

Introduction to insulin pump therapy

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Classification of Type 1 and Type 2 Diabetes

- Type 1

- Absolute insulin deficiency
- Idiopathic
- Immune-Mediated

Requires both
Basal and Bolus Insulin

- Type 2

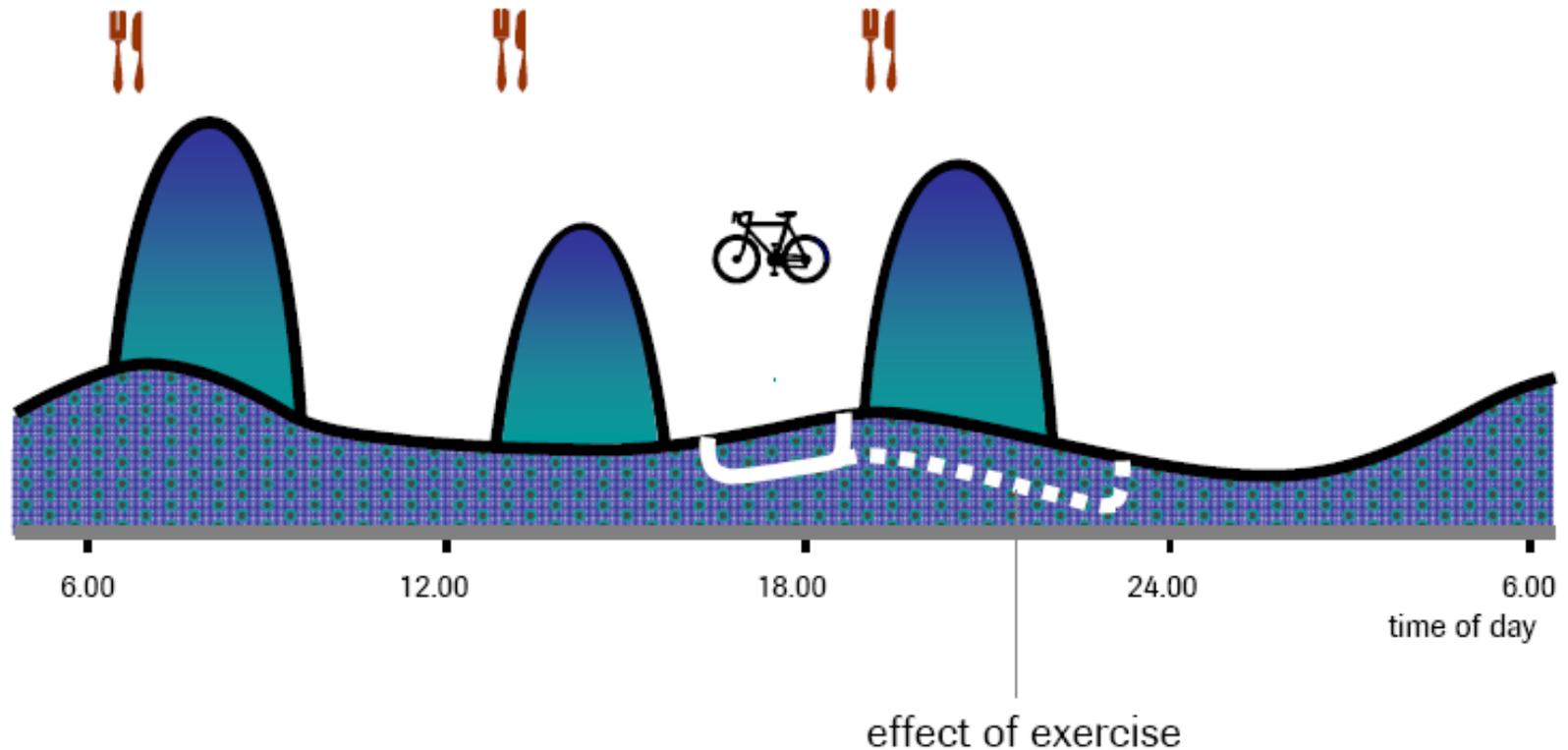
- Relative insulin deficiency (initially)
- Insulin resistance
- Progressive beta cell deterioration

