# Accu Chek® Combo insulin pump – a comprehensive diabetes management system

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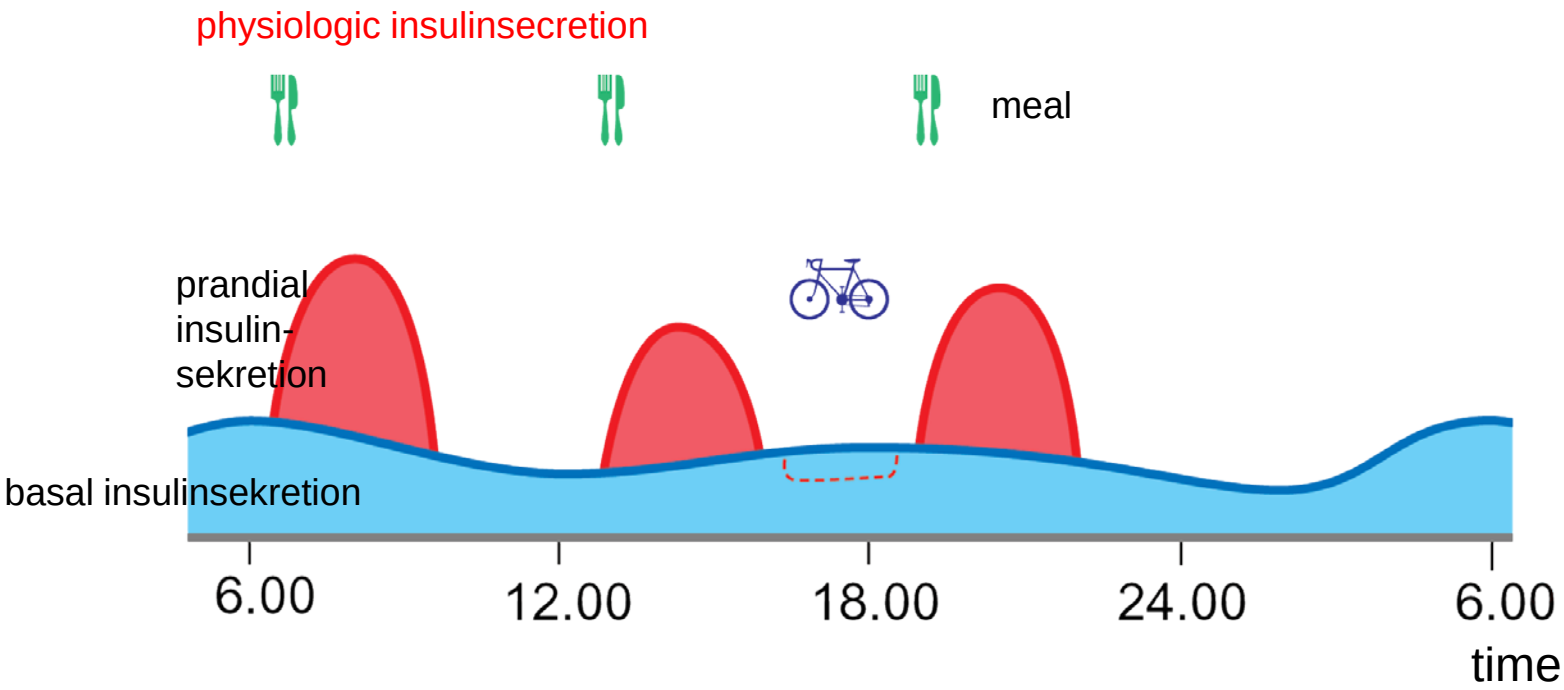
we have come a long way in the therapy of Diabetes

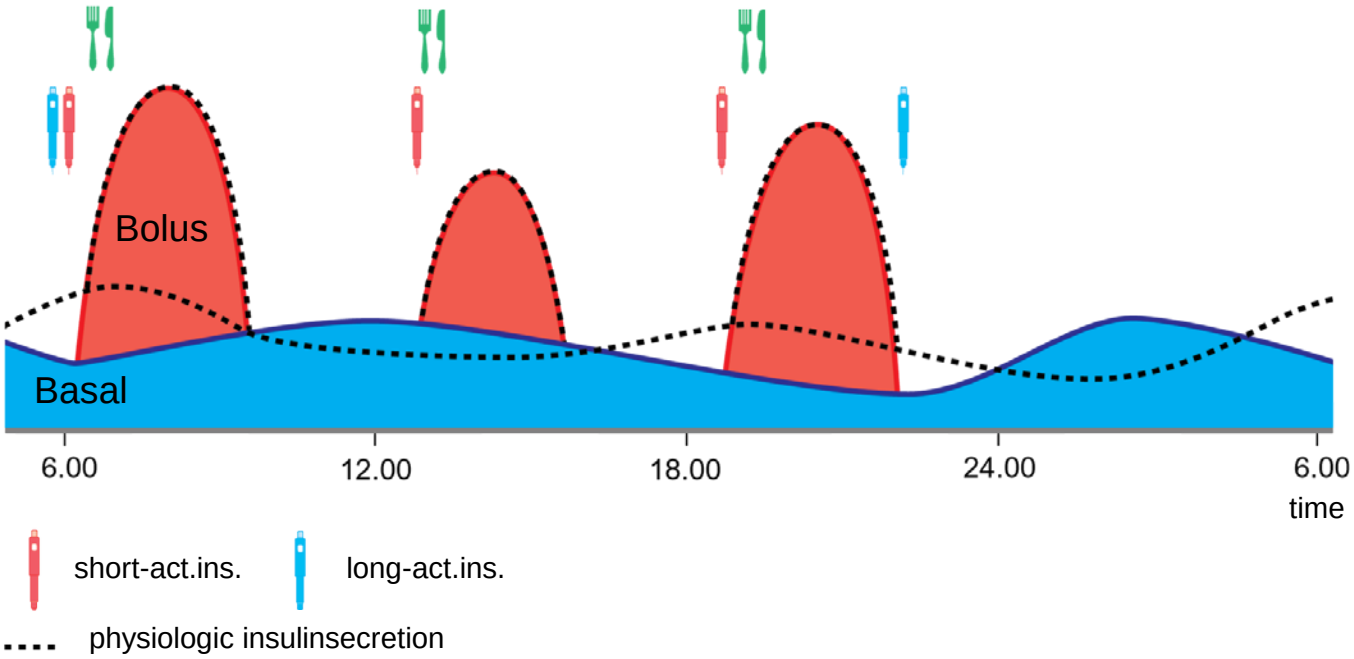
but far enough ???

# Type 1 Diabetes mellitus: where do we want/need to go?



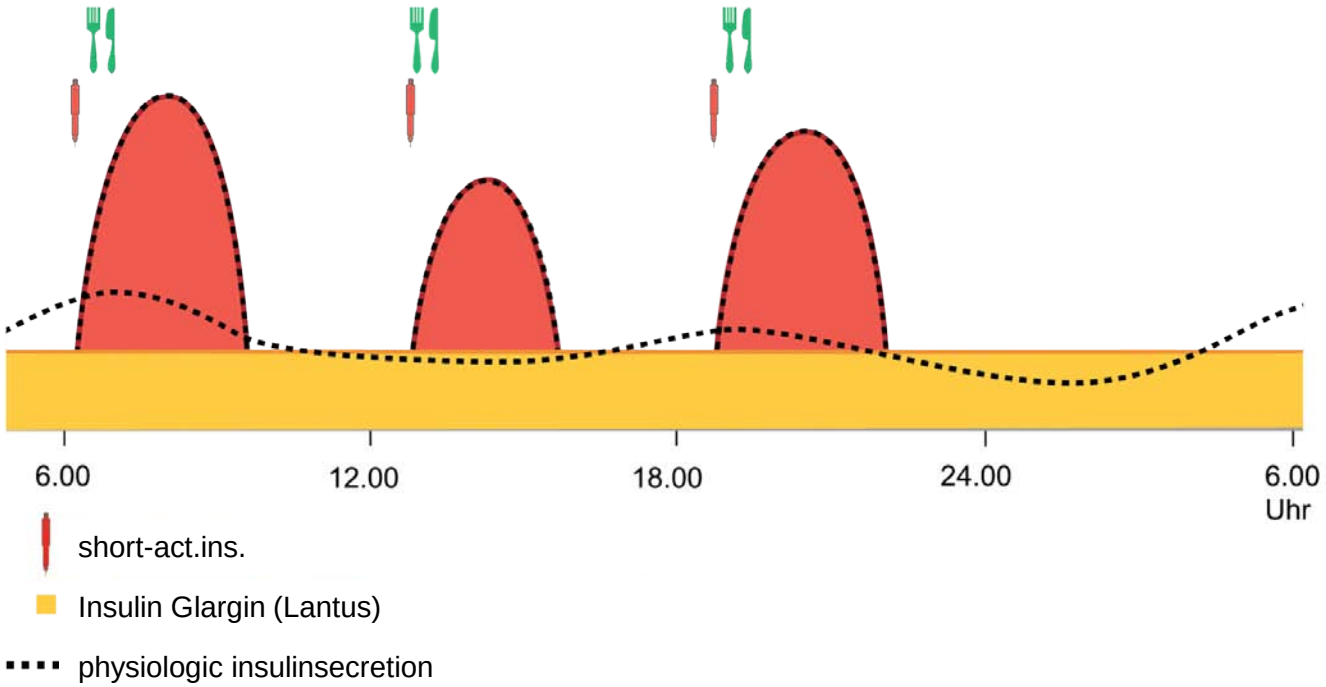
## Different therapy regimes

MDI with twice daily NPH injections



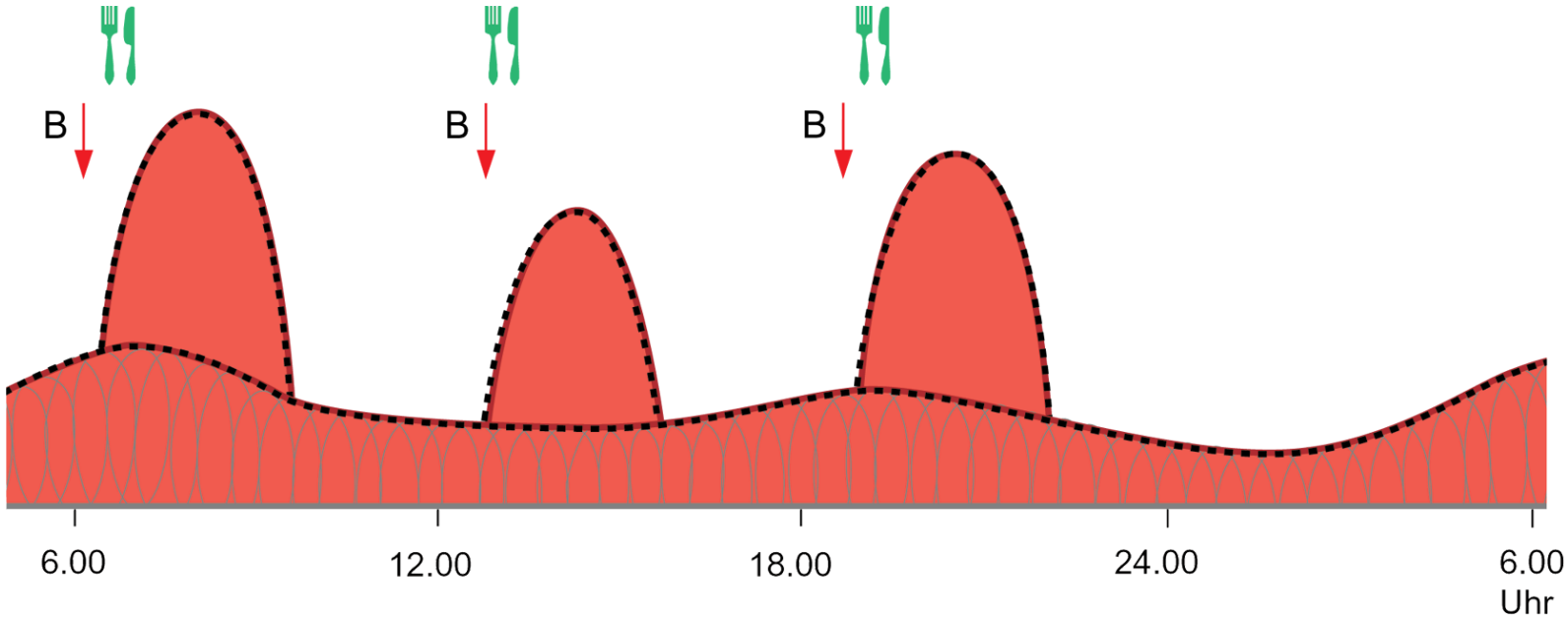
## Different therapy regimes

MDI with 1 injection of Insulin Glargin (Lantus)



## Different therapy regimes

Insulin with insulinpump, CSII (continuous subcutaneous insulin infusion)



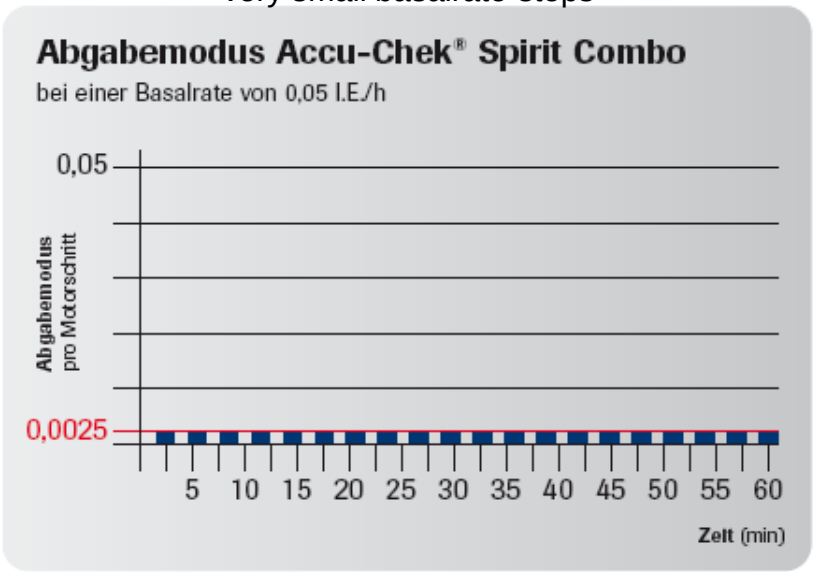

variable Basalrate (Normal-Insulin or short-acting Analogon)

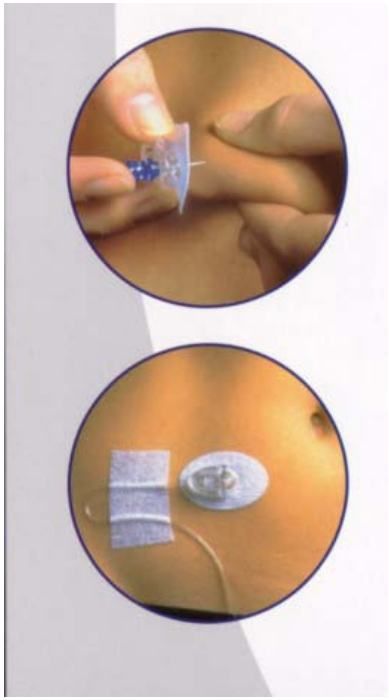
B Bolus (Normal-Insulin or short-acting Analogon)

physiologic insulinsecretion

# CSII therapy : the insulinpump


very small basalrate-steps



# Advantages of the insulinpump (CSII)

- no injections needed, catheder change every 2-3 days
- only one insulin, short-acting
- Insulin being constantly „secreted“ in very small portions
- Basal insulinrate can be adjusted individually and independently for different times
- Bolus can be given at nearly any time, even in very small dosage
- Insulin is always „on board“, and can be given without noticing by others
- Insulin can be reduced or stopped on short notice or for any given time (up to 24hrs)

# Disadvantages of the insulinpump (CSII)

- patient is carrying a technical device all the time close to the body, „Diabetes is visible“
- because there is only short-acting insulin in the insulinpump, blood Glucose can rise more rapidly in case of malfunction of the insulinpump
- after only 4-6 hrs of disrupted insulin-infusion blood Glucose can rise substantiately, up to occuring ketoacidosis (because of lacking long-acting insulin).
- technical malfuncions of the pump/catheter is not always immediately noticeable
- the patient has to use it !

