Readings</th>
<th>Sensor Duration</th>
<th>Manual Boluses</th>
<th>Bolus Wizard Events</th>
<th>With Food</th>
<th>With Correction</th>
<th>Overridden</th>
<th>Rewind</th>
<th>Cannula Fills</th>
<th>Cannula Amount (U)</th>
<th>Tubing Fills</th>
<th>Tubing Amount (U)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Friday 12/6/2013</td>
<td>3</td>
<td>22:30</td>
<td>6</td>
<td>1</td>
<td></td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
<td>0.3</td>
<td>1</td>
<td>11.2</td>
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<tr>
<td>Saturday 12/7/2013</td>
<td>3</td>
<td>23:15</td>
<td>7</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0.3</td>
<td>1</td>
<td>11.2</td>
</tr>
<tr>
<td>Sunday 12/8/2013</td>
<td>2</td>
<td>23:00</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
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<td>0.3</td>
<td>1</td>
<td>11.2</td>
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<tr>
<td>Monday 12/9/2013</td>
<td>5</td>
<td>12:50</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
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<td>0.3</td>
<td>1</td>
<td>11.2</td>
</tr>
<tr>
<td>Tuesday 12/10/2013</td>
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<td>Wednesday 12/11/2013</td>
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<td>24:00</td>
<td>2</td>
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<td>Thursday 12/12/2013</td>
<td>4</td>
<td>18:55</td>
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<td>Friday 12/13/2013</td>
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<td>22:40</td>
<td>8</td>
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</tr>
<tr>
<td>Saturday 12/14/2013</td>
<td>2</td>
<td>22:55</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<td>1</td>
<td>1</td>
<td>0.3</td>
<td>1</td>
<td>11.2</td>
</tr>
<tr>
<td>Sunday 12/15/2013</td>
<td>4</td>
<td>19:40</td>
<td>8</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<td>3</td>
<td>19:50</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
<td>0.3</td>
<td>1</td>
<td>11.2</td>
</tr>
<tr>
<td>Tuesday 12/17/2013</td>
<td>2</td>
<td>23:30</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<td>Wednesday 12/18/2013</td>
<td>3</td>
<td>20:45</td>
<td>5</td>
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<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
<td>0.3</td>
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</tr>
<tr>
<td>Thursday 12/19/2013</td>
<td>3</td>
<td>22:45</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
<td>0.3</td>
<td>1</td>
<td>11.2</td>
</tr>
</tbody>
</table>

**Summary**: 3.0/day 12d 11h 35m  5.1/day 0.9/day 50.0% 100.0% 66.7%  5 4 0.3U 4 6.1U fill 1d 22h 53m
Evaluate Overnight & Meal Glucose

Start with Overnight

24-Hour Analysis – Sensor, Insulin, & Settings

Statistics
- Avg BG: 181 ± 76mg/dL
- Estimated A1C: 7.0%
- BG Readings: 6.8 per day
- Carbs Entered: 151 ± 25g per day

Hypoglycemic Patterns (2)
- Time Period: 8:21 AM-9:21 AM (1)

Hyperglycemic Patterns (7)**
- Time Period: 12:30 AM-6:40 AM (1)

Pump Use Per Day
- Insulin TDD: 47.1 ± 1.7U
- Basal/Bolus Ratio: 43 / 57
- Manual Boluses: 4.0U (2.7 boluses)
- Bolus Wizard: 22.6U (6.5 boluses)
- Food: 18.7U (3.8 boluses)
- Correction: 6.0U (3.6 boluses)
- Override (+): 0.8U (1.2 boluses)
- Override (-): 0.1U (0.2 boluses)

Suspend Duration: 5m per day
Res/Site Change: Every 1.4 / 1.4 days

Sensor Use
- Avg SG: 154 ± 50 mg/dL
- Wear Duration: 5d 18h per week
- Low SG Alarms: 2.2 per day
- High SG Alarms: 2.2 per day

* Most recent pump settings are displayed
ASPIRE In-Home
Outpatient Study to Evaluate Safety and Effectiveness of the Threshold Suspend Feature (NCT01497938)

- **Primary endpoints:**
  - **Efficacy:** Nocturnal hypoglycemia event mean area under the curve (AUC)
  - **Safety:** Change in A1C from baseline

- **19 Centers in the United States**
ASPIRE In-Home Study: Participants

Study conducted with Veo pump that is not FDA approved and not commercially available in the US. Study data and final report have not been submitted to FDA.


