The Future of Diabetes Care: Insulin Pumps, Continuous Glucose Sensors and other devices

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Objectives:

* Promote Understanding of existing and new technologies in the treatment and management of patients with diabetes including Insulin Pumps, Continuous Glucose Monitors, New Meters and Digital Applications
* Identify components of an insulin pump and how it works.
* Identify components of a Continuous Glucose Monitor and how it works
* Advantages and Disadvantages of insulin pump therapy
* What does the future hold?????
Times are changing!
Insulin Pumps

- The first insulin pump was developed in the late 1960’s/early 1970s.
- Little early excitement due to concerns from size, safety, efficacy and complications.
Early Insulin Pumps
Insulin Pumps Available in the US Today
Components of Insulin Pump

* Insulin Pump
Components of an Insulin Pump

* Reservoir: Holds the insulin
Components of an Insulin Pump

- Infusion Set: What is inserted in the body and is changed every 2 to 3 days
Basal rate

- Continuous flow of insulin from pump to patient
- This is background insulin
- Controls blood glucose in a fasting state.
- Different rates can be programmed throughout the day to deal with variable need
- It mimics the steady and small amount of insulin secreted by pancreas throughout day and night
- Very precise delivery
**Bolus**
- Insulin given at meals to “cover” food eaten and correct elevated blood glucose levels
- **Insulin to Carb Ratio:** example) 1 unit of insulin taken for every 15 grams of carbs.
- **Correction/Sensitivity:** amount of insulin given to correct for high blood glucose levels. Think of it as the sliding scale or correction.
- **Target Blood Glucose:** the blood glucose level you are aiming for.
- **Insulin Action/Active Insulin Time:** Effects the amount of correction that can be given and helps to prevent ‘stacking’ of correction boluses that can lead to lows. It will calculate how much active insulin is on board and not allow extra to be given. The usual setting is 2 to 4 hours.
Advantages of Pump Therapy

- Using an insulin pump means eliminating individual insulin injections: LESS SHOTS!
- Pumps deliver insulin more accurately and precisely than injections
- Ideal for athletes/exercise to decrease insulin delivery during an event or after through Temp Basal Rates
- Meal time doses can be delivered over a period of time instead of all at once—i.e. Extended boluses for high-fat/high carb meals
- Insulin pumps often improve A1C and glycemic control
**Disadvantages of Pump Therapy**

* Increased risk for Diabetic Ketoacidosis (DKA): Pump only delivers short acting insulin so there is a potential for rapid onset of significant hyperglycemia and DKA if insulin delivery is interrupted

* Risk for site infection

* Something is always attached to the person

* Cost (pump $4500-$8500+; yearly supplies ~ $1,500.) That does not include the cost of sensors.
Continuous Glucose Monitoring System (CGM)

* Measures the Glucose in the body’s interstitial fluid
* Not the same thing as a finger stick
* Interstitial Glucose levels lag behind blood glucose levels by 15-20 minutes.
Three Parts to a CGM: The Sensor

- Worn on the body, inserted with a needle and changed out every 6-7 days.
- The Sensor under the skin is the thickness of an eyelash.
The Transmitter hooks into the sensor and sends all the glucose information to the receiver/monitor.

This is the expensive part of the system and reused with each new sensor.
Three Parts to a CGM: The Receiver

* The Receiver has a screen where you can check your current glucose level, look at historical data, and get trends about whether the glucose is likely to go up or down and how fast.
* Can be a traditional receiver, a phone or an insulin pump.
Throughout the day, the wearer can look down and see what their glucose value is within a 90% accuracy.

Perhaps even more valuable than the immediate glucose level is the direction and speed at which glucose levels are heading.
The wearer can be alerted when they go above a pre-set high glucose level as well as a pre-set low glucose level.

Advanced alerts can also be set to alert the wearer when they are dropping or rising at certain rates.