TAMBORLANE WV, SHERWIN RS, GENEL M, FELIG P. Reduction to normal of plasma glucose in juvenile diabetics by subcutaneous administration of insulin with a portable infusion pump. N Engl J Med 1979: 300: 573–578.

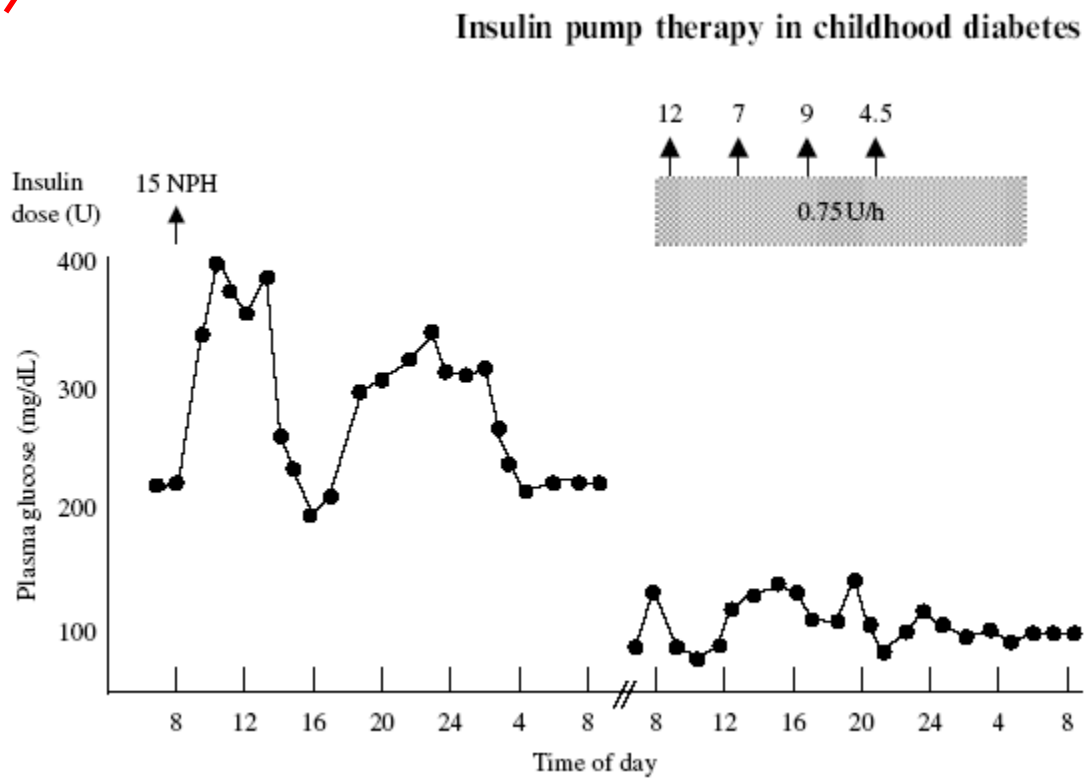
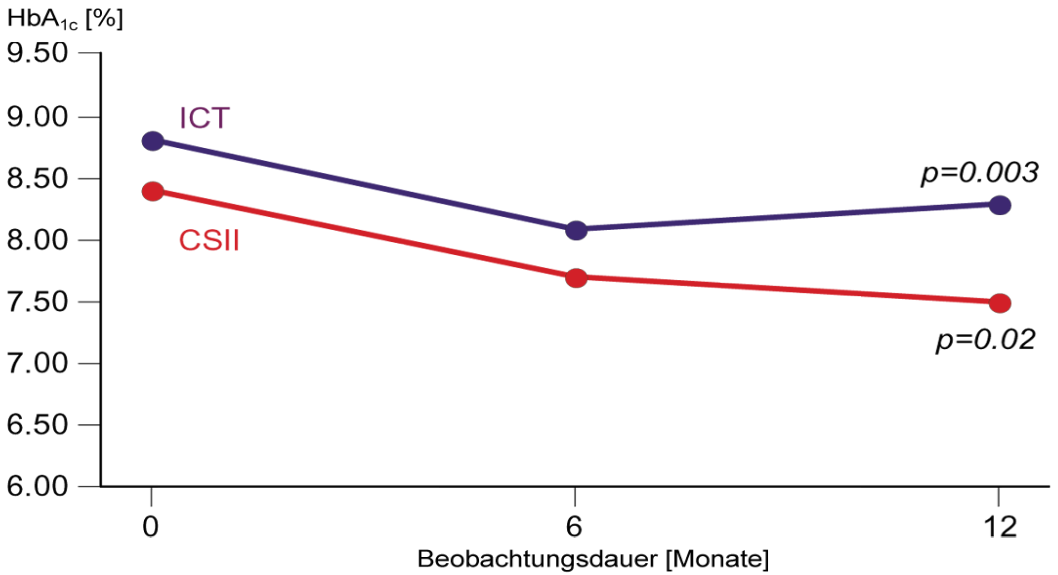



*Fig. 1.* 24 h glucose profiles before and after 3 d of insulin pump therapy in a 12 yr old with type 1 diabetes in our first insulin pump study. Data are taken from reference (2).

# HbA1c in adolescents with type 1 diabetes with CSII vs MCI (ICT)

Von 75 jugendlichen Typ-1-Diabetikern (Alter: 12-20 Jahre) wurden die Stoffwechselverläufe unter intensivierter Insulintherapie (n=50) und Insulinpumpen-Behandlung (n=25) dokumentiert*.

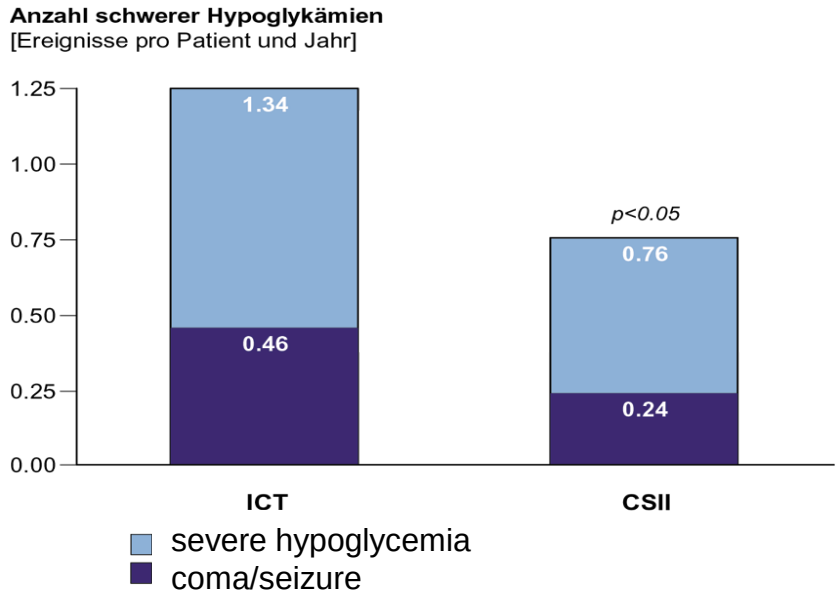



$HbA_{1c}$-Normbereich: 4,3 - 6,3 %

*Boland E.A.. et al.; Diabetes Care (1999); 22 (11): 1779-1784

# Hypoglycemia in adolescents with type 1 diabetes with CSII vs MCI (ICT)

Von 75 jugendlichen Typ-1-Diabetikern (Alter: 12-20 Jahre) wurden über 12 Monate die schweren Hypoglykämien unter intensivierter Insulintherapie (n=50) und Insulinpumpen-Behandlung (n=25) dokumentiert*.




*Boland E.A. et al.; Diabetes Care (1999); 22 (11): 1779-1784

**Diabetes-Leitlinie DDG Pädiatrie** 2009

# Diagnostik, Therapie und Verlaufskontrolle des Diabetes mellitus im Kindes- und Jugendalter

**Herausgeber: W.A. Scherbaum, W. Kiess**
**Autoren:** Holterhus PM , Beyer P, Bürger-Büsing J, Danne T, Etspüler J, Heidtmann B, Holl RW, Karges B, Kiess W, Knerr I, Kordonouri O, Lange K, Lepler R, Marg W, Näke A, Neu A, Petersen M, Podeswik A, Stachow R, von Sengbusch S, Wagner V, Ziegler R

| BZ- Kontrolle - Klinisch-chemische Bewertung | Stoffwechsel gesund | good control | Mäßig (Maßnahmen empfohlen) | Schlecht (Maßnahmen erforderlich) |
|---|---|---|---|---|
| Fasting BG or preprandial (mmol/l mg/dl) | 3.6-5.6<br>65-100 | 5-8<br>90-145 | > 8<br>> 145 | > 9<br>> 162 |
| postprandial BG (mmol/l mg/dl) | 4.5-7.0<br>80-126 | 5-10<br>90-180 | 10-14<br>180-250 | > 14<br>> 250 |
| BG at night | 3.6-5.6<br>65-100 | 4.5-9<br>80-162 | < 4.2 oder > 9<br>< 75 oder > 162 | < 4.4 oder > 11<br>< 80 oder > 200 |
| HbA1c (stand. methods reg..DCC-Trials) | < 6.05 | < 7.5 | 7.5-9.0 | > 9.0 |

POSITION STATEMENT

# Standards of Medical Care in Diabetes—2010

American Diabetes Association

DIABETES CARE, VOLUME 33, SUPPLEMENT 1, JANUARY 2010

per 100 patient-years of therapy). Since the time of the DCCT, a number of rapid-acting and long-acting insulin analogs have been developed. These analogs are associated with less hypoglycemia with equal A1C lowering in type 1 diabetes (77,78).

Recommended therapy for type 1 diabetes therefore consists of the following components: *1*) use of multiple dose insulin injections (3–4 injections per day of basal and prandial insulin) or CSII therapy; *2*) matching of prandial insulin to carbohydrate intake, premeal blood glucose, and anticipated activity; and *3*) for many patients (especially if hypoglycemia is a problem), use of insulin analogs.

Diabetes Care. 2007 Jun;30(6):1653-62.

Reviews/Commentaries/ADA Statements

CONSENSUS STATEMENT

# Use of Insulin Pump Therapy in the Pediatric Age-Group

## Consensus statement from the European Society for Paediatric Endocrinology, the Lawson Wilkins Pediatric Endocrine Society, and the International Society for Pediatric and Adolescent Diabetes, endorsed by the American Diabetes Association and the European Association for the Study of Diabetes

Moshe Phillip, MD[1]
Tadej Battelino, MD, PhD[2]
Henry Rodriguez[3]
Thomas Danne, MD[4]
Francine Kaufman[5]
for the Consensus Forum Participants*

gained increasing popularity among patients with diabetes. CSII is the most physiologic method of insulin delivery currently available. It is able to closely

CONCLUSIONS— There are very few published long-term studies on pump use in children and adolescents, and almost all of those are observational studies. The vast majority of the studies cited use a multidisciplinary trained team that usually is not available to the general pediatrician or nonacademic pediatric endocrinologist. This may be a caveat to prescribing CSII. However, based on the available evidence and the experience of the expert panel, CSII therapy may be appropriate for children and youth of all ages provided that appropriate support personnel are available. CSII use in children and adolescents may be associated with improved glycemic control and improved QOL and poses no greater, and possibly less, risk than MDI.