Depends on
glycemic status and disease
progression

INSULIN

- PHYSIOLOGIC INSULIN SECRETION
- TIME COURSE OF THE ACTION OF VARIOUS INSULIN PREPARATIONS
- USE OF RAPID-ACTING INSULIN IN PUMPS
- CURRENT INTENSIVE INSULIN REGIMENS

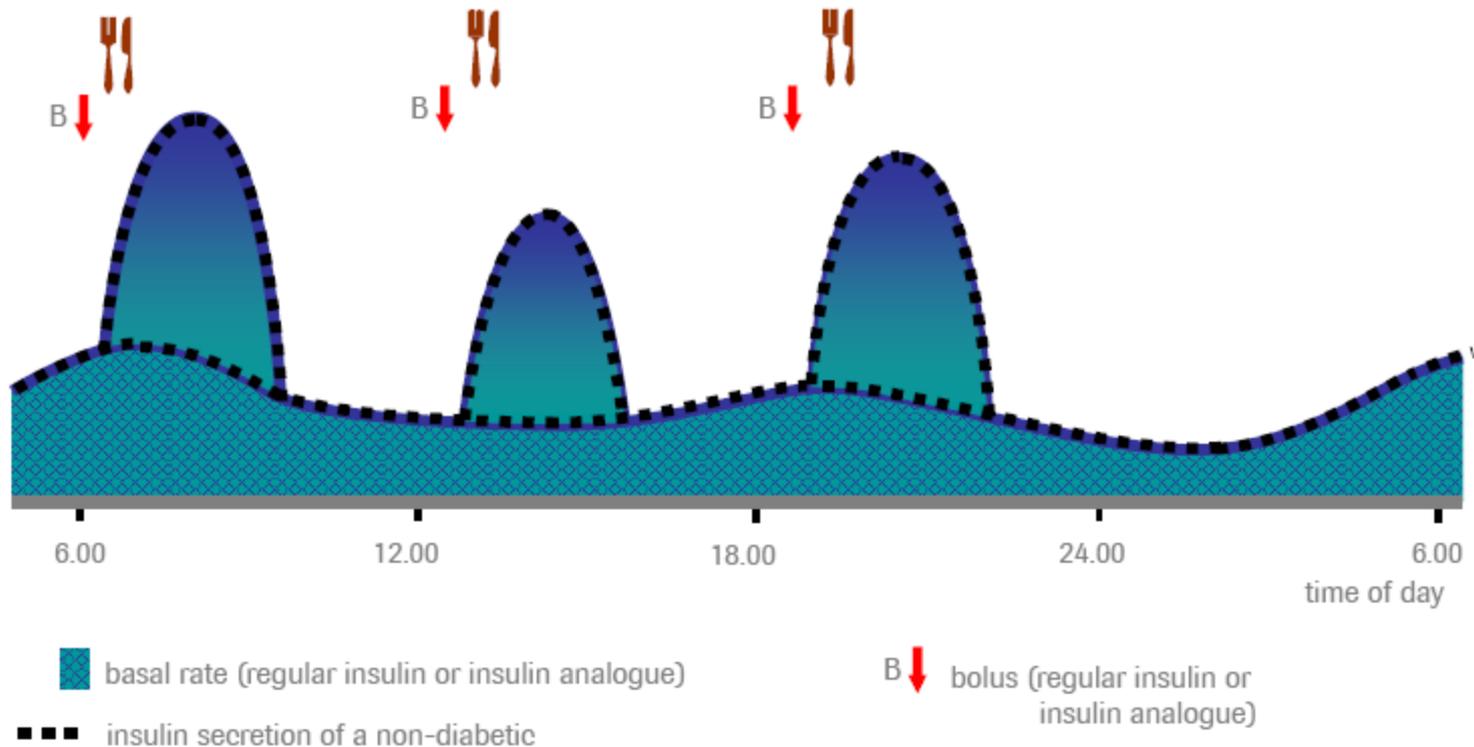
The Insulin Secretion of a Non-Diabetic



 Insulin peaks at meals

 Continuous basal insulin secretion with circadian fluctuations

Insulin “Secretion” Under Pump Therapy (CSII)



