INNOVATIVE TECHNOLOGY & DIABETES
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PWD FOR 25 YEARS

OBJECTIVES
- Identify important safety features and differences of 3 Continuous Glucose Monitoring (CGM) systems
- Identify important safety features and differences of 3 insulin pump delivery systems
- Identify 3 companies working on the artificial pancreas (AP)

THE PAST

DIABETES MIS-MANAGEMENT
- Misdiagnosed as Type 2 in 1992
- NPH & Regular mixed in one syringe
- Given BID (breakfast & dinner)
- Ultimately matched FOOD to insulin
- Was on a daily roller coaster
- Insulin Pump Therapy not even a consideration

IMPROVEMENTS IN DIABETES MANAGEMENT
- 1996: Introduction of insulin analog lispro
- Changed dosing from BID to TID
- Added lispro at dinner (& no NPH)
- Moved NPH to HS

Activity Profiles of Different Types of Insulin

<table>
<thead>
<tr>
<th>Glucose infusion rate (mg/dL/min)</th>
<th>Time (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin lispro aspart, glulisine</td>
<td>0–3 3 6 9 12 15 18 21 24</td>
</tr>
<tr>
<td>Regular</td>
<td>0–3 3 6 9 12 15 18 21 24</td>
</tr>
<tr>
<td>NPH</td>
<td>0–3 3 6 9 12 15 18 21 24</td>
</tr>
<tr>
<td>Insulin detemir</td>
<td>0–3 3 6 9 12 15 18 21 24</td>
</tr>
<tr>
<td>Insulin glargine</td>
<td>0–3 3 6 9 12 15 18 21 24</td>
</tr>
</tbody>
</table>
Y2K & IPT
- Worked in ICU/CCU
- Started IPT on 9/11/2000
- It rocked my world!
- It changed my attitude about T1D!
- 1st A1C = 7% after 3 months on IPT!

My First Pump

Deltec Cozmo
R.I.P. 2002-2009
ANIMAS
- IR 1000, IR 1200, IR 1250
- 2020
- One Touch Ping
- Vibe

R.I.P.
1999-2017

ANIMAS
- Warranties being honored until 9/30/2019
- Letters sent to patients recommending Medtronic: Switch2System program
- Tandem: One time payment of $999 & Tandem Touch Simplicity program
- Omnipod: No upfront costs: Omnipod welcome program

CONTINUOUS GLUCOSE MONITORING (CGM)

GLUCOWATCH
R.I.P. 2002-2007
THE PRESENT

CONTINUOUS GLUCOSE MONITORING in 2017
- DEXCOM G5 Mobile CGM System
  - Integrated with Tandem/t:slim x2
  - G4 Integrated with Animas/Vibe
- MEDTRONIC GUARDIAN SENSOR 3
  - Integrated with MiniMed’s 670G System
- Abbott’s FreeStyle Libre

DEXCOM
- 1999: G1–founded
- 2006: G2–3 day sensor
- 2007: G3–7 day sensor
- 2008: G4–Agreement/Insulet & Animas
- 2015: G5–Partnered with Tandem

DEXCOM 2017
- G5 Mobile CGM System
  - Approved for dosing without fingersticks
  - 1st & only CGM system approved to replace a BG meter for diabetes treatment decisions

DEXCOM G5
- Sensor: measures glucose levels just below the skin
- Transmitter: communicates to your mobile device or Dexcom G5 Mobile Receiver
- Dexcom Receiver
- Mobile Device

Transmitter & Sensor
**DEXCOM G5**
- Gives BG every 5 minutes with directional arrows
- Requires calibrations q. 12 hours
- Approved for ages 2 and older
- 9% MARD (adult)
- 10% MARD (pediatric)
- Dexcom Share (allows up to 5 followers)

**MEDTRONIC**
- 1949: founded in a garage
- 2001: acquired MiniMed
  - 1983: first pump was 502
  - 1999: first MD use CGM/3 day sensor & 508
- 2003: Paradigm 512
- 2004: Pt. use Guardian CGM
- 2005: Guardian RT CGM system
- 2010: Paradigm RT Revel System
- 2011: Enlite Sensor
  - 1st gen AP device with Threshold Suspend automation for ages 16+
- 2013: 530G w/Enlite Sensor
- 2015: 620G (Japan), 630G (US), 640G