# Indications for CSII

- Dawn-Phänomen
- Hypoglycemia / „Hypo-Unawareness“
- to reduce Glycemic Variation
- Hyperglycemia : high HbA1c / recurrent ketoacidosis
- Flexibility at meals and daily routine
- micro- or macravascular complications
- Pregnancy
- Insulinresistence
- Injection phobia
- Motivation / Patient wish
- „Ultima ratio“

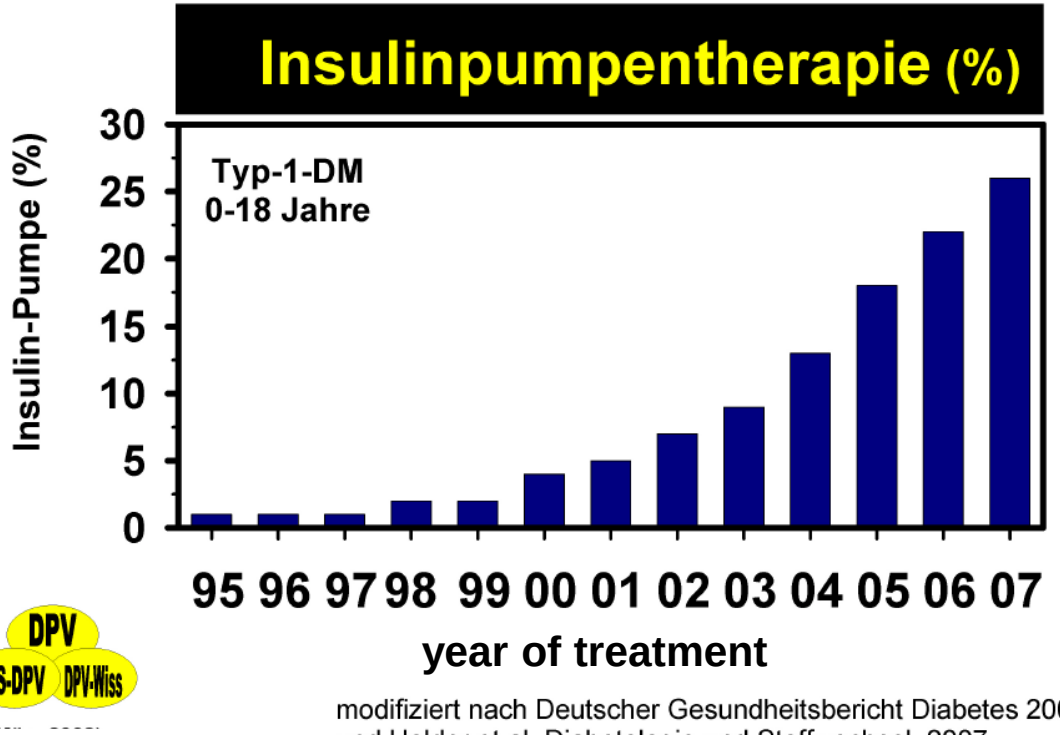
Consensus Guidelines Pediatric Diabetes
Consensus Guidelines Type 1 Diabetes
DDG, 2009, Germany

# Trends in the insulinregimes in children and adoloescents 1995-2007 in Germany

in 2008

total :
27%

age under 5 yrs:
52%




modifiziert nach Deutscher Gesundheitsbericht Diabetes 2009
und Holder et al, Diabetologie und Stoffwechsel, 2007

# Results of CSII in children

Pediatrics. 2004 Dec;114(6):1601-5.

**Persistence of benefits of continuous subcutaneous insulin infusion in very young children with type 1 diabetes: a follow-up report.**

**Weinzimer SA, Ahern JH, Doyle EA, Vincent MR, Dziura J, Steffen AT, Tamborlane WV.**
Department of Pediatrics, Yale University School of Medicine, PO Box 208064, 333 Cedar St, New Haven, Connecticut 06520, USA. stuart.weinzimer@yale.edu

**65 children, age median 4,5 J., followed 48 mon. after transfer to CSII**

- HbA1c reduced 7,4 +/- 1,0 vs 6,8 +/- 0,9
- Hypoglycemia reduced from 78 to 37/100 pat.-yrs. (53%)
- children in day-care centers profited most

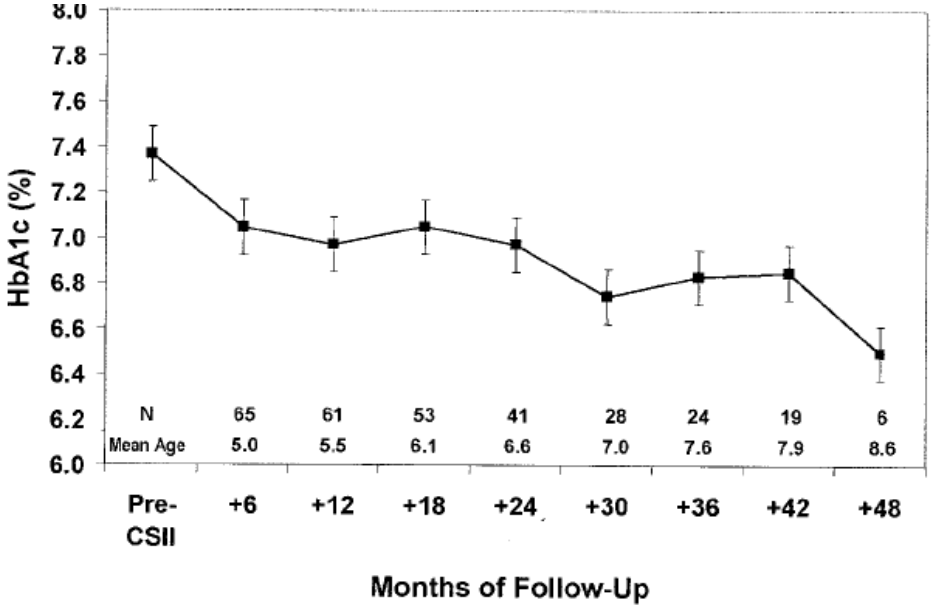



Fig 1. Glycemic control before and after transition to insulin pump therapy. The number of subjects included at each time point (N) and the mean age at the given month of follow-up are indicated above the corresponding month. $P$ = .006 for all postpump values compared with prepump.

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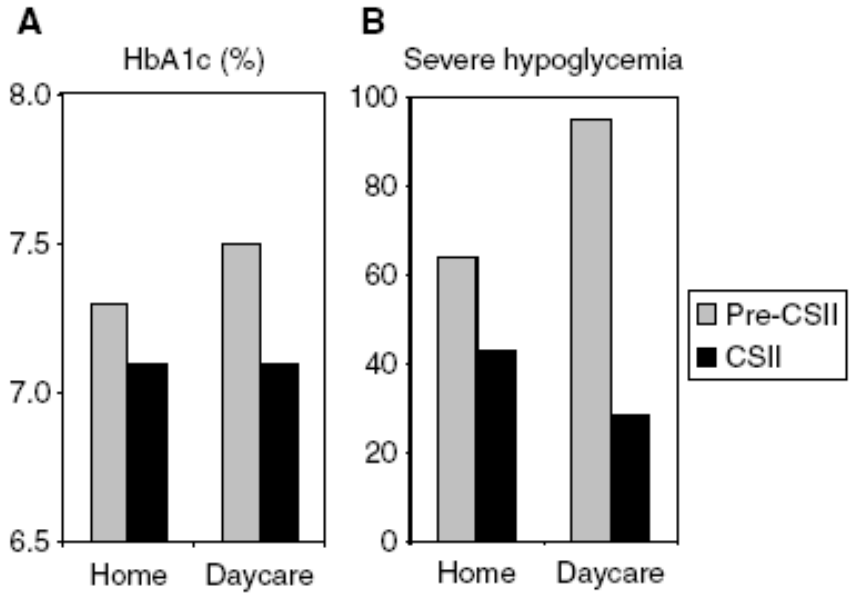



*Fig. 2.* Comparison of hemoglobin A1c (HbA1c) (A) and severe hypoglycemia rates (per 100 patient-years, B) between young children (under 7) receiving primary daytime care from mothers (home) and from paid care providers (daycare) in children in the Yale Pediatric Diabetes Program (12). CSII, continuous subcutaneous insulin infusion.

# Results of CSII in adolescents

Pediatrics. 2004 Jul;114(1):e91-5.

**Beneficial effects of continuous subcutaneous insulin infusion and flexible multiple daily insulin regimen using insulin glargine in type 1 diabetes.**

**Alemzadeh R, Ellis JN, Holzum MK, Parton EA, Wyatt DT.**
Children's Hospital of Wisconsin Diabetes Center, Department of Pediatrics, Medical College of Wisconsin, Milwaukee, Wisconsin 53226, USA. ralemzad@mcw.edu

**40 matched adolescents followed 12 mon. after transfer to CSII or MDI**

**CSII:**

- Increase of Bolus/Basal-Quot. 1.01 +/- 0.43 vs 1.32 +/- 0.52
- Improvement of HbA1c 8.4 +/- 1.0% vs 7.8 +/- 0.8%
- 40% of patients reached an improvement of HbA1c of >/= 1.0%

**MDI:**

- Increase of Bolus/Basal-Quot. 1.07 +/- 0.41 vs 1.29 +/- 0.47
- Improvement of HbA1c 8.5 +/- 1.1% vs 8.2 +/- 0.9%
- 22% of patients reached an improvement of HbA1c of >/= 1.0%

# Results of CSII in children and adolescents

Diabetes Care. 2006 Jan;29(1):133-4

**Age-specific advantages of continuous subcutaneous insulin infusion as compared with multiple daily injections in pediatric patients: one-year follow-up comparison by matched-pair analysis.**

Kordonouri O, Hartmann R, Lauterborn R, Barnekow C, Hoeffe J, Deiss D.
Children's Hospital, Charite, General Pediatrics, Berlin, Germany. olga.kordonouri@charite.de

**104 children and adolescents in matched pairs followed for 12 mon. after transfer to CSII**

Matching criteria: age (11.5 ± 3.3 J.), diabetes-duration (+/- 1 J), HbA1c (+/- 0.3%) at begin of study and gender

- HbA1c CSII stable: 8.17 ± 1.03% vs 8.02 ± 1.12% vs 8.27 ± 1.01%
- HbA1c MDI rose: 8.17 ± 1.02% vs 8.41 ± 1.09% vs 8.51 ± 1.19% (p=.031)
- Basalinsulinportion reduced:
  CSII: 51.0 ± 12.9% vs 42.3 ± 12.3% vs 38.8 ± 10.9% (p<.05)
  MDI not significant 57.0% vs 55.2% vs 52.8%
- severe Hypoglycemia und BMI-SDS no difference

# Results of transfering back from CSII in adolescents

**Durability of Insulin Pump Use in Pediatric Patients With Type 1 Diabetes**

**Jamie R. Wood, MD, Elaine C. Moreland, MD, Lisa K. Volkening, BA, Britta M. Svoren, MD, Deborah A. Butler, MSW and Lori M.B. Laffel, MD, MPH**

Pediatric, Adolescent, and Young Adult Section, Genetics and Epidemiology Section, Joslin Diabetes Center, Boston, Mass.

**Diabetes Care** 29:2355-2360, 2006

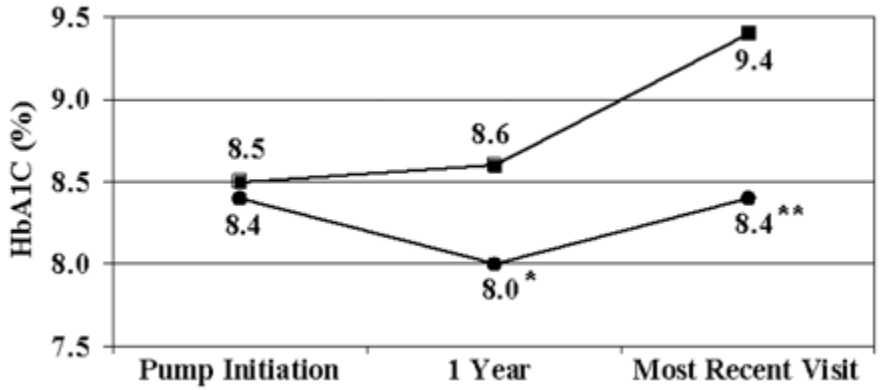



**Figure 2—** Glycemic outcomes. After 1 year (*$P$ = 0.04) and at the most recent visit (**$P$ = 0.01), those who remained on pump therapy had significantly lower A1C compared with those who discontinued pump therapy. •, remained on pump therapy;  , discontinued pump therapy.

mean age of 14.1 ± 3.7 years, diabetes duration of 7.1 ± 4.0 years

# Results of CSII vs MDI in pregnant women with type 1 diabetes

Diabetes Technol Ther. 2010 Apr;12(4):263-9.

**Continuous subcutaneous insulin infusion versus multiple daily injections in pregnant women with type 1 diabetes.**

González-Romero S, González-Molero I, Fernández-Abellán M, Domínguez-López ME, Ruiz-de-Adana S, Olveira G, Soriguer F. Malaga, Spain

case-control study, 35 pregnancies treated with CSII
64 pregnancies treated with MDI

CSII group improved their metabolic control:

| | | | |
|---|---|---|---|
| | HbA1c | before CSII | 7.83 +/- 0.97%; |
| | 3-6 months | with CSII | 6.77 +/- 0.61%; ($p < 0.05$). |

HbA1c before birth was lower in the CSII group (6.62% +/- 0.60%)
than in the MDI group (7.59% +/- 1.61%) ($p < 0.05$).

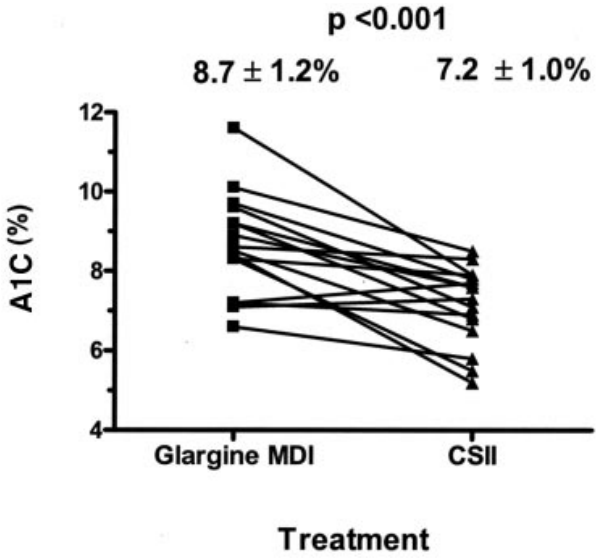
No significant differences in obstetric and perinatal outcome were found.