Overview

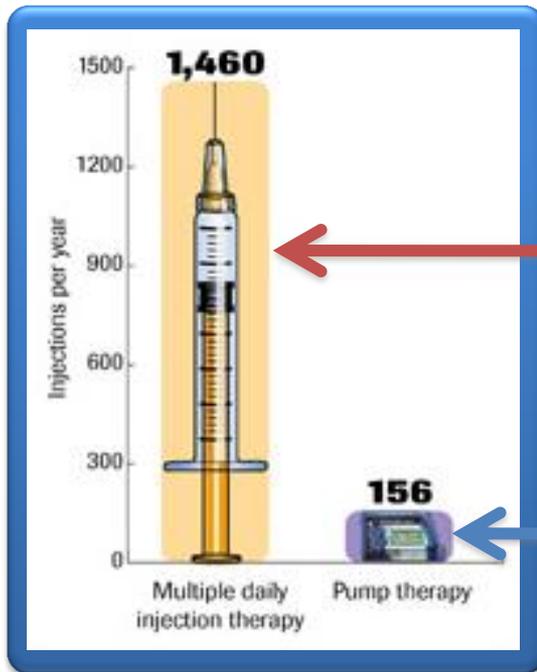
Insulin pump therapy

- Small, external device that delivers rapid- or short-acting insulin 24 hours a day.
- With most systems, the pump is attached to a thin plastic tube (infusion set) that has a soft cannula (plastic needle) that is inserted under the skin.
- Patch-pumps/Micropumps where the insulin reservoir is connected directly to the cannula (no infusion set) are also available.
- The pump can be disconnected from the tubing while showering or swimming. However, some pumps can not be disconnected.

Overview

Benefits of CSII

- Improved glycemic control ^{3,5}
- Reduced rate of severe hypoglycemia compared with multiple daily injection (MDI) insulin therapy ^{1,2,3,4}
- Greater patient comfort, convenience, quality of life ^{2,4}