**MEDTRONIC GUARDIAN SENSOR 3**
- Integrated with MiniMed 670G Insulin Pump
- 1st & only CGM sensor FDA approved to control insulin dosing
- 7 day wear
- Requires calibrations q. 12 hours
GUARDIAN SENSOR 3
- Gives BG every 5 minutes with directional arrows
- Approved for ages 14 and older
- 10.66% MARD (with 2 calibrations)
- 9.64% MARD (with 3-4 calibrations)

ABBOTT’S FreeStyle Libre
- Flash glucose monitoring system
- No fingerstick calibration required
- 10 day wear (in Europe 14 days)
- 12 hour warm-up (in Europe 1 hour)
- Ages 18+ (outside USA age is 4+)

ABBOTT’S FreeStyle Libre
- Considered CGM since it collects glucose every minute, displays a number and a trend arrow
- To obtain real time BG & trend, sensor must be scanned (within 1.5”) using a reader device
- Can be scanned through clothing
- 9.7% MARD
INSULIN DELIVERY SYSTEMS

INSULET: Omnipod
TANDEM: t:slim x2
MEDTRONIC: MiniMed 670G

OMNIPOD
- 2000: company founded
- 2005: 1st generation: launched 1st and only tubeless insulin delivery system, then & now
- 2013: 2nd generation

INSULET OMNIPOD

Approved for all ages
OMNIPOD
Personal Diabetes Manager

- PDM is a handheld remote that communicates within 5 feet of Pod to make changes in basal program, for a bolus delivery or to check pod status
- For activation Pod must be placed to the right of and touching PDM

OMNIPOD

- POD
  - Holds 200 units
  - Wear for 3 days/72 hours
  - Waterproof: IPX8 rating for up to 25 feet of water for 60 minutes
  - 6.5mm cannula

OMNIPOD

- Basal program, I:C ratio, ISF, Temp Basal, Extended bolus, Suspend, Status
- Integrated FreeStyle meter registers BG for treatment options
- 2 AAA alkaline – average life is 3 weeks

OMNIPOD

- Omnipod Insulin Management System
  - Downloads insulin delivery totals
  - BG values
  - Carb records
- CoPilot Health Management System and Omnipod Extension Software (app is free to download)
TANDEM

**t:slim**
- 2007: founded
- 2011: FDA approved
- 2012: started shipping
- 2015: t:flex (480u) t:slim & G4
- 2016: t:slim x2

**t:slim x2**
- Approved for ages 6 and older
- Holds 300 units
- Built-in rechargeable battery/USB
- Recharges in about 10 minutes
- Average battery use is 10% a day

**t:slim**
- Watertight: IPX7 rating tested to 3 feet of water for 30 minutes
- Micro-delivery technology
- Pouch inside cartridge to hold insulin
- Cartridge with pigtail
TANDEM t:slim
- t:connect Diabetes Management Application
- USB on pump
- Data from last 90 days

TANDEM t:slim x2
- Integration with Dexcom G5
- Can be used with or without CGM
- Bluetooth radio capable of communicating with compatible devices and future technologies

TANDEM t:slim x2
- Tandem Device Updater
- Allows users to update their pumps through use of personal computer
- Can deliver future software

MEDTRONIC
MiniMed 670G

MiniMed 670G SYSTEM
- First hybrid closed-loop system
- Can be used with or without CGM integration with Guardian Sensor 3
- Waterproof: IBX8 rating 12 feet of water for 24 hours
MiniMed 670G SYSTEM

For ages 14+

AA battery
- Rechargeable or Dollar Store or Lithium
- Average is 4-6 weeks, user dependent

Warning: “May not be safe for use in children under the age of 7 because of the way the system is designed and the daily insulin requirements.”

Warning: Should NOT be used if TDD is <8 units a day

Manual Mode
- Auto Mode
- Smart Guard HCL Technology
  - Suspend before low
  - Auto Mode Option

Suspend Before Low Option
- Automatically stops insulin delivery 30 minutes before BG reaches the pre-selected low limits

THEN automatically resumes insulin when BG levels recover

Auto Mode Option
- Automatically adjusts basal insulin delivery every 5 minutes based on sugar levels to keep BG in target range.

