Infusion Sets 2015: Your Critical Link to Success on a Pump

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Outline
- Today’s infusion set options
- Do infusion sets, occlusions, or duration of infusion set use affect glucose?
- How do insulin infusion sets (IIS) fail?
  - Design, physiology, or technique?
  - Mechanisms: occlusions, leaks, bleeds, and site issues
  - Inspect, inquire, and diagnose
- Silent occlusions as a new source of problems
- Potential solutions

Infusion Sets in 2015: An Evolving State of the Art
- Today’s sets offer many improvements and options
- Yet reports and blogs suggest IIS issues are widespread
- Surveys are helpful but only a handful of direct studies
- IIS leaks and failures create random unexplained hyperglycemia – source is difficult to identify
  - Make up most phone calls to manufacturers
  - A common reason for pump discontinuation
- Problems far more likely to come from IIS than pump
- More oversight and research of IIS is advised

Major Sign of An Infusion Set Problem: Unexplained HyperGlycemia

Brand Loyalty
- Initial IIS often selected by pump manufacturer
- Pump wearer often does not change infusion set brand despite repeated episodes of UHG
  - Years of use of same brand: 5.2 ± 4.3 years in 1,142 pump wearers (diabetes duration 7.9 ± 6.1 years)

Solve the Infusion Set Problem

- More than one infusion set problem a month?
  - Modify your set technique
  - Change infusion set brand

Goal: Less than 1 failure a year!

Infusion Set Options

- Straight
- Slanted

Tubing lengths: 24, 32, and 43 inches for most sets

Disconnect Options

- Pinch and pull: easier
- Pinch, twist, and lift: hardest
- Twist and pull: easiest
- Pinch and lift: harder

Auto-Inserter Options

- Pro:
  - Consistent insertion
  - Higher perceived comfort
- Con:
  - Initial failure rates of 3.2%, 8.9%, 10%, and 15%.
  - Among 1,142 German pump wearers, 72% using an auto-inserter reported that it failed to work ~10% of the time.
  - Failures average 0.3-2.2 times/month for 2-3 day set use

Needle/Cannula Length

- With 90° insertion, use 4-6 mm needles.
- Slanted lengths of 13 mm work best for most pump users
  - Excess cannula length can kink or cause discomfort
  - Longer cannulas may work better with high BMI or large bolus doses

Auto-Inserters

Straight or Slanted Cannula

**Straight:**
- Less dexterity required
- More site options
- Anchor line with tape to stop "pump bumps" and leakage

**Slanted:**
- More placement options in lean or muscular individuals
- Infusion site can be viewed for earlier detection of irritation, leak, or infection
- Less tunnelling and leakage with longer cannulas, especially when anchored with tape

Infusion Set Use Differs in the United States and Germany

<table>
<thead>
<tr>
<th>Infusion Set</th>
<th>United States</th>
<th>Germany</th>
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</thead>
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<tr>
<td>Rapid-D</td>
<td>n: 4</td>
<td>n: 103</td>
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<tr>
<td></td>
<td>%: 1</td>
<td>%: 25</td>
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<tr>
<td>Contact™ D/Sure-T</td>
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<td>n: 81</td>
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<tr>
<td></td>
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<tr>
<td></td>
<td>%: 3</td>
<td>%: 20</td>
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<tr>
<td>inset™/micro®</td>
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<td>n: 22</td>
</tr>
<tr>
<td></td>
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<td>%: 5</td>
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<tr>
<td>Comfort™/Silhouette®</td>
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<td>n: 15</td>
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<tr>
<td></td>
<td>%: 25</td>
<td>%: 4</td>
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<tr>
<td>Quickset®</td>
<td>n: 149</td>
<td>n: 59</td>
</tr>
<tr>
<td></td>
<td>%: 30</td>
<td>%: 14</td>
</tr>
<tr>
<td>OmniPod®</td>
<td>n: 37</td>
<td>n: 20</td>
</tr>
<tr>
<td></td>
<td>%: 7</td>
<td>%: 5</td>
</tr>
</tbody>
</table>


Steel or Teflon

**Steel:**
- No kinking
- Fewer silent occlusions
- Manual insertion
- Less failure
- Better biocompatibility and less back pressure
- Easier to train
- 28-30 gauge

**Teflon:**
- More selections
- Straight or slanted
- Manual or automatic insertion
- Less needle phobia
- 25 gauge (27-gauge introducer needle)
- FlowSmart: 28 gauge (30-gauge introducer)


Legs and Arms?

Muscle areas move a lot, are slower to absorb insulin except during exercise (variable insulin action), and can irritate skin from cannula motion.

