Patch Pumps for Insulin Delivery

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Disclosures

• **Research Support**: Abbott, Ambra, Ascensia, BD, Boehringer Ingelheim, Calibra Medical, Companion Medical, Dance Biopharm, Dexcom, Eli Lilly, Glooko, Glysens, Kowa, Lexicon, MannKind, Medtronic, Novo Nordisk, sanofi, Senseonics, Taidoc, Versartis, Xeris

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• **Speaking Honoraria**: Abbott, Eli Lilly, Medtronic, Novo Nordisk, Sanofi
Diabetes (simplified...)

Know Glucose

Eating? Exercise? Emotion? Other?

Do the right things

repeat, repeat, repeat, repeat, repeat, repeat, repeat, repeat, repeat, repeat, repeat, repeat, repeat, repeat, repeat
Mitigating the A1c – Hypo Tradeoff

![Graph showing the relationship between severe hypoglycemia and retinopathy across different HbA1c levels for intensive and conventional treatment groups.](image-url)
Can Technology Change the Curve?
Better Insulin; Better Monitoring

Lower risk of hypoglycemia for insulin glargine vs NPH at any level of HbA1c in T1DM

Meta-analysis of 5 randomized trials comparing insulin glargine and NPH in HbA1c in T1DM

Rate of hypoglycemia (events per patients/year)

Glargine
NPH

P=0004

HbA1c (%; LOCF)

HbA1c

Risks

Hypoglycemia
Complications
w/CGM


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Insulin Delivery Options

vs.
Patch Pump Positioning

• “Untethered”
  – Tubing is a logistical consideration
• Where should the UI (user interface) go?
  – Dedicated controller vs. Phone (vs. Patch itself)
• Where should the “brain” (controller) be?
  – Increased importance for APS
• What should be the body interface be?
• Can a sensor be integrated?
## UK T1 Pump Real-World Data

Greater HbA1c Lowering with Tethered vs. Small Insulin Pumps in a Large Insulin Pump Service

<table>
<thead>
<tr>
<th>Pump type</th>
<th>Initial HbA1c range (mol/mol (%))</th>
<th>Baseline HbA1c</th>
<th>6 months HbA1c</th>
<th>p vs baseline</th>
<th>12 months HbA1c</th>
<th>p vs baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tethered (n=509)</td>
<td>All starting values</td>
<td>71±0.7</td>
<td>63±0.6*</td>
<td>&lt;0.001</td>
<td>65±0.7'</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Small (n=85)</td>
<td>≥ 69 (85%)</td>
<td>71±0.9</td>
<td>70±1.6</td>
<td>NS</td>
<td>69±1.6</td>
<td>NS</td>
</tr>
<tr>
<td>Tethered (n=273)</td>
<td></td>
<td>83±0.7</td>
<td>69±0.8**</td>
<td>&lt;0.001</td>
<td>71±0.9'</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Small (n=43)</td>
<td></td>
<td>83±2.3</td>
<td>77±2</td>
<td>&lt;0.05</td>
<td>77±2.1</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Tethered (n=132)</td>
<td>59-68 (7.5-8.4%)</td>
<td>64±0.2</td>
<td>59±0.7**</td>
<td>&lt;0.001</td>
<td>59±0.8*</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Small (n=28)</td>
<td></td>
<td>64±0.5</td>
<td>66±1.4</td>
<td>NS</td>
<td>64±1.4</td>
<td>NS</td>
</tr>
</tbody>
</table>

Data shown as mean±SEM. * p<0.05, ** p<0.001 for tethered vs small.
Patch Pump Types

- “Semi-Patch” (i.e. short tubing)
  - Cell Novo
  - Kaleido
  - t:sport (Tandem)
  - Lilly (DEKA)

- Infusion set flexibility?

- Patch (NO tubing)
  - Omnipod
  - YpsoPod
  - Terumo
  - Evopump (Cam Med)
  - EOPatch (EOFlow)
  - Jewel
  - Solo
  - P6 EasyPatch
  - *CeQur
  - *V-Go
  - *Swatch (BD)
  - *One Touch Via (J&J) – bolus only

*= targets T2 DM
J&J Via

- Bolus only
  - 2 units / click
- Subjects and HCPs preferred
- Improved (vs pen)
  - subject experience
  - treatment satisfaction
  - QoL associated
- Same A1c / hypo
- Same insulin doses

**ADA 2018**
cellnovo

- Durable/disposable components
- Cell network connectivity
- Exercise tracker
- Integrated BGM / controller
Kaleido

- Colorful
- Friendly UI
- Rechargable
Omnipod – U500
**Study Design**

People with T2D:
- Age 18-85 years
- BMI 25-50 kg/m²
- A1C ≥7.5 to <12.0%
- TDD >200 to ≤600 U

Transition to U-500R by MDI 40:30:30

U-500R MDI (3x/d)

U-500R CSII

1:1 randomization

Treatment period

2 Weeks

26 Weeks
Vivid Study

U-500R by CSII and MDI led to significant A1C reduction from baseline

CSII led to a significantly greater A1C reduction compared to MDI at Week 26

<table>
<thead>
<tr>
<th></th>
<th>A1C change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDI</td>
<td>-0.85% ± 0.07%</td>
</tr>
<tr>
<td>CSII</td>
<td>-1.27% ± 0.07%</td>
</tr>
</tbody>
</table>

95% CI: (-0.62, -0.22%)
Vivid Study

CSII treatment led to greater A1C reduction with lower TDD compared to MDI.

