The long and winding road to the bionic pancreas

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Our Bihormonal Bionic Pancreas on the iPhone Platform

Continuous glucose monitor measures glucose levels just under the skin and transmits the data wirelessly to an iPhone.

iPhone receives data and runs an app with an algorithm that computes insulin and glucagon doses.

Dual pump is commanded by iPhone to deliver insulin when glucose levels rise and glucagon when glucose levels fall.
Our Bihormonal Bionic Pancreas on the iPhone Platform

**Summer Camp Studies:** Summers of 2013 & 2014

- **Beacon Hill Study:** Q1 – Q3 2013
- **Bionic Pancreas Multi-Center Study:** Q2 2014 – Q2 2015
The Clinical Results – Bihormonal Configuration

2013 Summer Camp Study:  Summer 2013
32 Teens (12–20 years)
5-Day Experiments

Control
Mean CGM: 158 ± 27 mg/dl
(Projected A1C: 7.1%)
Time < 60 mg/dl: 2.2%
Time > 180 mg/dl: 31%

Bionic Pancreas
Mean CGM: 142 ± 12 mg/dl
(Projected A1C: 6.6%)
Time < 60 mg/dl: 1.3%
Time > 180 mg/dl: 21%

Russell et al. (2014) 371, 313–325
New England Journal of Medicine

2014 Summer Camp Study:  Summer 2014
19 Pre-Teens (6–11 years)
5-Day Experiments

Control
Mean CGM: 168 ± 30 mg/dl
(Projected A1C: 7.5%)
Time < 60 mg/dl: 2.8%
Time > 180 mg/dl: 36%

Bionic Pancreas
Mean CGM: 137 ± 11 mg/dl
(Projected A1C: 6.4%)
Time < 60 mg/dl: 1.2%
Time > 180 mg/dl: 17%

Russell et al. (2016) 4, 233–243
The Lancet Diabetes & Endocrinology

Bionic Pancreas Multi-Center Study:  Q2 2014 – Q2 2015
39 Adults (≥ 18 years)
11-Day Experiments

Control
Mean CGM: 162 ± 29 mg/dl
(Projected A1C: 7.3%)
Time < 60 mg/dl: 1.9%
Time > 180 mg/dl: 34%

Bionic Pancreas
Mean CGM: 141 ± 10 mg/dl
(Projected A1C: 6.5%)
Time < 60 mg/dl: 0.6%
Time > 180 mg/dl: 20%
The Clinical Results – Bihormonal Configuration

2013 Summer Camp Study: Summer 2013
32 Teens (12–20 years)
5-Day Experiments

32 Teens (12–20 years)
5-Day Experiments

Control
TDD Insulin: 0.79 Units/kg/day
Bionic Pancreas
TDD Insulin: 0.82 Units/kg/day

Russell et al. (2014) 371, 313–325
New England Journal of Medicine

2014 Summer Camp Study: Summer 2014
19 Pre-Teens (6–11 years)
5-Day Experiments

Control
TDD Insulin: 0.68 Units/kg/day
Bionic Pancreas
TDD Insulin: 0.68 Units/kg/day

Russell et al. (2016) 4, 233–243
The Lancet Diabetes & Endocrinology

Bionic Pancreas Multi-Center Study: Q2 2014 – Q2 2015
39 Adults (≥ 18 years)
11-Day Experiments

Control
TDD Insulin: 0.62 Units/kg/day
Bionic Pancreas
TDD Insulin: 0.66 Units/kg/day
The Clinical Results – Bihormonal Configuration

2013 Summer Camp Study: Summer 2013
32 Teens (12–20 years)
5-Day Experiments

Control
Bionic Pancreas
TDD Glucagon:
0.72 mg/day
(11 µg/kg/day)

Russell et al. (2014) 371, 313–325
New England Journal of Medicine

2014 Summer Camp Study: Summer 2014
19 Pre-Teens (6–11 years)
5-Day Experiments

Control
Bionic Pancreas
TDD Glucagon:
0.36 mg/day
(11 µg/kg/day)