# Results of CSII in adults

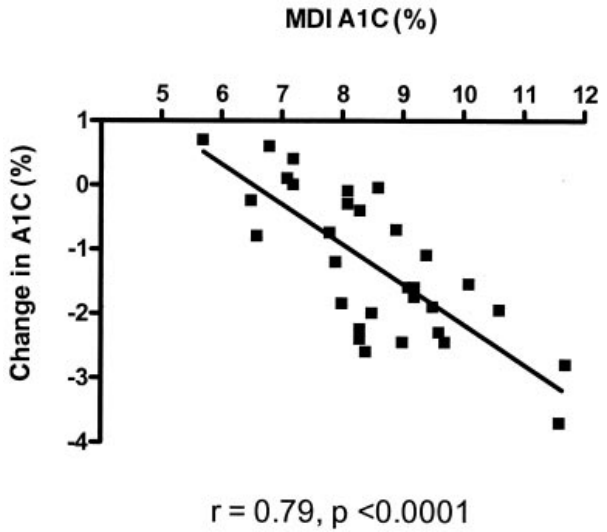
## Long-Acting Insulin Analogs Versus Insulin Pump Therapy for the Treatment of Type 1 and Type 2 Diabetes

John C. Pickup, DPHIL, FRCPATH[1] and Eric Renard, MD, PHD[2]

DIABETES CARE, VOLUME 31, Suppl.2, 2008




A1C in hypoglycemia-prone type 1 diabetic subjects when treated by MDI based on glargine and after switching to CSII.




Correlation in type 1 diabetes between the A1C on MDI and the subsequent change in A1C when patients were switched to CSII.

# Results of CSII in adults

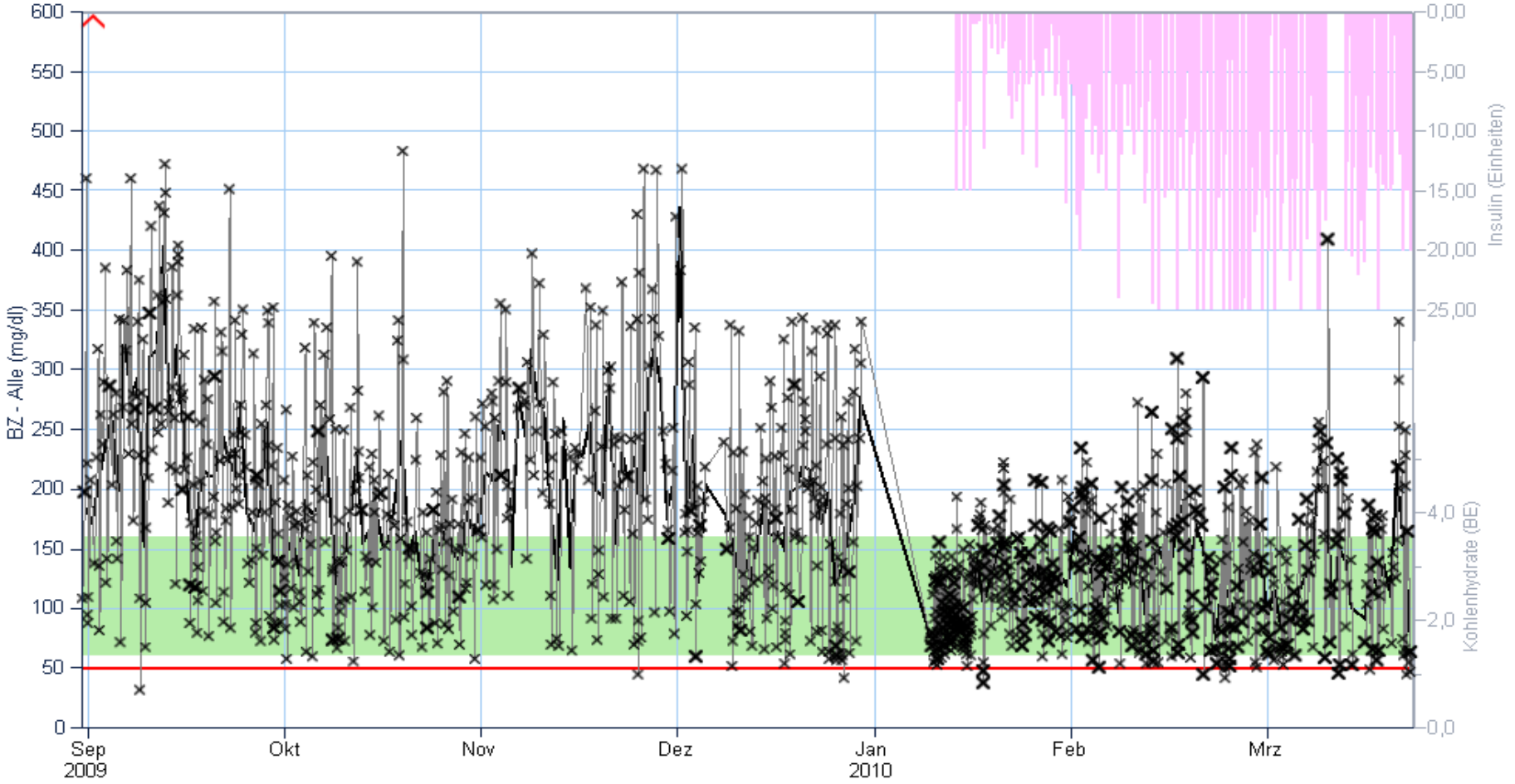
## Long-Acting Insulin Analogs Versus Insulin Pump Therapy for the Treatment of Type 1 and Type 2 Diabetes

John C. Pickup, DPHIL, FRCPATH[1] and Eric Renard, MD, PHD[2]

DIABETES CARE, VOLUME 31, Suppl.2, 2008

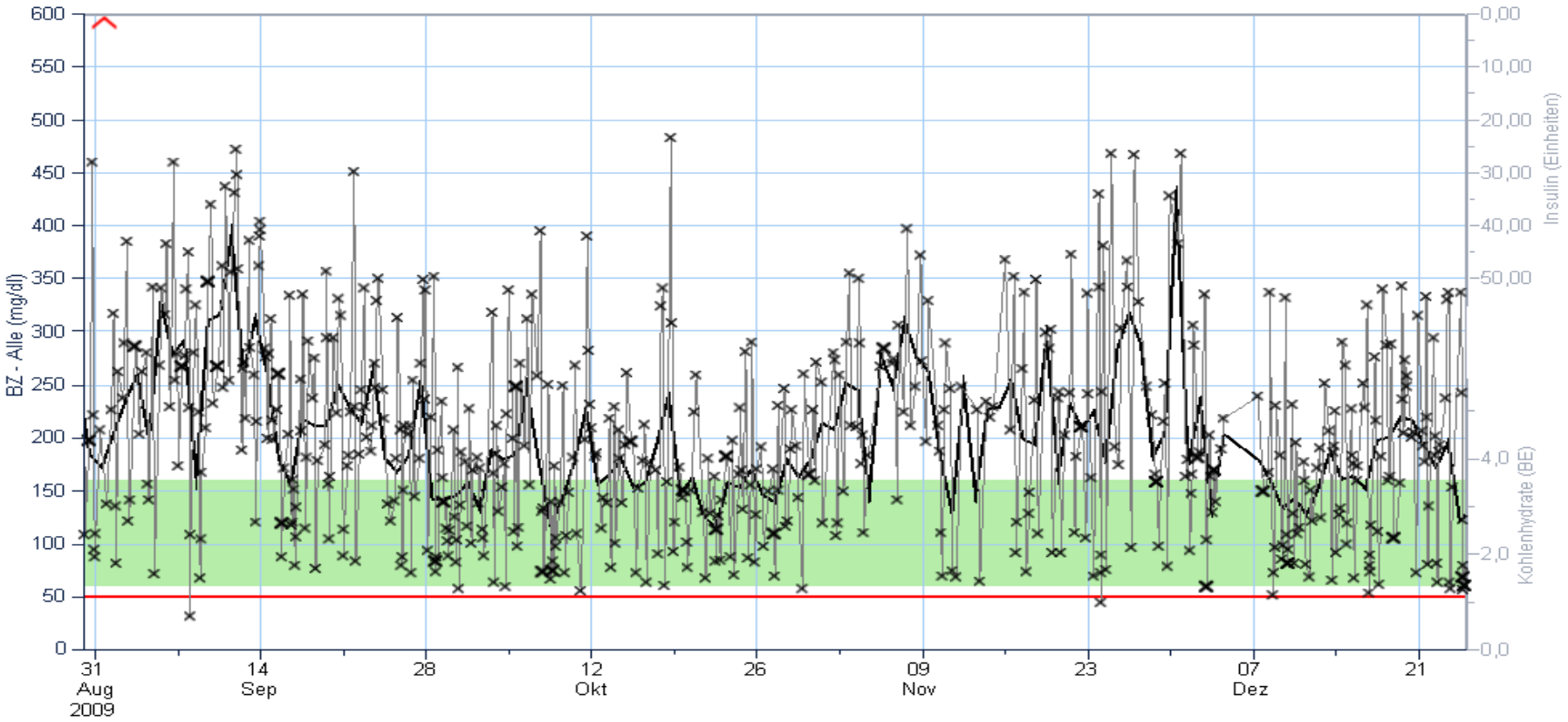
…..interesting information has been provided on the feasibility of CSII in type 2 diabetic patients and pointers given about which patients could be good candidates for pump therapy: socially active subjects looking for flexibility would likely be ranked first among them. Reduction of postmeal excursions with CSII as shown in two trials supports considering this therapy in patients for whom blood glucose spikes are likely to be particularly deleterious, e.g., those with retinal macular edema or cardiovascular lesions…..

# Case Miriam: transfer to CSII



# Case Miriam: before transfer to CSII

Bereich: Benutzerdefini... | 30.08.2009 - 24.12.2009 | Kohlenhydrate: BE

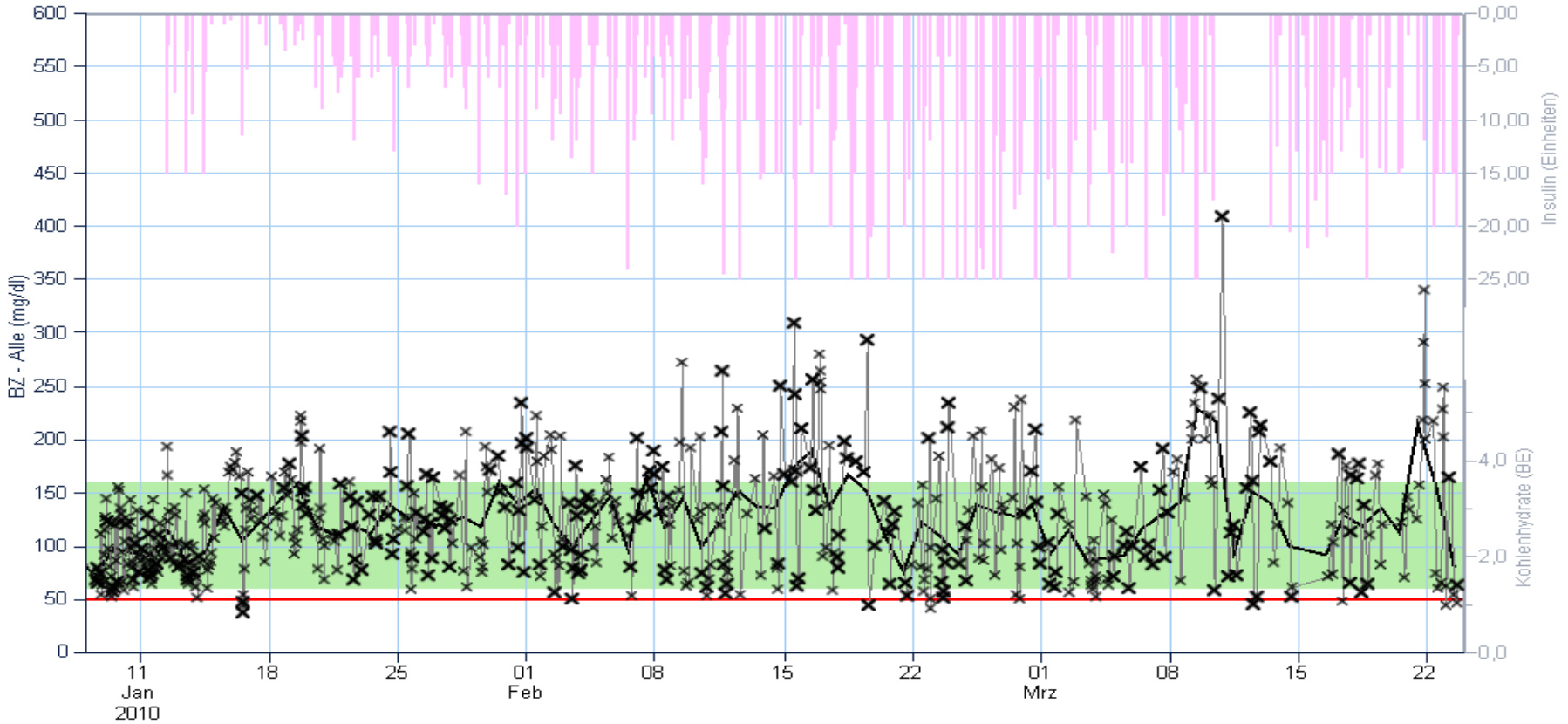



**BZ - Alle**

| | | | | | | |
|---|---|---|---|---|---|---|
| Anzahl Tests: | 586 | Durchschn. Tests/Tag: | 5,0 | Über Ziel > 160 mg/dl: | 60,8% | (355) |
| Durchschnitt (mg/dl): | 196,9 | # HI: | 2 | Im Ziel 60 - 160 mg/dl: | 37,2% | (217) |
| SD (mg/dl): | 95,1 | # LO: | 0 | Unter Ziel 50 - 60 mg/dl: | 1,7% | (10) |
| Höchster Wert (mg/dl): | 483 | BG Index niedrig: | 1,2 | Hypo < 50 mg/dl: | 0,3% | (2) |
| Niedrigster Wert (mg/dl): | 31 | BG Index hoch: | 15,0 | | | |