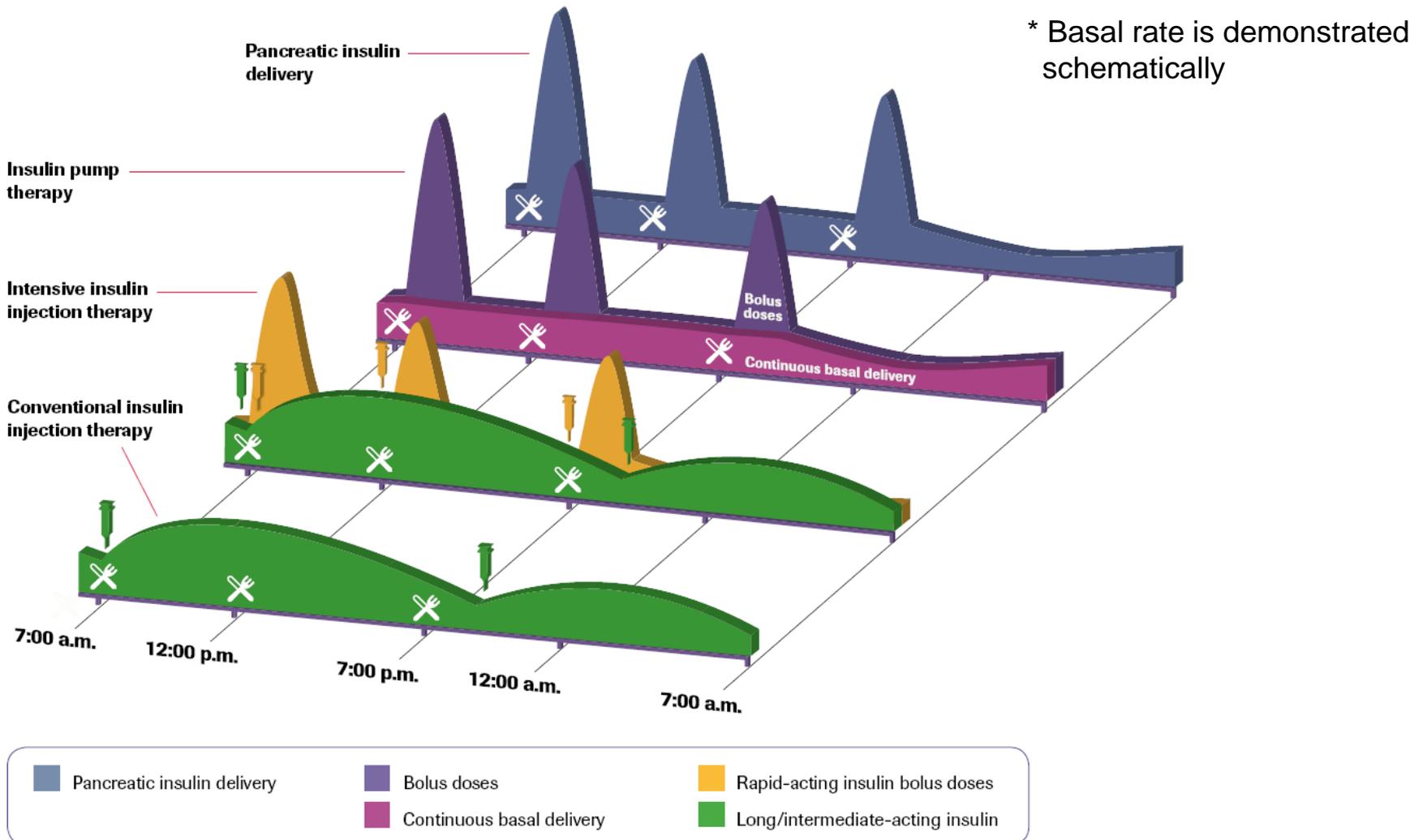


Multiple Daily Injection Therapy (MDI):
Patients inject an average of 4 times a day; approximately 1,460 times per year

Pump Therapy (CSII):
Delivers small doses of insulin every few minutes, which closely mimics the actions of a normal pancreas. This requires just one infusion site change every 2-3 days; approximately 156 times per year