Russell et al. (2016) 4, 233–243
The Lancet Diabetes & Endocrinology

Bionic Pancreas Multi-Center Study: Q2 2014 – Q2 2015
39 Adults (≥ 18 years)
11-Day Experiments

Control
Bionic Pancreas
TDD Glucagon:
0.51 mg/day
(7 µg/kg/day)
11 Days on Usual Care – One Subject
11 Days on Bionic Pancreas – One Subject
11 Days on Usual Care – Entire Cohort
11 Days on Bionic Pancreas – Entire Cohort
The bionic pancreas simultaneously solves the 4 greatest concerns of T1D management:

1. It reduces mean blood sugar levels in everyone to levels that would likely eradicate long-term microvascular and neurological complications if implemented at the time of diagnosis.

2. It profoundly curtails mild low blood sugar levels in everyone, and would likely eliminate severe hypoglycemia in people with T1D.

3. It automates blood sugar control for everyone, thus unburdening people with T1D of the relentless need to comply with therapy, as the bionic pancreas itself is the first technology to be entirely compliant with the patient's needs rather than the other way around.

4. It unburdens people with T1D and their families of the emotional hardship that is, for now, part of everyday life, and of the constant fear of hypoglycemia, and of the worry and dread of long-term complications.
11 Days on Usual Care – One Subject
11 Days on Bionic Pancreas – One Subject
Daily Average Glucose on **Bionic Pancreas** versus **Usual Care**

TDD of Insulin on **Bionic Pancreas** versus **Usual Care**
% Difference in Standard Deviation of Daily TDD on Bionic Pancreas Relative to Usual Care

"Do you want to follow your insulin, or do you want your insulin to follow you?"
The Clinical Results – Insulin-Only Configuration

**Insulin-Only Stanford Study:** Q4 2015 – Q1 2016

16 Adults (≥18 years)
7-Day Experiments

- **Control:**
  - Mean: 151 ± 26 mg/dl
  - 1.9% <60, 26% >180

- **Insulin Only:**
  - Mean: 160 ± 9 mg/dl
  - 0.9% <60, 30% >180

1% <60 mg/dl
5% <60 mg/dl
Our Bihormonal Bionic Pancreas on the iPhone Platform
The iLet™

Carry your glucose metabolism in your pocket.
Next Steps

- Beacon Hill Study: February – September 2013
- Summer Camp Study: Summers of 2013 & 2014
- Bionic Pancreas Multi-Center Study: June 2014 – April 2015
- Bionic Pancreas Set-Point Study: August 2015 – May 2016

- Bionic Pancreas Insulin-Only Bridging Study: Q4 2016

- Phase 2 Insulin-Only–Bihormonal Comparison Study: Q1 2017

- Bionic Pancreas Pivotal Trial (Insulin-Only & Bihormonal): Begins Q2 2017
Clinical Sites for the Bionic Pancreas Pivotal Trial

Northeast Clinical Sites:
- Joslin Diabetes Center (Wolpert)
- Cleveland Clinic (Hatipoglu)
- Naomi Berrie Center (Goland)

Northeast Coordinating Center:
- MGH (Russell)

Southeast Clinical Sites:
- Emory/Children’s Healthcare of Atlanta (Muir)
- Washington University (McCullough)
- UNC, Chapel Hill (Buse)

Southeast Coordinating Center:
- Nemours (Mauras)

Central Clinical Sites:
- U of Texas, Southwestern (White)
- U of Texas, San Antonio (Hale)
- Henry Ford Medical Center (Kruger)

Central Coordinating Center:
- Barbara Davis Center (Maahs)

West Coast Clinical Sites:
- U of Washington (Hirsch)
- UCSD (Henry)
- CHOC (Daniels)

West Coast Coordinating Center:
- Stanford (Buckingham)

National Coordinating Center:
- Jaeb Center (Beck)
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