No temp basal, instead temp target
MiniMed 670G SYSTEM

- GUARDIAN SENSOR 3 CGM
- 2 hour warm-up
- 7 day wear
- 1st & only CGM sensor FDA approved to control insulin dosing
- Calibrations required q. 12 hours
- **3-4 recommended**

MiniMed 670G SYSTEM

- Contour NEXT LINK meter 2.4 glucose meter
- For CGM calibration
- For remote bolusing
- Guardian Connect APP
- Carelink Personal Data Reports

Artificial Pancreas (AP) Projects

- 53 AP trials currently underway in FDA approved human trials (out of a total of 442 T1D projects)
- AP development has evolved from academia & is now almost exclusively led by commercial for-profit entities
ARTIFICIAL PANCREAS (AP)
- BIGFOOT BIOMEDICAL
- BETA BIONICS: iLet BIONIC PANCREAS
- TANDEM & TYPE ZERO TECHNOLOGIES

BIGFOOT BIOMEDICAL
- 2011: trio of diabetes dads
  - Bryan Mazlish (the original “Bigfoot”)
  - Jeffrey Brewer (former JDRF leader)
  - Lane Desborough (former Medtronic Chief Engineer)
- 2015: acquired Asante Snap

ASANTE SNAP 2013-2015

BIGFOOT BIOMEDICAL
- 2015: partnered with Dexcom
- 2017: broke-up with Dexcom
- 2017: partnership with Abbott Diabetes Care to integrate next generation version of FreeStyle Libre Flash CGM system
- 2017: bought Timesulin Insulin Pen Tracker

[Diagram showing connections between devices and mobile application]
BIGFOOT BIOMEDICAL

Pre-filled cartridge & tubing
Former Snap Pump: Bluetooth chip inside will talk to
Abbott FreeStyle Libre sensor
Smart phone app

BIGFOOT BIOMEDICAL

Their goal is to “submit our investigational system for Premarket Approval (PMA) to the U.S. FDA in early 2018.”
...we shall see...

BETA BIONICS

iLet

iLet Bionic Pancreas

Introducing the iLet

The one and only fully integrated, fully automated bihormonal bionic pancreas

BETA BIONICS

iLet Bionic Pancreas

iLet Bionic Pancreas

Dr. Edward Damiano’s son David was dx’d with T1D 17 yrs ago at 11 months of age
College of Engineering Professor of Biomedical Engineering at Boston University
He began working on the bionic pancreas soon after his son’s dx
iLet Bionic Pancreas

10/21/2015 Beta Bionics was founded as a Public Benefit Corporation by
A trio of brainiacs:
- Dr. Edward Damiano
- Toby Milgrome
- Firas El-Khatib

$22 million from National Institute of Health
$5 million from Eli Lilly & Co.
$5 million from Novo Nordisk
$1 million from 700+ donors

iLet Bionic Pancreas

Dual infusion set with 2 cannulas
Dual chamber with 2 cartridges
Insulin & glucagon
One sensor/Dexcom G5
2020 (?)... we shall see...

TANDEM & TYPE ZERO

Tandem's t:slim x2
Dexcom G5 sensor
Type Zero Artificial Pancreas In Control algorithm
Controlled by smartphone
TANDEM & TYPE ZERO
- NIH funding the new International Diabetes Closed Loop (IDCL) trial
- Pivotal study planned to be completed by end of 2017
- Launch goal timeline (as of 10/12/17): Summer 2018

CONFERENCES
- Diabetes Technology Society’s 17TH Annual Diabetes Technology Meeting in Bethesda, MD 11/2/17-11/4/17
- Clinical Diabetes Technology Meeting in Houston, TX, 4/21/17-4/22/17

NEW & NOVEL INSULINS
- Intraperitoneal Insulin
- Hepatic Directed Insulin
- Biosimilar Insulin
- Glucose Responsive Insulin

WEARABLE TECHNOLOGY
- Contact Lens: Google X investigating a contact lens that can monitor diabetics’ blood sugar levels by testing their tears
- Smart skin pump patches
- Tattoos: change color based on glucose values

WEARABLE TECHNOLOGY
“Our foremost goal is to establish a new diabetes treatment paradigm. The AP is not a single function device. It is an adaptable, wearable network surrounding the patient in a digital treatment ecosystem.”

Boris Kovatchev, Director of UVA Center for Diabetes Technology, University of Virginia Project
WEARABLE TECHNOLOGY

- to establish a new diabetes treatment paradigm
- AP is not a single function device
- It is an adaptable, wearable network surrounding the patient in a digital treatment ecosystem

TECHNOLOGY vs. QUALITY OF LIFE

And so we wait for future technology &/or a cure...until there is Type None Diabetes