Overview

CSII is more closely matched to natural insulin delivery*



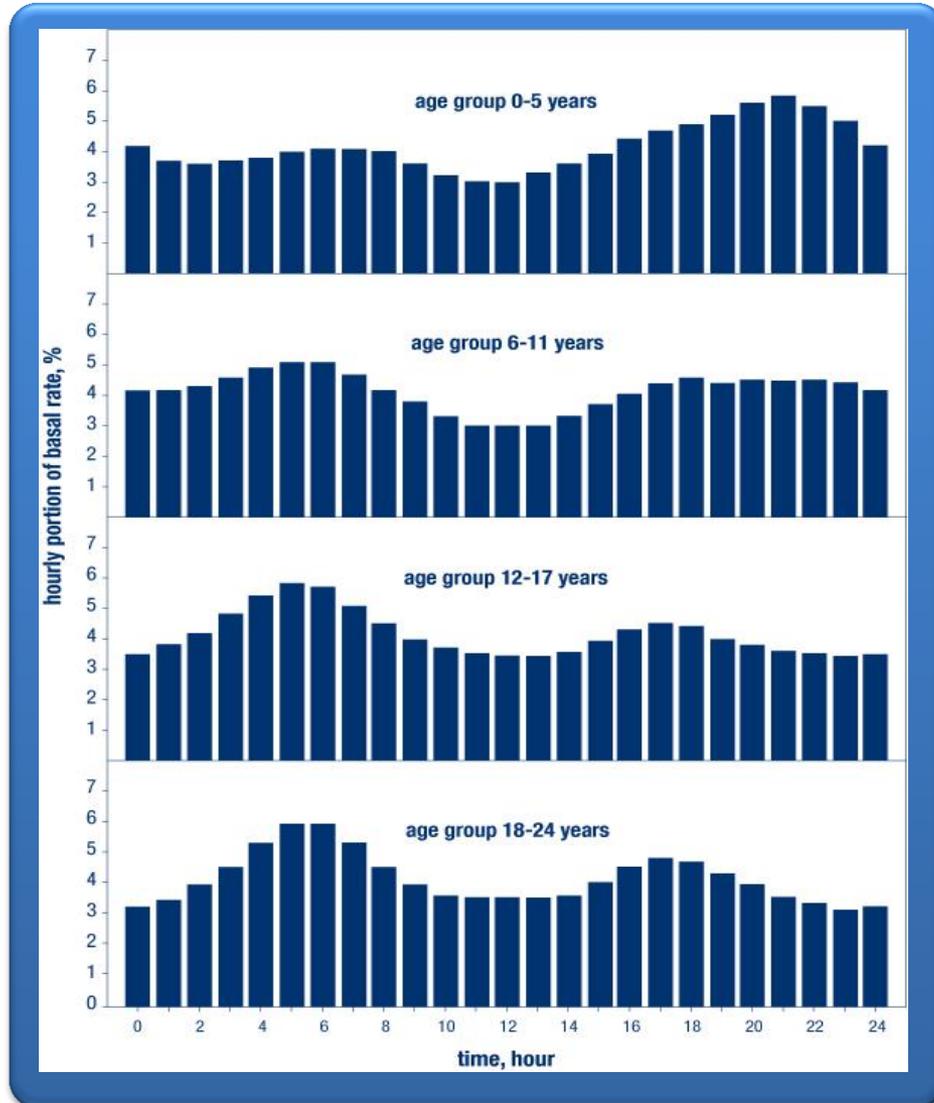
Patients with Type 2 Diabetes may also benefit from CSII therapy

- Insulin pump therapy has been shown to yield a marked improvement in glucose concentrations with a corresponding decrease in HbA1c levels in patients with poorly controlled diabetes.
 - Nielsen et al. 2005 The Diabetes Educator
- This larger study of 40 obese type 2 diabetic subjects demonstrates improved metabolic control with CSII without significant weight gain in poorly controlled obese Type-2 Diabetes Mellitus patients.
 - Wainstein et al. 2005 Diabetic Medicine
- A study by Raskin et al. found that insulin pump therapy provided efficacy and safety comparable to MDI for type 2 diabetes.
 - Raskin et al. 2001 Diabetes Care

Overview

- Basal insulin addresses patient's food-independent insulin requirement and regulates hepatic glucose production-comprises 40-60% of total daily dose⁵
- Key difference between MDI and CSII therapy:
 - MDI therapy covers basal insulin requirements through insulin injections of long-acting insulin
 - CSII provides ability to program flexible basal insulin infusion rates in pre-defined time intervals ^{2,4,5}
- Studies have shown basal insulin requirements can increase significantly during the early morning hours ⁵.

Basal Insulin Needs by Age Group



0-5 Years (average of 837 profiles)

- Highest peak before midnight
- Small peak in early morning lowest compared with other age groups
- Lowest insulin need at noon

6-11 Years (average of 1739 profiles)

- Highest peak between 5-6 AM
- Consistent basal from 5 PM to 2 AM
- Lowest insulin need at noon

12-17 Years (average of 2985 profiles)

- Highest peak in the morning
- Lowest insulin need at noon
- Moderate afternoon peak

18-24 Years (average of 380 basal profiles)

- Highest peak in the morning
- Lowest insulin need at midnight
- Moderate afternoon peak

BOLUS CALCULATION

- BOLUS CALCULATION: KEY FACTORS
- ADVANTAGES OF USING AN AUTOMATED
BOLUS CALCULATOR
- OVERVIEW AUTOMATED BOLUS
CALCULATORS ON THE MARKET
- SCIENTIFIC EVIDENCE