We usually recommend just the High and Low Alerts. Typically our patients will not have their Advanced Alerts turned on as they tend to go off a lot and “drive kids crazy.”
Key Point to Remember:
The Systems being used today are accurate enough that they can replace finger sticks throughout the day and/or insulin can be dosed off the readings.
Continuous Glucose Monitoring Systems on the Market
Dexcom G4 Sensor

- Allows sensor data to be remotely shared with up to 5 people so they can follow the patient's glucose data and trends on their compatible smart devices.
- Wearer must carry receiver and phone.
Dexcom G5 Sensor

- Worn for 7 days
- Provides real-time glucose readings every 5 minutes
- Patient can use a receiver or a phone to receive their data and alerts. Don’t have to carry both as with the Dexcom G4 Sensor
- If patient is using a phone as a receiver, up to 5 people can follow them on their phones and receive real-time glucose readings and alerts on their phones as well.
Dexcom G5 Sensor: Apps

Dexcom G5 Mobile App
App on the child’s phone to receive the real-time glucose data

Dexcom Clarity app
App on child’s phone, allows medical professionals and families to track and download data and reports

Dexcom Follow App
For the followers phone
The only FDA approved system, for ages 2 and older that is approved to replace finger sticks throughout the day:

- If the wearer is calibrating the sensor, meaning entering a finger stick glucose into the sensor to update it, every 12 hours, the Dexcom Reading may be used in replace of a finger stick at other times throughout the day.
- We recommend calibrating each morning before breakfast and each evening before dinner. Bedtime calibrations are often done as well.
The FDA has approved the Dexcom Readings can also be used for treatment decisions.

- The wearer can use the Dexcom reading to enter into their insulin pump for insulin dosing.
- If not on an insulin pump, the reading can be used for determining sliding scale/correction insulin before meals.
- The trend arrows can also be used to determine if less or more insulin is required before a meal or snack as well.
* Take Away for You:

If you have a child wearing a Dexcom G5 Sensor, and they are calibrating every 12 hours at home, you don’t have to do a finger stick glucose:

- Before lunch
- Before/After PE
- Before/After Recess
- Before dismissal or getting on the bus

*IF the Dexcom reading does not match the child’s symptoms, a finger stick should be done to confirm the reading.
Dexcom G5 Sensor: Watch Integration

- The Dexcom G5 Mobile App supports Apple Watch or Android Wear watches and can be used to discreetly view your glucose reading, trend arrow, and trend graph.
- Phone must be carried when linked to watch. The Dexcom Transmitter must first be connected to phone and then the phone connects to the watch.
Dexcom in the Future

* Dexcom is sharing its technology with various insulin pump makers as they are developing their own closed loop systems (artificial pancreases).

* Dexcom is waiting on FDA approval for the Dexcom G6 Sensor in 2017
  * 10 day wear
  * 1 finger stick calibration
  * Smaller transmitter
  * One button push insertion of the sensor
Dexcom
Customer Service
1(888)738-3646
FreeStyle LibrePro
Professional CGM

- Sensor is placed on the back of the upper arm of patient in clinic
- Worn for 14 days
- No calibrations needed
- No separate receiver, transmitter, or recorder is needed to be carried by patient
- Device is downloaded and reports are viewed once patient returns to clinic.
Insulin Pumps on the market
Animas Insulin Pumps: One Touch Ping Insulin Pump

- Approved for use in all ages: pediatric through elderly
- Consists of insulin pump and One Touch Ping meter that sends all blood sugars to the pump.
- Patient can bolus from either the meter or the pump.
Animas Insulin Pumps: Animas Vibe with Dexcom G4 Sensor

- Animas pump acts as the receiver for the Dexcom G4 sensor.
- The sensor and all data from it is displayed on the pump.
- Insulin delivery is not affected/controlled by the CGM.
- Approved for ages 2 and older
Animas has a Hybrid Closed Loop system they are working on at this time.

Animas has a pump that works with the Dexcom G5 CGM that has been approved by the FDA, but they have not launched its production at this time.
Animas
Customer Service
1-877-937-7867
Medtronic Insulin Pumps

MiniMed Paradigm Real-Time Revel

Approved for all ages

Medtronic MiniMed 530G with Enlite Sensor

Approved for ages 16 and older
Medtronic Insulin Pumps

MiniMed 530G Pump and Enlite Sensor with Connect Transmitter

Medtronic Pump and Sensor
Medtronic Insulin Pumps:
MiniMed 630G System

- New Pump Design
- Waterproof
- New link meter that allows for a manual bolus to be given from the meter
- Threshold Suspend feature is designed to automatically stop insulin delivery when your sensor value reaches or falls below a pre-set threshold
- Upgraded Guardian Sensor

Started Shipping in Late fall 2016

Approved for ages 16 and older
Medtronic Insulin Pumps: MiniMed 670G System

- It is a Hybrid closed loop system
- Allows patient and Health Care provider to choose from increasing levels of automation that best fits their diabetes management needs
- New Guardian 3 Sensor, allows for 7 day wear
- The only sensor FDA approved to control insulin dosing

Approved for ages 14 and older
* It has the Smart Guard technology with the **Suspend before low feature**: avoids lows and rebound highs proactively by automatically stopping insulin 30 minutes before you reach your pre-selected low limits, then automatically restarts insulin when your levels recover, all without bothersome alerts.