# Case Miriam: after transfer to CSII

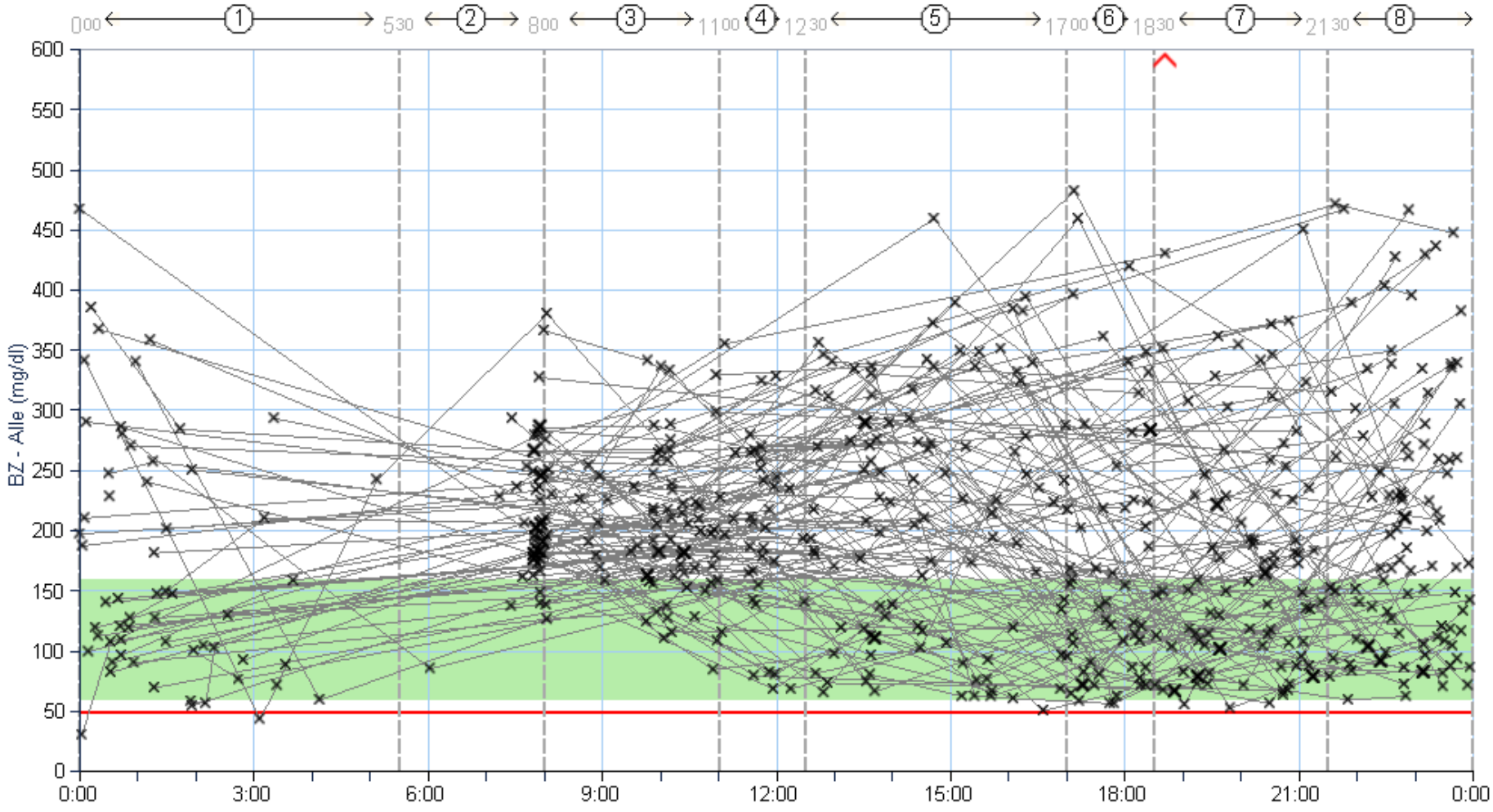
Bereich: Benutzerdefini... | 08.01.2010 - 23.03.2010 | Kohlenhydrate: BE




**BZ - Alle**

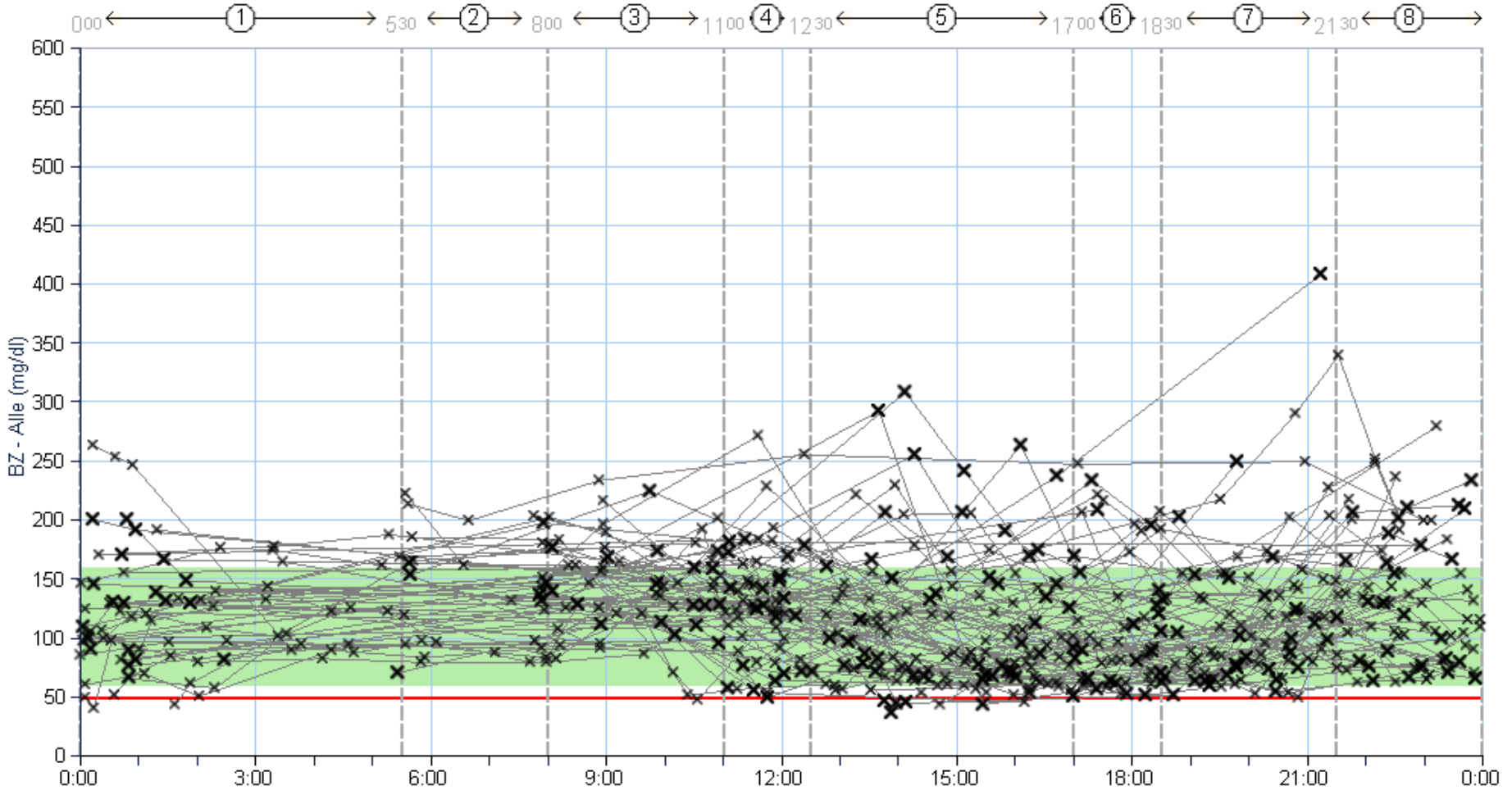
| | | | | | | |
|---|---|---|---|---|---|---|
| Anzahl Tests: | 796 | Durchschn. Tests/Tag: | 10,6 | Über Ziel > 160 mg/dl: | 22,6% | (180) |
| Durchschnitt (mg/dl): | 122,7 | # HI: | 0 | Im Ziel 60 - 160 mg/dl: | 70,1% | (558) |
| SD (mg/dl): | 55,0 | # LO: | 0 | Unter Ziel 50 - 60 mg/dl: | 5,4% | (43) |
| Höchster Wert (mg/dl): | 409 | BG Index niedrig: | 3,5 | Hypo < 50 mg/dl: | 1,9% | (15) |
| Niedrigster Wert (mg/dl): | 37 | BG Index hoch: | 3,2 | | | |

# Case Miriam: before transfer to CSII



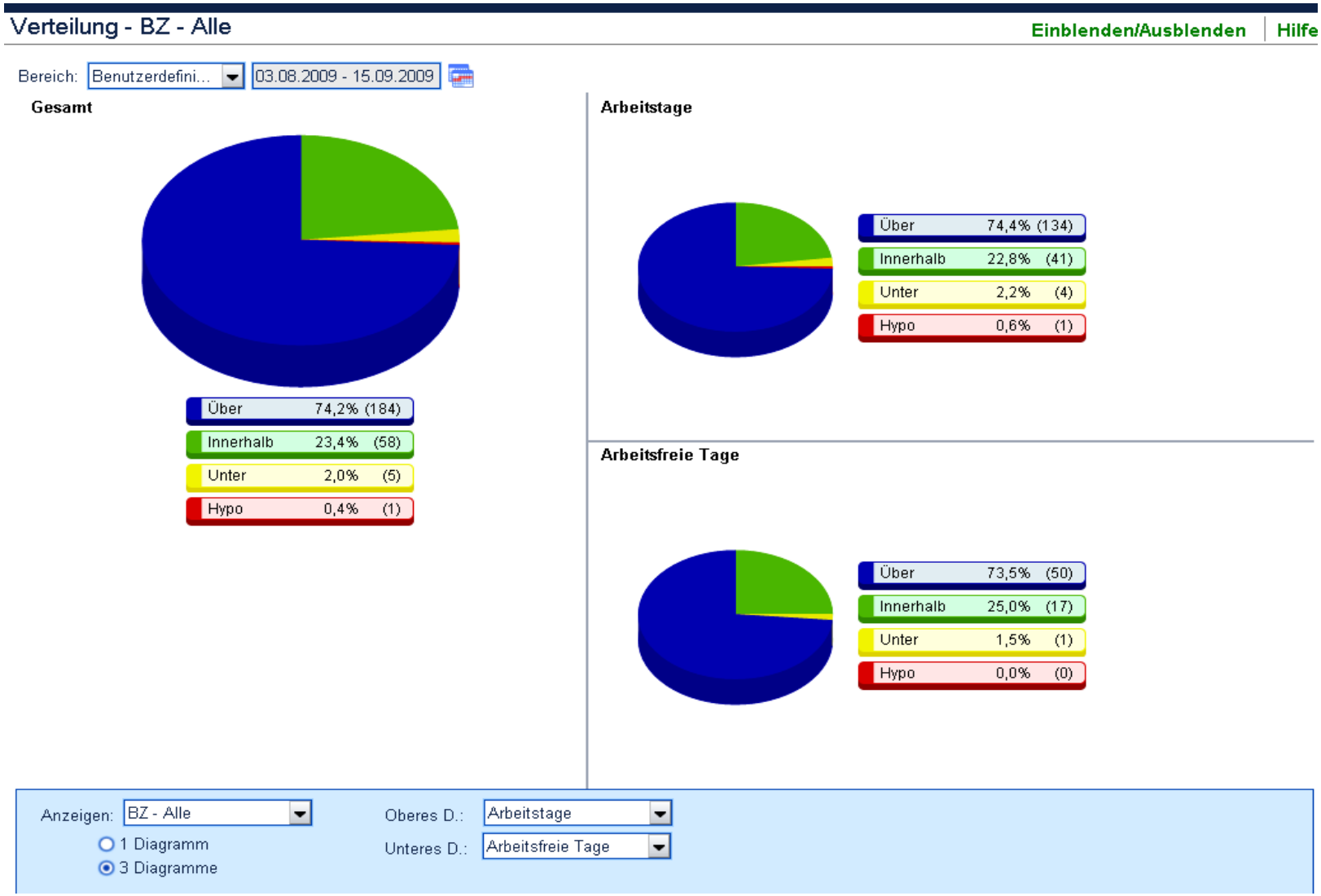

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Anzahl der Werte | 59 | 45 | 85 | 39 | 105 | 56 | 97 | 100 |
| Durchschnitt | 172,7 | 212,2 | 207,5 | 199,8 | 215,2 | 180,6 | 172,2 | 207,5 |

# Case Miriam: after transfer to CSII

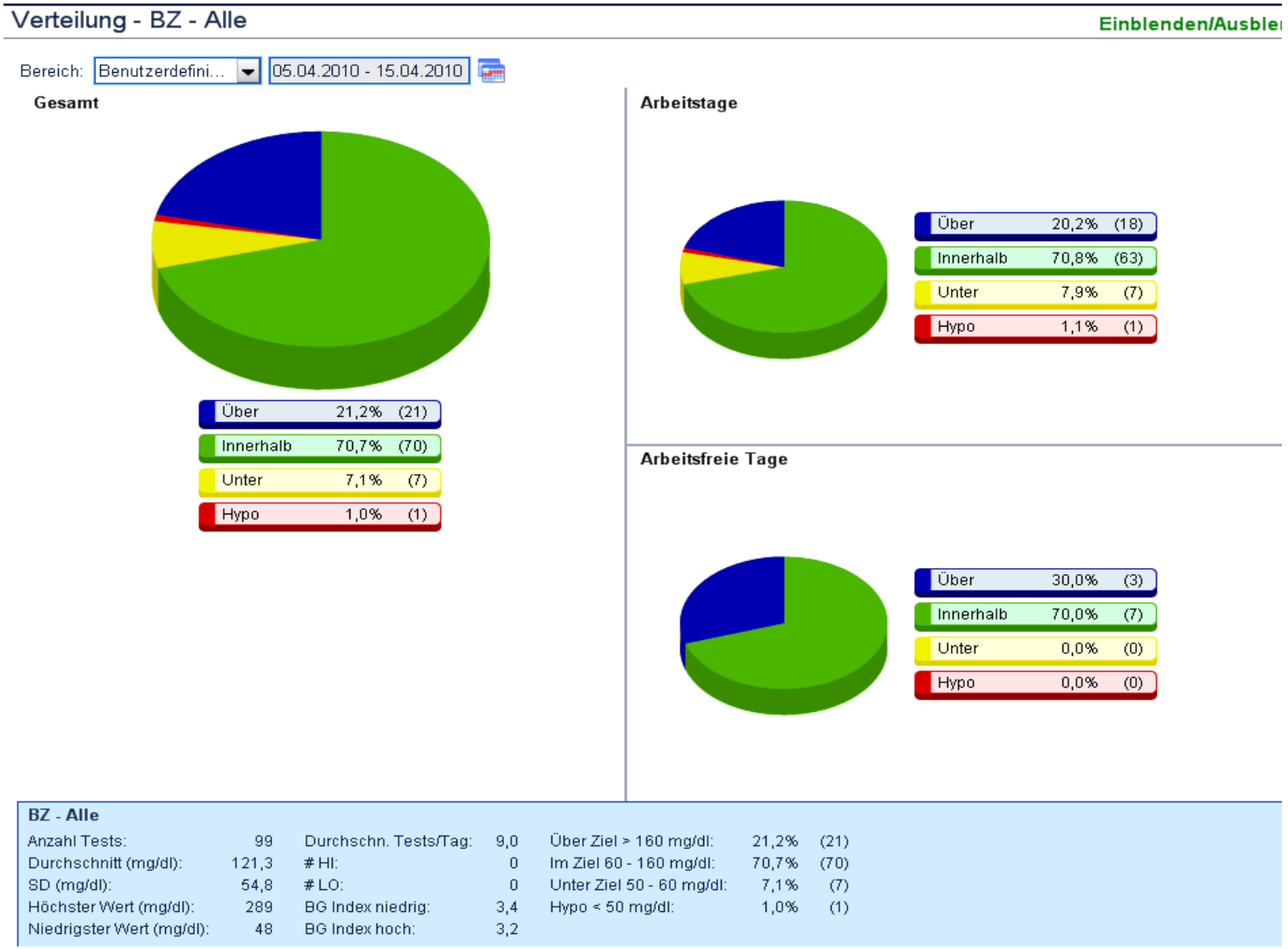



| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Anzahl der Werte | 104 | 38 | 78 | 76 | 186 | 75 | 129 | 110 |
| Durchschnitt | 121,6 | 140,8 | 143,8 | 127,3 | 111,8 | 111,8 | 115,1 | 133,7 |