Bolus Calculation: Key Factors

- Current blood glucose level
- bG Target
- Total grams of CHO in meals/snacks
- Insulin sensitivity factor (ISF)
- Insulin-to-carbohydrate ratio (I:CHO)
- Insulin on board
- Offset time
- Acting time
- Meal rise

Bolus Calculation: Key Factors

Insulin Sensitivity Factor (ISF)

- The ISF ratio (“correction factor”) defines the expected decrease in bG from 1 unit of insulin
- A common method for calculating ISF:
 - Divide 100 by total Daily Dose of insulin (example 50 units)

Example: Patient A

- **TDD: 50 units**
- **Calculation:**
 - $100 \div 50 = 2.00$ ISF → 1 unit of insulin will lower glucose by 2.00 mmol/L

Bolus Calculation: Key Factors

Insulin to Carbohydrate-Ratio (I:CHO)

- Defines the number of CHOs (grams) covered by 1 unit of insulin.
- Common method for initial calculation of I:CHO:
 - Divide 500* by the **TDD** (example 50 units)

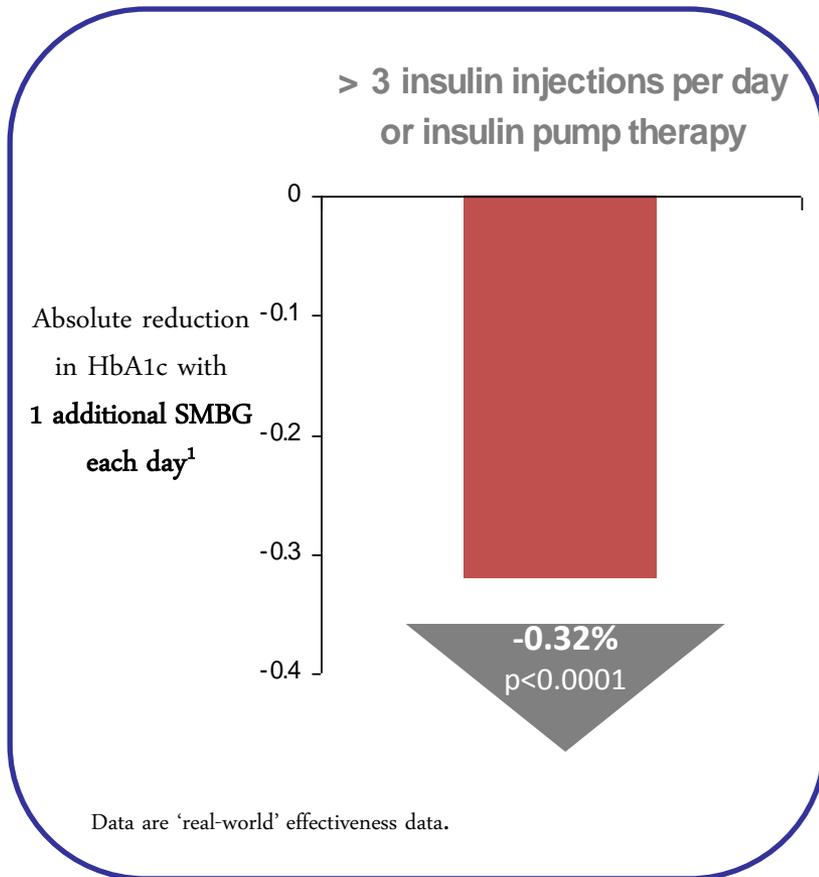
Example: Patient B

- **TDD: 50 units**
- **Calculation:**
 - $500 \div 50 = 1:10$ (I:CHO) \rightarrow 1 unit of insulin will cover \sim 10 g CHO (I:CHO is rounded to whole number)

