Diabetes Technology Update

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Diabetes & Endocrine Assoc.
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Disclosures

None

No future technologies are FDA approved
Continuous Glucose Monitors
Continuous Glucose Monitors (CGM)

- Transmitter
- Sensor
- Glucose
- Interstitial fluid
- Capillary
- Receiver
Two Eras of Diabetes Management

DCCT: 1986 to 1993

JDRF CGM Study
Control Group 2006-2007

Rate of severe Hypoglycemia (per 100 patient-years)

Glycosylated Hemoglobin (%)
Time Spent in Hypoglycemia Significantly Reduced with CGM

Frequency of CGM Glucose Levels ≤ 70, ≤ 60 and ≤ 50 mg/dL

Each comparison Baseline vs 13 and 26 wks

Diabetes Care 2009: 32:1378-1383
Dexcom G5
Medtronic Guardian Connect

• Available Summer, 2018

• 7 Day Guardian Sensor 3 connects via Bluetooth to Guardian Connect app

• Sugar.IQ™ intelligent diabetes assistant app
Freestyle Libre
10 Day Sensor

Measures glucose every minute

No separate transmitter. Must be scanned by reader

Each scan provides a current glucose reading, a trend arrow, and an 8-hour history
Future Technologies

• Freestyle Libre Link
  • Communicate to smart phone
  • Shorter warm up
  • Longer wear
Future Technologies

• Dexcom G6
  • 10 Days Wear
  • Thinner transmitter
  • Easier insertion
  • 1 Calibration daily
  ? Zero calibrations
• No acetaminophen interference
• Availability ? 2018

• Direct communication with smartwatches + Fitbit
Future Technology

• Verily + Dexcom
  • Disposable CGM
  • Lower cost
  • ? Available 2020
Future technology

- Senseonics
  - 90 Day implantable CGM
  - FDA review pending

_Eversense® CGM System Components_
Patch Pumps
V-go

- Type 2 Diabetes
- Fill and replace daily
- Fixed basal doses
- Bolus for meals (up to 36 units daily)
Two part System: Personal Diabetes Manager (PDM) and Pod

Communicate wirelessly to deliver basal and bolus insulin based on personalized settings

PDM must be within 5 feet to communicate with the Pod

Once basal program is set, the Pod will deliver basal insulin 24 hours a day regardless of PDM location
Future Technologies

• BD 3 day disposable patch pump
  • ? Available 2018

An elegant solution to simplify the lives of type 2 patients

Deliver transformative solutions

Intuitive design
Adjustable basal and bolus
Affordable pricing

Emerging billion-dollar product category
Future Technologies

• Cellnovo
  • Patch pump with short tube
  • FDA review currently
Pumps
Tandem

Integrated Dexcom G5

T:slim X2

T-Flex
• 480 units insulin/cartridge
Medtronic

530G

630G

670G
Hybrid Closed Loops
THE MINIMED® 670G SYSTEM WITH SMARTGUARD® HCL TECHNOLOGY

WHAT ARE THE COMPONENTS OF THE SYSTEM?

Indicated for people with type 1 diabetes age 14 and older.
SmartGuard® HCL Technology

- Suspend on low
- Suspend before low
- Auto Mode (Hybrid Closed Loop)
# Details of the Pivotal trial for Minimed 670G System

## SINGLE ARM, NON-RANDOMIZED STUDY DESIGN*PUBLISHED IN JAMA, DTT

### Study Design
- Multicenter: 9 sites in US & 1 site in Israel
- Single-arm (no control group)
- Non-randomized

### Patients
- N=124
- Type 1 ≥ 2 years
- A1C < 10%
- Ages 14-75 yr
- Pump therapy ≥ 6 months, with or without CGM

## Study Protocol

<table>
<thead>
<tr>
<th>RUN-IN PERIOD: Pump + CGM</th>
<th>STUDY PERIOD: Auto Mode*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 weeks</td>
<td>3 months</td>
</tr>
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</table>

**Day 1: HCL Training (Auto Mode)**

**Day 7: Auto Mode turned ON**

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**WARNING:** Medtronic performed an evaluation of the Minimed 670G close loop system and determined that it may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. Therefore, this device should not be used in anyone under the age of 7 years old. This device should also not be used in patient who require less than a total daily insulin does of 8 units per day because the device requires a minimum of 8 units per day to operate safely.
A1c lowering across broad glycemic range
75% OF PATIENTS LOWERED THEIR A1C

Patients on average experienced 0.5% reduction in A1C* in 3 months
SmartGuard HCL technology adjusts insulin in real time based on glucose levels. It can help keep levels between 70 to 180mg/dL 72% of the time, maximizing time in control day and night.

<table>
<thead>
<tr>
<th>Sensor Glucose</th>
<th>Run-in % Time in Range</th>
<th>Study % Time in Range</th>
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<tbody>
<tr>
<td>&gt; 300 mg/dL</td>
<td>2.3</td>
<td>1.7</td>
</tr>
<tr>
<td>&gt; 180 mg/dL</td>
<td>27.4</td>
<td>24.5</td>
</tr>
<tr>
<td>71 – 180 mg/dL</td>
<td>66.7</td>
<td>72.2</td>
</tr>
<tr>
<td>≤ 70 mg/dL</td>
<td>5.9</td>
<td>3.3</td>
</tr>
<tr>
<td>≤ 50 mg/dL</td>
<td>1.0</td>
<td>0.6</td>
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<tbody>
<tr>
<td>&gt; 300 mg/dL*</td>
<td>2.1</td>
<td>1.4</td>
</tr>
<tr>
<td>&gt; 180 mg/dL</td>
<td>26.8</td>
<td>21.6</td>
</tr>
<tr>
<td>71 – 180 mg/dL</td>
<td>66.8</td>
<td>75.3</td>
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Future Technology

• Omnipod Horizon Automated Glucose Control System
  • Step 1: OmniPod Dash
    • FDA review currently
  • U200 and U500 pods
  • Step 2: Tubeless pump + Dexcom G6 + Android based handheld receiver
    • ? Available 2010

• Tandem T:slim X2 pump + Dexcom G5 sensor
  • Step 1: X2 pump stops insulin delivery before glucose is low
    • ? Available 2018
  • Step 2: Automatic delivery of basal and correction insulin
    • ? Available 2019
Omnipod Dash

Introducing Omnipod Dash Insulin Management System
One Digital Mobile Platform... Many Products

BLE Pod
BLE Blood Glucose Meter
PDM (Android Locked-Down Device)

Secure Cloud
Data Analytics

User Secondary Display Mobile App
Caregiver Follow Mobile App

BLE = Bluetooth Low Energy
PDM = Personal Diabetes Manager

Insulet Investor Day - November 16, 2016
Insulet Corporation
Future Technologies

• Bigfoot Biomedical
  • "Bigfoot Loop," investigational infusion-pump based automated insulin delivery (AID) system
    • Not yet in trials

• Beta Bionics
  • iLet4 system, a dual-hormone glucagon and insulin closed loop device
    • In trials