Match an Infusion Set

**To the individual:**
- Young children
- Pregnancy
- Visual impairment
- Dexterity issues
- Low or high BMI
- Small or large doses
- Prefer auto-inserter
- Steel needle phobia

**To their skin:**
- Allergies
- Hairy torso
- Lipohypertrophy (LH)
- Scarring

**And to activity:**
- Sweating and swimming
- Golf, tennis, contact

Infusion Set Failure
Design, Technique, or Physiology?
Glucose Levels Before and After Infusion Set Changes

Average glucose levels for 6-hour intervals before and after infusion set change in 396 pumps (>20 set changes/pump).


Individual Responses Vary with Length of Infusion Set Use

Design, technique, or physiology?

The Weak Spots in Insulin Delivery

How Infusion Sets Fail

- Failure on insertion
  - Auto-inserter failure → kink or partial detachment
- Detachment — full or partial*
- Occlusion/blockage — full or partial
- Insulin leak along cannula to skin,* at connection, or from line damage
- Bleeding at the tip of the cannula

* Often due to lack of anchoring

Goal: Less than 1 failure a year!

Infusion Set Questions to Ask

- How many days can you usually wear an IIS?
- Do your glucoses go up on day 2, 3, or 7?
- Do sites sometimes not work?
- Do you have scarring or poor absorption?
- How often do you have UHG?
- Do correction boluses sometimes not work?
- Do some highs only correct when you change your infusion set?

If You Answer Yes, Ask Your Clinician to Help You

- Check meter and CGM data for UHGs
- Inspect your site, skin, and line anchoring
- Review site preparation and set insertion technique
- Demonstrate proper infusion set technique
Inspect the Site

Better solutions for those who swim or sweat:

- Skin Tac
- Benzoin
- Mastisol & Detachol
- Toupee glue
- Opsite Flexifix
- Hypafix
- IV3000 or Tegaderm
- Aeroskin wet suit T-shirt for long-distance swims

Inspect for Site Issues

Look and Feel:

- Allergies:
  - Adhesive
  - Cannula lubricant
  - Nickel in steel needle
- Infection/abscess
- Motion of cannula ("pump bumps" and leaks)
- LH (fat buildup from repeated use of same site)
- Scarring

Look for Lipohypertrophy

- LH is frequent: 26.1% and higher
- 27% insert at the same site
- A CGM study of pump infusion into LH and non-LH areas in eight individuals found no difference in glycemic control
- No difference in A1C (9.6 vs. 9.5%) was found between those with (32) and those without (41) LH
- BG variability and hyperglycemia due to delayed absorption in LH is more likely when subcutaneous scarring is present

Diagnose Infusion Set Issues

- Look for UHG patterns on blood glucose meter and CGM downloads
  - Average glucose levels arranged 1 day before and up to 5 days after time of set change reveals whether pump user is having IIS issues
- Can you find a source for UHG
  - Check first for partial or complete detachment
  - Next look for blood in the line
  - Then smell for insulin leak: O-rings, hub, line
  - After removal of set, feel for a lump under skin
  - If present, squeeze to check for blood, pus, or scarring

A Full Detachment Resembles a Missed Bolus at First

Partial Detachments Are Harder to Detect

- UHG began after lunch on May 1 until late on May 2 when infusion set was changed
- "Do some highs only correct after you change the infusion set?"

References:

**Two UHGs in a Row?**

**Change the Infusion Set!**

**Do Occlusions Affect Glucose?**

**Occlusion Alarms Provide a Late Notification**

- Long before occlusion alarm sounds, UHG will occur
- With 0.5 unit/hour basal rate in an occluded 60-cm set, time to an occlusion alarm averaged:
  - 1 hour, 42 minutes in Medtronic Veo
  - 2 hours, 4 minutes in Accu-Chek Spirit Combo
  - 9 hours, 10 minutes in D-Tron Plus
  - More than 24 hours in OmniPod
- Children and adults on low doses are at greater risk of having an occlusion lead to ketosis and diabetic ketoacidosis


**Infusion Set Issues: Occlusions**

A survey of 985 insulin pump wearers in the United States and Germany found:

- 20% remembered having ≥1 occlusion alarm per month (23% in the United States, 17% in Germany)
- A1c trended higher for those having ≥1 occlusion per month (7.6%) than for those with <1 occlusion per month (7.3%; \( P = 0.09 \))


**Frequency of Occlusions**

Occlusion Alarms/30 Days versus Avg. Glucose

- Average Blood Glucose Versus Occlusions/30 Days
- P < 0.0001
- \( r = 0.24 \)

Does Duration of Infusion Set Use Affect Glucose?  
And, More Importantly, Why?