Summary

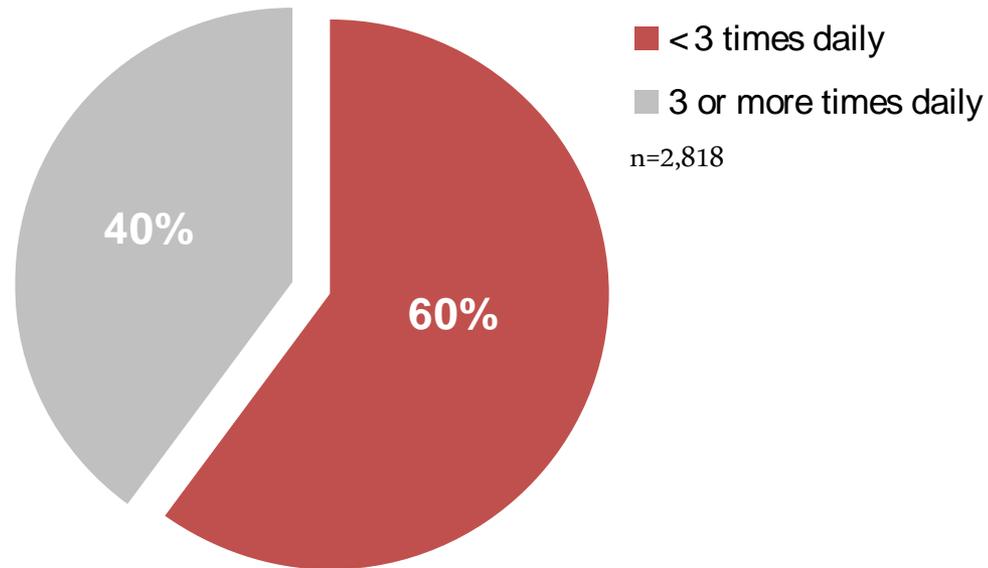
- CSII mimics normal insulin delivery better than injections because it provides more precise insulin delivery if used properly with appropriate basal rates
- The use of short (rapid)-acting insulin to cover for both basal and bolus requirements allows a more flexible delivery on demand which is closer to physiology
- CSII is associated with a better control of glucose levels, reflected in levels of HbA1c, fewer problems with hypoglycaemia, quality of life gain and greater flexibility of lifestyle
- Properly used insulin boluses cover consumed carbohydrates and lower elevated bG readings
- A correct programmed pump can provide precise delivery that results in reasonable blood glucose control and improved diabetes management

Increased SMBG frequency is associated with a significant reduction in HbA1c¹



The majority of people with insulin-treated diabetes do not adhere to recommended SMBG frequency