<table>
<thead>
<tr>
<th></th>
<th>Threshold Suspend</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>41.6 ± 12.8</td>
<td>44.8 ± 13.8</td>
</tr>
<tr>
<td>% Male</td>
<td>38</td>
<td>39.7</td>
</tr>
<tr>
<td>Diabetes Duration</td>
<td>27.1 ± 12.5</td>
<td>26.7 ± 12.7</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>27.6 ± 4.7</td>
<td>27.1 ± 4.3</td>
</tr>
</tbody>
</table>

Screen failures or withdrawals (94)
Withdrawals or did not meet randomization criteria (73)
Baseline Enrollment (414)
Run-in Phase (2 weeks) (320)
Randomized (247)
Control (126)
Study Phase (3 months)
A1C and Nocturnal Hypoglycemia AUC
Early withdrawals (5 Threshold Suspend, 2 Control)
Randomized
Threshold Suspend (121)
Control (126)
### ASPIRE In-Home Study: Predictors of Nocturnal Hypoglycemia

Data taken from the run-in phase of the ASPIRE study

<table>
<thead>
<tr>
<th>Continuous Variable</th>
<th>P value</th>
<th>P value (adjusted for GV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline A1c</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Coefficient of Variation</td>
<td>&lt;0.001</td>
<td>N/A</td>
</tr>
<tr>
<td>Basal : Bolus Ratio</td>
<td>0.76</td>
<td>0.20</td>
</tr>
<tr>
<td>Age</td>
<td>&lt;0.001</td>
<td>0.26</td>
</tr>
<tr>
<td>Diabetes Duration</td>
<td>&lt;0.001</td>
<td>0.92</td>
</tr>
<tr>
<td>BMI</td>
<td>0.026</td>
<td>0.39</td>
</tr>
</tbody>
</table>

Study conducted with Veo pump that is not FDA approved and not commercially available in the US. Study data and final report have not been submitted to FDA.

Study conducted with Veo pump that is not FDA approved and not commercially available in the US. Study data and final report have not been submitted to FDA.


The severity and/or duration of nocturnal hypoglycemic events was lower in the Threshold Suspend Group.
Hypoglycemic events were less frequent in the Threshold Suspend Group.

Study conducted with Veo pump that is not FDA approved and not commercially available in the US. Study data and final report have not been submitted to FDA.

ASPIRE In-Home Study: Results

Reduction in hypoglycemia in the Group Threshold Suspend

There were fewer SG values in hypoglycemic ranges in the Threshold Suspend Group.

Study conducted with Veo pump that is not FDA approved and not commercially available in the US. Study data and final report have not been submitted to FDA.

ASPIRE In-Home Study: Results

Glycated Hemoglobin (A1C)

\[ \Delta \text{A1C} \] was similar in the two groups. The 95% CI of the difference in \( \Delta \text{A1C} \) (\(-0.05, 0.15\)) did not include the non-inferiority limit of 0.4%.

Study conducted with Veo pump that is not FDA approved and not commercially available in the US. Study data and final report have not been submitted to FDA.

Phase IV: Closing the Loop

- Predictive LGS algorithm
- Treat-to-Range
- Overnight closed loop
- Fully-automated delivery
Artificial Pancreas

Technology

Investigators

Algorithms

Data

Veo and Enlite are not FDA approved, and other products and features mentioned are under development.
### Closed-loop vs. Hybrid Closed-loop control

#### Graph Description
- **Y-axis:** Glucose (mg/dl)
- **X-axis:** Time (0-42 hours)
- **Legend:**
  - Dotted line: setpoint
  - Red line: Closed Loop (N=5)
  - Blue line: Hybrid Closed Loop (N=5)
  - Green triangles: Meals

#### Data Table
<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Nocturnal</th>
<th>Peak PP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Closed Loop</td>
<td>156 (149-163)</td>
<td>109 (87-131)</td>
<td>232 (208-256)</td>
</tr>
<tr>
<td>Hybrid Closed Loop</td>
<td>135 (129-141)</td>
<td>114 (98-131)</td>
<td>191 (168-215)</td>
</tr>
</tbody>
</table>
Connectivity – Remote Monitoring
Connectivity - Future
Connectivity - Future
Conclusions

We have a lot to learn
The future is bright
Technology will revolutionize diabetes care
Continuous glucose sensing will drive CSII
Thank you
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