No significant difference in documented symptomatic or severe hypoglycemia; CSII led to significantly higher rate of nocturnal hypoglycemia.
T2 Switched to Omnipod

- Retrospective (n=81)
- 3 month outcome after switch
  - MDI to Omnipod
- 46.2% reduction in hypos
  - 1.3 to 0.7 episodes/wk ($P = .004$)
Jewel Pump

- MEMS precise delivery
- 500U insulin for up to 7 days use.
- The disposable unit is filled once and discarded entirely after use (controller unit -2 years)
- Remotely controlled by the JewelCOM (Smartphone-PDA) – 3G cell
- Integrated BGM
- JewelPUMP2 – up to 800U insulin
V-Go

• 20, 30, or 40 Units of insulin in one 24-hour period (0.83 U/hr, 1.25 U/hr or 1.67 U/hr)
• Bolus dosing in 2 Unit increments (up to 36 Units per 24-hour time period).
Retrospective V-Go Study

<table>
<thead>
<tr>
<th>Baseline Characteristics</th>
<th>All Patients N=283</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/Female</td>
<td>46% / 54%</td>
</tr>
<tr>
<td>Caucasian</td>
<td>222 (78)</td>
</tr>
<tr>
<td>African American</td>
<td>52 (18)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (4)</td>
</tr>
<tr>
<td>Age, years</td>
<td>60 ± 11</td>
</tr>
<tr>
<td>Weight, lbs</td>
<td>221 ± 45</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>34.8 ± 6.7</td>
</tr>
<tr>
<td>A1C, %</td>
<td>9.2 ± 1.5</td>
</tr>
<tr>
<td>Insulin TDD, U/day</td>
<td>76 ± 47</td>
</tr>
<tr>
<td>Insulin TDD, U/day range</td>
<td>14 to 300</td>
</tr>
<tr>
<td>Basal-Bolus Insulin Regimen a</td>
<td>192 (68)</td>
</tr>
<tr>
<td>Basal Insulin Regimen</td>
<td>64 (23)</td>
</tr>
<tr>
<td>Premix Insulin Regimen</td>
<td>15 (5)</td>
</tr>
<tr>
<td>Other Insulin Regimens*</td>
<td>12 (4)</td>
</tr>
<tr>
<td>Insulin Injections, #/day</td>
<td>3.4 ± 1.4</td>
</tr>
<tr>
<td>Concomitant Meds**</td>
<td>220 (78)</td>
</tr>
<tr>
<td>Metformin</td>
<td>116 (41)</td>
</tr>
<tr>
<td>GLP-1 Receptor Agonist</td>
<td>80 (28)</td>
</tr>
<tr>
<td>SGLT-2 Inhibitor</td>
<td>61 (22)</td>
</tr>
<tr>
<td>DPP-4 Inhibitor</td>
<td>40 (14)</td>
</tr>
<tr>
<td>Sulfonylurea</td>
<td>35 (12)</td>
</tr>
<tr>
<td>Thiazolidinedione (TZD)</td>
<td>15 (5)</td>
</tr>
<tr>
<td>DPP-4 Inhibitor/Metformin</td>
<td>8 (3)</td>
</tr>
<tr>
<td>SGLT-2 Inhibitor/Metformin</td>
<td>9 (3)</td>
</tr>
</tbody>
</table>

Data are n (%) or mean ± SD unless otherwise noted.

*6 patients prescribed only 1 prandial injection (basal-plus)
*Prandial (n=5), Premix/Prandial (n=3), Basal/Premix (n=4)
**Concomitant meds prescribed in ≤ 1% of population not shown

Change in A1C (%) on V-Go
- 3 month: -1.01*
- 7 month: -1.04*

Change in TDD (U/day) on V-Go
- 3 month: -17 U*
- 7 month: -14 U*

% Achievement of A1C Targets
- Baseline
- On V-Go (7 months)

High Risk (A1C > 9%)
- < 7.0%
- < 8.0%
- ≤ 9.0%
- > 9.0%

N=283
*P<0.0001 compared to baseline
Duration rounded to month.

*P=0.001 compared to baseline
Achievement percentages for <7%, < 8% and ≤ 9% are cumulative & represent the total % of patients achieving each target threshold independently
Bioresponsive Core–Shell Microneedle Array Patch

APS Landscape- Patch Pumps

- Insulet
- Lilly
- CellNovo (DiabeLoop, TypeZero)
- EOPancreas
- SFC Fluidics
Practical Pearls

• **Pumps are better** insulin-delivery devices than pens/syringes
• Traditional pumps aren’t for everyone
  – Body real estate
  – Insulin capacity
  – Complexity
• Patch Pumps offer an alternative to expand pump benefits to more people who could benefit from pumps
• Patch Pumps may be preferred by PWD for APS