# Case Miriam: before transfer to CSII



# Case Miriam: after transfer to CSII



# ACCU-CHEK® Smart Pix

**Plug&Play:**

- *no software neccessary*
- *use common USB*

**compatibel :**

*can read all ACCU-CHEK meters and pumps and AccuChek Combo insulinpump*

**flexible:**

*wide variety of reports*

# ACCU-CHEK® 360°

WHAT IS IT:

Comprehensive software solution to store, access and analyze diabetes data

WHO IS IT FOR:

HCPs and Teams using diabetes management software (and patients)

WHAT IS THE BENEFIT:

Effective communication between healthcare team and patients. Enables cause and effect analysis of bG to insulin, carbs, exercise and more.

ACCU-CHEK 360°

ACCU-CHEK Combo

# integrated insulin pump/bG meter solutions


Roche Accu-Chek® Combo

# integrated insulin pump/bG meter solutions




Roche Accu-Chek® Combo

# integrated insulin pump/bG meter solutions with Diabetes Management and Bolus/bG-Test alarm and with bolus calculator


Roche Accu-Chek® Combo

# Case: Mario

| Datum und Uhrzeit | BZ (mg/dl) | Insulin (Einheiten) | Kohlenhydr |
|---|---|---|---|
| Mo 02.03.2009 21:44 | | 14,00 Insulinpumpe | |
| 21:39 | | 10,00 Insulinpumpe | |
| 15:29 | | 10,00 Insulinpumpe | |
| 11:18 | | 4,00 Insulinpumpe | |
| 3:14 | | 8,00 Insulinpumpe | |
| So 01.03.2009 23:22 | | 5,00 Insulinpumpe | |
| 18:48 | | 10,00 Insulinpumpe | |
| 16:08 | | 14,00 Insulinpumpe | |
| 15:57 | | 7,50 Insulinpumpe | |
| Sa 28.02.2009 23:15 | | 16,00 Insulinpumpe | |
| 15:14 | | 12,00 Insulinpumpe | |
| 9:29 | | 3,50 Insulinpumpe | |
| Fr 27.02.2009 22:33 | | 3,00 Insulinpumpe | |
| 22:07 | | 8,50 Insulinpumpe | |
| 15:38 | | 12,00 Insulinpumpe | |
| Do 26.02.2009 19:25 | | 10,00 Insulinpumpe | |
| 17:45 | | 9,00 Insulinpumpe | |
| 8:53 | | 6,00 Insulinpumpe | |
| Mi 25.02.2009 22:51 | | 6,00 Insulinpumpe | |
| 16:57 | | 12,00 Insulinpumpe | |
| 14:28 | | 10,00 Insulinpumpe | |
| Di 24.02.2009 23:44 | | 9,00 Insulinpumpe | |
| 20:48 | | 12,00 Insulinpumpe | |

# The Use of Insulin Pumps With Meal Bolus Alarms in Children With Type 1 Diabetes to Improve Glycemic Control

**H. PETER CHASE, MD BRIAN HORNER, MS KIM MCFANN, PHD HANNAH YETZER, MS JANA GASTON, RD CAROLYN BANION, PNP ROSANNA FIALLO-SCHARER, MD ROBERT SLOVER, MD GEORGEANNA KLINGENSMITH, MD**
**Denver, USA**

DIABETES CARE, VOLUME 29, NUMBER 5, MAY 2006

In summary, the use of meal bolus alarms in the insulin pump did result in fewer missed meal boluses and initial improvement in HbA1c values. However, the improvement was not sustained in the long term. The data obtained from this study indicates that technology, per se, may not solve behavioral problems, such as omission of insulin boluses, in children and adolescents with suboptimal diabetes control. Future research is needed to explore additional techniques that may sustain the effects initially observed in this study.

POSITION STATEMENT

# Standards of Medical Care in Diabetes—2010

American Diabetes Association

DIABETES CARE, VOLUME 33, SUPPLEMENT 1, JANUARY 2010

per 100 patient-years of therapy). Since the time of the DCCT, a number of rapid-acting and long-acting insulin analogs have been developed. These analogs are associated with less hypoglycemia with equal A1C lowering in type 1 diabetes (77,78).

Recommended therapy for type 1 diabetes therefore consists of the following components: *1*) use of multiple dose insulin injections (3–4 injections per day of basal and prandial insulin) or CSII therapy; 2) matching of prandial insulin to carbohydrate intake, premeal blood glucose, and anticipated activity; and 3) for many patients (especially if hypoglycemia is a problem), use of insulin analogs.

Pediatric Diabetes

ISPAD

Pediatric Diabetes 2009: 10(Suppl. 12): 82–99
doi: 10.1111/j.1399-5448.2009.00578.x

Pediatric Diabetes

**ISPAD Clinical Practice Consensus Guidelines 2009 Compendium**

# Insulin treatment in children and adolescents with diabetes

Bangstad H-J, Danne T, Deeb LC, Jarosz-Chobot P, Urakami T, Hanas R.

Improvements in glycemic control, particularly when provided by intensive insulin treatment with MDI or pump therapy, reduce the risks of vascular complications (A). There is no reason to believe that this is not the case also in younger children (E).
In all age-groups, as close to physiological insulin replacement as possible and optimal glycemic control must be the aim; the attainment of this aim should include the consideration of an intensive insulin regimen (E).

An insulin pump is an alternative to treatment with MDI (including basal analogues) if HbA1c is persistently above the individual goal, hypoglycemia is a major problem, or quality of life needs be improved (109) (E).

The newer generation of ‘‘smart’’ pumps that automatically calculate meal or correction boluses based on insulin-to-carbohydrate ratios and insulin sensitivity factors have enabled alternate providers, such as grandparents, nannies, and daycareworkers, to participate in diabetes management tasks (E)

The use of pumps requires special education for users but does not need to be restricted to centers with 24 h access to pump expertise

# integrated insulin pump/bG meter solutions
# “smart pump” with bolus calculator

Questions :

- What is my current bG ?
- How much insulin do I need for the planned meal at this time of the day?
- Which factor of insulinsensitivity do I need to observe at this time of the day?
- How much insulin do I need to cover the carb‘s of the meal and how much to correct my current bG to the target bG?
- When did I give how much Insulin – and how much is still active?
- What do I have to observe for e.g my activity?


Roche Accu-Chek® Combo

# integrated insulin pump/bG meter solutions
# “smart pump” with bolus calculator

Answers :

The bolus calculator advises a bolus
taking into account following parameters:

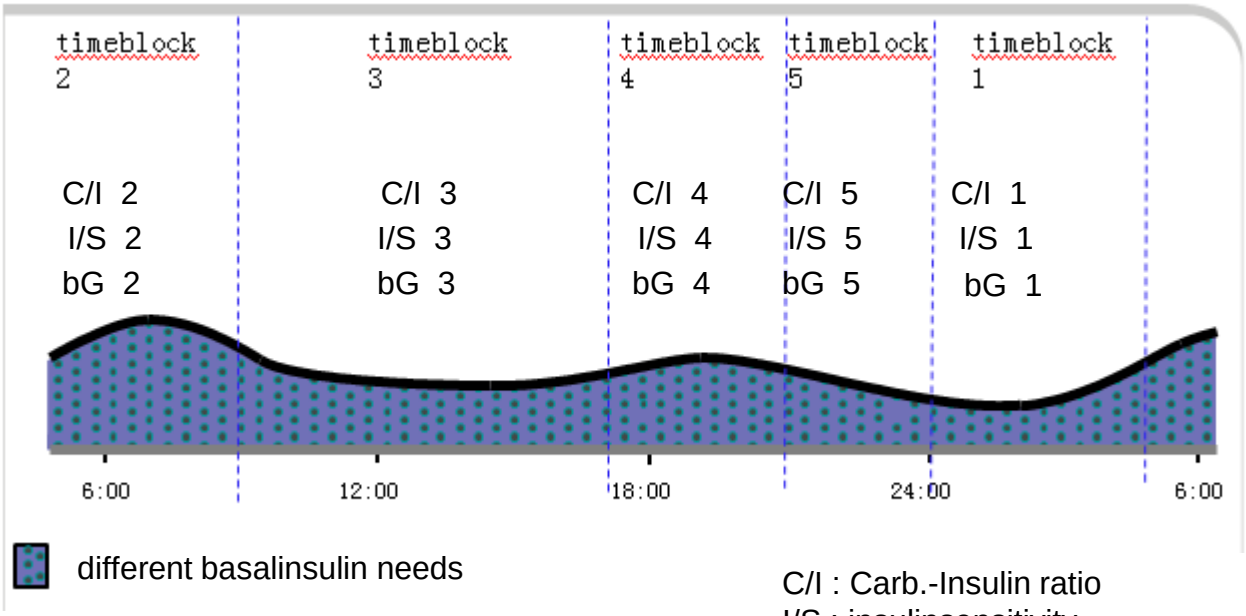
- current bG-value and target bG-value
- planed meal (carbohydrates)
(insulin-to-carb ratio or vice versa)
- individual and time dependent variable parameters

  e.g.
  - carb./insulin factor
  - insulinsensitivity (correction factor)

- state of health , planned activity
- different types of bolus
- safety programs (no double bolus)


Roche Accu-Chek® Combo

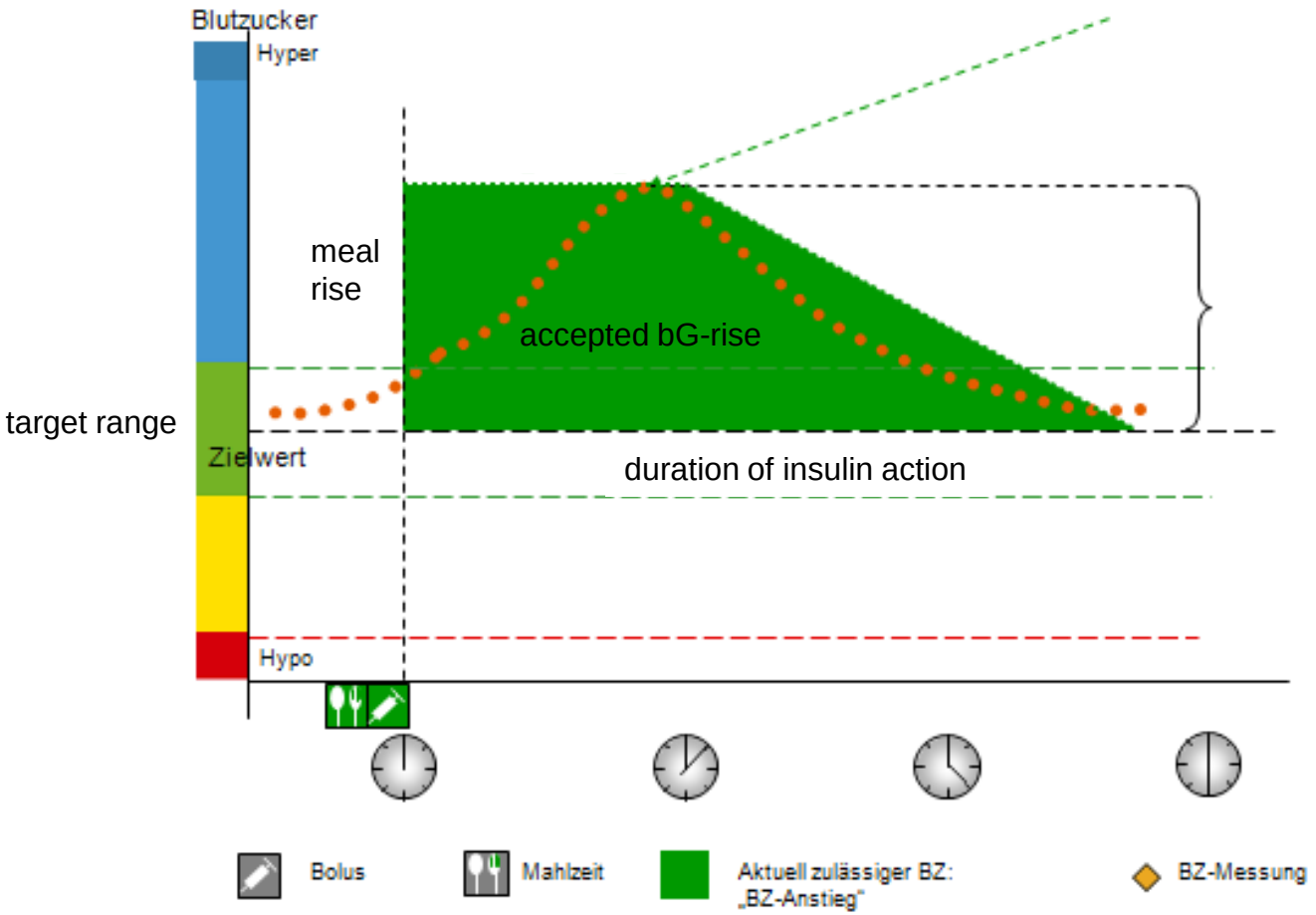
# "smart pump" with bolus calculator: how does it work ? - at different times different rules