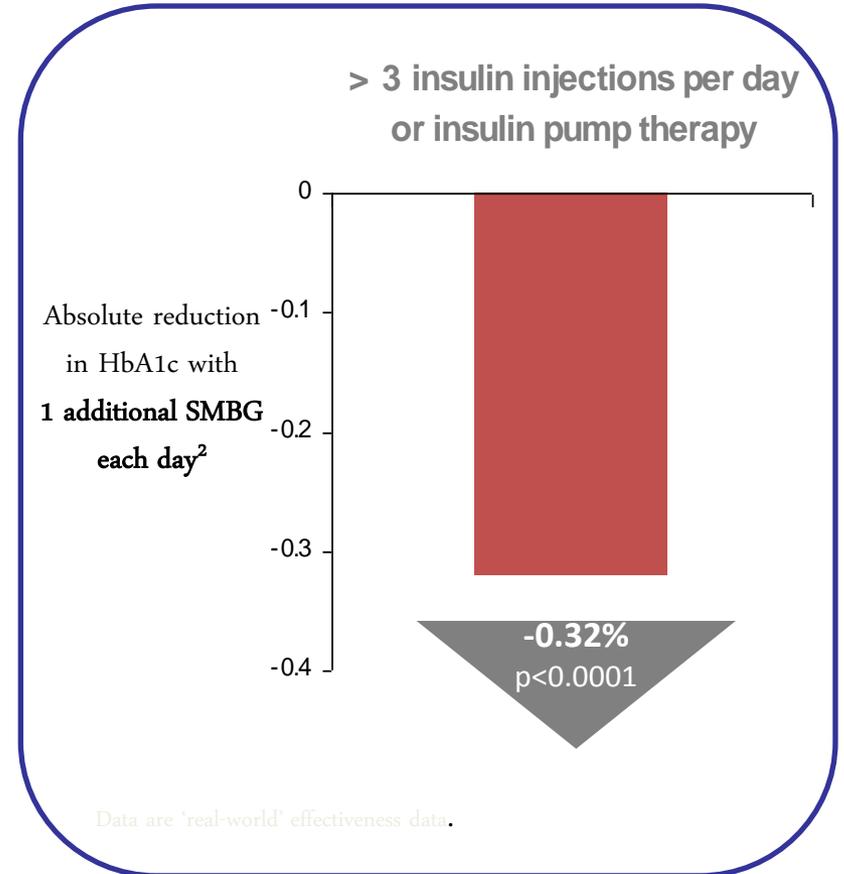
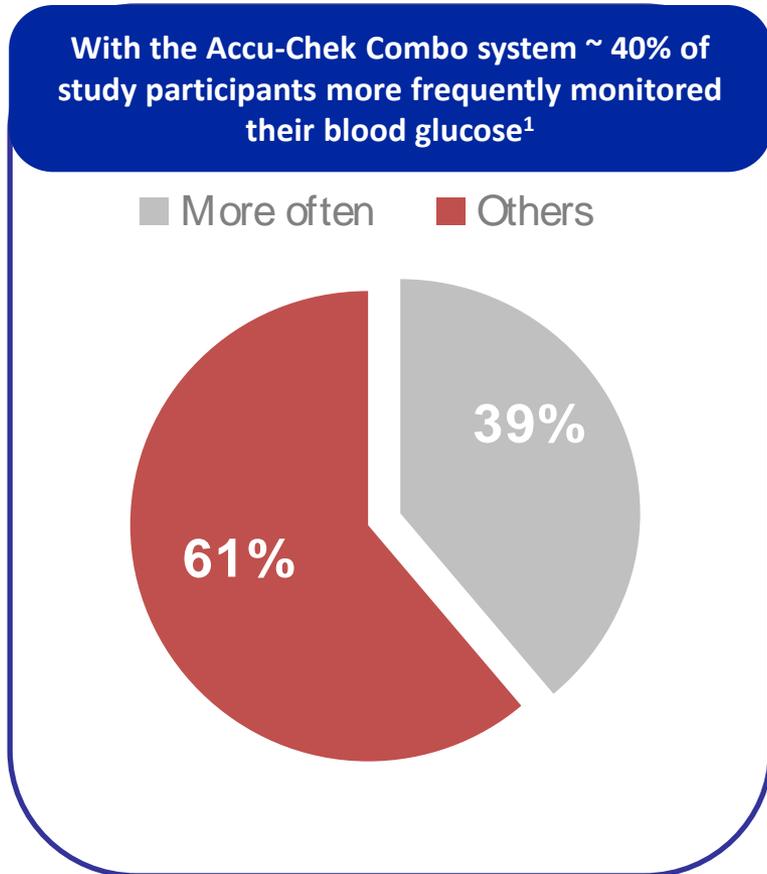
60% of people with type 1 diabetes monitor less frequently than ADA recommendations of ≥ 3 tests daily^{1,2}



¹ Karter AJ et al. Diabetes Care 2000

² ADA Diabetes Care 2009

Accu-Chek Combo system encourages patient adherence to SMBG regimen for a better HbA1c



¹ Data on file at Roche Diagnostics 2010

² Schütt M et al. Exp Clin Endocrinol Diabetes 2006

Programmable features that support individualized Diabetes Management

bG Targets – enable users to set upper and lower bG limits to match their desired level of bG control.

Offset Time – length of time until significant bG lowering begins

Acting Time – total length of time the insulin remains effective in lowering bG

Meal Rise – accommodates the normal physiologic rise in bG levels in response to food intake

Snack Size – defines a certain threshold of CHOs above which a Meal Rise bG is triggered