Average Duration of Use for Steel and Teflon IIS

<table>
<thead>
<tr>
<th></th>
<th>Teflon</th>
<th>Steel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended use (days)</td>
<td>3</td>
<td>2</td>
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<tr>
<td>United States survey (n = 534)</td>
<td>3.4</td>
<td>3.7</td>
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<tr>
<td>Germany survey (n = 451)</td>
<td>2.8</td>
<td>2.6</td>
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<tr>
<td>Swedish survey (n = 102)</td>
<td>4.8</td>
<td>3.8</td>
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</tbody>
</table>


Actual Pump Practices Study: Duration of Infusion Set Use

Most pump wearers use an infusion set for 2-3 days


Site Infections

- Staph carriers have a higher risk of site infections
  - 30% of people are constant and 25% intermittent staph carriers
  - Methicillin-resistant staph aureas (MRSA) is common
- Requires more caution in site preparation
- Infusion site infections occur at 0.06 to 0.27 events per patient per year (30,000 to 135,000 infections per year for each 500,000 pumps)

Do You Carry Staph?

- Have you had an infusion site infection or abscess in the past?
- Has a skin cut or abrasion required treatment with an antibiotic ointment or oral antibiotic?

Improve Your Technique

Sterile Procedure

- Use clean countertop, wash hands, don’t touch face or extraneous items, open packages over countertop, keep contents inside package until used, clean top of insulin bottle with alcohol
- Cleanse skin in an outward snail pattern to the size of a tennis ball and never go back (or back and forth), so cleanest spot is where infusion set goes in
- Don’t blow or fan the site
- Place IV3000 bio-occlusive material on the skin under Teflon sets and over metal sets

Tape the Tubing

To stop:
- Tugs and pullouts
- Irritation
- Some bleeding
- Many UHG episodes

Lose tape, not insulin!

Use Low-Failure Infusion Set-Ups

- Infusion set safety is essential for children, pregnancy (and everyone else)
- When anchored, steel sets and manually inserted, anchored Teflon sets provide greater reliability and safety


New Research – Silent Occlusions

An Accidental, Significant Discovery

- BD researchers suspected infusion pressure might increase with a new intradermal sets, but not with standard sets
- Silent occlusions were seen in both
- Blood insulin diluent levels fell as line pressure rose
- Silent occlusions lasting >30 minutes were common in the first 4 hours of set use but might occur at any time
- A likely source for UHG


Unexpected Silent Occlusions with Subcutaneous IIS

- Both intradermal and subcutaneous IIS were found to have silent occlusions
- A greater number of events were seen in the first 4 hours
- Insulin diluent is used in trial, so insulin coagulation is not involved

Graph of pressure-rise events lasting >30 minutes during first 6 hours of 1 unit/hour basal delivery (insulin diluent only)


Dual-Port FlowSmart Infusion Set

- FlowSmart IIS compared with standard Teflon IIS in three pump brands
- ~30 insulin diluent infusions in healthy volunteers
- 74-79% reduction in percent time of flow interruptions with dual-port IIS in Animas, Medtronic, and Roche pumps, respectively

What Causes Silent Occlusions?

- Silent occlusions are common in the first 4 hours after cannula insertion
  - Fibrosis is unlikely within 4 hours
  - As common with first 34 gauge microneedle that has less edema and erythema
  - May result from mechanical tissue compression at cannula tip, like putting a finger over the end of a low-pressure hose
- Less likely with steel-needle IIS
- Absence of kinking and introducer needle?
- Less likely with dual-port delivery from smaller cannula
  - Less edema and tissue compression?

Solutions for Silent Occlusions?

- Stronger motor in insulin pump *
- Switch to steel infusion set *
- Use FlowSmart Teflon set with side port and standard port
- Minimize inflammation & fibrosis
- Modify diluent or modify plastics in line/cannula
  - Available now
- Slow the retraction speed of introducer needle
- Monitor pressure for earlier high-pressure alerts

Silent Occlusion Frequency Varies by Infusion Set Type

<table>
<thead>
<tr>
<th>Infusion Set</th>
<th>Number with &gt;1 Silent Occlusion</th>
<th>Mean Duration of Silent Occlusions (min)</th>
<th>Number of Silent Occlusions Lasting &gt;1 Hour</th>
<th>Mean Percentage of Infusion Time with Silent Occlusion (%)</th>
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<tbody>
<tr>
<td>Animas/Microneedle B</td>
<td>16/21 infusions</td>
<td>22.5</td>
<td>4</td>
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<td>5/20 infusions</td>
<td>30.2</td>
<td>2</td>
<td>1.9</td>
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