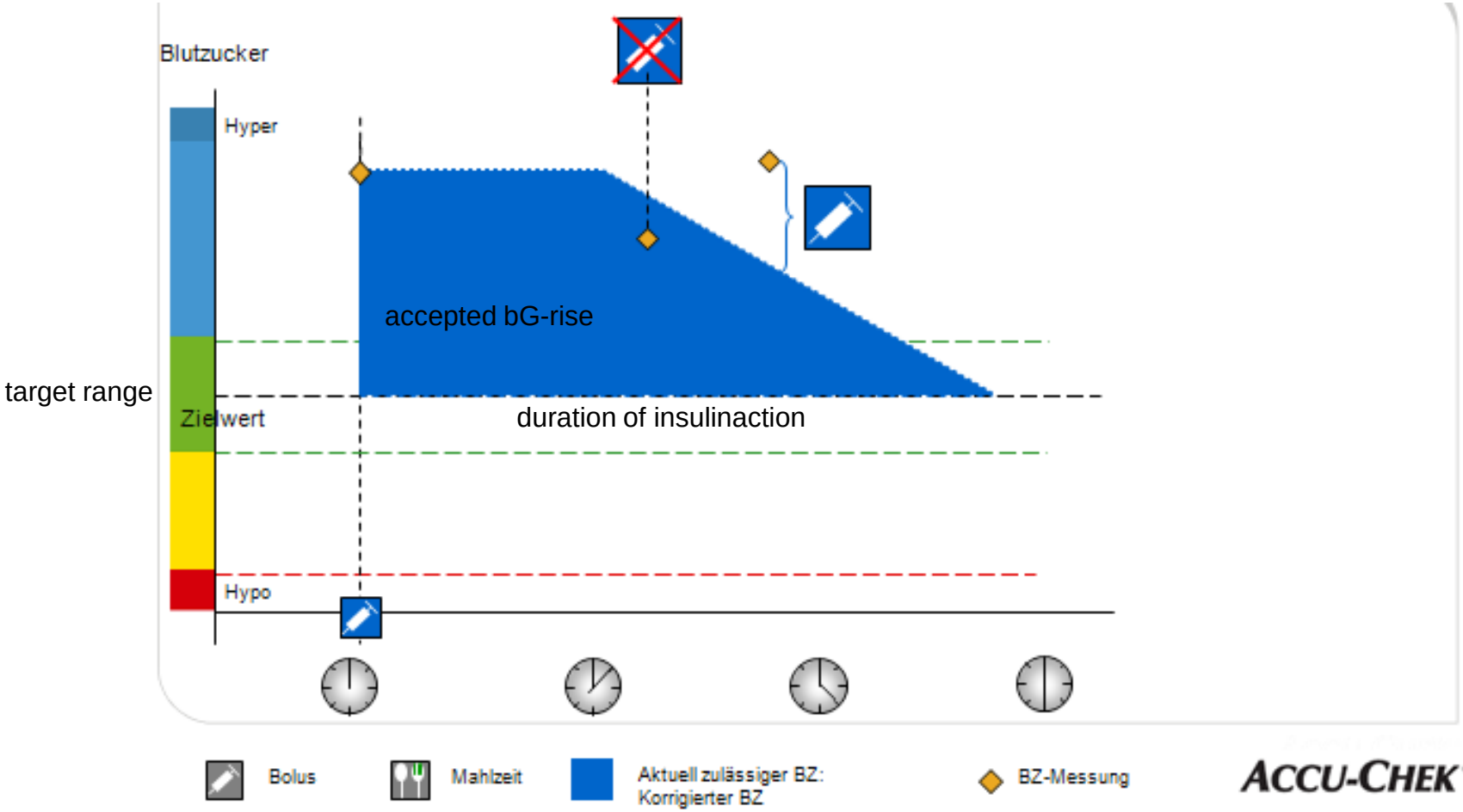

C/I : Carb.-Insulin ratio
I/S : insulinsensitivity
bG : blood Glucose target

individual rules for Carb.-Insulin ratios, Insulinsensitivity and blood Glucose targets can be set for different timeblocks

# "smart pump" with bolus calculator: how does it work ? - meals

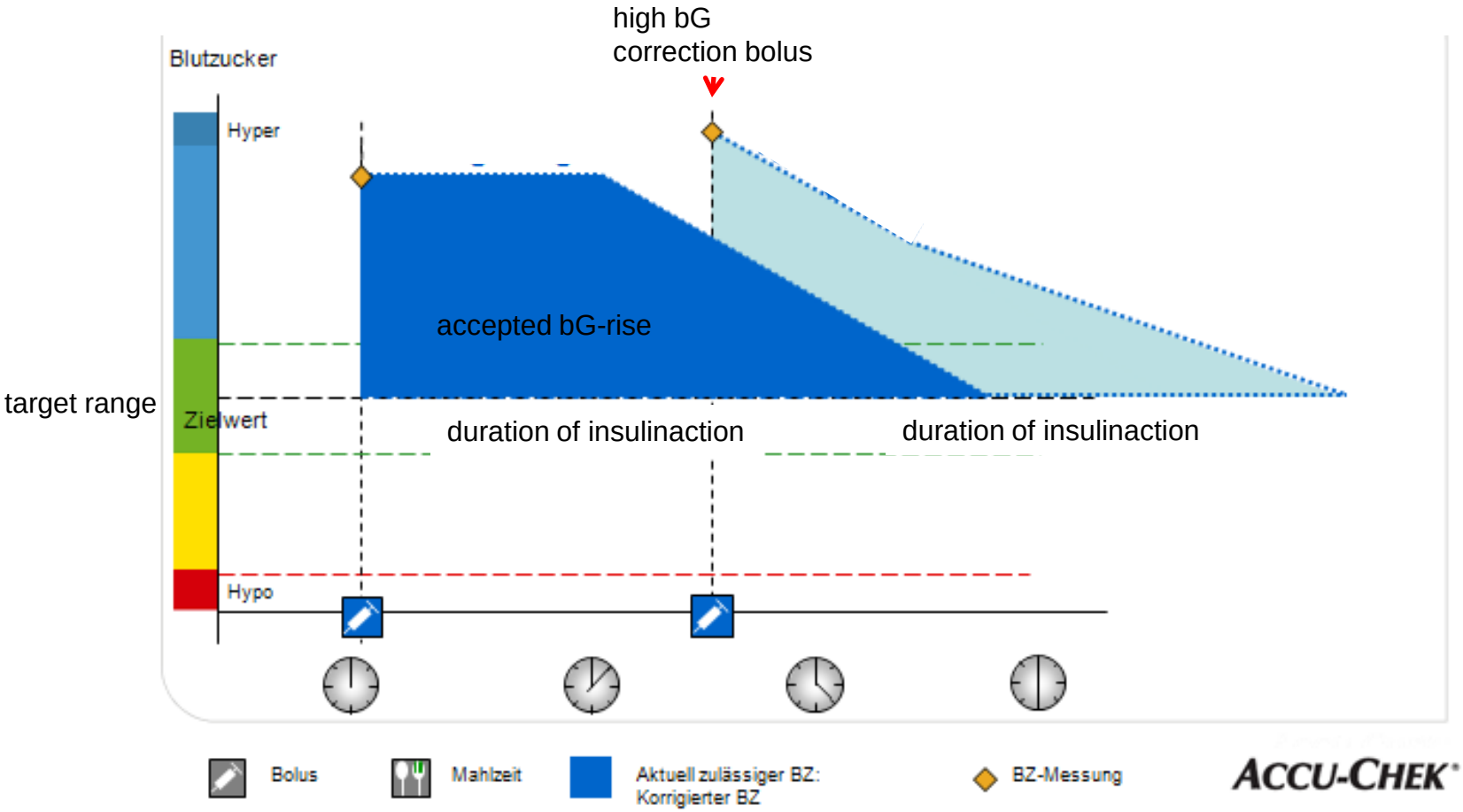


# "smart pump" with bolus calculator: how does it work ?




Roche Accu-Chek® Combo

# "smart pump" with bolus calculator: how does it work ? - correction bolus



# Differences in Management of Post-Prandial Hyperglycemia by Automated Bolus Calculators is Due to Distinct Insu

**Angela McDaniel, Ejimofor Oruche**
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The **objective** of this study was to estimate how different bolus advisors **manage PPH**
**Post Prandial Hyperglycemia**

**Presented at the ATDD, Basel, 2010**

## ABSTRACT

**AIMS:**
There is strong evidence that postprandial hyperglycemia (PPH) is an independent risk factor for macrovascular disease. Because of this, automated bolus calculators (ABC) associated with insulin pump systems are programmed to manage PPH. The purpose of this experiment was to determine how different ABCs manage PPH.

**METHODS:**
The following ABCs were used in this experiment: Roche Accu-Chek® Combo Insulin Pump System, the Medtronic Paradigm™ 722, the Animas™ 2020, and the Deltec Cozmo™ 1800 systems. Identical blood glucose (bG), carbohydrate (CHO), and therapy parameters were used. A preprandial bG (174 mg/dl) and a meal size (80g CHO) were entered. A 2-hour postprandial value (246 mg/dL) was entered and insulin dosing advice was compared.

**RESULTS:**
Three of the systems gave a similar preprandial insulin dose for CHO intake; the Medtronic Paradigm system recommended significantly less insulin (0.6 U vs 1.4 U). There was a significant difference in bolus advice given at 2 hours post-prandial. The Roche ABC recommended 1.4 U; whereas, the other ABCs gave no recommendation for addition insulin.

**CONCLUSIONS:**
The difference in PPH management is likely due to differences in how ABC algorithms manage insulin on board (IOB) in a postprandial state. Most count all insulin given preprandially as IOB; whereas, the Roche ABC only counts insulin given to correct preprandial hyperglycemia as IOB. Insulin given to cover CHO intake is not counted as IOB. More aggressive management of PPH by the Roche ABC may result in better glycemic control and less risk for macrovascular disease.

## INTRO

- Continuous subcutaneous insulin infusion (CSII) therapy is increasingly popular as a means of insulin delivery for individuals with type 1 diabetes (T1DM) and type 2 diabetes (T2DM).[1] This is due mainly to improvements in quality of life, better blood glucose control, reduced hypoglycemia and the greater independence these systems offer.[1-8]

4 bolus advisors were used **Accu Chek Combo Insulin pump system**, **Medronic paradigm 722, Animas 2020 and Deltec Cozmos 1800**.

The same exact parameters were entered: same BG value, CHO and therapy parameters : Pre prandial BG 174mg/dl, 80gr CHO and 2h post prandial BG 274mg/dl **The advise given by the 4 bolus advisors was compared.**

## ST

**De**
**ma**

## M

| | |
|---|---|
| **Active Time** | **4 hours** |
| **Upper Blood Glucose Limit** | **140 mg/dL** |
| **Lower Blood Glucose Limit** | **70 mg/dL** |

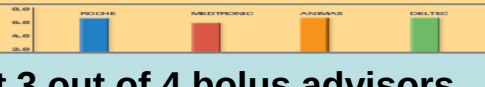
- For the Roche ABC, the Meal Rise was set at 50 mg/dl and the Offset time was set to 45 min.
- A preprandial bG (174 mg/dl) and a meal size (80g CHO) were entered. A 2-hour postprandial value (246 mg/dL) was entered and insulin dosing advice was compared.

## RESULTS

**I. Pre-Prandial Bolus Advice**


- For an 80 gram CHO meal, all pumps gave bolus advice of 5.3 units.
- For a pre-prandial blood glucose of 174 mg/dl, all pumps gave correction bolus advice of approximately 1.3 units except Medtronic, which provided a correction of 0.6 units.
- The difference in correction bolus amounts was due to Medtronic's correcting to the top target range (140 mg/dl) while the others corrected to the midpoint of this range (105 mg

**II. Correction Bolus for 2 Hour Post-Prandial Hyperglycemia**




**III. Insulin on Board (Active Insulin) at 2 Hours Post-Prandial**


- The Roche ABC shows significantly less insulin on board or active insulin at 2 hrs post-p
- This is because the other ABCs consider the insulin given in the pre-prandial bolus (mea correction) as potentially available to lower elevated blood glucose.
- In contrast, the Roche ABC only counts insulin given to correct pre-prandial hyperglycem IOB or active insulin. Insulin given to cover the meal is not considered to be available to l elevated blood glucose.