* The **Auto Mode** option automatically adjusts your basal insulin delivery every 5 minutes based on your sugar levels to keep you in target range, all day and night.

* **CONTOUR®NEXT LINK 2.4** meter links to pump provides remote set dose bolusing.
Medtronic Insulin Pumps: MiniMed 670G System

THE MINIMED® 670G SYSTEM
THE WORLD'S FIRST HYBRID CLOSED LOOP SYSTEM

Maximizes time in target range

SmartGuard HCL Technology
- Automated basal delivery
- Predictive low glucose suspend
- Suspend on low

More consumer-friendly design
Medtronic Insulin Pumps: MiniMed 670G System

Increasing levels of automation to best fit your diabetes management needs.

**Suspend on low**
Suspends insulin delivery when glucose levels reach a pre-set low limit providing greater protection against lows.

**Suspend before low**
Suspends insulin delivery before glucose levels reach a pre-set low to help you further address lows.

**Auto mode**
Automatically adjusts basal insulin delivery based on sensor glucose readings to help you stay within your target glucose range.
The 670G is considered a “hybrid closed loop” system because it is not fully automated. The patient is still required to enter their finger stick glucose before meals and the total carbohydrates they will be eating throughout the day.

It automatically adjusts basal insulin throughout the day based on the Guardian 3 sensor readings. It doesn’t give large correction boluses for elevated blood sugars.

For example: If patient forgets to give insulin for a meal, they will still have elevated blood sugars. The basal rate will increase due to the elevation in blood sugars, but it won’t give a large correction bolus amount at one time.
Medtronic
Customer Service
1-800-646-4633
Insulet Insulin Pumps: Omnipo

- Only Tubeless insulin pump
- Waterproof
- Auto-Cannula insertion
- Approved for all ages: Pediatric through elderly

- PDM must be within 5 feet to communicate with Pod (for boluses)
- The Pod will deliver basal insulin 24 hours a day regardless of PDM location
- Personal Diabetes Manager (PDM) includes a Freestyle glucose meter
- 80 hour forced change-out (Pod can not be worn longer than 80 hours)
Insulet Insulin Pumps: Omnipod

Mobile Apps

My Omnipod® Mobile App
- Convenient Pod reorder
- Instructional web videos
- Interactive carbohydrate counter

Toby's T1D Tale
- Virtual storybook for tablets
- Fun, interactive diabetes learning tool for children

iPad only
Insulet Insulin Pump: Omnipod Future Dash System

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
Omnipod Dash, basically replaces the current PDM with a locked-down Android phone. "Locked down” means the phone will have no other regular cellular capabilities or other apps available, nor will it have an integrated finger-stick glucose meter like the current PDM. It also means that users will basically be carrying around two smartphones.

Agreement has been made to link a Contour meter to DASH via Bluetooth, which will use the readings to calculate and deliver the appropriate insulin dose. Insulet is still hoping for spring 2018 launch, depending on FDA consideration.
Insulet Insulin Pump: OmnipoD Future

* DASH is an "interim step" to their full Pump+CGM closed loop system controlled directly from a regular (non locked-down) smart phone that they're calling OmniPod Horizon

* Date of approval for this is unknown
OmniPod/Insulet
Customer Service
1-800-591-3455
Tandem Insulin Pumps:

<table>
<thead>
<tr>
<th>Model</th>
<th>Description</th>
<th>Capacity</th>
<th>Maximum Bolus</th>
<th>Smallest Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>t:slim X2</td>
<td>The next-generation color touchscreen pump with advanced Bluetooth radio. Optimized for use with the Tandem Device Updater.¹</td>
<td>300 units</td>
<td>25 units</td>
<td>Smallest available pump</td>
</tr>
<tr>
<td>t:slim G4</td>
<td>The first CGM-enabled, touchscreen insulin pump. Fully integrated with the Dexcom G4™ PLATINUM Continuous Glucose Monitor.</td>
<td>300 units</td>
<td>25 units</td>
<td>Smallest available CGM-enabled pump</td>
</tr>
<tr>
<td>t:flex</td>
<td>Designed for people with greater insulin needs (over 80 units/day from a pump, or &gt;120 units/day with MDI.)</td>
<td>480 units</td>
<td>60 units</td>
<td>Smaller than Medtronic® &amp; Animas® models²</td>
</tr>
</tbody>
</table>

¹. Software updates and new features are not currently available for the t:slim X2 Pump and are subject to FDA approvals. Charges may apply.
². 36% smaller than Medtronic 630G and 25% smaller than Animas Vibe. Data on file, Tandem Diabetes Care, Inc.
Tandem Insulin Pumps:

* Color Screen
* Micro-delivery: Delivers insulin in the tiniest increments available
* Rechargeable battery
* USB connectivity: for convenient charging and fast data transfer speeds
* Watertight: up to 3 feet for 30 minutes
Tandem Insulin Pumps: t:slim x2

- Two-way Bluetooth radio allowing it to communicate with more than one external device at a time. (i.e. Phone, meter, CGM)
- Fully Upgradable Pump: Tandem Device Uploader is a tool for the remote update of Tandem insulin pump software, allowing users to update their pump from a personal computer as new features are approved by the FDA.
Tandem Insulin Pumps: Future Upgrades Coming...

Dexcom G5 Mobile CGM Integration

The addition of Bluetooth to glucose monitoring technology opens up new opportunities for connected systems. We are currently working on integration with the Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) system.

Timelines as of 11/1/2016:
- FDA submission planned for late 2016
- Launch goal: Mid-2017
Predictive Low Glucose Suspend (PLGS)

Our first-generation Automated Insulin Delivery (AID) system is planned to include a Predictive Low Glucose Suspend (PLGS) algorithm. The algorithm will use CGM data to help predict future hypoglycemia (low blood sugar) before it happens and is designed to adjust insulin to help minimize the frequency and/or duration of hypoglycemic events. The algorithm was developed internally in consultation with thought leaders in Automated Insulin Delivery and Artificial Pancreas research.

Timelines as of 11/1/2016:
- Feasibility study completed in August 2016
- Pivotal study planned to begin in Q1 2017
- Launch goal: Late 2017

Graph is for illustrative purposes only, and does not reflect individual results.
Tandem Insulin Pumps: Future Upgrades Coming

AUTOMATED INSULIN DELIVERY SYSTEM

Hybrid Closed Loop (HCL)

In July 2016 we announced a license agreement with TypeZero Technologies to accelerate development of a hybrid closed loop system. TypeZero’s AP technology includes a series of treat-to-target algorithms developed by TypeZero from initial research conducted at the University of Virginia. In 2016, this technology had been used in more than 28 clinical studies including more than 475 participants, with data referenced in a number of journal articles.9

Tandem, Dexcom and TypeZero are working together on the integration of their technologies into the NIH-funded International Diabetes Closed Loop (IDCL) Trial. A Tandem insulin pump and Dexcom G6 sensor will be included as part of a blood glucose control system that combines these devices with a smartphone running TypeZero’s inControl hybrid closed loop algorithm. Tandem is also working on development on a Tandem insulin pump that integrates the data from a Dexcom G6 sensor and TypeZero’s inControl algorithm directly into the pump’s touchscreen interface.

- Press Release: Tandem Diabetes Care and TypeZero Technologies Announce License Agreement to Accelerate Development and Commercialization of Closed-Loop Artificial Pancreas System
- Press Release: NIH-funded International Diabetes Closed Loop (IDCL) Trial to Combine Technologies from Tandem Diabetes Care, Dexcom and TypeZero

Timelines as of 11/1/2016:
- Pivotal study planned in 2017
- Launch goal: 2018
Tandem
Customer Service
1-858-375-1178
There’s an App for that...

- Calorie King
- Glooko
- My Fitness Pal
- Glucose Buddy
- Carb Counting with Lenny
- Go Meals
Questions???????


References