**The results showed that 3 out of 4 bolus advisors gave similar** post prandial bolus advises: **Animas, Deltec and Paradigm 0,6U** whereas the **Accu Chek Combo system 1,4U reducing postprandial hyperglycemia with no increased risk of hypoglycemia**

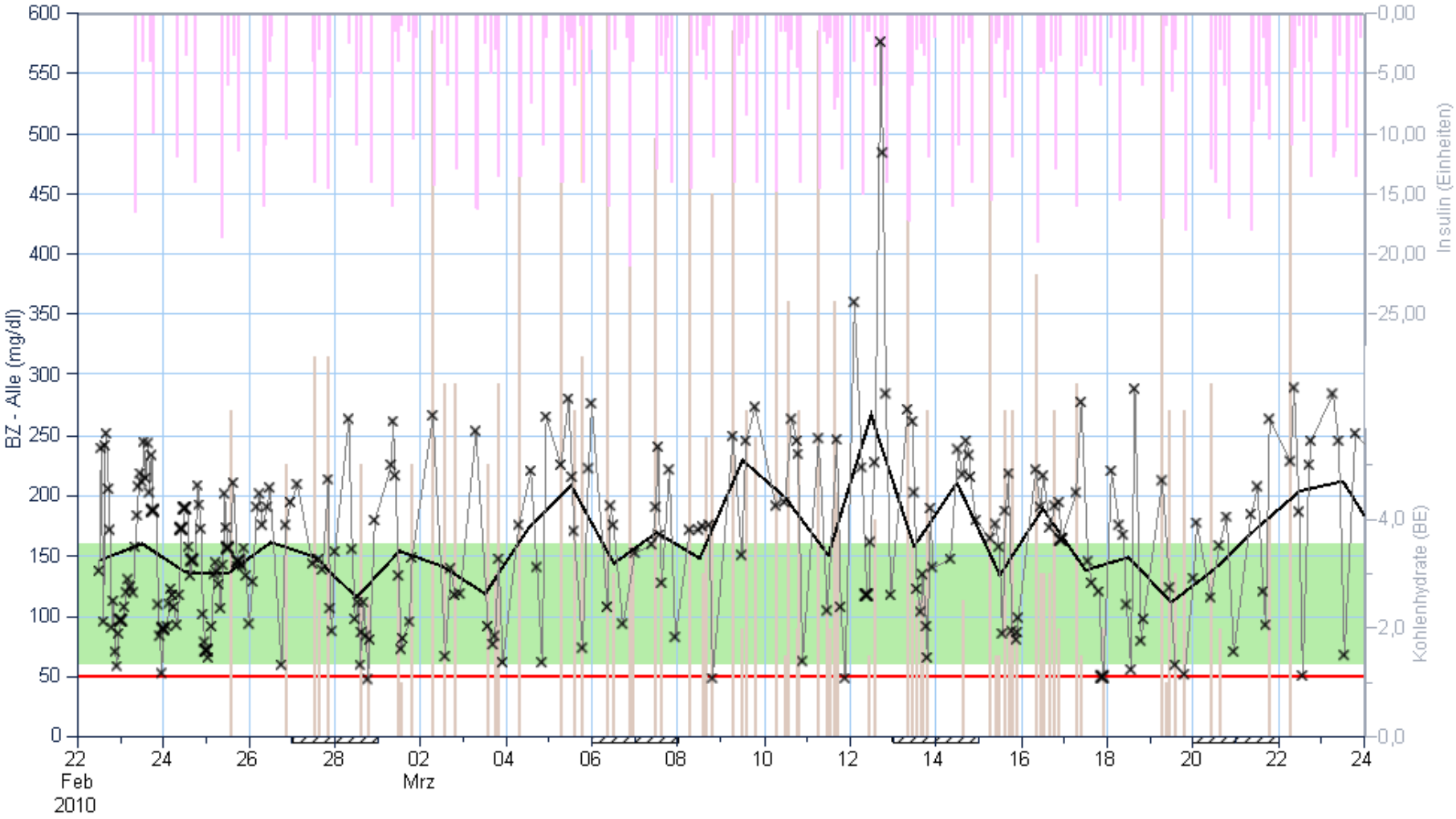
## CONCLUSIONS

- **Pre-prandial bolus advice given by the bolus calculators used in this experiment was very similar.**
- **The Roche ABC recommended a correction bolus to address 2 hour post-prandial hyperglycemia while the other ABCs did not.**
- **This difference is due to the manner in which the ABC algorithms assess insulin on board or active insulin.**
- **More aggressive management of PPH by the Roche ABC may result in better glycemic control and less risk for cardiovascular disease.**

## REFERENCES

1. Pickup J, Keen H. Continuous subcutaneous insulin infusion at 25 years: evidence base for the expanding use of insulin pump therapy in type 1 diabetes. Diabetes Care 2002; 25(3):593–598.
2. Bode BW, Sabbah HT, Gross TM, Fredrickson LP, Davidson PC. Diabetes management in the new millennium using insulin pump therapy. Diabetes Metab Res Rev 2002; 18 Suppl 1 S14–S20.
3. Likarekova R, Raoul M, Bott U, Berger M, Spraul M. Less severe hypoglycaemia, better metabolic control, and improved quality of life in Type 1 diabetes mellitus with continuous subcutaneous insulin infusion (CSII) therapy: an observational study of 100 consecutive patients followed for a mean of 2 years. Diabet Med 2002; 19(9):746–751.
4. Bode BW, Steed RD, Davidson PC. Reduction in severe hypoglycemia with long-term continuous subcutaneous insulin infusion in type I diabetes. Diabetes Care 1996; 19(4):324–327.
5. Boland EA, Gray M, Oesterle A, Fredrickson L, Tamborlane WV. Continuous subcutaneous insulin infusion: A new way to lower risk of severe hypoglycemia, improve metabolic control, and enhance coping in adolescents with type 1 diabetes. Diabetes Care 1999; 22(11):1779–1784.
6. Joha GS, Karavitl LP, Anderson B et al. Insulin pump therapy in preschool children with type 1 diabetes mellitus improves glycemic control and decreases glucose excursions and the risk of hypoglycemia. Diabetes Technol Ther 2005; 7(6):876–884.
7. Kaufman FR, Halvorson M, Miller D, Mackenzie M, Fisher LK, Pitukcheewanont P. Insulin pump therapy in type 1 pediatric patients: now and into the year 2000. Diabetes Metab Res Rev 1999; 15(5):334–352.
8. Weinstein J, Metzger M, Bouz M et al. Insulin pump therapy vs. multiple daily injections in obese Type 2 diabetic patients. Diabet Med 2005; 22(8):1037–1046.
9. Zisser H, Robinson L, Bevier W et al. Bolus Calculator: A Review of Four "Smart" Insulin Pumps. Diabetes Technol Ther 2008; 6(10):441–444.

# Case Fabian: bolus calculator



# Case Fabian: bolus calculator

| Datum und Uhrzeit | BZ (mg/dl) | Insulin (Einheiten) | Kohlenhydrate (BE) | Ereignisse und Kommentare |
|---|---|---|---|---|
| 17:10 | | 5,00 Insulinpumpe | | |
| 15:34 | 127 | | | Ereignis: Vor Mahlzeit |
| 13:25 | 145 | | | |
| 12:10 | | 3,50 Insulinpumpe | | |
| 9:42 | | 4,40 Insulinpumpe | | |
| 9:41 | **277** | | 1,5 | Ereignis: Vor Mahlzeit |
| 7:21 | | 16,00 Insulinpumpe | | |
| 7:18 | | 16,00 Insulinpumpe | | |
| 6:46 | **202** | | 6,5 | Ereignis: Vor Mahlzeit |
| Di 16.03.2010 22:45 | **165** | | | Ereignis: Schlafenszeit |
| 22:25 | **163** | | | |
| 21:31 | | 3,50 Insulinpumpe | | |
| 21:20 | **194** | | 2,0 | Ereignis: Vor Mahlzeit |
| 19:36 | | 13,00 Insulinpumpe | | |
| 18:52 | **191** | | 6,0 | Ereignis: Vor Mahlzeit |
| 16:47 | | 4,00 Insulinpumpe | | |
| 16:05 | **173** | | 3,0 | Ereignis: Vor Mahlzeit; Krankheit |
| 12:31 | | 5,00 Insulinpumpe | | |
| 12:28 | **216** | | 3,0 | Ereignis: Nach Mahlzeit; Krankheit |
| 10:46 | | 4,50 Insulinpumpe | | |
| 10:46 | **190** | | 3,0 | Ereignis: Vor Mahlzeit; Krankheit |
| 8:57 | | 19,00 Insulinpumpe | | |
| 8:10 | **221** | | 8,5 | Ereignis: Vor Mahlzeit; Krankheit |

# Case Sophia: bolus calculator and diabetes management in a small child

| Datum und Uhrzeit | BZ (mg/dl) | Insulin (Einheiten) | Kohlenhydrate (BE) | Ereignisse und Kommentare |
|---|---|---|---|---|
| 17:49 | **165** | | 0,0 | Ereignis: Sport 1 |
| 15:10 | | 0,50 Insulinpumpe | | |
| 15:08 | | | 1,0 | |
| 13:56 | | 2,00 Insulinpumpe | | |
| 13:54 | 103 | | 4,0 | Ereignis: Vor Mahlzeit |
| 12:22 | 80 | | 0,0 | |
| 11:30 | | 0,20 Insulinpumpe | | |
| 11:30 | | 0,20 Insulinpumpe | | |
| 11:29 | | | 0,5 | |
| 11:28 | 95 | | 0,5 | |
| 9:26 | | 3,50 Insulinpumpe | | |
| 9:23 | 87 | | 5,7 | Ereignis: Vor Mahlzeit; Sport 2 |
| 18:18 | 142 | | 4,0 | Ereignis: Vor Mahlzeit |
| 15:58 | | 3,40 Insulinpumpe | | |
| 15:57 | 143 | | 6,0 | Ereignis: Vor Mahlzeit |
| 13:56 | | 1,60 Insulinpumpe | | |
| 13:55 | | | 3,2 | |
| 13:37 | | 2,10 Insulinpumpe | | |
| 13:36 | **193** | | 2,0 | Ereignis: Vor Mahlzeit |
| 13:35 | **183** | | | |
| 9:49 | | 1,40 Insulinpumpe | | |
| 9:48 | | | 1,7 | |
| 9:37 | | 3,30 Insulinpumpe | | |
| 9:36 | 135 | | 3,7 | Ereignis: Vor Mahlzeit |

# Results CSII with bolus calculator

Diabet Med. 2008 Sep;25(9):1036-42.

## Benefits of a bolus calculator in pre- and postprandial glycaemic control and meal flexibility of paediatric patients using continuous subcutaneous insulin infusion (CSII).

Shashaj B, Busetto E, Sulli N., Italy

- a significant reduction in blood glucose levels before and 2 h after meals
- reduction of the number of necessary correction boluses

thirty-six T1D patients on CSII treatment (19 males; mean age 13.9 +/- 3.5 years; range 4.9-17.8 years), two-period crossover study

# Results CSII with bolus calculator

J Int Med Res. 2008 Sep-Oct;36(5):1112-6.

## Clinical usefulness of a bolus calculator in maintaining normoglycaemia in active professional patients with type 1 diabetes treated with continuous subcutaneous insulin infusion.

Klupa T, Benbenek-Klupa T, Malecki M, Szalecki M, Sieradzki J., Poland

- mean Hb(A1c) and fasting blood glucose levels were not significantly different between the two groups
- mean post-prandial blood glucose was significantly lower in bolus calculator users than non-users.
- …..showed more blood glucose levels within the target range (AUC) in bolus calculator users than non-users

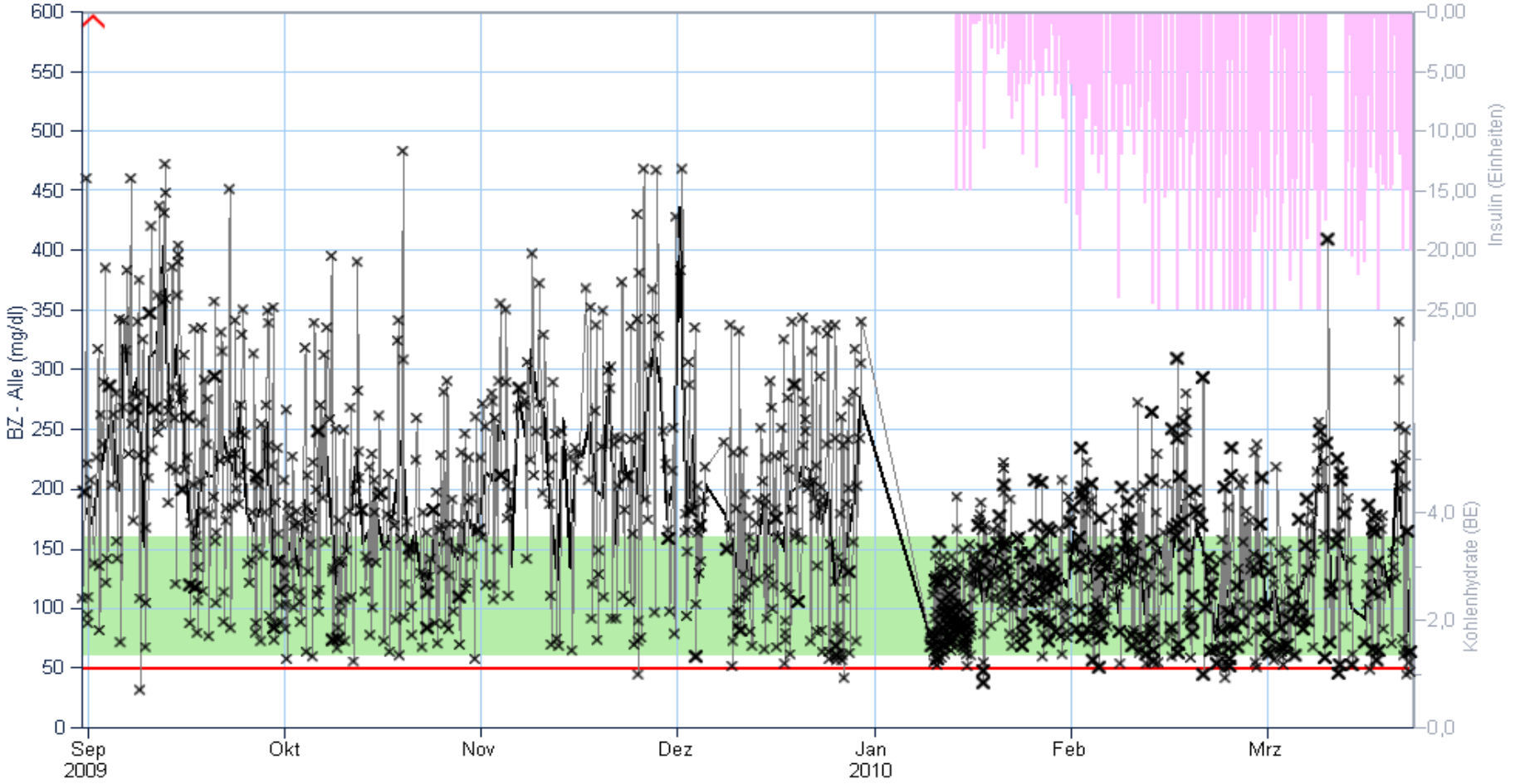
eighteen patients aged 19 - 51 years with diabetes duration of 6 - 22 years

# integrated insulin pump/bG meter solutions "smart pump" with bolus calculator and Diabetes Management




Roche Accu-Chek® Combo

# Case Miriam: CSII with bolus calculator and data management



# Insulin pumps, like the Accu Chek® Combo, with comprehensive diabetes management systems: the future of diabetes care devices ?

- Yes, this will be the future for patients treated with intensified insulin therapy !!!

- fast and effective way of calculating the right dose of insulin at any time and delivering the insulin
- opportunity for the patients and the doctors to review valid data and make decisions on therapy changes - and therefor to engage and motivate the patients to comply with the therapy regime
- getting to better targets : less glycemic variation / reduce postprandial bG excursions
- reduce hypoglycemia
- get better HbA1c (and GV) in the long run and thus reduce the risk for micro- and macrovascular complications